AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO



FEDERAL REGISTER

Vol. 91 Tuesday,

No. 148 August 4, 2026

Pages 49269–50468

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.federalregister.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.govinfo.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $860 plus postage, or $929, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 91 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

The Federal Register Printing Savings Act of 2017 (Pub. L. 115–120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: *https://www.gpo.gov/frsubs.*

Printed on recycled paper.

Contents

Federal Register

Vol. 91, No. 148

Tuesday, August 4, 2026

Agriculture Department
See National Agricultural Statistics Service
See Rural Utilities Service

Architectural and Transportation Barriers Compliance Board
PROPOSED RULES
Freedom of Information Act Regulations, 49377–49385

Centers for Medicare & Medicaid Services
RULES
Medicare Program:
Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2027 Rates; etc., 49570–50461
NOTICES
Hearings, Meetings, Proceedings, etc.:
Healthcare Advisory Committee; Fiscal Year 2026–2027, 49433–49434

Coast Guard
RULES
Safety Zone:
Ohio River River, Aurora, IN, 49278–49279

Commerce Department
See Foreign-Trade Zones Board
See Industry and Security Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration

Defense Department
See Navy Department

Energy Department
See Federal Energy Regulatory Commission

Environmental Protection Agency
RULES
Pesticide Tolerances:
Isofetamid, 49279–49283
NOTICES
Administration of Cross-State Air Pollution Rule Trading Program Assurance Provisions for 2025 Control Period, 49430–49431

Federal Aviation Administration
RULES
Airworthiness Directives:
Diamond Aircraft Industries Inc. Airplanes, 49269–49271
IFR Altitudes; Miscellaneous Amendments, 49271–49272
PROPOSED RULES
Airspace Designations and Reporting Points:
Wilmington International Airport, NC, 49372–49376
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Fueling Aviation's Sustainable Transition Grant Program, 49483
National Air Tours Safety Standards, 49482

Federal Communications Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 49431–49433

Federal Emergency Management Agency
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application for Community Disaster Loan Program, 49435–49436

Federal Energy Regulatory Commission
NOTICES
Combined Filings, 49427–49430
Environmental Assessments; Availability, etc.:
Texas Gas Transmission, LLC; Dearborn County Lateral Project, 49427
Establishment of Answer Period:
PJM Interconnection, LLC; AEP Appalachian Transmission Co., Inc.; AEP Indiana Michigan Transmission Co., Inc.; et al., 49426
PJM Governance and Stakeholder Reforms, 49430

Federal Mediation and Conciliation Service
RULES
Requests for Arbitration Panels, 49273–49278

Federal Motor Carrier Safety Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Commercial Driver's License Drug and Alcohol Clearinghouse, 49483–49485

Federal Reserve System
PROPOSED RULES
Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks; Bank Holding Companies, 49526–49568
Regulatory Modernization and Relief for Mutual Holding Companies, 49490–49524
NOTICES
Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 49433

Federal Trade Commission
PROPOSED RULES
Petition for Rulemaking:
Matheus Garcia Pereira, 49376–49377

Foreign Assets Control Office
NOTICES
Sanctions Action, 49485–49488

Foreign-Trade Zones Board
NOTICES
Authorization of Production Activity:
Avant Technology, Inc., Foreign-Trade Zone 12, Pharr, TX, 49406
Proposed Production Activity:
Foreign-Trade Zone 80, CGT US Ltd., New Braunfels, TX, 49406

Health and Human Services Department
See Centers for Medicare & Medicaid Services
See National Institutes of Health
RULES
Medicare Program:
Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2027 Rates; etc., 49570–50461

Homeland Security Department
See Coast Guard
See Federal Emergency Management Agency
See U.S. Customs and Border Protection

Housing and Urban Development Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Indian Housing Block Grants Formula and Competitive Programs, 49436–49438
Management Review for Multifamily Housing Projects, 49440–49441
Privacy Act; Matching Program, 49438–49440

Industry and Security Bureau
NOTICES
Reduction of Tariffs:
Patented Pharmaceuticals and Pharmaceutical Ingredients for Products of the United Kingdom Implemented by Presidential Proclamation 11020, 49406–49407

Internal Revenue Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Withholding and Information Reporting for Transfers of Partnership Interests, 49488

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Boltless Steel Shelving Units Prepackaged for Sale from the People's Republic of China, 49410–49411
Chassis and Subassemblies Thereof from the People's Republic of China, 49423–49424
Large Diameter Welded Pipe from the Republic of Korea, 49419–49422
Non-Refillable Steel Cylinders from the People's Republic of China, 49422–49423
Opportunity to Request Administrative Review and Join Annual Inquiry Service List; Note Regarding Format of Review Requests, 49412–49416
Prestressed Concrete Steel Wire Strand from the People's Republic of China, 49411–49412
Sales at Less Than Fair Value; Determinations, Investigations, etc.:
Van-Type Trailers and Subassemblies Thereof from Canada, 49407–49410
Van-Type Trailers and Subassemblies Thereof from Mexico, 49416–49419

International Trade Commission
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Fresh Mushrooms from Canada, 49446–49448
Linear hydraulic cylinders from Canada, China, India, Mexico, and South Korea, 49442–49443
Investigations; Determinations, Modifications, and Rulings, etc.:
Certain Arrowheads with Deploying Blades and Components Thereof, 49445
Certain Computer Cables, Chargers, Adapters, Peripheral Devices and Packaging Containing the Same, 49443–49444
Certain Mobile Cellular Communications Devices, 49441–49442
Certain Portable Battery Jump Starters and Components Thereof, 49445–49446
Certain Portable Power Stations and Packaging Therefor, 49444–49445
Certain Radio Control Transmitters and Receivers and Products Containing Same, 49446
Corrosion Inhibitors from China, 49448
Difluoromethane (R–32) from China, 49448

Justice Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Crime Victim's Rights Act Complain Form, 49448–49449
Proposed Consent Decree, 49449

National Aeronautics and Space Administration
NOTICES
Privacy Act; Systems of Records, 49449–49451

National Agricultural Statistics Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 49402–49405

National Highway Traffic Safety Administration
PROPOSED RULES
Federal Motor Vehicle Safety Standards:
Child Restraint Anchorage Systems; Child Restraint Systems, 49385–49401

National Institutes of Health
NOTICES
Hearings, Meetings, Proceedings, etc.:
National Library of Medicine, 49434

National Oceanic and Atmospheric Administration
RULES
Fisheries of the Northeastern United States:
Northeast Multispecies Fishery; Framework Adjustment 72, 49358–49371
NOTICES
Hearings, Meetings, Proceedings, etc.:
New England Fishery Management Council, 49425
Taking or Importing of Marine Mammals:
U.S. Army Corps of Engineers Bonneville Lock 1 Bridge Replacement Project on the Columbia River in Oregon, 49424–49425

National Science Foundation
RULES
Nondiscrimination in Federally Assisted Programs, 49283–49290

Navy Department
NOTICES
Certificate of Alternate Compliance:
Landing Craft Utility Vessel 1710 Class (LCU 1710 through LCU 1721), 49425–49426

Nuclear Regulatory Commission
NOTICES
Facility Operating and Combined Licenses:
Applications and Amendments Involving Proposed No Significant Hazards Considerations, etc., 49452–49458
Meetings; Sunshine Act, 49451–49452

Personnel Management Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Optional Form 306, Declaration for Federal Employment, 49458

Pipeline and Hazardous Materials Safety Administration
RULES
Hazardous Materials:
Adoption of Department of Transportation Special Permit 14175, 49354–49358
Adoption of Department of Transportation Special Permit 21287, 49310–49315
Adoption of Department of Transportation Special Permit 21379, 49315–49320
Adoption of Department of Transportation Special Permit 21478, 49335–49340
Adoption of Department of Transportation Special Permits 12412 and 11646 into the Hazardous Materials Regulations, 49349–49354
Improving Efficiencies for Special Permits and Approvals Renewals, 49291–49295
Modernizing Payments to and from America's Bank Account, 49295–49298
Reduce Training Burdens for America's Farmers, 49329–49332
Reducing Burdens by Allowing Continued Use of Department of Transportation Special Permit Packaging, 49340–49345
Reducing Burdens on Domestic Aerosol Shippers, 49301–49305
Reducing Burdens on Domestic Companies Using Battery-Powered Equipment in Trades, 49345–49349
Reducing Costs to Domestic Shippers and Carriers of Limited Quantities, 49332–49335
Reducing Recordkeeping Requirements for Domestic Carriers, 49298–49301
Reducing Undue Paperwork Burdens to Domestic Carriers, 49325–49329
Remove Redundant List of U.S. Environmental Protection Agency CERCLA Hazardous Substances, 49305–49310
Removing Burdensome Rail Reporting Requirements, 49320–49325

Postal Regulatory Commission
NOTICES
New Postal Products, 49458–49459

Presidential Documents
ADMINISTRATIVE ORDERS
Cameron County, TX; Authorization To Own, Operate, and Maintain Brownsville and Matamoros Bridge in Brownsville, TX (Presidential Permit of July 30, 2026), 50467–50468
Defense Production Act of 1950, as Amended; Presidential Determination Pursuant to Section 101 on Recoverable Critical Minerals and Materials (Presidential Determination No. 2026–19 of July 30, 2026), 50463–50466

Rural Utilities Service
NOTICES
Funding Opportunity:
Powering Affordable Reliable Technology Energy Program 2026, 49405–49406

Securities and Exchange Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 49459–49460, 49475–49476
Application:
Yorkville America Investment Trust and Yorkville America Equities, LLC, 49481
Self-Regulatory Organizations; Proposed Rule Changes:
Cboe Exchange, Inc., 49469–49470
Municipal Securities Rulemaking Board, 49460–49469
Nasdaq ISE, LLC, 49470–49475
Nasdaq PHLX LLC, 49476–49481
NYSE American LLC, 49469

State Department
NOTICES
Imposition of Nonproliferation Measures Against Foreign Persons, Including a Ban on U.S. Government Procurement, 49481–49482

Transportation Department
See Federal Aviation Administration
See Federal Motor Carrier Safety Administration
See National Highway Traffic Safety Administration
See Pipeline and Hazardous Materials Safety Administration
RULES
Accessible Lavatories on Single-Aisle Aircraft and Ensuring Safe Accommodations for Air Travelers With Disabilities Using Wheelchairs, 49272–49273

Treasury Department
See Foreign Assets Control Office
See Internal Revenue Service

U.S. Customs and Border Protection
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Guam-CNMI Visa Waiver Information, 49434–49435

Separate Parts In This Issue

Part II
Federal Reserve System, 49490–49524

Part III
Federal Reserve System, 49526–49568

Part IV
Health and Human Services Department, Centers for Medicare & Medicaid Services, 49570–50461
Health and Human Services Department, 49570–50461

Part V
Presidential Documents, 50463–50468

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Administrative Orders:

Presidential Determinations:
No. 2026–19 of July 30, 2026 50465
Permits:
Presidential Permit of July 30, 2026 50467

12 CFR

Proposed Rules:

215.....49526
217.....49490
225.....49526
239.....49490

14 CFR

39.....49269
95.....49271
382.....49272

Proposed Rules:

71.....49372

16 CFR

Proposed Rules:

1.....49376

29 CFR

1404.....49273

33 CFR

165.....49278

36 CFR

Proposed Rules:

1120.....49377

40 CFR

180.....49279

42 CFR

405.....49570
412.....49570
413.....49570
415.....49570
419.....49570
495.....49570
512.....49570

45 CFR

170.....49570
611.....49283

49 CFR

107 (3 documents) 49291, 49295, 49298
171 (5 documents) 49301, 49305, 49310, 49315, 49320
172 (5 documents) 49305, 49325, 49329, 49332, 49335
173 (7 documents) 49305, 49310, 49315, 49332, 49335, 49340, 49345
174.....49320
177.....49349
180.....49354

Proposed Rules:

571.....49385
585.....49385

50 CFR

648.....49358

Rules and Regulations

Federal Register
Vol. 91, No. 148
Tuesday, August 4, 2026

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–4636; Project Identifier MCAI–2026–00070–A; Amendment 39–23430; AD 2026–15–18]

RIN 2120–AA64

Airworthiness Directives; Diamond Aircraft Industries Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Diamond Aircraft Industries Inc. (DAI) Model DA20–C1 airplanes. This AD was prompted by a report of a certain emergency locator transmitter (ELT) not activating due to a missing jumper wire. This AD requires a continuity inspection of the D-sub connector of the Artex ELT 1000 and, if necessary, corrective actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 8, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 8, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2026–4636; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–91, West Building Fifth Floor, Room W58–213, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Diamond Aircraft Industries material identified in this AD, contact DAI, 1560 Crumlin Sideroad, London, Ontario, Canada, N5V 1S2; phone: (519) 457–4041, fax: (519) 457–4045; email: *support-canada@diamondaircraft.com;* website: *diamondaircraft.com.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1100 Main, Kansas City, MO 64105. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2026–4636.

FOR FURTHER INFORMATION CONTACT: William Reisenauer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7301; email: *ECB-COS@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain DAI Model DA20–C1 airplanes. The NPRM was published in the **Federal Register** on May 15, 2026 (91 FR 27871). The NPRM was prompted by Transport Canada AD CF–2026–03, dated January 21, 2026 AD CF–2026–03) (referred to as the MCAI), issued by Transport Canada, which is the aviation authority for Canada to correct an unsafe condition on all DAI Model DA20–C1 airplanes having an Artex ELT 1000 installed. The MCAI states that DAI received a report of an occurrence where the Artex ELT 1000 installed in a DA20–C1 airplane did not perform as intended. Further investigation by the manufacturer revealed that some Artex ELT 1000 units might not have a jumper wire between the D-sub pins 5 and 12, which could prevent the ELT beacon from being activated by the internal G-Switch and the aural alert buzzer from being activated in the event of an accident.

In the NPRM, the FAA proposed to require a continuity inspection of the D-sub connector of the Artex ELT 1000 and, if necessary, corrective actions. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2026–4636.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Diamond Aircraft Industries Mandatory Service Bulletin No. DAC1–25–05 Rev. 1, dated July 19, 2024. This material specifies procedures for performing a continuity inspection on the D-sub connector of the Artex ELT 1000 and, if necessary, installing the jumper wire into the D-sub connector.

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Differences Between This AD and the Referenced Material

Although step 14 of the Accomplishment/Instructions of Diamond Aircraft Industries Mandatory Service Bulletin DAC1–25–05 Rev. 1, dated July 19, 2024, requires completing and sending an execution report to the manufacturer, this AD does not require that action.

Costs of Compliance

The FAA estimates that this AD affects 365 airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Continuity inspection and corrective actions	1 work-hour × $85 per hour = $85	$0	$85	$31,025

The FAA estimates the following costs to do any repairs that would be required based on the results of the inspection. The agency has no way of determining the number of airplanes that might need these repairs:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Install jumper wire	1 work-hour × $85 per hour = $85	$3	$88

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2026–15–18 Diamond Aircraft Industries Inc.: Amendment 39–23430; Docket No. FAA–2026–4636; Project Identifier MCAI–2026–00070–A.

(a) Effective Date

This airworthiness directive (AD) is effective September 8, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Diamond Aircraft Industries Inc. Model DA20–C1 airplanes, certificated in any category, that have an Artex emergency locator transmitter (ELT) 1000 installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 2562, Emergency Locator Beacon.

(e) Unsafe Condition

This AD was prompted by a report of a certain ELT not activating due to a missing jumper wire. The FAA is issuing this AD to detect and address a missing jumper wire on the Artex ELT 1000. The unsafe condition, if not addressed, could result in the ELT beacon and aural alert buzzer not activating in the event of an accident.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

Within 3 months after the effective date of this AD, perform a continuity inspection of the D-sub connector and accomplish all required corrective actions in accordance with the Accomplishment/Instructions, Paragraph I.9, of Diamond Aircraft Industries Mandatory Service Bulletin No. DAC1–25–05 Rev. 1, dated July 19, 2024.

(h) No Reporting Requirement

Although step 14 of the Accomplishment/Instructions of Diamond Aircraft Industries Mandatory Service Bulletin No. DAC1–25–05 Rev. 1, dated July 19, 2024, requires completing and sending an execution report to the manufacturer, this AD does not include that requirement.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to: *AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Additional Information

For more information about this AD, contact William Reisenauer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7301; email: *ECB-COS@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Diamond Aircraft Industries Mandatory Service Bulletin No. DAC1–25–05 Rev. 1, dated July 19, 2024.

(ii) [Reserved]

(3) For Diamond Aircraft Industries material identified in this AD, contact Diamond Aircraft Industries Inc., 1560 Crumlin Sideroad, London, Ontario, Canada, N5V 1S2; phone: (519) 457–4041, fax: (519) 457–4045; email: *support-canada@diamondaircraft.com;* website: *diamondaircraft.com.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1100 Main, Kansas City, MO 64105. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on July 27, 2026.

Paul R. Bernado,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2026–15825 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 31678; Amdt. No. 593]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en-route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

DATES: 0901 UTC, September 3, 2026.

FOR FURTHER INFORMATION CONTACT: Brian Murphy, Manager, Aeronautical Information Services, Aeronautical Information Group, Aeronautical Data Team, Federal Aviation Administration. Mailing Address: FAA Headquarters, Aeronautical Information Group, 800 Independence Ave. SW, Bldg. 10A, Room 507L, Washington, DC 20591. Telephone (202) 267–4389.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air).

Issued in Washington, DC, on July 31, 2026.

Tom Carrigan,

Manager, Aeronautical Information Services, Aeronautical Information Group, Data Systems Team, Federal Aviation Administration.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, 3 Sep 2026.

PART 95—IFR Altitudes

■ 1. The authority citation for part 95 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113 and 14 CFR 11.49(b)(2).

■ 2. Part 95 is amended to read as follows:

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINTS

[Amendment 593 effective date September 03, 2026]

From	To	MEA
§ 95.6001 Victor Routes-U.S.		
§ 95.6008 VOR Federal Airway V8 is Amended To Read in Part		
MEADS, NV FIX	*MORMON MESA, NV VORTAC	6000
*7800—MCA MORMON MESA, NV VORTAC , NE BND		MAA—17500
MORMON MESA, NV VORTAC	*JITKA, UT FIX	9000
*12000—MCA JITKA, UT FIX , NE BND		MAA—17500
JITKA, UT FIX	MATZO, UT FIX.	
	SW BND	*12000
	NE BND	*12400
*8100—MOCA		MAA—17500

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINTS—Continued

[Amendment 593 effective date September 03, 2026]

From	To	MEA
*9000—GNSS MEA.		
MATZO, UT FIX	BRYCE CANYON, UT VORTAC	12300 MAA—17500
§ 95.6016 VOR Federal Airway V16 is Amended To Read in Part		
BIG SPRING, TX VORTAC	ABILENE, TX VORTAC	4500 MAA—17500
§ 95.6020 VOR Federal Airway V20 is Amended To Read in Part		
LAFAYETTE, LA VORTAC	RESERVE, LA VOR/DME	2100 MAA—17500
§ 95.6235 VOR Federal Airway V235 is Amended To Read in Part		
MORMON MESA, NV VORTAC	*JITKA, UT FIX	9000
*12000—MCA JITKA, UT FIX , NE BND		MAA—17500
JITKA, UT FIX	MATZO, UT FIX.	
	SW BND	*12000
	NE BND	*12400
*8100—MOCA		MAA—17500
*9000—GNSS MEA.		

From	To	MEA	MAA
§ 95.7001 Jet Routes **§ 95.7523 Jet Route J523 is Amended To Read in Part**			
BRYCE CANYON, UT VORTAC *MEA IS ESTABLISHED WITH A GAP IN NAVIGATION SIGNAL COVERAGE.	ELY, NV VOR/DME	*22000	45000

Airway segment		Changeover Points	
From	To	Distance	From
§ 95.8005 Jet Routes Changeover Points **J523 is Amended To Modify Changeover Point**			
BRYCE CANYON, UT VORTAC	ELY, NV VOR/DME	138	BRYCE CANYON.

[FR Doc. 2026–15757 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Part 382

[Docket No. DOT–OST–2021–0137 and DOT–OST–2022–0144]

RIN 2105–AE89

Accessible Lavatories on Single-Aisle Aircraft and Ensuring Safe Accommodations for Air Travelers With Disabilities Using Wheelchairs

AGENCY: Office of the Secretary (OST), U.S. Department of Transportation.

ACTION: Notification of enforcement discretion.

SUMMARY: The U.S. Department of Transportation (DOT or Department) is extending its previously announced enforcement discretion for four provisions of the final rule on ''Ensuring Safe Accommodations for Air Travelers With Disabilities Using Wheelchairs'' (Wheelchair Rule I) related to airline liability for mishandled wheelchairs, refresher training frequency, pre-departure notifications, and fare difference reimbursements from December 31, 2026 to April 30, 2027. To maintain regulatory consistency, the Department is also expanding this enforcement discretion to include the 12-month hands-on training mandate for flight attendants regarding on-board wheelchair (OBW) assistance and lavatory accessibility in the final rule titled ''Accessible Lavatories on Single-Aisle Aircraft'' (Accessible Lavatory Rule). These provisions will be formally addressed in an upcoming rulemaking titled ''Airline Obligations to Accommodate Air Travelers with Disabilities Using Wheelchairs'' (Wheelchair Rule II). This extension is necessary to allow sufficient time for the Department to review and analyze public comments, and to make final determinations regarding the content of the final rule. This exercise of enforcement discretion is intended to remove the burden of complying with the requirements under review by DOT and does not prejudge the outcome of the new rulemaking. This notice does not affect the enforcement of requirements in the Accessible Lavatory Rule other than the one identified.

DATES: As of August 4, 2026, enforcement of 14CFR 382.125(e), 382.130(a), 382.132, and the at least once every 12-month training

requirements found in §§ 382.141(a)(6) and 14 CFR 382.63(h)(1) are delayed until April 30, 2027.

ADDRESSES: This notification of enforcement discretion, the notice of proposed rulemakings (NPRMs), all comments received, the final rules, and all background material may be viewed online at *www.regulations.gov* using the docket numbers listed above. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *www.federalregister.gov* and the Government Publishing Office's website at *www.GovInfo.gov.*

FOR FURTHER INFORMATION CONTACT: Tori Ford, Robert Gorman, or Blane Workie, Office of Aviation Consumer Protection, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–9342 (phone), *victoria.ford@dot.gov, robert.gorman@dot.gov,* or *blane.workie@dot.gov* (email).

SUPPLEMENTARY INFORMATION: On August 1, 2023, DOT issued a final rule on ''Accessible Lavatories on Single-Aisle Aircraft'' (Accessible Lavatory Rule).[1] Among other things, this rule requires airlines to train flight attendants to proficiency on an *annual* basis to assist in transporting qualified individuals with disabilities to and from the lavatory from the aircraft seat using an on-board wheelchair (OBW).[2] This training must include hands-on training on the retrieval, assembly, stowage, transfer features, and use of the OBW. It also requires flight attendants to be trained on the accessibility features of lavatories themselves. This provision of the rule is scheduled to become effective on October 2, 2026.

In May 2024, Congress passed the Federal Aviation Administration (FAA) Reauthorization Act of 2024 (2024 FAA Act). Section 542 of the 2024 FAA Act directed the Department to issue a rulemaking to develop requirements for minimum training standards for airline personnel or contractors who assist wheelchair users who board or deplane using an aisle chair or other boarding devices, and airline personnel or contractors who stow wheelchairs and scooters on aircraft. Under the 2024 FAA Act, recurrent training must be conducted within 18 months of initial training, and trainees must be recertified on the job every 18 months thereafter by a relevant superior to remain qualified for providing aisle chair assistance. On December 17, 2024, DOT issued a final rule on ''Ensuring Safe Accommodations for Air Travelers With Disabilities Using Wheelchairs'' (Wheelchair Rule I).[3] The final rule, which included certain provisions required by the 2024 FAA Act such as training requirements, expanded existing airline obligations in 14 CFR part 382 regarding the treatment of air travelers with disabilities. In that regulation, the Department requires initial training by June 17, 2026, and at least once every twelve months thereafter for these personnel.[4]

Recently, the Department has initiated a new rulemaking titled ''Airline Obligations to Accommodate Air Travelers with Disabilities Using Wheelchairs'' (Wheelchair Rule II) [5] that will address four provisions of Wheelchair Rule I related to airline liability for mishandled wheelchairs,[6] refresher training frequency,[7] pre-departure notifications,[8] and fare difference reimbursements.[9] The Department previously announced that it would exercise its enforcement discretion and not enforce these requirements while it engages in the rulemaking process.[10] In that prior announcement, the Department stated that the earliest date it expected to make a decision on whether to move forward with a final rule was December 31, 2026. However, the Department now anticipates that the earliest date it will be decided is April 30, 2027. Consequently, the Department is expanding its exercise of enforcement discretion and extending the temporary compliance pause for the four affected Wheelchair Rule I provisions from December 31, 2026 to April 30, 2027.

Recently, a large U.S. carrier asked the Department for flexibility in enforcement regarding the annual training requirements of the Accessible Lavatory Rule. The carrier explained that it received approval from the FAA to conduct certain flight attendant safety training, as required by 14 CFR part 121, on an 18-month cycle rather than a 12-month cycle. The carrier argued that it is inefficient to conduct one type of training (required by DOT) on an annual basis while conducting another type of training (required by the FAA) on an 18-month basis.[11]

To ensure that the various training requirements in part 382 are consistent with the law and Administration policies, the Department has decided that the training frequency issue raised by the Accessible Lavatory Rule will be addressed within the scope of Wheelchair Rule II. Wheelchair Rule II will consider the frequency of refresher training for flight attendants on how to assist passengers to and from aircraft lavatories, including hands-on training with the OBWs and the accessibility features of the lavatories. As such, the Department believes that the public interest is best served by the Department extending its temporary pause in enforcement to the frequency of the training requirement in 14 CFR 382.63(h)(1) to align with the updated Wheelchair Rule II. This notice of enforcement discretion does not affect the enforcement of requirements in the Accessible Lavatory Rule other than the one identified above.

Issued in Washington, DC, under authority delegated in 49 CFR 1.27(a):

Gregory Zerzan,

General Counsel.

[FR Doc. 2026–15835 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–9X–P

[1] 88 FR 50020 (Aug. 1, 2023).

[2] *See* 14 CFR 382.63(h)(1). OBWs are specialized wheelchairs that are stowed onboard the aircraft. They are used to transport passengers between the aircraft seat and the lavatory, often while in-flight. They are distinct from both standard wheelchairs (used to transport passengers within the airport) and aisle chairs (used for enplaning and deplaning).

[3] 89 FR 102398 (Dec. 17, 2024).

[4] 14 CFR 382.141(a)(6).

[5] Spring 2025 Unified Agenda of Regulatory and Deregulatory Actions, Department of Transportation, Airline Obligations to Accommodate Air Travelers with Disabilities Using Wheelchairs (RIN 2105–AF35) at *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202504&RIN=2105-AF35.*

[6] Codified at 14 CFR 382.130(a).

[7] Codified at 14 CFR 382.141(a)(6).

[8] Codified at 14 CFR 382.125(e).

[9] Codified at 14 CFR 382.132.

[10] *See* 90 FR 46751 (Sept. 30, 2025). Aside from refresher training frequency, our exercise of enforcement discretion applied to provisions of Wheelchair Rule I related to airline liability for mishandled wheelchairs, pre-departure notifications, and fare difference reimbursements.

[11] Specifically, the carrier stated that this ''incongruence'' would require the carrier to transport almost 30,000 flight attendants to training sessions off-cycle, removing them from operations for an additional day each year.

FEDERAL MEDIATION AND CONCILIATION SERVICE

29 CFR PART 1404

RIN 3076–AA31

Requests for Arbitration Panels

AGENCY: Federal Mediation and Conciliation Service.

ACTION: Interim final rule; request for comments.

SUMMARY: The Federal Mediation and Conciliation Service (FMCS) is issuing an interim final rule with requests for comments to amend its arbitration

services regulations. The interim final rule clarifies the circumstances in which the Office of Arbitration (OA) may decline to issue an arbitration panel, make a direct appointment, or provide related arbitration services. The rule would remove language that could be read to require FMCS to honor every unilateral request for an arbitration panel, regardless of legal constraints or FMCS's authority. FMCS seeks public comment on this interim final rule.

DATES: This interim final rule is effective August 4, 2026.

Comment date: Comments must be received on or before September 3, 2026.

FMCS will consider all timely comments received. After reviewing the comments, FMCS may revise, withdraw, or confirm this interim final rule through a subsequent document published in the **Federal Register**.

ADDRESSES: You may submit comments for this interim final rule within the Federal eRulemaking Portal at *https://www.regulations.gov/.* Follow the instructions for submitting comments.

All comments must be received by the end of the comment period for them to be considered. All comments and other submissions received generally will be posted on the internet at *regulations.gov* as they are received, without change, including any personal information provided. However, FMCS retains discretion to redact personal or sensitive information, including but not limited to personal or sensitive information pertaining to third parties, where appropriate.

A summary of this rule may be found in the docket for this rulemaking at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Anna Davis, General Counsel, Federal Mediation and Conciliation Service, (202) 606–3737, [EMAIL] *adavis@fmcs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

FMCS administers a Roster of Arbitrators and provides arbitration-related services under 29 CFR part 1404. Those regulations provide that voluntary arbitration and fact-finding are important means of resolving labor disputes and that OA administers requests for labor arbitration services. Current § 1404.9(b) states that a panel request, ''whether joint or unilateral, will be honored,'' while also stating that FMCS does not adopt any position on the status of an arbitration agreement, arbitrability of a dispute, or the terms of the parties' contract by issuing a panel or appointing an arbitrator. Current § 1404.10 similarly provides that the Office of Arbitration will not decide that a dispute is not subject to arbitration.

FMCS's authority is administrative and facilitative. Current § 1404.9(c) provides that FMCS has no power to compel parties to appear before an arbitrator, enforce an agreement to arbitrate, compel parties to arbitrate any issue, influence or set aside an arbitrator's decision, or compel, deny, or modify payment of compensation to an arbitrator. Current § 1404.9(d) also recognizes that the OA may decline to submit a panel or appoint an arbitrator if the request is overly burdensome or otherwise impracticable.

FMCS has determined that the current sentence stating that every joint or unilateral panel request ''will be honored'' could be misread as requiring FMCS to provide panels even where doing so would be inconsistent with law, a court order, or FMCS's statutory or regulatory authority. That was not the intended effect of the regulation. The proposed rule clarifies that FMCS retains authority to make limited threshold determinations concerning whether FMCS may lawfully provide the requested service.

FMCS's statutory authorities support that clarification. Section 203 of the Labor Management Relations Act authorizes FMCS to make services available to assist in the resolution of labor disputes and, in subsection (f), to make its services available to Federal agencies to aid in the resolution of disputes under subchapter IV of chapter 5 of title 5, including by maintaining rosters of neutrals and arbitrators. Those services are subject to provisions in 5 U.S.C. 572(a) and 572(c) making clear that alternative dispute-resolution procedures are voluntary and require mutual consent. In the Federal-sector collective-bargaining context, 5 U.S.C. 7121 separately governs negotiated grievance procedures and provides that unresolved grievances under such procedures are subject to binding arbitration invoked by either the exclusive representative or the agency.

Recent executive orders excluding certain agencies or subdivisions from Federal labor-management relations have increased the likelihood that FMCS will receive requests for arbitration panels in circumstances where one party asserts that participation in the requested arbitration process is prohibited by law, court order or otherwise outside FMCS's statutory or regulatory authority. Executive Order 14251 excluded identified agencies and subdivisions from coverage under chapter 71 of title 5 based on the President's national security determinations, and directed agencies covered by the exclusion, upon termination of applicable collective-bargaining agreements, to terminate agency participation in any pending grievance proceedings under 5 U.S.C. 7121. FMCS recognizes that litigation concerning these matters may affect particular requests and that FMCS must administer its arbitration services consistent with applicable law and any court orders.

This rule therefore clarifies the limited screening role FMCS may perform before issuing a panel or making an appointment. Where a request presents a threshold question about FMCS's authority to provide the requested service, FMCS may seek information from the parties and may decline the request, hold the request in abeyance, or take another administratively appropriate action. FMCS's action on such a threshold question does not adjudicate the parties' underlying contractual, statutory, or arbitrability dispute. These changes reflect the longstanding principle that arbitration is voluntary and correct confusing and potentially misleading language in FMCS's current regulation.

II. Regulatory Changes

This interim final rule amends 29 CFR part 1404, subpart C, which governs FMCS arbitration services, to clarify OA's authority to screen arbitration-panel and appointment requests before providing FMCS services. The rule preserves FMCS's existing role as an administrative provider of arbitration panels and appointments, but makes clear that FMCS is not required to issue a panel, make a direct appointment, or provide related arbitration services where doing so would be inconsistent with applicable law, a court order, or FMCS's statutory or regulatory authority.

Section 1404.9—Procedures for Requesting Arbitration Lists and Panels

The rule revises § 1404.9(b). Current § 1404.9(b) provides that, although parties are encouraged to make joint requests, a panel request ''whether joint or unilateral, will be honored,'' while also stating that issuance of a panel does not signify any FMCS position on the arbitration agreement, arbitrability, or contract terms.

The revised text retains the basic rule that, upon request, OA will refer a randomly selected panel of seven arbitrators to parties to an arbitration or fact-finding agreement, or where labor arbitration or fact-finding may be provided by statute. It also retains the requirement that each panel member's

biographical sketch include the background, qualifications, experience, and fee information furnished to FMCS by the arbitrator.

The rule clarifies when a panel request may be unilateral and when joint authorization is required. Under the revised text, a request for a panel may be joint or unilateral unless part 1404, applicable law, or the parties' agreement requires joint authorization for the requested service. Requests for a panel of other than seven names, for direct appointment of an arbitrator, or for special qualifications or other special service continue to require joint submission or authorization by both parties pursuant to mutual agreement.

The rule adds a new limited threshold-inquiry provision. OA may conduct a limited threshold inquiry to determine whether issuing a panel, making a direct appointment, or providing related arbitration services would be inconsistent with applicable law, a court order, or FMCS's statutory or regulatory authority. In conducting that inquiry, OA may request the parties' agreement, a statutory provision, regulation, court order, written authorization, or other information needed to determine whether FMCS may provide the requested service.

Following that limited threshold inquiry, FMCS may issue the panel or appointment, decline to provide the requested service, hold the request in abeyance, or take another administratively appropriate action. The revised text further clarifies that FMCS's issuance of a panel or appointment, refusal to issue a panel or appointment, or decision to hold a request in abeyance does not decide the validity of any collective-bargaining agreement, the merits of any grievance, the arbitrability of any dispute, or the parties' rights or obligations under any agreement or law.

For example, the doctrine of sovereign immunity requires statutory authorization before an agency can engage in binding arbitration. Without such authorization agencies cannot be brought before an external tribunal.[1] Congress has provided statutory authorization for agencies to engage in binding arbitration in a number of contexts involving both private parties and Federal employees.[2] However, in situations where statutory authorization is not available, the executive branch's obligation to take care that the law is faithfully executed precludes FMCS from providing panels for unlawful arbitration proceedings. FMCS cannot facilitate constitutional violations.

Section 1404.10—Arbitrability

The rule revises § 1404.10 to conform to the revised threshold-inquiry language in § 1404.9. The revised section preserves the rule that OA will not decide the merits of a claim by either party that a dispute is not subject to arbitration. It adds that OA may nevertheless conduct a limited threshold inquiry to determine whether FMCS may lawfully submit a panel, make a direct appointment, or provide related arbitration services under part 1404, consistent with § 1404.9.

Section 1404.11—Nominations of Arbitrators

The rule revises § 1404.11(b) and (c). Current § 1404.11(b) provides that OA will provide a randomly selected panel of arbitrators located near the hearing site, unless the parties jointly request special qualifications or no geographic restrictions. Current § 1404.11(c) provides that, if the parties do not agree on an arbitrator from the first panel, OA will furnish up to five additional panels upon joint request, or upon unilateral request if authorized by the applicable collective-bargaining agreement, and payment of additional fees.

The revised § 1404.11(b) makes nominations of arbitrators expressly subject to §§ 1404.9 and 1404.10. This conforming change ensures that ordinary panel nomination procedures do not override FMCS's threshold authority to decline or hold a request in abeyance where providing the requested service would be inconsistent with law, a court order, or FMCS's authority.

The rule also updates the nondiscrimination sentence in § 1404.11(b). It replaces ''gender'' with ''sex'' and adds a catchall prohibiting inclusions or exclusions based on ''any other basis prohibited by applicable law.''

The revised § 1404.11(c) preserves the existing additional-panel process but expands the sources of authority that may support a unilateral request for additional panels. Additional panels may be furnished upon joint request, or upon unilateral request if authorized by the applicable collective-bargaining agreement, statute, regulation, court order, or other binding authority, and payment of additional fees. The revised paragraph also states that the additional-panel process is subject to §§ 1404.9 and 1404.10, and that OA may decline to furnish an additional panel or hold the request in abeyance if furnishing the panel would be inconsistent with applicable law, a court order, or FMCS's statutory or regulatory authority.

Section 1404.12—Selection by Parties and Appointment of Arbitrators

The rule revises § 1404.12(b) and (c). Current § 1404.12(b) sets out the ranked-preference process for selecting an arbitrator from a panel and provides that, if one party submits its ranked preferences and the other party fails to respond within 14 days, the first party's choice will be honored. Current § 1404.12(c) provides that OA will make a direct appointment only upon joint request or as otherwise provided by part 1404.

The revised § 1404.12(b) retains the existing ranked preference process. Where the parties' collective-bargaining agreement permits each party to separately notify OA of its ranked preferences, or is silent on the selection method, FMCS will ask each party to rank the panel. If both parties respond, the arbitrator with the lowest combined number will be appointed. If one party fails to respond, the first party's choice will be honored.

The rule adds a conforming limitation to § 1404.12(b): the paragraph is subject to § 1404.9(b) and does not require OA to make an appointment where OA determines that the appointment would be inconsistent with applicable law, a court order, or FMCS's statutory or regulatory authority.

The revised § 1404.12(c) likewise makes direct appointments subject to §§ 1404.9 and 1404.10. OA will make a direct appointment only upon joint request or as otherwise provided by part 1404, but that appointment authority is now expressly subject to the rule's threshold-screening provisions.

III. Expected Impact

A. Statement of Need

FMCS is issuing this interim final rule to clarify its arbitration services regulations and prevent misinterpretation of current § 1404.9(b). The current language could be read to require FMCS to honor every unilateral request for an arbitration panel even when providing a panel, making a direct appointment, or providing related arbitration services would be inconsistent with applicable law, a court order, or FMCS's statutory or regulatory authority.

The interim final rule clarifies that OA may conduct a limited threshold inquiry into whether FMCS may

[1] *See United States* v. *Shaw,* 309 U.S. 495, 500–501 (1940) (''without specific statutory consent, no suit may be brought against the United States. No officer, by his action, can confer jurisdiction''). *See also U.S.* v. *Mitchell,* 463 U.S. 206, 215–216 (1983) (without statutory authorization ''no contracting officer or other official is empowered to consent to suit against the United States.'').

[2] *See* 5 U.S.C. 572 and 5 U.S.C. 7121.

lawfully provide the requested administrative arbitration service. The rule does not authorize FMCS to decide the merits of any grievance, the validity of any collective-bargaining agreement, the arbitrability of any dispute, or the rights or obligations of the parties under any agreement or law.

B. Costs

FMCS does not expect the rule to impose significant costs. The rule does not require any party to submit new recurring reports, maintain new records, or change the substantive terms of any collective-bargaining agreement. The rule clarifies FMCS's internal processing standards for arbitration-panel requests and related services. Some parties may submit information to FMCS in response to a threshold inquiry, but FMCS expects such submissions to be limited to circumstances in which a request presents a legal or authority-based objection to FMCS providing the requested service.

FMCS also expects any cost effects to be limited because the rule does not affect parties' ability to pursue any available remedy before the FLRA, a court, or another tribunal with jurisdiction. Where FMCS determines that it cannot provide a requested panel or appointment, parties remain free to pursue any other procedure or remedy available under law or their agreement.

C. Benefits

The rule will improve clarity, reduce confusion, and help ensure that FMCS administers its arbitration services consistent with law. The rule will make clear that FMCS's existing panel procedures do not require FMCS to provide a panel or appointment where doing so would exceed FMCS's authority or conflict with applicable law or court orders. The rule will also help parties understand that FMCS's threshold processing decisions do not decide the merits of a grievance, the validity of a collective-bargaining agreement, or the arbitrability of a dispute.

D. Alternatives Considered

FMCS considered retaining the current text of § 1404.9(b), but rejected that alternative because the phrase ''whether joint or unilateral, will be honored'' may be read too broadly and may create confusion about FMCS's obligations. FMCS also considered adopting a rule under which FMCS would decide arbitrability disputes before issuing a panel, but rejected that alternative because FMCS's role is administrative and facilitative, and current § 1404.10 provides that the Office of Arbitration does not decide the merits of arbitrability claims. The interim final rule adopts a narrower approach by authorizing only a limited threshold inquiry into FMCS's own authority to provide the requested administrative arbitration service.

E. Reliance Interests

FMCS recognizes that some parties may have relied on current § 1404.9(b) and prior FMCS practice when drafting or administering arbitration procedures. This interim final rule does not retroactively invalidate any panel previously issued, appointment previously made, or request previously submitted. Nor does it alter any party's contractual or statutory rights. The rule clarifies only FMCS's own authority and procedures for providing arbitration panels, appointments, and related services.

To the extent parties expected FMCS to honor unilateral panel requests in all circumstances, FMCS has determined that any such reliance is outweighed by the need to ensure that FMCS does not provide arbitration services where doing so would be inconsistent with applicable law, a court order, or FMCS's authority. Further, FMCS does not believe any expectation that FMCS would honor requests that conflicted with applicable law to be reasonable. FMCS also notes that parties remain free to pursue available remedies before the FLRA, a court, or another tribunal with jurisdiction. For example, any allegations that a party failed to comply with any provision of a CBA, including any arbitration provision, may be presented to the Federal Labor Relations Authority as an unfair labor practice pursuant to 5 U.S.C. 7116.

F. Severability

FMCS intends the provisions of this interim final rule to be severable. If any provision of this rule, or the application of any provision to any person or circumstance, is held invalid, FMCS intends that the remainder of the rule and its application to other persons or circumstances remain in effect to the fullest extent permitted by law.

IV. Regulatory Compliance

A. Administrative Procedure Act

FMCS is issuing this rule as an interim final rule with request for comments. FMCS finds good cause under 5 U.S.C. 553(b)(B) to issue this rule without first publishing a notice of proposed rulemaking because prior notice and public procedure are impracticable, unnecessary, and contrary to the public interest. Current § 1404.9(b) could be read to require OA to honor every joint or unilateral request for an arbitration panel regardless of whether providing the requested service would be inconsistent with applicable law, a court order, or FMCS's statutory or regulatory authority. FMCS has determined that it is necessary to clarify promptly that FMCS retains authority to conduct a limited threshold inquiry and to decline, hold in abeyance, or otherwise act on requests that FMCS cannot lawfully process or that would otherwise be inconsistent with law.

Delaying issuance of this clarification until after completion of notice-and-comment rulemaking would risk continued confusion regarding FMCS's authority and obligations when presented with requests that raise threshold legal or authority-based objections. FMCS therefore finds that issuing this rule on an interim final basis is in the public interest.

Although FMCS finds good cause to issue this rule without prior notice and comment, FMCS invites public comment on all aspects of this interim final rule. FMCS will consider all timely comments and may revise, withdraw, delay the effective date of, or confirm this interim final rule through a subsequent **Federal Register** document.

FMCS also finds good cause under 5 U.S.C. 553(d)(3) to make this rule effective upon publication. The same reasons supporting issuance without prior notice and comment also support immediate effectiveness because delaying the rule's effective date would perpetuate uncertainty regarding FMCS's authority to decline, hold in abeyance, or otherwise act on requests for arbitration services that FMCS may not lawfully process or that would otherwise be inconsistent with law.

B. Regulatory Review

FMCS has considered the costs and benefits of this rule. The rule clarifies FMCS's procedures for providing arbitration panels and appointments and does not impose significant compliance costs. OIRA has determined that this rule is not a significant regulatory action under Executive Order 12866. This rule is not an Executive Order 14192 regulatory action because it imposes no more than de minimis regulatory costs.

C. Regulatory Flexibility Act

Because FMCS is issuing this rule without prior notice and comment based on the good-cause exception in 5 U.S.C. 553(b)(B), the requirements of the Regulatory Flexibility Act for an initial or final regulatory flexibility analysis do not apply. In any event, FMCS certifies

that this interim final rule will not have a significant economic impact on a substantial number of small entities.

This rule clarifies FMCS's procedures for processing requests for arbitration panels, direct appointments, and related arbitration services. It does not impose new substantive compliance obligations, recurring reporting requirements, or recordkeeping requirements on small entities. The rule does not alter the fee schedule in appendix A to part 1404. To the extent a small entity requests FMCS arbitration services, the rule may affect whether FMCS issues a panel or appointment in the limited circumstance where FMCS determines that providing the requested service would be inconsistent with applicable law, a court order, or FMCS's statutory or regulatory authority. FMCS expects any economic effect to be minimal.

D. Federalism

FMCS has analyzed this rule under Executive Order 13132 and has determined that it will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

E. Civil Justice Reform

This rulemaking meets the applicable standards set forth in section 3(a) and (b)(2) of Executive Order 12988.

F. Unfunded Mandates Reform Act

This rule will not result in expenditures by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, adjusted for inflation. Accordingly, FMCS has not prepared a written statement under the Unfunded Mandates Reform Act.

G. Congressional Review Act

FMCS will submit this interim final rule to Congress and the Comptroller General in accordance with 5 U.S.C. 801. OIRA has determined that this rule is not a ''major rule'' within the meaning of 5 U.S.C. 804(2).

H. Paperwork Reduction Act

This rule does not impose a new collection of information within the meaning of the Paperwork Reduction Act because it does not require standardized reporting or recordkeeping by the public. If FMCS later revises Form R–43 or creates a standardized submission requirement to implement threshold inquiries under this rule, FMCS will evaluate whether approval from OMB is required under the Paperwork Reduction Act.

List of Subjects in 29 Part 1404

Administrative practice and procedures; Arbitration; Labor management relations.

For the reasons stated in the preamble, the Federal Mediation and Conciliation Service amends 29 CFR part 1404 as follows:

PART 1404—ARBITRATION SERVICES

■ 1. The authority citation continues to read as follows:

Authority: 29 U.S.C. 172 and 29 U.S.C. 173 *et seq.*

Subpart C—Procedures for Arbitration Services

■ 2. Amend § 1404.9 by revising paragraph (b) to read as follows:

§ 1404.9 Procedures for requesting arbitration lists and panels.

* * * * *

(b)(1) Upon request, OA will refer a randomly selected panel of seven arbitrators to parties to an agreement to arbitrate or engage in fact-finding, or where labor arbitration or fact-finding may be provided by statute. A biographical sketch will be provided for each member of the panel. This sketch states the background, qualifications, experience, and all fees as furnished to OA by the arbitrator.

(2) A request for a panel may be joint or unilateral unless this part, applicable law, or the parties' agreement requires joint authorization for the requested service. Requests for a panel of other than seven names, for direct appointment of an arbitrator, or for special qualifications or other special service will not be honored unless jointly submitted or authorized by both parties pursuant to mutual agreement.

(3) OA may conduct a limited threshold inquiry to determine whether issuing a panel, making a direct appointment, or providing related arbitration services would be inconsistent with applicable law, a court order, or FMCS's statutory or regulatory authority. OA may request from the parties the agreement, statutory provision, regulation, court order, written authorization, or other information necessary to determine whether OA may provide the requested service. Following such inquiry, FMCS may issue the panel or appointment, decline to provide the requested service, hold the request in abeyance, or take other administratively appropriate action.

(4) OA's issuance of a panel or appointment, refusal to issue a panel or appointment, or decision to hold a request in abeyance does not constitute a decision on the validity of any collective-bargaining agreement, the merits of any grievance, the arbitrability of any dispute, or the rights or obligations of the parties under any agreement or law.

* * * * *

■ 3. Revise § 1404.10 to read as follows:

§ 1404.10 Arbitrability.

OA will not decide the merits of a claim by either party that a dispute is not subject to arbitration. OA may, however, conduct a limited threshold inquiry to determine whether FMCS may lawfully submit a panel, make a direct appointment, or provide related arbitration services under this part, consistent with § 1404.9.

■ 4. Amend § 1404.11 by revising paragraphs (b) and (c) to read as follows:

§ 1404.11 Nominations of arbitrators.

* * * * *

(b) Subject to §§ 1404.9 and 1404.10, OA will provide a randomly selected panel of arbitrators located in geographical areas in proximity of the hearing site, as specified in the request. The parties may jointly request special qualification of arbitrators experienced in certain issues or industries or that possess certain backgrounds, or a panel with no geographic restrictions within the U.S. OA has no obligation to put an individual on any given panel or on a minimum number of panels in any fixed period. If at any time both parties request that a name or names be included, or omitted, from a panel, such name or names will be included, or omitted, unless the number of names is excessive. These inclusions/exclusions may not discriminate against anyone because of age, race, color, sex, national origin, disability, genetic information, religion, or any other basis prohibited by applicable law.

(c) If the parties do not agree on an arbitrator from the first panel, OA will furnish up to five additional panels to the parties upon joint request, or upon a unilateral request if authorized by the applicable collective bargaining agreement, statute, regulation, court order, or other binding authority, and payment of additional fees. This paragraph is subject to §§ 1404.9 and 1404.10. OA may decline to furnish an additional panel, or may hold the request in abeyance, if OA determines under § 1404.9(b) that furnishing the additional panel would be inconsistent with applicable law, a court order, or

FMCS's statutory or regulatory authority.

■ 5. Amend § 1404.12 by revising paragraphs (b) and (c) to read as follows:

§ 1404.12 Selection by parties and appointment of arbitrators.

* * * * *

(b) Where the parties' collective bargaining agreement permits each party to separately notify OA of its ranked order of preference, or is silent on the manner of selecting arbitrators, FMCS will ask each party to advise OA of its order of preference by numbering each name on the panel and submitting the numbered list in writing to OA. Upon receiving the rank order from one party, OA will notify the other party that it has fourteen (14) days in which to submit its selections. Where both parties respond, the name that has the lowest combined number will be appointed. If the other party fails to respond, the first party's choice will be honored. This paragraph is subject to § 1404.9(b) and does not require OA to make an appointment where OA determines that the appointment would be inconsistent with applicable law, a court order, or FMCS's statutory or regulatory authority.

(c) Subject to §§ 1404.9 and 1404.10, OA will make a direct appointment of an arbitrator only upon joint request or as otherwise provided by this part.

Dated: July 31, 2026.

Anna Davis,

General Counsel.

[FR Doc. 2026–15798 Filed 8–3–26; 8:45 am]

BILLING CODE 6732–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2026–0957]

RIN 1625–AA00

Safety Zone; Ohio River; River, Aurora, IN

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters on the Ohio River, from mile marker (MM) 499 to MM 497 in Aurora, Indiana. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with an over water powerline replacement. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Ohio Valley, or their designated representative.

DATES: This rule is effective from August 3, 2026, through August 9, 2026. It will be enforced from 7 a.m. to 5 p.m. each day during this period, or until operations are complete, whichever occurs first.

ADDRESSES: To view available documents go to *https://www.regulations.gov* and search for USCG–2026–0957.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact MST1 Jean Jimenez Sosa, MSD Cincinnati, U.S. Coast Guard; telephone 206–827–1363, or email *Jean.C.JimenezSosa@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background and Authority

The Coast Guard received notification that Duke Energy will be conducting aerial power line replacements within the Ohio River near Aurora, IN. Hazards from this project include but are not limited to deployment of heavy machinery, and various other activities which create hazards for workers and the public. The Captain of the Port (COTP) Ohio Valley has determined that potential hazards associated with power line replacements are a safety concern for anyone within the work area. Therefore, the COTP is issuing this rule under the authority in 46 U.S.C. 70034, which is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone.

Because of these potential hazards, the Coast Guard is issuing this rule without prior notice and comment. As is authorized by 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable and contrary to the public interest. The Coast Guard was notified of this event on July 13, 2026, but we must establish this safety zone by August 9, 2026, to protect personnel, vessels, and the marine environment. Therefore, we do not have enough time to solicit and respond to comments.

For the same reason, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

This rule establishes a safety zone from August 3, 2026, through August 9, 2026. The rule will be enforced from 7 a.m. to 5 p.m. on each day during this period, or until operations are complete. The safety zone will cover all navigable waters of Ohio River, from mile marker (MM) 499 to MM 497 in Aurora, Indiana. Vessels and persons will not be allowed to enter the zone during this time, unless authorized by the Captain of the Port.

IV. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. Impact on Small Entities

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to rules that are not subject to notice and comment. Because the Coast Guard has, for good cause, waived the notice and comment requirement that would otherwise apply to this rulemaking, the Regulatory Flexibility Act's flexibility analysis provisions do not apply here.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

B. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

C. Federalism and Indian Tribal Governments

We have analyzed this rule under Executive Order 13132, Federalism, and

have determined that it is consistent with the fundamental federalism principles and preemption requirements described in that Order.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

D. Unfunded Mandates Reform Act

As required by The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Coast Guard certifies that this rule will not result in an annual expenditure of $100,000,000 or more (adjusted for inflation) by a State, local, or tribal government, in the aggregate, or by the private sector.

E. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment.

This rule is a safety zone. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.4.

■ 2. Add § 165.T08–0957 to read as follows:

§ 165.T08–0957 Safety Zone; Ohio River, Aurora, IN.

(a) *Location.* The following area is a safety zone: All navigable waters of Ohio River, from mile marker (MM) 499 to MM 497 in Aurora, Indiana.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port, Ohio Valley (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative on VHF–FM channel 16 or by telephone at 1–800–253–7465. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement periods.* This section will be enforced from 7 a.m. to 5 p.m. daily from August 3, 2026, through August 9, 2026, or until operations are complete, whichever occurs first.

Randy L. Preston,

Captain, U.S. Coast Guard, Captain of the Port, Ohio Valley.

[FR Doc. 2026–15756 Filed 8–3–26; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2025–0041; FRL–13401–01]

Isofetamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of isofetamid in or on nut, tree, group 14–12, and almond, hulls. Under the Federal Food, Drug, and Cosmetic Act (FFDCA) ISK Biosciences Corporation submitted a petition to EPA requesting that EPA establish a maximum permissible level for residues of this pesticide in or on the identified commodities.

DATES: This regulation is effective August 4, 2026. Objections and requests for hearings must be received on or before October 5, 2026, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2025–0041, is available at *http://www.regulations.gov.* Additional information about dockets generally, along with instructions for visiting the docket in person, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is EPA's authority for taking this action?

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' FFDCA section 408(c)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes

exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify the docket ID number EPA–HQ–OPP–2025–0041 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 5, 2026.

The EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. *See* ''Order Urging Electronic Filing and Service,'' dated December 3, 2025, which can be found at *https://www.epa.gov/system/files/documents/2025-12/2025-12-03-order-urging-electronic-filing-and-service.pdf.*Although the EPA's regulations require submission via U.S. Mail or hand delivery, the EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, the EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/OA/EAB/EAB-ALJ_Upload.nsf.*

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute. If you wish to include CBI in your request, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules*and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Petitioned-For Tolerance

In the **Federal Register** of July 3, 2025 (90 FR 29516) (FRL–12474–05–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F9151) by ISK Biosciences Corporation, 7470 Auburn Rd., Suite A, Concord, OH 44027. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide isofetamid, in or on Tree nut, crop group 14–12 at 0.15 parts per million (ppm) and almond hulls at 15 ppm. The petition also requested to remove tolerances in 40 CFR part 180 for residues of the fungicide isofetamid including its metabolites and degradates in or on the raw agricultural commodities almonds at 0.01 ppm, almond hulls at 0.01 ppm. That document referenced a summary of the petition prepared by ISK Bioscience, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is proposing a higher tolerance for Almond, hulls, based on the available data and the tolerance calculation procedures of the Organization for Economic Cooperation and Development (OECD). The reason for these changes are explained in Unit IV.C.

III. Final Tolerance Action

A. Aggregate Risk Assessment and Determination of Safety

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for isofetamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with isofetamid is summarized in this Unit.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published several tolerance rulemakings for isofetamid in 2015, 2017, 2022 in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to isofetamid and established tolerances for residues of that chemical. EPA is incorporating previously published sections from the 2015 and 2017 rulemakings as described further in this rulemaking, as they remain unchanged.

Specific information on the risk assessment conducted in support of this action can be found in the document titled ''*Isofetamid. Human Health Risk Assessment for a New Tolerance Registration of Isofetamid on Tree Nuts, Crop Group 14–12 and the Amended Tolerance on Almond Hulls*'' and the documents cited therein, which are available in the docket for this action at *https://www.regulations.gov,* docket ID number EPA–HQ–OPP–2025–0041.

B. Toxicological Profile

Specific information on the studies received and the nature of the adverse effects caused by isofetamid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document Isofetamid. Human Health Risk

Assessment for a New Tolerance Registration of Isofetamid on Tree Nuts, Crop Group 14–12 and the Amended Tolerance on Almond Hulls. at page 10–12 in docket ID number EPA–HQ–OPP–2025–0041.

C. Toxicological Points of Departure/Levels of Concern.

For a summary of the Toxicological Points of Departure/Levels of Concern for isofetamid used for human risk assessment, please reference Unit III.B. of the July 30, 2015, rulemaking (80 FR 45438) (FRL–9923–86).

D. Exposure Assessment

1. Dietary Exposure From Food and Feed Uses

In evaluating dietary exposure to isofetamid, EPA considered exposure under the petitioned-for tolerances as well as all existing isofetamid tolerances in 40 CFR 180.681. EPA assessed dietary exposures from isofetamid in food as follows:

i. Acute Exposure

Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for isofetamid therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. Chronic Exposure

In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2005–2010 CSFII. This software uses 2005–2010 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The unrefined chronic dietary exposure assessment used tolerance-level residues and assumed 100 percent crop treated (PCT) for all registered and proposed commodities. Default processing factors were used for all other proposed and registered processed commodities. Exposure to drinking water was incorporated directly into the dietary assessment. A cancer dietary assessment was not conducted because isofetamid is classified as ''not likely to be carcinogenic to humans.''

2. Drinking Water and Non-Occupational Exposures

The previously recommended estimated drinking water concentrations (EDWCs) are unchanged and are considered protective potential drinking water residue levels anticipated from the proposed tolerance updates. As stated in the July 30, 2015, rulemaking, the chronic dietary exposure and risk assessment incorporate the highest total EDWC of 110 parts per billion directly into this dietary assessment (80 FR 45438) (FRL–9923–86). The residential exposure assessment has not changed since the June 14, 2017, rulemaking (new residential uses. For a summary of the residential exposure 82 FR 27149) (FRL–9961–80) because there are no proposed analysis for isofetamid used for the human risk assessment, please reference Unit III.C.3. of the June 14, 2017, rulemaking.

3. Cumulative Exposures

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found isofetamid to share a common mechanism of toxicity with any other substances, and isofetamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that isofetamid does not have a common mechanism of toxicity with other substances.

E. Safety Factor for Infants and Children.

1. *In general.* FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA safety factor were reduced to 1X. That decision is based on the following findings:

EPA concludes that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the July 30, 2015, rulemaking for a discussion of the Agency's rationale for that determination. (80 FR 45438) (FRL–9923–86).

F. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, isofetamid is not expected to pose an acute risk.

2. *Chronic risk.* Chronic Dietary risks of exposure for food and drinking water are below the level of concern (<100% chronic population-adjusted dose or cPAD) for the general U.S. population and all population subgroups. Isofetamid dietary exposure for food and drinking water is 1.1% of the cPAD for the general U.S. population and 3.9% of the cPAD for children 1–2 years old, the most highly exposed population subgroup. This unrefined chronic dietary exposure combined food and drinking water, and assumed 100% crop treated for all of the registered and proposed commodities.

A potential short-term adverse effect via the dietary and residential pathways of children 1 to <2 years old was identified; however, isofetamid is not registered for any use patterns that would result in short-term residential exposure. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, Isofetamid is not expected to pose a cancer risk to humans.

Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to isofetamid residues. More detailed information on this action can be found in the document titled ''Isofetamid. Human Health Risk Assessment for a New Tolerance Registration of

Isofetamid on Tree Nuts, Crop Group 14–12 and the Amended Tolerance on Almond Hulls.'' in docket ID number EPA–HQ–OPP–2025–0041.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the July 30, 2015, rulemaking (80 FR 45438) (FRL–9923–86).

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for isofetamid in or on almonds at 0.01 ppm and almond hulls at 0.8 ppm. Neither Mexico nor Canada has MRLs established on tree nuts. These MRLs are different than the tolerances established for isofetamid in the United States because of differences in the proposed U.S. use sites. No changes to the use pattern of almond were assessed.

C. Revisions to Petitioned-For Tolerances

The Agency is increasing the tolerance on almond, hulls from the proposed tolerance of 15 ppm, to 20 ppm, based on the available use data and the OECD calculation procedures.

V. Conclusion

Therefore, tolerances are established for residues of isofetamid, in or on almond, hulls at 20 ppm, and in or on Nut, tree, group 14–12 at 0.15 ppm. The existing 0.01 ppm tolerance on almond is removed.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/regulations/and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq.,* because it does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

Since tolerance actions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the RFA, 5 U.S.C. 601 *et seq.,* do not apply to this action.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or on the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because tolerance actions like this one are exempt from review under Executive Order 12866. However, EPA's 2026 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions under the FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . .'' (FFDCA 408(b)(2)(C)). The Agency's consideration is summarized in Unit III.E.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: July 27, 2026

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

For the reasons set forth in the preamble, 40 CFR chapter I is amended as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.681, in paragraph (a) amend table 1 to paragraph (a) by

■ a. Removing the entry for ''Almond'';

■ b. Revising the entry for ''Almond, hulls''; and

■ c. Adding in alphabetical order the entry ''Nut, tree, group 14–12''.

The revision and addition read as follows:

§ 180.681 Isofetamid; tolerances for residues.

* * * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Almond, hulls	20
* * * * *	
Nut, tree, group 14–12	0.15
* * * * *	

* * * * *

[FR Doc. 2026–15761 Filed 8–3–26; 8:45 am]

BILLING CODE 6560–50–P

NATIONAL SCIENCE FOUNDATION

45 CFR Part 611

RIN 3145–AA74

Nondiscrimination in Federally Assisted Programs of the National Science Foundation

AGENCY: U.S. National Science Foundation.

ACTION: Final rule.

SUMMARY: The U.S. National Science Foundation (NSF or Foundation) is revising its regulations implementing Title VI of the Civil Rights Act of 1964 (Title VI). NSF is taking this action to align the conduct prohibited by NSF's regulations with Title VI's text, avoid constitutional concerns, reduce compliance costs, serve the public interest, ensure consistency with the final rule recently issued by the Department of Justice (DOJ), and implement the direction outlined in Executive Order (E.O.) 14281.

DATES: The Rule is effective on August 4, 2026.

FOR FURTHER INFORMATION CONTACT: Scott Carr, Equal Opportunity Specialist, U.S. National Science Foundation, Randolph Building, 401 Dulany Street, Alexandria, VA, 22314, (703) 292–7020, *ACB@nsf.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

NSF is rescinding portions of its regulations promulgated pursuant to Title VI to more closely align its regulations with the language Congress enacted in Title VI prohibiting intentionally discriminatory conduct, *see* 42 U.S.C. 2000d. There are serious statutory and constitutional concerns with the legality of provisions in NSF's Title VI regulations that go beyond intentional discrimination by prohibiting conduct that has an unintentional disparate impact. This rule accordingly rescinds those portions of the regulations, which are in considerable tension with both the statute and the Constitution and do not sufficiently serve the public interest. First, this rule rescinds 45 CFR 611.3(b)(2), which currently prohibits the utilization of ''criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin.'' Second, this rule removes the two uses of the phrase ''or effect'' from 45 CFR 611.3(b)(3). Third, this rule rescinds 45 CFR 611.3(b)(6). Fourth, this rule rescinds 45 CFR 611.3(c)(4), which addresses employment practices of Federal funding recipients. Fifth, this rule rescinds CFR 611.5(6) and (7), which provide illustrative examples of disparate-impact liability without a showing of intentional discrimination.

These changes also align NSF's Title VI regulations with changes made by DOJ in its 2025 Final Rule (2025 DOJ Final Rule). 90 FR 57141. Finally, NSF's rule conforms to E.O. 14281, *Restoring Equality of Opportunity and Meritocracy,* 90 FR 7537 (Apr. 28, 2025). The practical impact of this rule's deletions will be to clarify for NSF Federal funding recipients that NSF's Title VI regulations do not prohibit disparate impact and prohibit only intentional discrimination, and that NSF thus will not pursue Title VI disparate impact liability against its Federal funding recipients.

II. Discussion

A. Statutory Background

NSF is a Federal agency that supports science and engineering in all 50 States and in U.S. territories. Established by the National Science Foundation Act of 1950, Public Law 81–507, 64 Stat. 149 (codified at 42 U.S.C. 1861 *et seq.*), NSF promotes the progress of science; advances the national health, prosperity, and welfare; and secures the national defense. To support these missions, NSF funds basic research conducted at U.S. colleges and universities, in fields such as mathematics, computer science, engineering, and biotechnology, and Science, Technology, Engineering, and Mathematics (STEM) workforce development. NSF also funds research infrastructure, ranging from individual instruments to major research facilities and equipment (*e.g.,* computing facilities, U.S. Antarctic stations, and large telescopes). The funding is provided chiefly through grants.

Title VI, as amended, prohibits intentional discrimination on the ''ground of race, color, or national origin'' in all programs or activities that receive Federal financial assistance. 42 U.S.C. 2000d. Title VI also directs Federal departments and agencies that extend Federal financial assistance to ''effectuate the provisions of'' Title VI ''by issuing rules, regulations, or orders of general applicability.'' 42 U.S.C. 2000d–1. The section of Title VI that sets forth the prohibited conduct, 42 U.S.C. 2000d, specifically prohibits intentional discrimination and makes no reference to unintentional disparate effects or impact. *See Alexander* v. *Sandoval,* 532 U.S. 275, 280 (2001) (''[I]t is . . . beyond dispute—and no party disagrees—that [Title VI] prohibits only intentional discrimination.''). The statute does not provide any Federal department or agency with authority to prohibit unintentional disparate impact. And despite ample opportunities, Congress has enacted no subsequent amendments to Title VI to impose disparate-impact liability.

B. Regulatory History of 45 CFR Part 611

NSF's Title VI implementing regulations are codified at 45 CFR part 611. NSF issued these regulations in 1964 upon approval by President Lyndon B. Johnson. NSF's Title VI regulations were subsequently amended

five times: in 1973, *see* 38 FR 17920 (July 5, 1973) (incorporating changes recommended by DOJ); in 1984, *see* 49 FR 37594 (Sept. 25, 1984) (making technical corrections); in 1986, *see* 51 FR 22938 (June 24, 1986) (simplifying internal NSF procedures for approving orders suspending, terminating, or refusing to grant federal financial assistance); in 1994, *see* 59 FR 37437 (July 22, 1994) (housekeeping amendments); and in 2003, s*ee* 68 FR 51334 (Aug. 26, 2003) (aligning with the Civil Rights Restoration Act of 1987, Pub. L. 100–259). NSF's implementing regulation describing the scope of conduct considered to be discriminatory and therefore prohibited, codified at 45 CFR 611.3, currently includes prohibitions addressing conduct giving rise to an unintentional disparate impact. NSF's regulations also include examples illustrating the application of these provisions to some of the programs funded by NSF, at 45 CFR 611.5.

C. Relevant Supreme Court Decisions

The Supreme Court has concluded that Title VI, 42 U.S.C. 2000d, does not prohibit facially neutral policies that result in disparate outcomes when there is no discriminatory intent. Rather, it prohibits only intentional discrimination. In 1978, the Supreme Court concluded that Congress intended Title VI to prohibit ''only those racial classifications that would violate the Equal Protection Clause'' if committed by a government actor. *Regents of the Univ. of Cal.* v. *Bakke,* 438 U.S. 265, 287 (1978) (Powell, J., announcing the judgment of the Court); *id.* at 325, 328, 352–53 (Brennan, White, Marshall, and Blackmun, JJ., concurring in part and dissenting in part); *see also Students for Fair Admissions, Inc.* v. *President & Fellows of Harvard Coll.,* 600 U.S. 181, 198 n.2 (2023) (*SFFA*). Shortly before *Bakke*'s Title VI holding, the Supreme Court held that the Equal Protection Clause prohibits only intentional discrimination and that ''a law or other official act'' that has a ''racially disproportionate impact'' alone does not violate that Clause. *Washington* v. *Davis,* 426 U.S. 229, 239 (1976); *see also Vill. of Arlington Heights* v. *Metro. Hous. Dev. Corp.,* 429 U.S. 252, 265 (1977) (''Proof of racially discriminatory intent or purpose is required to show a violation of the Equal Protection Clause.''). Taken together, these Supreme Court cases establish that Title VI's statutory prohibition, like the Equal Protection Clause, extends only to intentional discrimination.

In 2001, the Supreme Court, in *Alexander* v. *Sandoval,* reaffirmed that settled understanding. 532 U.S. at 280 (''[I]t is . . . beyond dispute . . . that [Title VI] prohibits only intentional discrimination.''). In *Sandoval,* the Supreme Court held that private plaintiffs lacked a private right of action to enforce DOJ's ''disparate-impact regulations.'' *Id.* at 285–87. Though the Supreme Court had previously found a private cause of action to enforce Title VI's bar on intentional discrimination, *id.* at 279–80, that conclusion did not extend to enforcing DOJ's ''disparate-impact regulations.'' *Id.* at 285. As the Supreme Court explained, it is ''clear'' that ''the disparate-impact regulations do not simply apply'' the statutory prohibition, as the regulations ''forbid conduct that [Title VI] permits,'' so it is equally ''clear that the private right of action to enforce [Title VI] does not include a private right to enforce these regulations.'' *Id.* While the Supreme Court in *Sandoval* ''assume[d],'' without deciding, that DOJ's disparate-impact regulations were valid, the Court explained that the regulations are in ''considerable tension'' with the Supreme Court's Title VI precedents. *Id.* at 282. Similarly, the regulations do not ''authoritatively'' construe Title VI because the regulations ''forbid conduct''—namely, policies that unintentionally result in a disparate impact—that Title VI ''permits.'' *Id.* at 281–82, 284–85; *see also id.* at 286 n.6 (''[Title VI] permits the very behavior that the regulations forbid.''). The rationale of that holding applies with equal force to NSF's Title VI regulations, which mirror DOJ's Title VI regulations.

In 2023, the Court emphasized that ''the equal protection clause requires equality of treatment before the law for all persons without regard to race or color.'' *SFFA,* 600 U.S. at 205 (cleaned up). In reviewing the admissions policies of certain higher education institutions, the Court explained that the Constitution requires ''eliminating all'' racial discrimination. *Id.* at 206. To that end, it held that ''[a]ny exception to the Constitution's demand for equal protection must survive a daunting two-step examination known in our cases as 'strict scrutiny,' '' which requires that racial classifications '' 'further compelling government interests' '' and be '' 'narrowly tailored'—meaning 'necessary'—to achieve [such] interest[s].'' *Id.* at 206–07. Moreover, the Court explained that its ''precedents have identified only two compelling interests that permit resort to race-based government action,'' only one of which is relevant in general government administration: ''remediating specific, identified instances of past discrimination that violated the Constitution or a statute.'' *Id.* at 207.

Finally, in 2024, the Supreme Court overruled *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.,* 467 U.S. 837 (1984). *See Loper Bright Enters.* v. *Raimondo,* 603 U.S. 369, 409–12 (2024). In reaching that result, the Supreme Court made clear that ''statutes . . . have a single, best meaning'' that is '' 'fixed at the time of enactment.' '' *Id.* at 400 (quoting *Wis. Cent. Ltd.* v. *United States,* 585 U.S. 274, 284 (2018)). Thus, Title VI's bar on discrimination can have only one meaning. And under Supreme Court precedent, the single, best meaning of Title VI is that it ''prohibits only intentional discrimination'' and ''permits'' facially neutral policies that result in disparate outcomes when there is no discriminatory intent. *Sandoval,* 532 U.S. at 280, 286 n.6.

D. Executive Order 14281

On April 23, 2025, the President issued E.O. 14281. This Order restated the ''bedrock principle of the United States . . . that all citizens are treated equally under the law.'' 90 FR at 17537. The Order explained that this ''principle guarantees equality of opportunity, not equal outcomes,'' and ''promises that people are treated as individuals, not components of a particular race or group.'' *Id.*

The Order also explained that disparate-impact liability ''endangers this foundational principle.'' *Id.* Disparate-impact liability, the Order reasoned, ''all but requires individuals and businesses to consider race and engage in racial balancing to avoid potentially crippling legal liability.'' *Id.* As the Order explained, disparate-impact liability ''not only undermines our national values, but also runs contrary to equal protection under the law and, therefore, violates our Constitution.'' *Id.*

The Order relayed that because of disparate-impact liability's problems, ''[i]t is the policy of the United States to eliminate the use of disparate-impact liability in all contexts to the maximum degree possible to avoid violating the Constitution, Federal civil rights laws, and basic American ideals.'' *Id.* The Order directed the Attorney General to, among other things, review Title VI regulations and ''initiate appropriate action to repeal or amend'' them ''to the extent they contemplate disparate-impact liability.'' *Id.* at 17538. Accordingly, this rule revises the Foundation's Title VI regulations to effectuate the Order's policy and purpose under the leadership of the Attorney General.

In any event, the Foundation would have initiated steps toward making these changes regardless of E.O. 14281. The Order states, and the Foundation firmly agrees, a ''bedrock principle of the United States is that all citizens are treated equally under the law. This principle guarantees equality of opportunity, not equal outcomes. It promises that people are treated as individuals, not components of a particular race or group. It encourages meritocracy and a colorblind society,'' not race-, color-, or national-origin-based favoritism. 90 FR at 17537. And adherence to this principle, including in the issuance of grants, ''is essential to creating opportunity, encouraging achievement, and sustaining the American Dream.'' *Id.*

Imposing disparate-impact liability endangers these policy objectives. Disparate-impact liability also raises serious constitutional concerns, is in considerable tension with the single, best meaning of Title VI, creates confusion, increases the costs of compliance, and does not serve the public interest. After considering the relevant issues and factors and weighing the relevant considerations, the Foundation concludes that these reasons, separately and together, support eliminating disparate-impact liability from the Foundation's Title VI regulations.

E. 2025 DOJ Final Rule

Pursuant to E.O. 12250, *Leadership and Coordination of Nondiscrimination Laws,* 45 FR 72995 (Nov. 4, 1980), DOJ is the lead Federal agency responsible for defining the nature and scope of Title VI's prohibition of discrimination on the basis of race, color, and national origin in programs or activities receiving Federal financial assistance. As part of this responsibility, E.O. 12250 requires the Attorney General to approve other agencies' regulations implementing Title VI. *See id.* at 72995–96.

On December 10, 2025, DOJ issued the 2025 DOJ Final Rule rescinding portions of its Title VI regulations to more closely align the regulations with Title VI's prohibition on intentionally discriminatory conduct. 90 FR 57141 (Dec. 10, 2025). DOJ articulated statutory and constitutional concerns with the legality of provisions in DOJ's Title VI regulations that went beyond intentional discrimination by prohibiting conduct that has an unintentional disparate impact. *See id.* The 2025 DOJ Final Rule rescinded those portions of the regulations because DOJ concluded they were in considerable tension with the statute and Constitution and did not sufficiently serve the public interest. *See id.*

NSF agrees with the reasoning expressed in DOJ's final rule and provides a similar rationale for this rulemaking.

F. Need for Rulemaking

The Foundation's regulations at 45 CFR part 611, entitled ''Nondiscrimination in Federally-Assisted Programs of the National Science Foundation—Effectuation of Title VI of the Civil Rights Act of 1964,'' contain several provisions that prohibit conduct or activities causing unintentional disparate impact, without a statutory or constitutional basis for doing so. And in some instances, the regulations may encourage or even require unlawful discrimination labeled as ''reasonable action.'' Section 611.3(b)(2) is the current regulation's general disparate-impact prohibition, which states that a ''recipient . . . may not . . . utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin.'' 45 CFR 611.3(b)(2). Beyond that general prohibition, section 611.3(b)(3) addresses a Federal funding recipient's selection of the site or location of facilities and includes two references to ''effect'' that extend the scope of prohibited conduct to include conduct with unintentional disparate impact. *Id.* 611.3(b)(3). Section 611.3(b)(6) concerns the use of ''reasonable action,'' and provides that funding recipients may (and sometimes must) use race, color, or national origin to overcome unintentional disparate ''effects,'' but does not expressly specify that the funding recipient must narrowly tailor such use to serve a compelling governmental interest, as is required to satisfy strict scrutiny. *Id.* 611.3(b)(6). Section 611.3(c) addresses prohibited discriminatory employment practices and extends beyond intentional discrimination to prohibiting conduct that ''tends'' to have a discriminatory effect. *Id.* 611.3(c)(4). Finally, 45 CFR 611.5(6) and (7) provide illustrative examples of disparate-impact liability without a showing of intentional discrimination. *Id.* 611.5(6)–(7).

There are serious statutory and constitutional concerns with the legality of the Foundation's Title VI disparate-impact regulations. The Foundation also has serious policy concerns with its current disparate-impact regulations because they create confusion, undermine public confidence in the Nation's civil rights laws and the rule of law, and may produce burdensome litigation and compliance costs for the Foundation's grantees.

1. Serious Legal Concerns

There are serious statutory concerns as to whether Title VI authorizes the disparate-impact provisions of the current regulations. As the Supreme Court has made clear, Title VI prohibits ''only intentional discrimination'' and ''permits'' facially neutral policies that result in disparate outcomes when there is no discriminatory intent. *Sandoval,* 532 U.S. at 280, 286 n.6. That is the ''single, best meaning'' of Title VI. *Loper Bright,* 603 U.S. at 400. As summarized above, *Sandoval* calls into serious doubt the legality of the Foundation's ''disparate-impact regulations.'' 532 U.S. at 281–82, 284–85 (noting that DOJ's regulations are in ''considerable tension'' with the Supreme Court's Title VI precedents);[1] *see also id.* at 286 n.6 (''[Title VI] permits the very behavior that the regulations forbid.''). Although *Sandoval* resolved only the question of private enforceability, subsequent cases such as *Loper Bright* have made clear that the Foundation cannot extend Title VI beyond its single, best meaning. *See* 603 U.S. at 412–13 (holding that ''courts must . . . ensur[e] that [an] agency acts within'' its statutory authority). And even in the absence of Supreme Court precedent, the Foundation would have concluded that the best reading of Title VI is that it prohibits only intentional discrimination.

Title VI authorizes agencies to promulgate regulations ''to effectuate'' the statute's prohibition of intentional discrimination. 42 U.S.C. 2000d–1. The current regulations' extension of prohibited conduct to include conduct with an unintentional disparate impact reaches a vastly broader range of conduct than the statute itself. This range is too broad to be considered a simple prophylactic measure aimed at preventing intentional discrimination. *See Sandoval,* 532 U.S. at 286 n.6 (''[Title VI] permits the very behavior that the regulations forbid.''). Thus, the disparate-impact regulations do not ''effectuate'' Title VI. 42 U.S.C. 2000d-1.

There are also serious concerns about whether the Foundation's Title VI regulations pass constitutional muster under the Equal Protection Clause. As the Supreme Court recently held in *SFFA,* ''the Equal Protection Clause . . . applies without regard to any differences of race, of color, or of

[1] NSF's regulations, which are modeled off DOJ's regulations, and are approved by the Attorney General, would similarly be in tension with *Sandoval.*

nationality—it is universal in its application'' and the ''guarantee of equal protection cannot mean one thing when applied to one individual and something else when applied to a person of another color.'' 600 U.S. at 206 (internal quotation marks omitted) (first quoting *Yick Wo* v. *Hopkins,* 118 U.S. 356, 369 (1886); and then quoting *Bakke,* 438 U.S. at 289–90 (Powell, J.)). Despite the promises of the Equal Protection Clause, a funding recipient's risk of disparate-impact liability under the Foundation's regulations is triggered by unintentional disparate outcomes, which the recipient may not even know about without investigation. To evaluate and avoid this risk, the funding recipient must incur investigatory costs, such as conducting an impact analysis, and is coerced to proactively consider race, color, and national origin, and potentially use it to change the unintended disparate outcomes.

In short, disparate-impact liability encourages and, in some cases, requires covered entities to engage in the intentional use of race and racial balancing to eliminate those disparate outcomes by treating certain racial groups differently from others—the exact conduct the Equal Protection Clause forbids. *See id.* This serious constitutional concern further confirms that the best reading of Title VI is that it prohibits only intentional discrimination and does not authorize the Foundation to impose disparate-impact liability. *See Edward J. DeBartolo Corp.* v. *Fla. Gulf Coast Bldg. & Constr. Trades Council,* 485 U.S. 568, 575 (1988) (''[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress.'' (citing *NLRB* v. *Catholic Bishop of Chi.,* 440 U.S. 490, 499–501, 504 (1979)).

This use of race, color, or national origin violates the Equal Protection Clause unless it survives review under the ''daunting'' strict-scrutiny standard. *SFFA,* 600 U.S. at 206; *see also Free Speech Coal., Inc.* v. *Paxton,* 145 S. Ct. 2291, 2310 (2025) (''Strict scrutiny—which requires a restriction to be the least restrictive means of achieving a compelling governmental interest—is 'the most demanding test known to constitutional law.' '' (quoting *City of Boerne* v. *Flores,* 521 U.S. 507, 534 (1997)). The use of race, color, or national origin necessitated by the disparate-impact provisions runs into serious issues with the requirement of narrow tailoring to achieve a compelling interest. *SFFA,* 600 U.S. at 206–07.

Similarly, the ''reasonable action'' provision authorizes and sometimes requires the intentional use of race without requiring that this use be narrowly tailored to serve a recognized compelling interest. Instead, it encourages intentional racial balancing ''to overcome the consequences of'' unintended racial disparities. 45 CFR 611.3(b)(6). Thus, for substantially the same reasons as above, the ''reasonable action'' provision raises serious constitutional concerns.

As summarized above, there are serious statutory and constitutional concerns with the Foundation's disparate-impact regulations. But even if the regulations were legal, the Foundation finds that eliminating the potential constitutional concerns addressed above would independently justify the amendment of the regulations. *Cf. U.S. Tel. Ass'n* v. *FCC,* 188 F.3d 521, 528 (D.C. Cir. 1999) (concluding it was not ''arbitrary and capricious'' to adopt a certain policy in order to ''avoid[ ] raising a non-trivial constitutional question''). And even if the regulations did not raise serious constitutional concerns, the Foundation finds that eliminating the costs and confusion caused by the mismatch between the statute and the disparate-impact regulations would independently justify the repeal of the regulations.

2. Serious Policy Concerns

The Foundation also has serious policy concerns with the Title VI regulations' imposition of disparate-impact liability. While the Foundation expresses its policy concerns with disparate-impact liability independent of E.O. 14281, that Order sets forth many valid policy concerns with disparate-impact liability. As noted in section 1 of the Order, ''[o]n a practical level, disparate-impact liability has hindered businesses from making hiring and other employment decisions based on merit and skill, their needs, or the needs of their customers because of the specter that such a process might lead to disparate outcomes, and thus disparate-impact lawsuits. This has made it difficult, and in some cases impossible, for employers to use bona fide job-oriented evaluations when recruiting, which prevents job seekers from being paired with jobs to which their skills are most suited—in other words, it deprives them of opportunities for success.'' 90 FR at 17537. Moreover, the legal concerns identified above have caused uncertainty and confusion for Federal funding recipients as to whether and when they need to comply with the disparate-impact regulations and when they can or must consider race, color, and national origin. As explained above, *Sandoval* casts substantial doubt on the validity of the disparate-impact regulations that many Federal departments and agencies have promulgated pursuant to Title VI. 532 U.S. at 280–82.

Additionally in practice, and as explained above, disparate-impact liability leads covered entities to engage in racial balancing even as Title VI forbids intentional racial discrimination. This tension tends to create confusion, undermine public confidence in the Nation's civil rights laws, and undermine public confidence in the rule of law itself, as the law seems to both forbid and require the same conduct.

These problems are amplified by the arbitrary nature of the racial and ethnic categories typically used to measure disparate effects, which, by virtue of their arbitrariness, typically lack a meaningful connection to a compelling interest. *See, e.g., SFFA,* 600 U.S. at 216–17 (explaining that the ''[racial] categories'' at issue were ''themselves imprecise in many ways'' and ''the use of these opaque racial categories undermine[d], instead of promote[d], [their] goals''). Although many of the Foundation's grant proposals focus on minority groups to comply with statutory requirements, *see e.g.,* 42 U.S.C. 1862n–10 (minority-serving institutions undergraduate program); 42 U.S.C. 1862p–4 (undergraduate broadening participation program), some of them may have explicitly targeted certain racial groups without specific statutory authorization. For example, in 2025, NSF terminated awards to ensure alignment with agency priorities. A list of those awards, publicly available at *https://www.nsf.gov/updates-on-priorities#archived-information-41b,* identifies awards that targeted racial groups and inclusion and diversity in STEM education.[2] The Foundation believes that amending its regulations to avoid encouraging the use of imprecise and arbitrary racial categories will help maintain clarity and public confidence in the Nation's civil rights laws.

The Foundation has considered the view that looking at disparate effects can be useful in identifying and deterring subtle intentional discrimination or intentional

[2] This list can be found under the Frequently Asked Question, *Is there a publicly available list of the awards NSF has terminated?* The entries on this list notwithstanding, NSF has complied with the terms and conditions of all preliminary and permanent injunctions requiring award reinstatement.

indifference to unnecessary and arbitrary barriers. But any benefits are outweighed by the other issues and factors that the Foundation has considered, such as, for example, the need for NSF's regulations to be consistent with DOJ's regulations and other grant-making agencies' regulations. And in any event, the concern is mitigated by the fact that eliminating disparate-impact liability does not preclude the use of data on disparate outcomes to help prove intentional discrimination. Indeed, NSF's regulations at section 611.6, which remain unchanged by this rulemaking, require that recipients of NSF grant funding keep complete and accurate compliance information available for inspection by the responsible Foundation official. Private litigants rely on such data as a potential indicator of intentional discrimination. This use of statistical disparity to help establish, as an evidentiary matter, liability for intentional discrimination materially differs from using such disparity to impose liability for an unintentional disparate impact.

The Foundation has also considered the alternative of trying to adopt a modified version of disparate-impact liability, for example, by requiring covered entities to remedy unintentional discrimination for only certain types of cases involving areas with historical patterns of discrimination, such as education. But any version of imposing liability for unintentional discrimination is inconsistent with Title VI's single, best meaning. Regardless, even a modified version of disparate-impact liability would not eliminate the Foundation's serious legal and policy concerns. The Foundation determines that any benefits from a regulation adopting alternative versions of disparate-impact liability are outweighed by those concerns. And even if possible, developing such a rule would not solve the confusion or rule-of-law concerns expressed above, nor reduce the compliance and litigation costs that covered entities face. The Foundation believes that the better course is to avoid the complexities, costs, and litigation associated with this alternative, even if eliminating disparate-impact liability ultimately would leave some problems unaddressed and others inadequately addressed.

The Foundation additionally has considered the potential reliance interests of funding recipients and others on the disparate-impact regulations. As noted in section IV.B of this preamble NSF estimates that since 2017, fewer than 30 percent of the total number of civil rights complaints received included alleged violations of Title VI, and of that number, NSF accepted and investigated only 1.3 percent.[3] Moreover, NSF has not identified any Title VI violations by NSF awardees since 2005 and presently has no ongoing disparate-impact complaints, investigations, or other enforcement activity. Based on this data, NSF believes there exists minimal evidence of meaningful reliance interests. In addition, the *Sandoval* decision cast serious doubt on the continuing viability of the regulations more than 25 years ago. E.O. 14281 also directed all agencies to ''deprioritize enforcement of all statutes and regulations to the extent they include disparate-impact liability,'' which includes the Foundation's Title VI disparate-impact regulations. 90 FR at 17538. The Foundation accordingly believes that such minimal reliance interests would likely not outweigh the Foundation's legal and policy concerns. Further, each of the Foundation's concerns, whether considered cumulatively or separately, outweighs any reliance interests.

The Foundation notes that *Sandoval* has also led to a divergence between Title VI enforcement by private plaintiffs and enforcement by Federal departments and agencies. After *Sandoval,* private plaintiffs can enforce only Title VI's statutory prohibition on intentional discrimination, while the Foundation could continue to pursue disparate-impact liability. Repealing the disparate-impact regulations would eliminate this incongruent enforcement.

Overall, after considering the relevant issues and factors and weighing the relevant considerations, the Foundation finds that, regardless of the legality of the Foundation's disparate-impact regulations, the above summarized policy concerns, when viewed separately or cumulatively, independently justify the repeal of its disparate-impact regulations.

III. Regulatory Changes

For the reasons summarized above, NSF is revising its Title VI regulations at 45 CFR part 611 consistent with the 2025 DOJ Final Rule and the authorities described in the 2025 DOJ Final Rule. The practical impact of this rule's revisions will be to clarify for NSF federal funding recipients that NSF's Title VI regulations do not prohibit unintentional disparate impact and NSF thus will not pursue Title VI disparate-impact liability against its Federal funding recipients. A section-by-section analysis of the changes follows, consistent with the changes in the 2025 DOJ Final Rule.

A. Table Summarizing Amendments

The table below indicates the exact wording changes. For each section indicated in the left column, the text shown in the middle column is removed and the text shown in the right column is added:

Section	Remove	Add
611.3(b)(2)	Full text of paragraph: ''(2) A recipient . . . or national origin.''	''[Reserved]''.
611.3(b)(3)	Both instances of ''or effect''.	
611.3(b)(6)	Full text of paragraph: ''(6) This regulation . . . to accomplish the purposes of the Act.''.	
611.3(c)(4)	Full text of paragraph: ''(4) Where a primary objective of . . . beneficiaries.''.	
611.5	Full text of paragraphs (6) and (7)..	

B. Section-by-Section Analysis

Section 611.3(b)(2)

Section 611.3(b)(2) is the current regulation's general prohibition of unintentional disparate impact. This paragraph expands prohibited conduct from purposeful discrimination to Federal funding recipients who ''utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin.'' Because this paragraph's only purpose is to extend the scope of the regulation

[3] Of the 75 formal complaints filed with NSF that included an alleged violation of Title VI, 1 (1.3 percent) was accepted for investigation, 46 (61.3 percent) were dismissed due to jurisdictional, procedural, or contextual issues, 26 (34.7 percent) were referred to another office, 1 (1.3 percent) was withdrawn by the complainant, and 1 (1.3 percent) is currently under review.

to conduct causing unintentional disparate impacts, this rule deletes the paragraph, consistent with Title VI and the 2025 DOJ Final Rule. The rule replaces paragraph (b)(2) with a placeholder to maintain the numbering accuracy of previous citations and other references to parts of this section.

Section 611.3(b)(3)

Section 611.3(b)(3) addresses a Federal funding recipient's or applicant's selection of sites or locations of facilities. The paragraph provides that a funding recipient may not make selections with the ''purpose or effect'' of discriminating, or ''with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of'' Title VI or NSF's implementing regulations. The paragraph's two references to ''effect'' extend its scope to unintentional disparate impacts. This rule deletes both instances of ''or effect'' to conform paragraph (b)(3) more closely to Title VI, the 2025 DOJ Final Rule, and the other authorities described herein.

Section 611.3(b)(6)

Section 611.3(b)(6) addresses a recipient's ''reasonable action'' with respect to race, color, and national origin. Paragraph (b)(6) authorizes affirmative action in programs even in the absence of a finding of prior discrimination in a program ''if the purpose and effect are to remove or overcome the consequences of practices or impediments which have restricted the availability of, or participation in, the program or activity receiving Federal financial assistance, on the grounds of race, color, or national origin.'' This provision points not to intentional discrimination, but rather to the unintentional ''consequences of practices or impediments.'' The provision consequently authorizes intentional racial classifications, racial preferences, and other race-based actions without the compelling interest and narrow tailoring required by the Equal Protection Clause—practices that have long been unlawful under an Equal Protection Clause analysis.

Paragraph (b)(6) also requires a recipient ''to take reasonable action to remove or overcome the consequences of the prior discriminatory practice or usage, and to accomplish the purposes of the Act'' ''[w]here previous discriminatory practice or usage tends, on the grounds of race, color, or national origin, to exclude individuals from participation in, to deny them the benefits of, or to subject them to discrimination under any program or activity to which this regulation applies.'' This provision goes beyond the Equal Protection Clause, which, in limited circumstances permits, but does not mandate, a government to take narrowly tailored action to remedy the effects of its identified past discrimination. *See, e.g., Bakke,* 438 U.S. at 307 (Powell, J.). Moreover, even putting aside the mandatory language, this provision does not expressly require narrow tailoring to counter particular past discrimination. Accordingly, it promotes potentially illegal race, color, and national origin discrimination. This rule, therefore, removes paragraph (b)(6).

Section 611.3(c)(4)

Section 611.3(c) addresses prohibited discriminatory employment practices for Federal funding recipients. Paragraph (c)(4) extends the prohibition to employment practices of the recipient even ''[w]here a primary objective of the Federal financial assistance is not to provide employment'' if discrimination in the nonfunded ''employment practices tends, on the ground of race, color, or national origin, to exclude persons from participation in, to deny them the benefits of or to subject them to discrimination under the program receiving Federal financial assistance.'' This paragraph does not prohibit only intentional discrimination but rather extends to conduct that ''tends'' to have a discriminatory effect on a program without the primary objective of providing employment. Moreover, paragraph (c)(4)'s extension to employment practices where the Federal funding's primary objective is not to provide employment conflicts with Congress's statutory limitation wherein ''[n]othing contained in [Title VI] shall be construed to authorize action under [Title VI] by any department or agency with respect to any employment practice of any employer, employment agency, or labor organization except where a primary objective of the Federal financial assistance is to provide employment.'' *See* 42 U.S.C. 2000d–3. Consistent with Title VI and the 2025 DOJ Final Rule, this removes paragraph (c)(4).

Section 611.5

Section 611.5 provides examples to illustrate the application of the Title VI regulatory provisions to some of the programs aided by NSF. To conform with the changes discussed above, NSF is removing the two examples, paragraphs (6) and (7), that illustrate disparate-impact enforcement.

IV. Regulatory Certifications

A. Administrative Procedure Act

NSF issues this final rule without prior public notice and comment or a delayed effective date pursuant to the exception in the Administrative Procedure Act (APA) for rules ''relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.'' 5 U.S.C. 553(a)(2).

Title VI and NSF's implementing regulations concern nondiscrimination conditions on the receipt of Federal financial assistance. They apply to the receipt of Federal ''[g]rants and loans,'' ''property,'' ''personnel'' and ''[a]ny Federal agreement, arrangement, or other contract which has as one of its purposes the provision of assistance.'' 45 CFR 611.13(e); *see also* 45 CFR 611.4 (requiring funding recipients to provide assurance of compliance with Title VI in such form as specified by the ''responsible Foundation official.''). *Cf. Education Programs or Activities Receiving or Benefitting From Federal Financial Assistance,* 82 FR 46655 (Oct. 6, 2017) (invoking the exception to amend Title IX regulations to ''promote consistency in the enforcement of Title IX for [Department of Agriculture] financial assistance recipients''); *Preserving Community and Neighborhood Choice,* 85 FR 47899 (Aug. 7, 2020) (invoking exception to repeal a Housing and Urban Development rule regarding Federal grantees); *Participation by Minority Business Enterprise in Department of Transportation Programs,* 53 FR 18285 (May 23, 1988) (invoking the exception to expand coverage of a Department of Transportation regulation regarding the Federal Aviation Administration's airport financial assistance program); *Nondiscrimination on the Basis of Handicap in Federally Assisted Programs: Suspension of Guidelines With Respect to Mass Transportation,* 46 FR 40687 (Aug. 11, 1981) (invoking the exception to suspend DOJ guidelines prohibiting disability discrimination in transportation programs and activities receiving Federal financial assistance).

Invoking this exception to notice and comment is consistent with the definition for Federal financial assistance provided by the U.S. Office of Management and Budget (OMB) in 2 CFR 200.1, which defines such assistance with the same categories as the APA's exception for rules ''relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.'' With potentially limited exceptions not applicable to the Foundation, all the forms of Federal

financial assistance set forth under 2 CFR 200.1 that the Foundation administers would fall under the ''public property, loans, grants, benefits, or contracts'' exception. Finally, prompt alignment with the 2025 DOJ Final Rule is also necessary to ensure uniform administration of Title VI, and to avoid inconsistent enforcement and potential confusion by recipients of Federal funding assistance. Thus, NSF issues this final rule without prior public notice and comment or a delayed effective date.

B. Executive Orders 12866 (Regulatory Planning and Review), 13563 (Regulatory Review), and 14192 (Unleashing Prosperity Through Deregulation)

Executive Orders 12866, 58 FR 51735 (Sep. 30, 1993), and 13563, 76 FR 3821 (Jan. 18, 2011), direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. It also recognizes that some benefits and costs are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify. In a similar vein, E.O. 14192, 90 FR 9065 (Jan. 31, 2025), directs agencies to significantly reduce the private expenditures required to comply with Federal regulations and provides that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least ten prior regulations.''

OMB has designated this rule a ''significant regulatory action'' under section 3(f) of E.O. 12866, although not economically significant under section 3(f)(1). Accordingly, this rule has been reviewed by OMB. It is also considered a deregulatory action under E.O. 14192.

As explained in the preamble, the regulatory modifications this rule makes are necessary to conform NSF's Title VI regulations to Title VI, the 2025 DOJ Final Rule, and the other authorities described therein. The practical impact of this rule's deletions will be to clarify for NSF Federal funding recipients that NSF's Title VI regulations do not prohibit conduct giving rise to disparate impact and that NSF thus will not pursue Title VI disparate-impact liability against its funding recipients.

As with the 2025 DOJ Final Rule, data limitations make the costs and benefits of the rule difficult for NSF to quantify. This rule affects NSF funding recipients. Congress appropriated approximately $8.8 billion to NSF in fiscal year 2025 to support NSF's rigorous merit review system. In that same fiscal year, NSF received over 43,000 proposals, generating 8,377 competitive awards to 1,621 institutions in 50 states, the District of Columbia, and 3 territories. *See* FY 2025 Agency Financial Report (Dec. 18, 2025), *https://www.nsf.gov/reports/performance/agency-financial-report.*

NSF estimates that, since 2017, fewer than 30 percent of the total number of civil rights complaints it received included alleged violations of Title VI. Of that number, 64 percent were dismissed due to insufficient evidence or other disqualifying factors, 33 percent were referred to another Federal agency, 1.5 percent were withdrawn by the complainant, and 1.5 percent were accepted and investigated by NSF. Although Title VI requirements are considered during on-site as well as virtual compliance reviews, since NSF established its awardee compliance review program in 2005, NSF reviews have not identified any Title VI violations by NSF awardee organizations.

Presently, NSF has no disparate-impact complaints under consideration, no active disparate-impact investigations, and no associated disparate-impact compliance-review activity. For enforcement actions that relate to both intentional discrimination and unintentional disparate impact, NSF does not track and cannot reliably quantify the costs attributable to the varying disparate-impact portions of enforcement actions. That disparate impact is sometimes a factor that may be considered in determining whether discrimination was intentional further impedes monetizing costs and benefits. Therefore, the overall cost effect on NSF is difficult to quantify. However, this deregulatory action should decrease NSF's enforcement costs. And the benefit of this rule is to align NSF's regulations with Title VI and DOJ regulations.

Similarly, NSF is unable to quantify how funding recipients will respond to the regulatory changes. But the deregulatory action may result in greater flexibility and lower compliance costs for recipients. NSF recognizes that a funding recipient may receive Federal funds from sources other than, and in addition to, NSF. DOJ noted in its rule that DOJ expected its rule will cause other Federal departments and agencies to consider similarly revising their Title VI regulations. Like DOJ, NSF does not envision that this rule will appreciably increase administrative costs or compliance costs for funding recipients who must also adhere to the regulations of other departments or agencies. The deregulatory action that NSF takes here does not create any new obligations for funding recipients. On the contrary, by eliminating disparate-impact liability from NSF's regulation, NSF eliminates a source of regulatory confusion, narrows and makes more specific the conduct prohibited, and thus lessens the costs of compliance and potential liability. Moreover, recipients who receive funds for the same program or activity from more than one Federal entity already enter into separate contractual assurances with each funding entity. *See, e.g.,* 45 CFR 611.4; 34 CFR 100.4. These contractual assurances already impose varying requirements that each Federal funding source deems necessary. Funding recipients will continue to be held to the most stringent contractual assurance standards. And in any event, NSF notes that it and other agencies are currently amending their regulations to align with the changes made in the DOJ Final Rule, so the Foundation anticipates that there will be little, if any, disparity in Federal requirements regarding disparate-impact liability going forward.

Based on the analysis of the practical qualitative costs and benefits noted above, NSF believes that this rule is consistent with the principles of EOs 12866 and 13563, including the requirements that, to the extent permitted by law, NSF adopt a regulation only upon a reasoned determination that its benefits justify its costs and choose a regulatory approach that maximizes net benefits. This action is also consistent with the directive of E.O. 14192 to reduce regulatory compliance costs.

C. Executive Order 12250

Pursuant to E.O. 12250, DOJ has the responsibility to ''review . . . proposed rules . . . of the Executive agencies'' implementing nondiscrimination statutes such as Title VI in order to identify those which are inadequate, unclear or unnecessarily inconsistent.'' 45 FR at 72995. DOJ has reviewed and approved this rule.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires an agency to prepare and make available to the public a final regulatory flexibility analysis that describes the effect of a rule on small entities (*i.e.,* small

businesses, small organizations, and small governmental jurisdictions) when the agency was required ''to publish a general notice of proposed rulemaking'' prior to issuing the final rule. *See* 5 U.S.C. 604(a). This rule does not require a regulatory flexibility analysis because, for the reasons described above, no notice of proposed rulemaking is required under 5 U.S.C. 553. *See Or. Trollers Ass'n* v. *Gutierrez,* 452 F.3d 1104, 1123–24 (9th Cir. 2006) (noting that the RFA does not apply when an agency validly invokes an exception to the public comment requirements of 5 U.S.C. 553).

Further, even if a final regulatory flexibility analysis were required, NSF, in accordance with 5 U.S.C. 605(b), has reviewed these regulations and certifies that the rule's changes will not have a significant economic impact on a substantial number of small entities, because these regulatory changes do not impose any new substantive obligations on NSF's funding recipients. The rule merely amends and clarifies existing regulations that are required by Title VI, bringing NSF into compliance with Title VI and changes made by the 2025 DOJ Final Rule. All Federal funding recipients have been previously bound by the standards that will remain in place following this rule.

E. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number issued by OMB. This rule does not propose new, or revisions to existing, ''collection[s] of information'' as that term is defined under the PRA, and its implementing regulations.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (UMRA) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and Tribal governments. Title II of UMRA requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate that may result in an expenditure of $100 million or more (adjusted annually for inflation) in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector. The term ''Federal mandate'' means a Federal intergovernmental mandate or a Federal private sector mandate. *See* 2 U.S.C. 658(6), 1502(1). A ''Federal intergovernmental mandate,'' in turn, is a provision that would impose an enforceable duty upon State, local, or Tribal governments (except as a condition of Federal assistance or a duty arising from participation in a voluntary Federal program). *See* 2 U.S.C. 658(5). And the term ''Federal private sector mandate'' refers to a provision that would impose an enforceable duty upon the private sector (except as a condition of Federal assistance or a duty arising from participation in a voluntary Federal program). *See* 2 U.S.C. 658(7).

NSF has determined that this rulemaking will not result in the expenditure by State, local, and Tribal governments, in the aggregate, nor by the private sector, of $100 million or more in any one year as a result of a Federal mandate, and it will not significantly or uniquely affect small governments. In addition, UMRA's requirements do not apply to any provision in a proposed or final Federal regulation that establishes or enforces any statutory rights that prohibit discrimination on the basis of race, color, religion, sex, national origin, age, handicap, or disability. 2 U.S.C. 1503(2). Therefore, no actions are deemed necessary under UMRA.

G. Congressional Review Act

The Office of Information and Regulatory Affairs has found that this is not a ''major rule'' as defined by Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the Congressional Review Act. 5 U.S.C. 804(2). This rule would not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets. The rule merely narrows the scope of NSF's Title VI regulations to conform them to the scope of Title VI, the 2025 DOJ Final Rule, and the authorities described therein. Doing so does not impose any new obligations on any recipients of Federal funding.

H. Federalism

A rule has implications for federalism under E.O. 13132, *Federalism,* 64 FR 43255 (Aug. 4, 1999), if it has substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. NSF has analyzed this rule under this order and determined it does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

I. Civil Justice Reform

This rule meets applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, *Civil Justice Reform,* 61 FR 4729 (Feb. 5, 1996) to minimize litigation, eliminate ambiguity, and reduce burden.

List of Subjects for 45 CFR Part 611

Civil rights, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the National Science Foundation amends 45 CFR part 611 as follows:

PART 611—NONDISCRIMINATION IN FEDERALLY–ASSISTED PROGRAMS OF THE NATIONAL SCIENCE FOUNDATION—EFFECTUATION OF TITLE VI OF THE CIVIL RIGHTS ACT OF 1964.

■ 1. The authority citation for part 611 continues to read as follows:

Authority: Sec. 11(a), National Science Foundation Act of 1950, as amended, 42 U.S.C. 1870(a); 42 U.S.C. 2000d–1.

■ 2. In section 611.3:
■ a. Remove and reserve paragraph (b)(2);
■ b. Revise paragraph (b)(3);
■ c. Remove paragraph (b)(6); and
■ d. Remove paragraph (c)(4).

The revisions read as follows:

§ 611.3 Discrimination prohibited.

* * * * *

(b) * * *

(2) [Reserved]

(3) In determining the site or location of facilities, a recipient or applicant may not make selections with the purpose of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any program to which this regulation applies, on the grounds of race, color, or national origin; or with the purpose of defeating or substantially impairing the accomplishment of the objectives of the Act or this regulation.

* * * * *

§ 611.5 [Amended]

■ 3. In § 611.5, remove paragraphs 6 and 7.

Brian Stone,

Senior Official Performing the Duties of the Director, U.S. National Science Foundation.

[FR Doc. 2026–15778 Filed 8–3–26; 8:45 am]

BILLING CODE 7555–01–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 107

[Docket No. PHMSA–2025–0095 (HM–268G)]

RIN 2137–AG09

Hazardous Materials: Improving Efficiencies for Special Permits and Approvals Renewals

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule amends the Hazardous Materials Program Procedures to allow an application to renew a special permit or approval to be filed any time on or before its expiration date rather than requiring the renewal application to be filed 60 days in advance as under the current regulations.

DATES: Effective September 3, 2026.

FOR FURTHER INFORMATION CONTACT: Eugenio Cardez, Transportation Regulations Specialist, 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–8553, *eugenio.cardez@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. PHMSA Action

A. What action is PHMSA taking in this final rule?

PHMSA is revising the Hazardous Materials Program Procedures (49 CFR part 107) to simplify the renewal process for special permits and approvals. Instead of requiring applicants to file for a renewal at least 60 days in advance of the expiration date, this final rule allows for submittal at any time on or before the expiration date. This revision ensures that the special permit or approval remains active while PHMSA completes its administrative review.

B. Does this action apply to me?

The action applies to holders of special permits or approvals with an expiration date. Effective 30 days after publication of this final rule, persons will be able to apply for the renewal of a special permit or approval at any time on or before its expiration date.

C. Why is PHMSA taking this action?

PHMSA is taking this action because the agency no longer needs the 60-day lead time to process renewal applications. PHMSA established the 60-day requirement when the application process relied on paper filings submitted by mail. PHMSA has transitioned to an electronic system since that time and can process renewal applications far more efficiently. PHMSA has determined there is no safety case supporting the need for a special permit to expire if a special permit holder fails to submit a renewal application less than 60 days prior to the expiration date and the application is not approved before the expiration date.

II. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published a notice of proposed rulemaking (NPRM), cited as *HM–268G,* to gather feedback on PHMSA amending the timeframe for filing of a renewal application.[1] Please refer to the NPRM for background and discussion of the proposed changes.

The following table alphabetically lists commenters to the NPRM:

Commenter name	Docket No.
Alliance for Chemical Distribution (ACD)	PHMSA–2025–0095–0024
American Coatings Association (ACA)	PHMSA–2025–0095–0009
American Pyrotechnics Association (APA)	PHMSA–2025–0095–0005
Association of American Railroads (AAR) and American Short Line and Regional Railroad Association	PHMSA–2025–0095–0028
Brotherhood of Locomotive Engineers and Trainmen (BLET)	PHMSA–2025–0095–0013
Commercial Vehicle Safety Alliance (CVSA)	PHMSA–2025–0095–0025
Compressed Gas Association, Inc. (CGA)	PHMSA–2025–0095–0011
Council on Safe Transportation of Hazardous Articles, Inc (COSTHA)	PHMSA–2025–0095–0014
Dangerous Goods Advisory Council	PHMSA–2025–0095–0023
Delaware Riverkeeper Network	PHMSA–2025–0095–0015
Household & Commercial Products Association	PHMSA–2025–0095–0016
Independent Cylinder Training LLC	PHMSA–2025–0095–0003
Industrial Packaging Association of North America (IPANA)	PHMSA–2025–0095–0020
Institute of Makers of Explosives	PHMSA–2025–0095–0019
International Vessel Operators Dangerous Goods Association (IVODGA)	PHMSA–2025–0095–0017
Medical Device Transport Council	PHMSA–2025–0095–0012
National Tank Truck Carriers (NTTC)	PHMSA–2025–0095–0006
PerVisum Ltd	PHMSA–2025–0095–0002
Reusable Industrial Packaging Association (RIPA)	PHMSA–2025–0095–0008
SMART TD	PHMSA–2025–0095–0022
Sporting Arms and Ammunition Manufacturers' Institute	PHMSA–2025–0095–0010
Transportation Trades Department, AFL–CIO (TTD)	PHMSA–2025–0095–0027
Utility Solid Waste Activities Group	PHMSA–2025–0095–0026
William Forbes	PHMSA–2025–0095–0018

PHMSA received widespread support for the proposal from a diverse range of industry stakeholders, including trade associations representing shippers, carriers, and packaging manufacturers. Commenters such as the APA, NTTC, and RIPA strongly endorsed the rulemaking, agreeing with PHMSA's assessment that the 60-day advance filing requirement is antiquated given the transition from mail-based paper correspondence to electronic filing systems. Supporters, including COSTHA and IVODGA, emphasized that the current rigid deadline creates unnecessary operational risks, noting that inadvertent lapses can lead to halted production, refused cargo, and supply chain disruptions. Furthermore, entities such as IPANA and AAR concurred that streamlining these

[1] 90 FR 28524 (Jul. 1, 2025).

renewal procedures would reduce administrative burdens and costs without having any adverse impact on transportation safety. Collectively, these commenters—which also included the ACA, CGA, and ACD—urged PHMSA to finalize the amendments to 49 CFR 107.109(b) and 107.705(c) as written to provide greater regulatory flexibility and certainty.

However, some commenters had additional questions or concerns regarding PHMSA oversight and transparency. In addition, two commenters requested clarification of implementation. PHMSA addresses the concerns and requests below.

A. Comments on Accountability

PHMSA received comments from BLET, Smart TD, TTD, and the Delaware Riverkeeper Network stating that the proposals increase the burden on agency personnel and undermine accountability by reducing the time available for review. Commenters further argued that eliminating the 60-day advance filing requirement would create administrative ambiguity and could allow unsafe special permits to remain in effect longer than allowed under the current system.

PHMSA appreciates these comments but disagrees that allowing grantees to file a renewal application at any time on or before expiration would impose undue burdens on agency personnel or create additional ambiguity. PHMSA established the 60-day timeframe when applicants submitted paper filings by mail to help ensure that the process for renewal could play out prior to expiration. However, the modern electronic system allows applications to be received, processed, and evaluated far more quickly, eliminating the need for 60-days of additional lead time. Regarding commenter concerns about the unsafe use of special permits beyond its expiration date, PHMSA disagrees. The underlying safety of a special permit is considered at the outset with the initial application based on a determination by the Associate Administrator,[2] and there is no need to terminate a special permit based solely on the failure to make a filing 60 days in advance, particularly with the transition from a mail-based to an electronic system. Furthermore, the administrative process and evaluation of applications for renewal is not the sole mechanism for safety oversight. PHMSA uses incident reporting, inspections and fitness determinations to help identify and address safety issues during the lifespan of a special permit. The legacy 60-day advance notice should not be misunderstood as necessary to determine safety of a special permit but rather was used as a marker to initiate renewal applications.

B. Comments on Continued Use

PHMSA received comments from CVSA and William Forbes stating that allowing grantees to file an application at any time on or before expiration of the special permit may cause confusion regarding timely submission and whether a special permit has indeed expired, possibly frustrating shipments made under a special permit that is in process under renewal application.

PHMSA appreciates these comments and notes that persons submitting a special permit renewal application via the PHMSA portal will automatically receive a timely filing letter. This letter will verify the submission of the renewal application, alleviating any confusion about the validity of the special permit and preventing frustration of shipments operating under the special permit in question. As stated in 49 CFR 107.109(b), if the application for renewal is received on or before the expiration date, the special permit will not expire prior to final administrative action on the application being taken. This will allow applicants to continue to operate with a special permit that would otherwise have been terminated unnecessarily.

C. Comments on Transparency

PHMSA received comments from BLET, Smart TD, and TTD stating that eliminating the 60-day renewal notice requirement undermines transparency by effectively limiting the time stakeholders have to evaluate special permit renewals. The commenters also argued that the 60-day requirement ensures that decisions regarding the extension of special permits are made with complete visibility and input from those most directly impacted.

PHMSA appreciates these comments and notes that, under the current regulations, new special permit applications—and applications for a modification—are docketed and published in the **Federal Register** under a notice for public comment. Renewals are not. PHMSA further notes that, as under the current process, stakeholders may publicly inspect special permit renewals via the PHMSA portal or request information associated with special permit renewals.[3] This transparency should alleviate commenters' concerns.

D. Additional PHMSA Clarification

PHMSA is making a conforming revision to 49 CFR 107.109(b) to mirror the language in 49 CFR 107.705(c) and clearly state that the use of an expired special permit not filed on or before the expiration date is prohibited. PHMSA notes that hazardous material placed into transportation on or before expiration of a special permit (or an approval) with timely filing for renewal may continue in transportation to its destination.

For these reasons, PHMSA is revising 49 CFR 107.109(b) and 49 CFR 107.705(c) to remove the requirement that renewal applications be filed at least 60 days prior to expiration. The text is revised to state that applications must simply be filed ''on or before'' the expiration date. PHMSA notes this is modified from simply ''before'' in the proposed rule to read ''on or before'' in order to make clear the date by which the renewal must be submitted and that it includes the day on which the PHMSA-issued document expires. In addition, language regarding late filings in 49 CFR 107.705(c) is updated to reflect that applications are timely if filed on or before the expiration date. PHMSA has determined that these revisions will not have any adverse impact on safety.

III. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation as set forth in the Federal Hazardous Materials Transportation Laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [4] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify''

[2] 49 CFR 107.113(f)(2).

[3] 49 CFR 107.127.

[4] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This final rule is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B and determined that this final rule will result in cost savings by reducing regulatory burdens and regulatory uncertainty for affected entities by simplifying the special permit and approval renewal procedures. PHMSA finds those cost savings will also result in reduced costs for the public to whom those entities generally transfer a portion of their compliance costs.

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[5] PHMSA finds the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . . [or] that undermine[s] the national interest.'' [6]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[7] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserted a Federal policy to unleash American energy by ensuing access to abundant supplies of reliable, affordable energy from (inter alia) the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule is consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products and will give affected entities greater flexibility for renewing and continued use special permits and approvals.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [8] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

E. Executive Order 13132; Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[9] E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation laws contain an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and Tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses items that may be covered in Paragraphs 2 and 5 above and would preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Though the final rule may operate to preempt some State requirements, it would not impose any regulation that has substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. The preemptive effect of the regulatory amendments in this final rule is limited to the minimum level necessary to achieve the objectives of the Federal Hazardous Materials Transportation laws. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to notice-and-comment rulemaking under the APA unless the agency head certifies that the final rule will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act.[10] DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[11] This final rule was developed in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. The final

[5] 90 FR 9065 (Feb. 6, 2025).

[6] 90 FR 10583 (Feb. 25, 2025).

[7] 90 FR 8433 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

[8] 66 FR 28355 (May 22, 2001).

[9] 64 FR 43255 (Aug. 10, 1999); 74 FR 24693 (May 22, 2009).

[10] 67 FR 53461 (Aug. 16, 2002).

[11] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

rule will reduce burdens on special permit and approval holders looking to renew these government-issued documents. PHMSA finds the final rule will not impact safety as the timing for submittal of a renewal application has changed but the processing and evaluation of a renewal application remains unchanged. Therefore, PHMSA certifies the final rule does not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, among other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under Section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[12]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A (*Department of Transportation Tribal Consultation Policies and Procedures*).[13] E.O. 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined it will not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded that the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) requires that PHMSA provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking will not create, amend, or rescind any existing information collections.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) requires agencies consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally.[14] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of the final rule and has determined that its regulatory amendments will not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

Executive Order 14028 (*Improving the Nation's Cybersecurity)* directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [15] PHMSA has considered the effects of the final rule and has determined that its regulatory amendments would not materially affect the cybersecurity risk profile for affected entities.

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, or on DOT's website at *http://www.dot.gov/privacy.*

List of Subjects in 49 CFR Part 107

Administrative practice and procedure, Hazardous materials transportation, Penalties, Reporting and recordkeeping requirements.

[12] DOT, PHMSA, *Implementing Procedures* (Aug. 28, 2025), *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[13] 65 FR 67249 (Nov. 9, 2000).

[14] 77 FR 26413 (May 4, 2012).

[15] 86 FR 26633 (May 17, 2021).

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 107—HAZARDOUS MATERIALS PROGRAM PROCEDURES

■ 1. The authority citation for part 107 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 Section 4; Pub. L. 104–121 Sections 212–213; Pub. L. 104–134 Section 31001; Pub. L. 114–74 Section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97; 33 U.S.C. 1321.

■ 2. In § 107.109, revise paragraph (b) to read as follows:

§ 107.109 Application for renewal.

* * * * *

(b) If, on or before an existing special permit expires the holder files an application for renewal that is complete and conforms to the requirements of this section, the special permit will not expire until final administrative action on the application for renewal has been taken. Operation under an expired special permit not filed for renewal before the expiration date is prohibited. This paragraph does not limit the authority of the Associate Administrator to modify, suspend, or terminate a special permit under § 107.121.

■ 3. In § 107.705, revise paragraph (c) to read as follows:

§ 107.705 Registrations, reports, and applications for approval.

* * * * *

(c) For an approval with an expiration date, each application for renewal or modification must be filed in the same manner as an original application. If, on or before an existing approval expires the holder files an application for renewal that is complete and conforms to the requirements of this section, the approval will not expire until final administrative action on the application for renewal has been taken. Operation under an expired approval not filed for renewal on or before the expiration date is prohibited. This paragraph does not limit the authority of the Associate Administrator to modify, suspend, or terminate an approval under § 107.713.

* * * * *

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15811 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 107

[Docket No. PHMSA–2025–0096 (HM–268H)]

RIN 2137–AG10

Hazardous Materials: Modernizing Payments To and From America's Bank Account

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule modernizes the payment system for hazardous materials transportation registration fees by eliminating the option to pay by paper check and requiring electronic payment through the U.S. Department of Transportation (Department or DOT) e-Commerce internet site. This action improves processing efficiency, reduces administrative burden, and aligns payment procedures with current Government-wide electronic commerce practices.

DATES: This final rule is effective September 3, 2026.

FOR FURTHER INFORMATION CONTACT: Yul B. Baker Jr., Transportation Regulations Specialist, 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–8553, *yul.baker@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. PHMSA Action

A. What action is PHMSA taking in this final rule?

PHMSA is revising 49 CFR 107.616 to eliminate the option to pay the hazardous materials transportation registration fee by paper check and require electronic payment.

B. Does this action apply to me?

Effective 30 days after publication of this final rule, persons subject to the registration requirements in 49 CFR 107.601 must pay registration fees electronically.

C. Why is PHMSA taking this action?

PHMSA is taking this action in response to commenter feedback and to advance the goals of Executive Order (E.O.) 14247 (*Modernizing Payments To and From America's Bank Account*).[1] Executive Order 14247 directs that, as soon as practicable and to the extent permitted by law, all payments to the Federal Government must be processed electronically. The Order further requires the Secretary of the Treasury to take appropriate action to eliminate the need for the Department of the Treasury's (''Treasury'') physical lockbox services and to expedite the receipt of Federal payments—including fees—through electronic means.

II. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published a notice of proposed rulemaking (NPRM), cited as *HM–268H,* to gather feedback on revising the hazardous materials registration fee payment system.[2] Please refer to the NPRM for background and discussion of the proposed change.

The following table alphabetically lists commenters to the NPRM:

Commenter name	Docket No.
Council on Safe Transportation of Hazardous Articles, Inc. (COSTHA)	PHMSA–2025–0096–0003
Dangerous Goods Advisory Council	PHMSA–2025–0096–0005
Institute of Makers of Explosives	PHMSA–2025–0096–0004
National Tank Truck Carriers	PHMSA–2025–0096–0002
Nuclear Energy Institute	PHMSA–2025–0097–0002

All commenters supported the proposed amendment requiring electronic-only payment of hazardous materials transportation registration fees. COSTHA expressed support for the proposal but requested clarification on whether members must use a credit card or may continue to make electronic bank-to-bank or Automated Clearing House (ACH) payments. COSTHA noted that many members use ACH payments through the Department's e-Commerce

[1] 90 FR 14001 (Mar. 25, 2025).

[2] 90 FR 28528 (Jul. 1, 2025).

site and that some users find ACH payments more practical and cost-effective than credit card transactions.

PHMSA is not removing the ability to make ACH payments. The electronic-only payment system will rely exclusively on digital or electronic methods for transactions related to hazardous materials transportation registration fees. Funds may be transferred through electronic networks using credit or debit cards, mobile wallets, direct bank transfers, or other digital platforms—including use of ACH payments.

III. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation as set forth in the Federal Hazardous Materials Transportation Laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

Executive Order 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [3] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B also specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This final rule is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B. PHMSA has determined that this final rule will impose negligible burdens for shippers and carriers who will be newly required to comply with electronic registration requirements because the means to make electronic payments have become ubiquitous and easy to obtain. PHMSA estimates a small cost savings to government focused on the reduction of processing paper forms and paper checks. Based on an estimated reduction of 156 hours per year of internal labor compensated at $49.31 per hour, PHMSA estimates an internal cost savings of $7,691.87 per year in 2024 dollars, at both three and seven percent discount rates.[4] The change to accept electronic-only payments aligns with the Treasury's initiative to eliminate the need for physical lockbox services and expedite receipt of payments through electronic means. This change will improve government efficiency for American taxpayers and result in additional unquantified cost savings accruing to the Treasury.[5]

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[6] PHMSA finds the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . . [or] that undermine[s] the national interest.'' [7]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[8] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserted a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from (inter alia) the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [9] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[10] E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation Laws contain an express preemption provision at 49 U.S.C. 5125(b) that

[3] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

[4] Quantified cost savings are based on General Schedule grade GS–7 step 5 pay of $63,381 per year, with wages representing 61.8 percent of compensation for government workers. PHMSA estimated an internal labor cost of three hours per week to process paper forms and checks based on interviews with employees involved in the process. *See:* OPM, *General Schedule (GS) Salary Calculator,* available at: *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2024/general-schedule-gs-salary-calculator/; see also* BLS, *Employer Costs for Employee Compensation Summary* (Mar. 20, 2026), available at: *https://www.bls.gov/news.release/ecec.nr0.htm.*

[5] *See* E.O. 14247, *Modernizing Payments To and From America's Bank Account* (Mar. 25, 2025), outlining the risks and costs of maintaining paper-based payments to the Federal Government.

[6] 90 FR 9065 (Feb. 6, 2025).

[7] 90 FR 10583 (Feb. 25, 2025).

[8] 90 FR 8433 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

[9] 66 FR 28355 (May 22, 2001).

[10] 64 FR 43255 (Aug. 10, 1999); 74 FR 24693 (May 22, 2009).

preempts State, local, and Tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule does not address any of the covered subject items listed above that would preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to a notice-and-comment rulemaking under the APA unless the agency head certifies that the final rule in the rulemaking will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act.[11] DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[12] PHMSA developed this final rule in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. PHMSA has concluded that the incremental costs of the final rule will be negligible and certifies that the final rule will not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, amongst other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under Section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[13]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A (*Department of Transportation Tribal Consultation Policies and Procedures*).[14] E.O. 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined that it will not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded that the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) require that PHMSA provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking will not create, amend, or rescind any existing information collections.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) requires agencies consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and to compete internationally.[15] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may

[11] 67 FR 53461 (Aug. 16, 2002).

[12] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

[13] DOT, PHMSA, *Implementing Procedures* (Aug. 28, 2025), *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[14] 65 FR 67249 (Nov. 9, 2000).

[15] 77 FR 26413 (May 4, 2012).

participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of this final rule and has determined that its regulatory amendments will not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

Executive Order 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [16] PHMSA has considered the effects of the final rule and has determined that its regulatory amendments would not materially affect the cybersecurity risk profile for affected entities.

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, or on DOT's website at *http://www.dot.gov/privacy.*

List of Subjects in 49 CFR Part 107

Administrative practice and procedure, Hazardous materials transportation, Packaging and containers, Penalties, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 107—HAZARDOUS MATERIALS PROGRAM AND PROCEDURES

■ 1. The authority citation for part 107 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 section 4; Pub. L. 104–121, Section 212–213; Pub. L. 104–134 Section 31001; Pub. L. 114–74 Section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97; 33 U.S.C. 1321.

■ 2. Revise § 107.616 to read as follows:

§ 107.616 Payment procedures.

(a) Each person subject to the requirements of this subpart must submit the registration statement and payment electronically in full through the Department's e-Commerce internet site. Access to this service is provided at: *https://www.phmsa.dot.gov/registration/registration-overview.* A registrant required to file an amended registration statement under § 107.608(c) of this subpart must submit it through the same internet site.

(b) Payment must be made by completing an authorization for payment by credit card or other electronic means of payment acceptable to the U.S. Department of Transportation as part of an internet registration as provided in paragraph (a) of this section.

(c) Payment must correspond to the total fees properly calculated in the ''Amount Due'' block of DOT form F 5800.2. A person may elect to register and pay the required fees for up to three registration years by filing one complete and accurate registration statement.

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15812 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

[16] 86 FR 26633 (May 17, 2021).

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 107

[Docket No. PHMSA–2025–0097 (HM–268I)]

RIN 2137–AG11

Hazardous Materials: Reducing Recordkeeping Requirements for Domestic Carriers

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule amends the hazardous materials program procedures to allow motor and vessel carriers to carry PHMSA registration documents in electronic form.

DATES: This final rule is effective September 3, 2026.

FOR FURTHER INFORMATION CONTACT: Yul B. Baker Jr., Transportation Regulations Specialist, 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–8553, *yul.baker@dot.gov.*

I. PHMSA Action

A. What action is PHMSA taking in this final rule?

PHMSA is revising 49 CFR 107.620 to allow motor and vessel carriers to carry their PHMSA registration certificate, or a document showing their registration number, in either electronic or paper form.

B. Does this action apply to me?

Effective 30 days after publication of this final rule, motor and vessel carriers may carry a copy of the certificate required by the recordkeeping requirements in 49 CFR 107.620—or a document showing the registration number—in either electronic or paper form. Carriers must make these documents available upon request to authorized enforcement and inspection personnel, regardless of whether they are in electronic or paper form.

C. Why is PHMSA taking this action?

PHMSA is taking this action in response to commenter feedback and to allow for flexibility with no reduction in safety. Currently, the hazardous materials program procedures require motor and vessel carriers to carry a paper copy of their current PHMSA-issued Certificate of Registration (''certificate'') or another document showing the U.S. DOT Hazmat Registration Number on each truck or vessel transporting hazardous materials, and to make these documents readily available to authorized enforcement personnel upon request. PHMSA is revising its regulations to permit these documents to be presented in electronic format. PHMSA does not expect the revision to cause any adverse safety impacts because electronically formatted documents can be made as readily available to inspectors and first responders as paper copies.

II. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published a notice of proposed rulemaking (NPRM), cited as *HM–268I,* to gather feedback on revising the registration recordkeeping requirements in 49 CFR 107.620. Please refer to the NPRM for background and discussion of the proposed changes.[1]

The following table alphabetically lists commenters to the NPRM:

[1] 90 FR 28531 (Jul. 21, 2025).

Commenter name	Docket No.
Alliance for Chemical Distribution	PHMSA–2025–0097–0008
Commercial Vehicle Safety Alliance	PHMSA–2025–0097–0009
Council on Safe Transportation of Hazardous Articles, Inc	PHMSA–2025–0097–0005
Dangerous Goods Advisory Council	PHMSA–2025–0097–0007
Institute of Makers of Explosives	PHMSA–2025–0097–0006
National Tank Truck Carriers	PHMSA–2025–0097–0003
Nuclear Energy Institute	PHMSA–2025–0097–0002
Sporting Arms and Ammunition Manufacturers Institute	PHMSA–2025–0097–0004

All commenters supported the proposed amendment permitting motor and vessel carriers to carry a copy of their PHMSA registration documents in an electronic or paper format. Commenters noted that this revision allows for flexibility in operations with no reduction in safety, as current technology allows electronic documents to be just as readily available to inspectors and first responders as paper copies. Therefore, PHMSA is revising 49 CFR 107.620 as proposed.

III. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation as set forth in the Federal Hazardous Materials Transportation Laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [2] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This final rule is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B and determined that this final rule will not generate economic costs to allow carriage of a copy of the Certificate of Registration or other document bearing the registration number in electronic form and will enhance efficiency for both motor and vessel carriers.

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[3] PHMSA finds the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . . [or] that undermine[s] the national interest.'' [4]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[5] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserts a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from, *inter alia,* the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [6] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[7] E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation Laws contain an express preemption provision at 49 U.S.C. 5125(b) that

[2] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

[3] 90 FR 9065 (Feb. 6, 2025).

[4] 90 FR 10583 (Feb. 25, 2025).

[5] 90 FR 8433 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

[6] 66 FR 28355 (May 22, 2001).

[7] 64 FR 43255 (Aug. 10, 1999); 74 FR 24693 (May 22, 2009).

preempts State, local, and Tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule does not address any of the covered subject items listed above that would preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to a notice-and-comment rulemaking under the APA unless the agency head certifies that the final rule in the rulemaking will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act.[8] DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[9] PHMSA developed this final rule in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. Because the final rule is expected to reduce burdens, PHMSA certifies that it does not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, among other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under Section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[10]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A (*Department of Transportation Tribal Consultation Policies and Procedures*).[11] E.O. 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined that it will not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded that the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) require that PHMSA provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking will not create, amend, or rescind any existing information collections.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) requires agencies to consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally.[12] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may

[8] 67 FR 53461 (Aug. 16, 2002).

[9] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

[10] DOT, PHMSA, *Implementing Procedures* (Aug. 28, 2025), *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[11] 65 FR 67249 (Nov. 9, 2000).

[12] 77 FR 26413 (May 4, 2012).

participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of this final rule and has determined that its regulatory amendments will not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

E.O. 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [13] PHMSA has considered the effects of the final rule and has determined that its regulatory amendments would not materially affect the cybersecurity risk profile for affected entities.

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, or on DOT's website at *http://www.dot.gov/privacy.*

List of Subjects in 49 CFR Part 107

Administrative practice and procedure, Hazardous materials transportation, Packaging and containers, Penalties, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 107—HAZARDOUS MATERIALS PROGRAM AND PROCEDURES

■ 1. The authority citation for part 107 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 section 4; Pub. L. 104–121, Section 212–213; Pub. L. 104–134 Section 31001; Pub. L. 114–74 Section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97; 33 U.S.C. 1321.

■ 2. Revise § 107.620 to read as follows:

§ 107.620 Recordkeeping requirements.

(a) Each person subject to the requirements of this subpart, or its agent designated under § 107.608(e), must maintain at its principal place of business in electronic or paper form for a period of three years from the date of issuance of each Certificate of Registration:

(1) A copy of the registration statement filed with PHMSA; and

(2) The Certificate of Registration issued to the registrant by PHMSA.

(b) Each motor carrier subject to the requirements of this subpart must carry a copy of its current Certificate of Registration issued by PHMSA or another document bearing the current registration number identified as the ''U.S. DOT Hazmat Reg. No.'' on board each truck and truck tractor (not including trailers and semi-trailers) used to transport hazardous materials subject to the requirements of this subpart. The Certificate of Registration or document bearing the current registration number may be carried in electronic or paper form and must be made available, upon request, to authorized enforcement personnel.

(c) Each person who transports by vessel a hazardous material subject to the requirements of this subpart must carry on board the vessel a copy of its current Certificate of Registration issued by PHMSA or another document bearing the current registration number identified as the ''U.S. DOT Hazmat Reg. No.'' The Certificate of Registration or document bearing the current registration number may be carried in electronic or paper form and must be made available, upon request, to authorized enforcement personnel.

(d) Each person subject to this subpart must furnish its Certificate of Registration (or a copy thereof) and all other records and information pertaining to the information contained in the registration statement to authorized enforcement personnel upon request. The Certificate of Registration and all other records and information may be furnished in electronic or paper form.

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15813 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

[13] 86 FR 26633 (May 17, 2021).

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 171

[Docket No. PHMSA–2025–0089 (HM–268A)]

RIN 2137–AG03

Hazardous Materials: Reducing Burdens on Domestic Aerosol Shippers

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: PHMSA is amending the Hazardous Materials Regulations by updating the definition of an aerosol to eliminate unnecessary regulatory burdens and maintain consistency with current international transportation standards.

DATES: This final rule is effective September 3, 2026.

FOR FURTHER INFORMATION CONTACT: Noah Jacobson, Transportation Regulations Specialist, 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–8553, *noah.jacobson@dot.gov.*

I. PHMSA Action

A. What action is PHMSA taking in this final rule?

PHMSA is revising the definition of an aerosol in 49 CFR 171.8 to add aerosols that consist solely of gases instead of requiring an aerosol to expel a liquid, paste, or powder.

The Hazardous Materials Regulations (HMR) currently define an aerosol in 49 CFR 171.8 as ''an article consisting of any non-refillable receptacle containing a gas compressed, liquefied or dissolved under pressure, the sole purpose of which is to expel a nonpoisonous (other than a Division 6.1 Packing Group III material) liquid, paste, or powder and fitted with a self-closing release device allowing the contents to be ejected by the gas.'' This HMR definition for aerosols is inconsistent with corresponding international standards, which do not include the limitation for gas to be used to expel a liquid, paste, or powder (*i.e.,* aerosol containers may expel a gas). The lack of harmonization between the HMR and international standards creates significant challenges for industry stakeholders engaged in global commerce, leading to confusion, increased compliance costs, and logistical inefficiencies, particularly for companies that manufacture, package,

or transport hazardous materials across borders. Lack of harmonization also impedes trade, delays shipments, and reduces the competitiveness of U.S. businesses in the global marketplace—all of which can increase prices for U.S. consumers. Therefore, PHMSA is revising the definition of an aerosol in § 171.8 to align with the international definition and no longer require that an aerosol container be designed for the sole purpose of expelling a liquid, paste or powder, thereby reducing undue regulatory burdens without compromising safety.

B. Does this action apply to me?

Effective 30 days after publication of this final rule, offerors of aerosols that consist solely of gases (*i.e.,* that do not contain a liquid, paste, or powder) may be shipped as aerosols when prepared and shipped in compliance with the HMR.

C. Why is PHMSA taking this action?

PHMSA is taking this action to align the HMR definition of ''aerosol'' with the international definition, which permits the shipment of pure gases as aerosols. As outlined in the final Regulatory Impact Analysis (RIA), PHMSA estimates that this change would result in annualized cost savings of $254,565.[1]

II. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published a notice of proposed rulemaking (NPRM), cited as *HM–268A,* to gather feedback on amending the definition of an aerosol to include a compressed gas other than the propellant, instead of restricting the definition to the expulsion of a liquid, paste, or powder.[2] Please refer to the NPRM for background and discussion of the proposed change.

The following table alphabetically lists commenters to the NPRM:

Commenter name	Docket No.
Aeropres Corporation	PHMSA–2025–0089–0014
American Coatings Association	PHMSA–2025–0089–0007
American Pyrotechnics Association	PHMSA–2025–0089–0004
Blaster Corporation	PHMSA–2025–0089–0010
Council on Safe Transportation of Hazardous Articles, Inc. (COSTHA)	PHMSA–2025–0089–0011
Dangerous Goods Advisory Council	PHMSA–2025–0089–0019
Diversified CPC International, Inc	PHMSA–2025–0089–0021
Household & Commercial Products Association	PHMSA–2025–0089–0017
Infotrac Inc	PHMSA–2025–0089–0003
International Vessel Operators Dangerous Goods Association	PHMSA–2025–0089–0018
ITW Techspray	PHMSA–2025–0089–0012
Medical Device Transport Council	PHMSA–2025–0089–0008
National Aerosol Association	PHMSA–2025–0089–0009
Pyro Shows, Inc	PHMSA–2025–0089–0005
Pyrotek Special Effects Inc	PHMSA–2025–0089–0002
Stoner Incorporated, Inc	PHMSA–2025–0089–0020

All commenters supported the proposal to harmonize the definition of an aerosol with international standards. In addition, COSTHA requested that, after publication of the amendment, PHMSA notify all holders of special permits for this type of aerosol product that their permits have been incorporated into the HMR. PHMSA clarifies that, while formal notice of incorporation will not be provided at the time of publication of the final rule, holders will be notified if their renewal applications are denied on the basis that the special permit is no longer necessary. Separately, Infotrac Inc. noted that 49 CFR 171.23(b)(1) would require a conforming revision to align with the new definition of an aerosol. PHMSA agrees and is revising 49 CFR 171.23(b)(1) in this final rule to reflect the revised definition for an aerosol in 49 CFR 171.8.

For these reasons, PHMSA is revising the definition of an aerosol in 49 CFR 171.8 and is making conforming revisions to 49 CFR 171.23 to align with the international definition of an aerosol, removing the requirement that an aerosol be designed for the sole purpose of expelling a liquid, paste, or powder. PHMSA has determined that these revisions will not have any adverse impact on safety.[3]

III. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation as set forth in the Federal Hazardous Materials Transportation Laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.''[4] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B specifies that regulations should generally ''not be issued unless their

[1] A copy of the RIA has been placed in the docket to this rulemaking.

[2] 90 FR 28540 (Jul. 1, 2025).

[3] PHMSA found minimal safety incidents in an analysis of 30 years of special permit data.

[4] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This final rule is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B and determined this final rule will result in cost savings by reducing regulatory burdens and regulatory uncertainty for manufacturers and shippers of aerosols. PHMSA finds cost savings will focus on those related to the reduction in burden for new special permit applications (*e.g.,* new entrants to the market) and renewals for current special permit holders, as well as cost savings from the ability to transition to a single system of marks, labels, and documentation for domestic and international transport. PHMSA finds those cost savings will result in reduced costs for U.S. consumers to whom those entities generally transfer a portion of their compliance costs.

The change aligns the HMR definition of aerosols with international standards (including the UN Model Regulations, IMDG Code, ICAO Technical Instructions, and ADR) and will not impose any new direct costs on U.S. aerosol manufacturers, shippers, or Federal regulatory agencies. The revision will expand regulatory flexibility by permitting the classification of gas-only aerosols without necessitating the presence of a liquid, paste, or powder. As a result, PHMSA finds this final rule will impose no new compliance, implementation, or oversight burdens.

The change offers multiple sources of cost savings and regulatory relief. The current U.S. definition excludes gas-only aerosols from qualifying for limited quantity exceptions, requiring their treatment as fully regulated hazardous materials. Aligning the HMR with international standards will eliminate added costs for qualifying products, streamlining logistics and reducing compliance burdens, such as preparation of shipping papers for highway and rail shipments, payment of hazmat transportation surcharges, investment in extensive employee training, and additional requirements for storage and documentation. In addition, companies currently operating under special permits to ship gas-only aerosols incur labor and administrative costs related to marking packages, using specific packaging, maintaining certain records, renewing permits every two to four years, and providing permit-specific training to relevant staff. PHMSA has issued dozens of special permits in different forms that allow for the transportation of pure gases in a manner equivalent to using the international definition of an aerosol. Examples of operational controls under these special permits include relaxation of the packaging requirements to allow transportation in DOT–2P, 2Q, or similar inner receptacles, and the elimination of certain shipping paper and placarding requirements.

Elimination of the special permit requirement will produce direct labor cost savings and reduce administrative overhead for the private sector and improve government efficiency for PHMSA. Harmonization with international definitions will simplify cross-border trade by eliminating inconsistencies in classification and labeling. U.S. companies currently face trade friction when exporting aerosols that qualify under international definitions but not under U.S. rules. By adopting the broader international standard, U.S. manufacturers and marketers will gain improved access to the global aerosol market. This change will enhance the international competitiveness of U.S. aerosol products, enabling companies to increase market share and reduce barriers to export. The regulatory change is broadly expected to increase efficiency in transportation and logistics, lower product costs for businesses and potentially for consumers, and foster economic activity by reducing barriers to entry. PHMSA does not expect the final rule to have any adverse impact on safety.

As outlined in the final RIA, PHMSA estimates this final rule will result in annualized cost savings from eliminating the need for new and renewal of special permits, reducing PHMSA reviews of special permit applications, and removing shipping paper requirements for qualifying gas-only aerosol shipments of about $254,565 (2024 dollars) at three percent and seven percent discount rates.

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[5] As discussed in detail in the previous section, PHMSA has determined the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . . [or] that undermine[s] the national interest.'' [6]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[7] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserted a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from (inter alia) the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [8] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[9] E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between

[5] 90 FR 9065 (Feb. 6, 2025).

[6] 90 FR 10583 (Feb. 25, 2025).

[7] 90 FR 8353 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

[8] 66 FR 28355 (May 22, 2001).

[9] 64 FR 43255 (Aug. 10, 1999); 74 FR 24693 (May 22, 2009).

the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation Laws contain an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and Tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses items covered in Paragraph 1 above and would preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Though the final rule may operate to preempt some State requirements, it would not impose any regulation that has substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. The preemptive effect of the regulatory amendments in this final rule is limited to the minimum level necessary to achieve the objectives of the Federal Hazardous Materials Transportation Laws. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to notice-and-comment rulemaking under the APA unless the agency head certifies that the final rule will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act.[10] DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[11] This final rule was developed in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. The final rule will reduce burdens and reflect current economic realities without adversely impacting safety. Therefore, PHMSA certifies the final rule does not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, amongst other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under Section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[12]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A (*Department of Transportation Tribal Consultation Policies and Procedures*).[13] E.O. 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined that it will not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded that the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) requires that PHMSA provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking will not create, amend, or rescind any existing information collections. There is potential for a slight reduction in the number of shipping papers required under OMB Control Number 2137–0034, *Hazardous Materials Shipping Papers & Emergency Response Information,* due to aerosols being shipped as limited quantities by highway or rail. However, this reduction will be minimal and difficult to quantify in relation to the overall shipping paper burden.

[10] 67 FR 53461 (Aug. 16, 2002).

[11] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

[12] Pipeline and Hazardous Materials Safety Admin., *Implementing Procedures* (last accessed Feb. 11, 2026), available at: *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[13] 65 FR 67249 (Nov. 9, 2000).

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) [14] requires agencies consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of the final rule and has determined that its regulatory amendments will not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

Executive Order 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [15] PHMSA has considered the effects of the final rule and has determined that its regulatory amendments would not materially affect the cybersecurity risk profile for affected entities.

[14] 77 FR 26413 (May 4, 2012).

[15] 86 FR 26633 (May 17, 2021).

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, or on DOT's website at *http://www.dot.gov/privacy.*

List of Subjects in 49 CFR Part 171

Definitions, Exports, Hazardous materials transportation, Hazardous waste, Imports, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

■ 1. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 section 4; Pub. L. 104–134, section 31001; Pub. L. 114–74 section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97.

■ 2. In § 171.8, revise the definition of ''Aerosol'' to read as follows:

§ 171.8 Definitions and abbreviations.

* * * * *

Aerosol means an article consisting of a non-refillable receptacle containing a gas (compressed, liquefied, or dissolved under pressure), with or without a nonpoisonous (other than a Division 6.1 Packing Group III material) liquid, paste, or powder, and fitted with a self-closing release device allowing the contents to be ejected as a foam, paste, or powder or in a liquid state or in a gaseous state.

* * * * *

■ 3. In § 171.23, revise paragraph (b)(1) to read as follows:

§ 171.23 Requirements for specific materials and packagings transported under the ICAO Technical Instructions, IMDG Code, Transport Canada TDG Regulations, or the IAEA Regulations.

* * * * *

(b) * * *

(1) *Aerosols.* Except for a limited quantity of a compressed gas in a container of not more than 4 fluid ounces capacity meeting the requirements in § 173.306(a)(1) of this subchapter, the proper shipping name ''Aerosol,'' UN1950, may be used only for a non-refillable receptacle containing a gas compressed, liquefied, or dissolved under pressure fitted with a self-closing release device (see § 171.8 of this subchapter). In addition, an aerosol must be in a metal packaging when the packaging exceeds 7.22 cubic inches.

* * * * *

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15803 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171, 172, and 173

[Docket No. PHMSA–2025–0093 (HM–268E)]

RIN 2137–AG07

Hazardous Materials: Remove Redundant List of U.S. EPA CERCLA Hazardous Substances

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: To improve efficiency and eliminate redundancy, this final rule streamlines the Hazardous Materials Regulations by modifying how hazardous substances are listed. Instead of maintaining a duplicative list, the regulations will now rely on the authoritative, comprehensive list already maintained by the U.S. Environmental Protection Agency.

DATES: This final rule is effective December 2, 2026.

FOR FURTHER INFORMATION CONTACT: Tony Horne, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration (PHMSA), 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–8553, *tony.horne@dot.gov.*

I. PHMSA Action

A. What action is PHMSA taking in this final rule?

PHMSA is modifying how hazardous substances and their reportable quantities are listed within the Hazardous Materials Regulations (HMR). Specifically, rather than maintaining a duplicative list found in Tables 1 and 2 to Appendix A of 49 CFR 172.101 that must be periodically

revised for consistency with the U.S. Environmental Protection Agency (EPA) list found at 40 CFR 302.4, PHMSA is amending Appendix A to reference the EPA list directly. In addition, PHMSA is revising the definitions of ''hazardous substance'' and ''reportable quantity (RQ)'' to reference the EPA list in a seamless manner. Finally, PHMSA is making a conforming revision to the requirements for empty packagings to reflect the newly modified structure of Appendix A.

B. Does this action apply to me?

Effective 120 days after publication of this final rule, persons offering for transportation and transporting materials that may be subject to hazardous substance requirements in the HMR must refer to the EPA regulations at 40 CFR 302.4 for the list of regulated hazardous substances and their reportable quantities. Importantly, because this action simply modifies how the list is referenced within the Code of Federal Regulations, it does not functionally change whether a material is classified as a hazardous substance.

C. Why is PHMSA taking this action?

To enhance government efficiency and eliminate regulatory redundancy, this final rule streamlines the HMR by modifying how hazardous substances are listed. Importantly, this action does not delete the entire Hazardous Materials Table (HMT); rather, it solely amends the HMR to modify Appendix A to the HMT—which currently houses a redundant list of hazardous substances and their reportable quantities (RQs)—by directing compliance to the comprehensive list already maintained by the U.S. Environmental Protection Agency (EPA) in a Table at 40 CFR 302.4. As a matter of sensible regulatory oversight, this alignment avoids the costly confusion of navigating out-of-sync regulations. In the past, stakeholders have expressed confusion whether a hazardous substance that is listed by EPA—but not yet listed by PHMSA via a rulemaking—is subject to transportation requirements under the HMR for hazardous substances.[1] It also ensures the regulated community can avoid the inverse; specifically, a circumstance where an entity incurs the unnecessary expense of continuing to transport a substance as a hazardous material simply because a separate DOT list lagged behind an EPA de-listing or an increase in the RQ.

In addition, this action conserves scarce government resources by eliminating the need for periodic, limited-purpose rulemakings previously required to keep the HMR's list and RQs consistent with EPA updates. Furthermore, directly referencing the EPA's list reflects the reality that treating these designated substances as hazardous materials in transport has been a statutory requirement all along, meaning that this rule should result in no real-world change to how regulated entities are operating.[2]

II. Discussion of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published a notice of proposed rulemaking (NPRM), cited as HM–268E, to gather feedback on revising the HMR to streamline the listing of hazardous substances and reportable quantities by referring directly to the source list found in EPA regulations.[3] Please refer to the NPRM for background and discussion of the proposed change.

The following table alphabetically lists commenters to the NPRM:

Commenter name	Docket No.
Alliance for Chemical Distribution (ACD)	PHMSA–2025–0093–0009
Council on Safe Transportation of Hazardous Articles, Inc. (COSTHA)	PHMSA–2025–0093–0006
Commercial Vehicle Safety Alliance (CVSA)	PHMSA–2025–0093–0010
Dangerous Goods Advisory Council (DGAC)	PHMSA–2025–0093–0008
Infotrac, Inc	PHMSA–2025–0093–0003
Institute of Hazardous Materials Management (IHMM)	PHMSA–2025–0093–0005
Rex Railsback	PHMSA–2025–0093–0002
William Forbes	PHMSA–2025–0093–0007

PHMSA received mixed support for the proposed changes among the eight sets of comments submitted in response to the NPRM. Some commenters supported the proposed changes because eliminating the redundant list is a practical way to ensure consistency in how hazardous substances are regulated in transportation. For instance, COSTHA noted that the revision removes duplication that has historically caused inconsistencies between PHMSA's list and EPA's authoritative list, thereby creating confusion for shippers, carriers, and enforcement personnel.

PHMSA received varied feedback on the proposed changes and appreciates the input from all commenters. To enhance consistency, efficiency, and clarity, the agency is proceeding with the revisions to address the issue of redundant regulatory text. Addressing this duplication aligns PHMSA's requirements with the EPA's authoritative list and resolves historical inconsistencies that have caused unnecessary and avoidable confusion for shippers, carriers, and enforcement personnel.

However, some commenters expressed concerns with the proposals. PHMSA responds to those concerns as follows:

A. Introducing Potential Burden From a Second Set of Regulations

ACD, CVSA, DGAC, Mr. Rex Railsback, and Mr. William Forbes shared concerns regarding additional economic burdens associated with purchasing new regulatory texts and associated retraining. CVSA stated that commercial motor vehicle inspectors who conduct hazardous materials inspections must have ready access to information that is reliable, and that the proposed change may require inspectors to navigate a second set of unfamiliar regulations. DGAC believed that the proposed change would require trainers to provide print copies of, or excerpts from, the relevant 40 CFR provisions to

[1] *See* PHMSA Letter of Interpretation 25–0013 (Sept. 23, 2025), available at: *https://www.phmsa.dot.gov/standards-rulemaking/hazmat/interpretations/25-0013.*

[2] *See* 49 CFR 172.101 app. A, note 1 (''It should be noted that 42 U.S.C. 9656(b) provides that common and contract carriers may be held liable under laws other than CERCLA for the release of a hazardous substance as defined in that Act, during transportation that commenced before the effective date of the listing and regulating of that substance as a hazardous material under 49 U.S.C. 5101–5127.'')

[3] 90 FR 28571 (Jul. 1, 2025).

every affected hazmat employee, and that enforcement officers would have to maintain copies as well. Mr. Railsback stated that the relevant 40 CFR provisions are not available via the electronic oCFR (which PHMSA notes is an unofficial source provided as a courtesy on the PHMSA website), and that PHMSA does not make the relevant 40 CFR provisions available in print without purchasing additional text.

PHMSA respectfully disagrees and asserts this change will not impose any economic burdens nor create any accessibility issues. PHMSA does not make any resources available in print. Instead, the Office of the Federal Register maintains a web-based version of the entire CFR, to include relevant 40 CFR provisions, that is available for free via the electronic CFR (eCFR), and it is updated in real-time.[4] The relevant portions of 40 CFR can also be downloaded on an electronic device to use in areas with limited internet or cellular connectivity. Therefore, because the entire CFR is available free online, and it is updated on a daily basis, PHMSA does not believe this rule will be a barrier or create any burdens for trainers, hazmat employees, or enforcement personnel.[5]

B. Training

DGAC and Infotrac, Inc. stated the proposed changes would necessitate additional training on different sets of regulations that hazmat employees normally do not receive. DGAC further argued that:

[A]n inordinately large number of individuals will be impacted. In addition, because the determination of whether or not a material is a hazardous substance under the HMR is based on whether the quantity per package equals or exceeds the listed reportable quantity, the proposed change would require numerous additional individuals who package materials to require training in the use of 40 CFR in addition to their existing required training on the HMR.

DGAC concluded that the need for additional training stems from the prospect of materials being added to or removed from the list of hazardous substances and persons having to monitor the **Federal Register** for changes to relevant 40 CFR provisions.

PHMSA acknowledges the concerns raised by these commenters but respectfully disagrees. First, this action does not delete the Hazardous Materials Table (HMT) itself; rather, it solely modifies Appendix A. In addition, those persons using the free, online eCFR will be able to access the relevant 40 CFR provisions directly via a hyperlink.

More importantly, this rule imposes no substantive, real-world changes to the applicability of the HMR to hazardous substances. A hazardous substance is regulated under the HMR if it is listed in the relevant 40 CFR provisions and it equals or exceeds the (listed) RQ in a package.[6] Whether the list resides in the HMR or in relevant 40 CFR provisions has no bearing on its applicability to hazardous substances. The EPA list remains the authoritative list and resides in 40 CFR 302.4. PHMSA now refers stakeholders to the authoritative list located in relevant 40 CFR provisions. The eCFR provides hyperlinks anytime a portion of the CFR is cited in the regulatory text, making it readily accessible by way of the HMR.

Moreover, part of the scope of HMR training is providing assurances that a hazmat employee has familiarity with the general provisions of the HMR and can recognize and identify the presence of hazardous materials. Persons in the business of transporting hazardous materials that are hazardous substances subject to HMR requirements should already be familiar with the applicable requirements. Such persons should also be aware that changes can be made to the list—including removals, additions, or changes to RQs. In addition, PHMSA believes this general awareness or familiarization training should already be captured under the standard recurrent training expected of hazmat employers.

C. Preserving Appendix B

COSTHA and DGAC recommend maintaining Appendix B as written and, instead of converting the Appendix B list of marine pollutant to Appendix A as proposed, they suggest revising Appendix A by providing a direct reference to 40 CFR 302.4 for the list of hazardous substances and their reportable quantities. Specifically, COSTHA noted that ''keeping the . . . placeholder and including a reference link would provide better continuity and make the regulation easier to navigate,'' and that ''while referencing two regulations adds an additional step for compliance, it does improve long-term efficiency and accuracy of these applicable regulatory updates.'' Further, DGAC reasoned that adopting the changes to the 49 CFR 172.101 appendixes would cause confusion and potentially result in frustration or denial of shipments.

PHMSA agrees with the commenters. Rather than adopting the proposed changes to 49 CFR 172.101 and to avoid introducing confusion from relabeling appendices, in this final rule PHMSA will maintain the Appendix B to § 172.101—List of Marine Pollutants as written and instead revise Appendix A to reference 40 CFR 302.4.

D. Delayed Effective Date

IHMM asked PHMSA to consider a delayed effective date to allow entities to update systems and training materials consistent with the transition from an HMR list at 49 CFR to the EPA list at 40 CFR.

In consideration of the comments about training and familiarity with alternate regulatory text, PHMSA agrees with IHMM and is providing a delayed effective date to allow time to adjust. This final rule has an effective date 120 days from the date of publication of the final rule when Appendix A to 49 CFR 172.101 will refer to the list of hazardous substances in 40 CFR 302.4. PHMSA's outreach program will make efforts to ensure stakeholders are aware of this change and are educated on how to navigate from the relevant provisions 49 CFR to those in 40 CFR.

III. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation as set forth in the Federal Hazardous Materials Transportation Laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [7] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless

[4] eCFR, available at: *https://www.ecfr.gov/*.

[5] eCFR, Reader Aids, Understanding the eCFR, available at *https://www.ecfr.gov/reader-aids/understanding-the-ecfr*.

[6] *See* note 2, *supra* (discussing 49 CFR 172.101 app. A, note 1).

[7] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This final rule is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B and determined this final rule will result in cost savings to the government by streamlining regulations and eliminating redundancy. The rule will also benefit the regulated public by clarifying applicability and reducing confusion.

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[8] PHMSA finds the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . . [or] that undermine[s] the national interest.'' [9]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[10] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserts a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from (inter alia) the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [11] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[12] E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation Laws contain an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and Tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses items covered in Paragraph 1 above and would preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Though the final rule may operate to preempt some State requirements, it would not impose any regulation that has substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. The preemptive effect of the regulatory amendments in this final rule is limited to the minimum level necessary to achieve the objectives of the Federal Hazardous Materials Transportation Laws. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (RFA) for a final rule that has been subject to notice-and-comment rulemaking under the APA unless the agency head certifies that the final rule will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act.[13] DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[14] This final rule was developed in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. The final rule will reduce burdens. Therefore, PHMSA certifies the final rule does not have a significant impact on a substantial number of small entities.

[8] 90 FR 9065 (Feb. 6, 2025).

[9] 90 FR 10583 (Feb. 25, 2025).

[10] 90 FR 8433 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

[11] 66 FR 28355 (May 22, 2001).

[12] 64 FR 43255 (Aug. 10, 1999); 74 FR 24693 (May 22, 2009).

[13] 67 FR 53461 (Aug. 16, 2002).

[14] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, amongst other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under Section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[15]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A (*Department of Transportation Tribal Consultation Policies and Procedures*).[16] E.O. 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined that it will not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded that the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) requires that PHMSA provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking will not create, amend, or rescind any existing information collections.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) requires agencies consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally.[17] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of the final rule and has determined that its regulatory amendments will not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

E.O. 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [18] PHMSA has considered the effects of the final rule and has determined that its regulatory amendments would not materially affect the cybersecurity risk profile for affected entities.

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, and may be viewed on DOT's website at *http://www.dot.gov/privacy.*

List of Subjects

49 CFR Part 171

Definitions, Exports, Hazardous materials transportation, Hazardous waste, Imports, Reporting and recordkeeping requirements.

49 CFR Part 172

Hazardous materials transportation, Hazardous waste, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

[15] DOT, PHMSA, *Implementing Procedures* (Aug. 28, 2025), available at: *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[16] 65 FR 67249 (Nov. 9, 2000).

[17] 77 FR 26413 (May 4, 2012).

[18] 86 FR 26633 (May 17, 2021).

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

■ 1. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 section 4; Pub. L. 104–134, section 31001; Pub. L. 114–74 section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97.

■ 2. In § 171.8, revise the definitions for ''hazardous substance'' and ''reportable quantity'' in alphabetical order to read as follows:

§ 171.8 Definitions and abbreviations.

* * * * *

Hazardous substance for the purposes of this subchapter, means a material, including its mixtures and solutions, that—

(1) Is listed in 40 CFR 302.4, as referenced in appendix A to § 172.101 of this subchapter;

(2) Is in a quantity, in one package, which equals or exceeds the reportable quantity (RQ) listed in the 40 CFR 302.4 as referenced in appendix A to § 172.101 of this subchapter; and

(3) When in a mixture or solution—

(i) For radionuclides, the following requirements shall be used in determining if a package contains an RQ of a hazardous substance: (a) if the identity and quantity (in curies or terabecquerels) of each radionuclide in a mixture or solution is known, the ratio between the quantity per package (in curies or terabecquerels) and the RQ for the radionuclide must be determined for each radionuclide. A package contains an RQ of a hazardous substance when the sum of the ratios for the radionuclides in the mixture or solution is equal to or greater than one; (b) if the identity of each radionuclide in a mixture or solution is known but the quantity per package (in curies or terabecquerels) of one or more of the radionuclides is unknown, an RQ of a hazardous substance is present in a package when the total quantity (in curies or terabecquerels) of the mixture or solution is equal to or greater than the lowest RQ of any individual radionuclide in the mixture or solution; and (c) if the identity of one or more radionuclides in a mixture or solution is unknown (or if the identity of a radionuclide by itself is unknown), an RQ of a hazardous substance is present when the total quantity (in curies or terabecquerels) in a package is equal to or greater than either one curie or the lowest RQ of any known individual radionuclide in the mixture or solution, whichever is lower.

(ii) For other than radionuclides, is in a concentration by weight which equals or exceeds the concentration corresponding to the RQ of the material, as shown in the following table:

RQ pounds (kilograms)	Concentration by weight	
	Percent	PPM
5,000 (2,270)	10	100,000
1,000 (454)	2	20,000
100 (45.4)	0.2	2,000
10 (4.54)	0.02	200
1 (0.454)	0.002	20

(iii) The term does not include petroleum, including crude oil or any fraction thereof which is not otherwise specifically listed or designated as a hazardous substance in 40 CFR 302.4, as referenced in appendix A to § 172.101 of this subchapter, and the term does not include natural gas, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas).

* * * * *

Reportable quantity (RQ) for the purposes of this subchapter, means the final RQ specified for each hazardous substance identified in 40 CFR 302.4, as referenced in appendix A to § 172.101 of this subchapter.

* * * * *

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, AND TRAINING REQUIREMENTS

■ 3. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96, and 1.97.

■ 4. In § 172.101, revise ''Appendix A to § 172.101—List of Hazardous Substances and Reportable Quantities'' to read as follows:

§ 172.101 Purpose and use of the hazardous materials table.

* * * * *

Appendix A to § 172.101—List of Hazardous Substances and Reportable Quantities.

Refer to 40 CFR 302.4 to see the list of hazardous substances and their reportable quantities (RQs) in Table 302.4. The list includes an Appendix B to § 302.4 for radionuclides and their adjusted RQs.

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 5. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96, and 1.97.

■ 6. In § 173.29, revise paragraph (h) to read as follows:

§ 173.29 Empty packagings.

* * * * *

(h) A package that contains a residue of a hazardous substance, Class 9, that does not meet the definition of another hazard class and is not a hazardous waste or marine pollutant, may remain marked, labeled and, if applicable, placarded in the same manner as when it contained a greater quantity of the material even though it no longer meets the definition in § 171.8 of this subchapter for a hazardous substance.

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15809 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171 and 173

[Docket No. PHMSA–2025–0101 (HM–268M)]

RIN 2137–AG15

Hazardous Materials: Adoption of Department of Transportation Special Permit 21287

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule removes undue regulatory burdens by adopting the provisions of U.S Department of Transportation (DOT) special permit (SP) 21287 to streamline the transportation of refrigerating machines—including common household appliances like refrigerators, window-mounted air-conditioning units, and dehumidifiers—that contain small quantities of certain low flammability refrigerant gases.

DATES: *Effective date:* This final rule is effective August 19, 2026.

Incorporation by reference date: The incorporation by reference of certain material listed in this rule is approved by the Director of the Federal Register as of August 19, 2026.

The incorporation by reference of certain other material listed in the rule

was approved by the Director of the Federal Register as of January 1, 2004.

FOR FURTHER INFORMATION CONTACT: Candace Casey, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration (PHMSA), 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–8553, *candace.casey@dot.gov.*

I. PHMSA Action

A. What action is PHMSA taking in this final rule?

PHMSA is adopting the provisions of DOT SP 21287 into the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180) by revising 49 CFR 173.307(a)(4) to provide an exception for the transportation of refrigerating machines containing certain low flammability refrigerant gases (*i.e.,* refrigerants). This revision expands the existing exception to include refrigerating machines that use a refrigerant that is a Category 1B refrigerant as specified in the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals (which PHMSA is incorporating by reference) or a Group A2L refrigerant as specified in American National Standards Institute/American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ANSI/ASHRAE) Standard 34. PHMSA is also incorporating by reference ANSI/ASHRAE Standard 34–2024, ''*Designation and Safety Classification of Refrigerants,*'' which refers users to the list of flammable gases eligible for this exception.

B. Does this action apply to me?

Effective 15 days after publication of this final rule, offerors and carriers of affected refrigerating machines may begin to transport these products in accordance with the exceptions in 49 CFR 173.307 without expending the time and resources associated with obtaining special permit.

C. Why is PHMSA taking this action?

PHMSA is taking this action in response to commenter feedback and to provide relief to stakeholders by allowing the transportation of refrigerating machines containing certain flammable gases by adopting the provisions in DOT SP 21287. This change facilitates the transportation of refrigerating machines affected by the American Innovation and Manufacturing (AIM) Act, which required manufacturers to transition away from certain hydrofluorocarbon (HFC) refrigerants and replace them with refrigerants that were regarded as less damaging to the environment.[1] This action allows the HMR to account better for the more widespread use of certain refrigerants following the new requirements imposed by the AIM Act. PHMSA is also taking this action as part of its ongoing review of special permits that are appropriate for adoption into the HMR based on their safety record and positive impact on stakeholders.

II. Incorporation by Reference Discussion Under 1 CFR Part 51

According to the Office of Management and Budget (OMB), Circular A–119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,* government agencies must use voluntary consensus standards wherever practical in the development of regulations.

PHMSA currently incorporates by reference into the HMR all or parts of numerous standards and specifications developed and published by standard development organizations (SDO). In general, SDOs update and revise their published standards every two to five years to reflect modern technology and best technical practices. The National Technology Transfer and Advancement Act of 1995 (NTTAA; Pub. L. 104–113) directs Federal agencies to use standards developed by voluntary consensus standards bodies in lieu of government-written standards whenever possible. Voluntary consensus standards bodies develop, establish, or coordinate technical standards using agreed-upon procedures. OMB issued Circular A–119 to implement section 12(d) of the NTTAA relative to the utilization of consensus technical standards by Federal agencies. This circular provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in the NTTAA. Accordingly, PHMSA is responsible for determining which standards currently referenced in the HMR should be updated, revised, or removed, and which standards should be added to the HMR. Revisions to materials incorporated by reference in the HMR are handled via the rulemaking process, which allows for the public and regulated entities to provide input.

During the rulemaking process, PHMSA must also obtain approval from the Office of the Federal Register to incorporate by reference any new materials. The Office of the Federal Register issued a rulemaking that revised 1 CFR 51.5 to require that an agency detail in the preamble of a notice of proposed rulemaking (NPRM) the ways the materials it proposes to incorporate by reference are reasonably available to interested parties, or how the agency worked to make those materials reasonably available to interested parties.[2]

In this final rule, PHMSA is incorporating by reference ANSI/ASHRAE Standard 34–2024, ''*Designation and Safety Classification of Refrigerants,* copyright 2024, including addenda approved through August 30, 2024,'' ANSI/ASHRAE Standard 34–2024 establishes a uniform system for assigning unambiguous reference numbers, safety classifications (based on toxicity and flammability), and refrigerant concentration limits to refrigerants. This document is available for viewing at: *https://www.ashrae.org/technical-resources/standards-and-guidelines/read-only-versions-of-ashrae-standards.* PHMSA is also incorporating by reference Globally Harmonized System of Classification and Labelling of Chemicals, 9th Revised Edition, ST/SG/AC.10/30/Rev.9 (2021). This document serves as the international standard for defining and classifying chemical hazards (physical, health, and environmental) and communicating safety information through harmonized labels and Safety Data Sheets (SDS). ANSI/ASHRAE Standard 34–2024 and the Globally Harmonized System of Classification and Labelling of Chemicals, 9th Revised Edition can be reasonably obtained by interested parties through the applicable publisher contact information listed in § 171.7.

ANSI/ASHRAE Standard 15–1994 is referenced in §§ 171.7 and 173.307 of this document but was previously approved for those sections.

III. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published an NPRM, cited as *HM–268M,* to gather feedback on adopting the provisions of DOT SP 21287 into the HMR.[3] Please refer to the NPRM for background and discussion of the proposed change.

The following table alphabetically lists commenters to the NPRM:

[1] 42 U.S.C. 7675 (2020).

[2] 79 FR 66278 (Nov. 7, 2014).

[3] 90 FR 28548 (Jul. 1, 2025).

TABLE 1—COMMENTERS TO THE NPRM

Commenter name	Docket No.
American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE)	PHMSA–2025–0101–0003
Council on Safe Transportation of Hazardous Articles, Inc. (COSTHA)	PHMSA–2025–0101–0004
Dangerous Goods Advisory Council	PHMSA–2025–0101–0005

All commenters were supportive of the proposed amendment to facilitate the streamlined ground transportation of refrigerating machines containing low flammability gases. However, some commenters had additional questions or suggestions related to the NPRM proposal.

First, ASHRAE expressed support for the proposed amendments but requested that PHMSA incorporate by reference the 2024 editions of both ANSI/ASHRAE Standards 15 and 34 in the relevant sections of the HMR. With respect to ANSI/ASHRAE Standard 15, *Safety Code for Mechanical Refrigeration,* PHMSA did not propose any changes to its current incorporation by reference and—therefore—the suggested change is considered beyond the scope of this rulemaking. However, PHMSA will consider this recommendation in a future rulemaking. With respect to ANSI/ASHRAE Standard 34, though the NPRM did not propose to incorporate by reference the 2024 edition, PHMSA agrees with ASHRAE that using this more recent version to include additional refrigerants that would otherwise not be eligible if the 2019 edition were incorporated by reference is appropriate. Moreover, PHMSA sees no safety concern with incorporating by reference the 2024 edition of ANSI/ASHRAE Standard 34 (instead of the proposed 2019 edition) for determination of eligible refrigerants.

Second, while supportive of the proposed amendments, COSTHA notes the provisions are limited to highway and rail only, and do not facilitate the transport of refrigerating machines to remote areas in the United States (*i.e.,* certain areas in Alaska) where air service is the only practical means of transportation. Similarly, COSTHA asked whether PHMSA intends to allow—or continue to restrict—vessel transportation under the exceptions for refrigerating machines. PHMSA recognizes that continuing to limit eligibility for exceptions to transportation by highway and rail may complicate the logistics of transporting these items to remote areas. However, PHMSA notes that, given the limited experience authorizing these items for vessel and air transportation, it is more appropriate at this time to continue permitting such transportation on a case-by-case basis through special permits, rather than codifying a general provision applicable to all modes. Once PHMSA gets more experience with these non-ground modes, we may consider this recommendation in a future rulemaking.

For these reasons, PHMSA is revising 49 CFR 173.307 to except from the HMR refrigerating machines containing up to 20 kg (44 pounds) of a flammable, non-toxic gas, classified as Category 1B in accordance with GHS or classified as an A2L refrigerant as specified in ANSI/ASHRAE Standard 34. PHMSA is also incorporating by reference ANSI/ASHRAE Standard 34 into 49 CFR 171.7 and referencing it in 49 CFR part 173.307.

One additional editorial note. At the proposed rule stage, PHMSA inadvertently omitted a cross-reference to 49 CFR 173.307 for the GHS Classification and Labelling of Chemicals publication in 49 CFR 171.7(dd)(3). Importantly, PHMSA included the full intent in the preamble and the substantive proposed regulatory text was correctly placed in 49 CFR 173.307. This text would add GHS criteria for Category 1B as an alternative criterion for eligibility for exception. PHMSA therefore asserts this additional editorial cross-reference revision to 49 CFR 171.7(dd)(3) is within the scope of this final rule and does not create a substantive amendment.

IV. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation as set forth in the Federal Hazardous Materials Transportation laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [4] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This final rule is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B and determined that this final rule will result in cost savings by reducing regulatory burdens and regulatory uncertainty for shippers of refrigerating machines by allowing for their transportation without the need for a special permit. Those cost savings may also result in reduced costs for the public to whom those entities generally transfer a portion of their compliance costs. In addition, the final rule will produce cost savings for the Federal Government, hence taxpayers, due to

[4] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

the reduction of special permit applications that would otherwise need to be processed by PHMSA personnel.

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[5] PHMSA finds the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . . [or] that undermine[s] the national interest.''[6]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[7] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserted a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from, *inter alia* the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.''[8] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has therefore not designated this final rule as a significant energy action.

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[9] E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation laws contain an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and Tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses a covered subject item listed in Paragraph (1) above and would preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Though the final rule may operate to preempt some State requirements, it would not impose any regulation that has substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. The preemptive effect of the regulatory amendments in this final rule is limited to the minimum level necessary to achieve the objectives of the Federal Hazardous Materials Transportation Laws. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to complete a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to notice-and-comment rulemaking under the Administrative Procedure Act unless the agency head certifies that the final rule in the rulemaking will not have a significant economic impact on a substantial number of small entities. Executive Order 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act.[10] PHMSA developed this final rule in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. Because the final rule is expected to reduce burdens, PHMSA certifies that it does not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, among other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's

[5] 90 FR 9065 (Feb. 6, 2025).

[6] 90 FR 10583 (Feb. 25, 2025).

[7] 90 FR 8433 and 90 FR 8353 (Jan. 29, 2025).

[8] 66 FR 28355 (May 22, 2001).

[9] 64 FR 43255 (Aug. 10, 1999); 74 FR 24693 (May 22, 2009).

[10] 67 FR 53461 (Aug. 16, 2002).

Categorical Exclusion Determination memo for this action is available on PHMSA's website.[11]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A (*Department of Transportation Tribal Consultation Policies and Procedures*).[12] E.O. 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined it will not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) requires PHMSA to provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking will not create, amend, or rescind any existing information collections. However, this rulemaking eliminates the need for persons to renew a special permit, resulting in a decrease in paperwork burden for special permit holders. PHMSA estimates the reduction in information collection burden as follows:

OMB Control No. 2137–0051: Rulemaking, Special Permits, and Preemption Requirements.

Decrease in Annual Number of Respondents: 12.

Decrease in Annual Responses: 12.

Decrease in Annual Burden Hours: 17.

Decrease in Annual Burden Cost: $0.

Please direct your requests for a copy of this information collection to Steven Andrews, Office of Hazardous Materials Standards (PHH–12), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE, 2nd Floor, Washington, DC 20590–0001.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) requires agencies to consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally.[13] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of the final rule and has determined that its regulatory amendments will not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

E.O. 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [14] PHMSA has considered the effects of the final rule and has determined that its regulatory amendments would not materially affect the cybersecurity risk profile for affected entities.

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, or on DOT's website at *http://www.dot.gov/privacy.*

N. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) directs Federal agencies to use voluntary consensus standards in their regulatory activities unless doing so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specification of materials, test methods, or performance requirements) that are developed or adopted by voluntary consensus standard bodies. This rulemaking involves a voluntary consensus standard.

List of Subjects

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements, Definitions and abbreviations.

49 CFR Part 173

Hazardous materials transportation, Incorporation by reference, Training, Packaging and containers, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

■ 1. The authority citation for part 171 continues to read as follows:

[11] DOT, *Implementing Procedures for Considering Environmental Impacts* (Aug. 28, 2025), available at *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[12] 65 FR 67249 (Nov. 9, 2000).

[13] 77 FR 26413 (May 4, 2012).

[14] 86 FR 26633 (May 17, 2021).

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 section 4; Pub. L. 104–134, section 31001; Pub. L. 114–74 section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97.

■ 2. Amend § 171.7 by:
■ a. Revising paragraph (d);
■ b. Redesignating paragraphs (g) and (h) as paragraphs (h) and (i);
■ c. Adding new paragraph (g); and
■ d. Revising paragraph (dd) introductory text and paragraph (dd)(3).

The revisions and addition read as follows:

§ 171.7 Reference material.

* * * * *

(d) *American National Standards Institute, Inc. (ANSI),* 1899 L Street NW, 11th Floor, Washington, DC 20036; phone: 202–293–8020; email: *psa@ansi.org.*

(1) ANSI N14.1 Uranium Hexafluoride—Packaging for Transport, 1971 Edition, into §§ 173.417; 173.420.

(2) ANSI N14.1 Uranium Hexafluoride—Packaging for Transport, 1982 Edition, into §§ 173.417; 173.420.

(3) ANSI N14.1 Uranium Hexafluoride—Packaging for Transport, 1987 Edition, into §§ 173.417; 173.420.

(4) ANSI N14.1 Uranium Hexafluoride—Packaging for Transport, 1990 Edition, into §§ 173.417; 173.420.

(5) ANSI N14.1 Uranium Hexafluoride—Packaging for Transport, 1995 Edition, into §§ 173.417; 173.420.

(6) ANSI N14.1 Uranium Hexafluoride—Packaging for Transport, 2001 Edition, into §§ 173.417; 173.420.

* * * * *

(g) *American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE),* 180 Technology Parkway NW, Peachtree Corners, GA 30092; phone (202) 833–1830; email: *GovAffairs@ASHRAE.org.*

(1) ANSI/ASHRAE Standard 15–1994, Safety Code for Mechanical Refrigeration, 1994, into §§ 173.306; 173.307.

(2) ANSI/ASHRAE Standard 34–2024, Designation and Safety Classification of Refrigerants, copyright 2024, including addenda approved through August 30, 2024; into § 173.307.

* * * * *

(dd) *United Nations,* Bookshop, GA–1B–103, New York, NY 10017; phone: 1–212–963–7680; email: *bookshop@un.org;* website: *https://shop.un.org.*

* * * * *

(3) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), 9th Revised Edition, ST/SG/AC.10/30/Rev.9 (2021); into §§ 172.401; 173.307.

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 3. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96, and 1.97.

■ 4. In § 173.307, revise paragraph (a)(4)(iv) to read as follows:

§ 173.307 Exceptions for compressed gases.

(a) * * *

(4) * * *

(iv) Except when offered or transported by air or vessel—

(A) 20 kg (44 pounds) or less of a Group A1 refrigerant gas specified in ANSI/ASHRAE Standard 15 (IBR, *see* § 171.7 of this subchapter); or

(B) 20 kg (44 pounds) or less of a flammable, non-toxic refrigerant gas in Category 1B as classified by the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals (IBR, *see* § 171.7 of this subchapter), or a Group A2L refrigerant gas as specified in ANSI/ASHRAE Standard 34 (IBR, *see* § 171.7 of this subchapter); or

* * * * *

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15817 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171 and 173

[Docket No. PHMSA–2025–0102 (HM–268N)]

RIN 2137–AG16

Hazardous Materials: Adoption of Department of Transportation Special Permit 21379

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule removes undue regulatory burdens by adopting the provisions of U.S. Department of Transportation (DOT) special permit (SP) 21379 to streamline the transportation of refrigerating machines and components containing certain low flammability refrigerant gases.

DATES:

Effective date: This final rule is effective September 3, 2026.

Incorporation by reference date: The incorporation by reference of certain material listed in this rule is approved by the Director of the Federal Register as of September 3, 2026.

The incorporation by reference of certain other material listed in the rule was approved by the Director of the Federal Register as of January 1, 2004 and December 28, 2020.

FOR FURTHER INFORMATION CONTACT: Candace Casey, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration (PHMSA), 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–8553, *candace.casey@dot.gov.*

I. PHMSA Action

A. What action is PHMSA taking in this final rule?

PHMSA is adopting the provisions of DOT SP 21379 into the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180) by revising 49 CFR 173.306 to streamline the transportation of refrigerating machines containing certain low flammability refrigerant gases (*i.e.,* refrigerants). This revision allows up to 5,000 lbs. of low flammability refrigerants in refrigerating machines if they are a Category 1B refrigerant as specified in the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals (which PHMSA is incorporating by reference) or a Group A2L refrigerant as specified in American National Standards Institute/American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ANSI/ASHRAE) Standard 34. PHMSA is also incorporating by reference ANSI/ASHRAE Standard 34–2024, *Designation and Safety Classification of Refrigerants,* which refers users to the list of flammable gases eligible for this exception.

B. Does this action apply to me?

Effective 30 days after publication of this final rule, offerors and carriers of affected refrigerating machines may begin to transport these products in accordance with the exceptions in 49 CFR 173.306 without expending the time and resources associated with obtaining a special permit.

C. Why is PHMSA taking this action?

PHMSA is taking this action in response to commenter feedback and to

streamline the transportation of refrigerating machines, or their components, containing certain flammable gases by adopting the provisions in DOT SP 21379. This change facilitates the transport of large refrigerating machines affected by the American Innovation and Manufacturing (AIM) Act, which required manufacturers to transition away from certain hydrofluorocarbon (HFC) refrigerants and replace them with refrigerants that were regarded as less damaging to the environment.[1] This action allows the HMR to account better for the more widespread use of certain refrigerants following the new requirements imposed by the AIM Act. PHMSA is also taking this action as part of its ongoing review of special permits that are appropriate for adoption into the HMR based on their safety record and positive impact on stakeholders.

II. Incorporation by Reference Discussion Under 1 CFR Part 51

According to the Office of Management and Budget (OMB), Circular A–119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,* government agencies must use voluntary consensus standards wherever practical in the development of regulations.

PHMSA currently incorporates by reference into the HMR all or parts of numerous standards and specifications developed and published by standards development organizations (SDO). In general, SDOs update and revise their published standards every two to five years to reflect modern technology and best technical practices. The National Technology Transfer and Advancement Act of 1995 (NTTAA; Pub. L. 104–113) directs Federal agencies to use standards developed by voluntary consensus standards bodies in lieu of government-written standards whenever possible. Voluntary consensus standards bodies develop, establish, or coordinate technical standards using agreed-upon procedures. OMB issued Circular A–119 to implement section 12(d) of the NTTAA relative to the utilization of consensus technical standards by Federal agencies. This circular provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in the NTTAA. Accordingly, PHMSA is responsible for determining which standards currently referenced in the HMR should be updated, revised, or removed, and which standards should be added to the HMR. Revisions to materials incorporated by reference in the HMR are handled via the rulemaking process, which allows for the public and regulated entities to provide input.

During the rulemaking process, PHMSA must also obtain approval from the Office of the Federal Register to incorporate by reference any new materials. The Office of the Federal Register issued a rulemaking that revised 1 CFR 51.5 to require that an agency detail in the preamble of a notice of proposed rulemaking (NPRM) the ways the materials it proposes to incorporate by reference are reasonably available to interested parties, or how the agency worked to make those materials reasonably available to interested parties.[2] In this final rule, PHMSA is incorporating by reference ANSI/ASHRAE Standard 34–2024, ''*Designation and Safety Classification of Refrigerants,* copyright 2024, including addenda approved through August 30, 2024.'' ANSI/ASHRAE Standard 34–2024 establishes a uniform system for assigning unambiguous reference numbers, safety classifications (based on toxicity and flammability), and refrigerant concentration limits to refrigerants. This document is available for viewing at: *https://www.ashrae.org/technical-resources/standards-and-guidelines/read-only-versions-of-ashrae-standards.* Documents are available for purchase at the ASHRAE bookstore at: *https://store.accuristech.com/ashrae/ashrae_standards.html.*

PHMSA is also incorporating by reference Globally Harmonized System of Classification and Labelling of Chemicals, 9th Revised Edition, ST/SG/AC.10/30/Rev.9 (2021). This document serves as the international standard for defining and classifying chemical hazards (physical, health, and environmental) and communicating safety information through harmonized labels and Safety Data Sheets (SDS). ANSI/ASHRAE Standard 34–2024 and the Globally Harmonized System of Classification and Labelling of Chemicals, 9th Revised Edition can be reasonably obtained by interested parties through the applicable publisher contact information listed in § 171.7.

The following standards appear in the amendatory text of this document and were previously approved for the locations in which they appear: ANSI/ASHRAE Standard 15–1994 and Section VIII of the ASME Code.

III. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published an NPRM, cited as *HM–268N,* to gather feedback on adopting the provisions of DOT SP 21379 into the HMR.[3] Please refer to the NPRM for background and discussion of the proposed change.

The following table alphabetically lists commenters to the NPRM:

Commenter name	Docket No.
American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE)	PHMSA–2025–0102–0004
Anonymous	PHMSA–2025–0102–0002
Council on Safe Transportation of Hazardous Articles, Inc. (COSTHA)	PHMSA–2025–0102–0005
Dangerous Goods Advisory Council	PHMSA–2025–0102–0006

PHMSA received four sets of comments in response to the NPRM, and the comments were largely supportive of the amendments as proposed. However, some commenters had additional questions or suggestions related to the NPRM proposal.

First, ASHRAE expressed support for the proposed amendments but requested that PHMSA incorporate by reference the 2024 editions of both ANSI/ASHRAE Standards 15 and 34 in the relevant sections of the HMR. With respect to ANSI/ASHRAE Standard 15, *Safety Code for Mechanical Refrigeration,* PHMSA did not propose any changes to its current incorporation by reference and—therefore—the suggested change is considered beyond the scope of this rulemaking. However, PHMSA will consider this recommendation in a future rulemaking. With respect to ANSI/ASHRAE Standard 34, though the NPRM did not propose to incorporate by reference the 2024 edition, PHMSA agrees that using this more recent version to include additional refrigerants that would otherwise not be eligible if the 2019 edition were incorporated by reference

[1] 42 U.S.C. 7675 (2020).

[2] 79 FR 66278 (Nov. 7, 2014).

[3] 90 FR 28552 (Jul. 1, 2025).

is appropriate. Moreover, PHMSA sees no safety concern with incorporating by reference the 2024 edition of ANSI/ASHRAE Standard 34 (instead of the proposed 2019 edition) for determination of eligible refrigerants.

Second, while supportive of the proposed amendments, COSTHA notes the provisions are limited to highway and rail only and may impact transporting refrigerating machines to remote areas in the United States (*i.e.,* certain areas in Alaska) where air service is the only practical means of transportation. Similarly, COSTHA asked whether PHMSA intends to allow—or continue to restrict—vessel transportation under the exceptions for refrigerating machines. PHMSA recognizes that continuing to limit eligibility for exceptions to transportation by highway and rail may complicate the logistics of transporting these items to remote areas. However, PHMSA notes that, given the limited experience authorizing these items for vessel and air transportation, it is more appropriate at this time to continue permitting such transportation on a case-by-case basis through special permits, rather than codifying a general provision applicable to all modes. Once PHMSA gets more experience with these non-ground modes, we may consider this recommendation in a future rulemaking.

Lastly, an anonymous commenter recommended that PHMSA prohibit the manufacture, use, and transportation of ''Group A1'' refrigerants, and instead promote ''more environmentally friendly products.'' Although PHMSA regulates the transportation of hazardous materials such as the refrigerants at issue here, PHMSA notes that the ability to prohibit the manufacture and use of any substance is beyond the scope of our Agency's authority.

For these reasons, PHMSA is revising 49 CFR 173.306 to allow up to 5,000 lbs. of a flammable, non-toxic gas, classified Category 1B in accordance with GHS or classified as an A2L refrigerant as specified in ANSI/ASHRAE Standard 34. PHMSA is also incorporating by reference ANSI/ASHRAE Standard 34 into 49 CFR 173.306.

Two additional editorial notes. First, at the proposed rule stage, PHMSA inadvertently omitted a cross-reference to 49 CFR 173.306 for the GHS Classification and Labelling of Chemicals publication in 49 CFR 171.7(dd)(3). Importantly, PHMSA included the full intent in the preamble and the substantive proposed regulatory text was correctly placed in 49 CFR 173.306. This text would add GHS criteria for Category 1B as an alternative criterion for eligibility for exception. PHMSA has determined that this additional editorial cross-reference revision to 49 CFR 171.7(dd)(3) is within the scope of this final rule and does not create a substantive amendment. Second, note also that the NPRM discussed the incorporation by reference of the 7th revised edition of the GHS of Classification and Labelling of Chemicals which was a typo. PHMSA meant the 9th revised edition, as the 9th revised edition is the correct version and is already incorporated by reference in the HMR.

IV. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation as set forth in the Federal Hazardous Materials Transportation laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [4] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This final rule is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B, and determined that this final rule will result in cost savings by reducing regulatory burdens and regulatory uncertainty for shippers of refrigerating machines by allowing for their transportation without the need for a special permit. Those cost savings may also result in reduced costs for the public to whom those entities generally transfer a portion of their compliance costs. In addition, the final rule will produce cost savings for the Federal Government, hence taxpayers, due to the reduction of special permit applications that would otherwise need to be processed by PHMSA personnel.

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[5] PHMSA finds the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . .[or] that undermine[s] the national interest.'' [6]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[7] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserted a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from, *inter alia,* the removal of ''undue burden[s]'' on the

[4] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

[5] 90 FR 9065 (Feb. 6, 2025).

[6] 90 FR 10583 (Feb. 25, 2025).

[7] 90 FR 8433 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [8] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[9] E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation laws contain an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and Tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses a covered subject listed in Paragraph (1) above and would preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Though the final rule may operate to preempt some State requirements, it would not impose any regulation that has substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. The preemptive effect of the regulatory amendments in this final rule is limited to the minimum level necessary to achieve the objectives of the Federal Hazardous Materials Transportation Laws. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to notice-and-comment rulemaking under the APA unless the agency head certifies that the final rule in the rulemaking will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act.[10] DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[11] PHMSA developed this final rule in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. Because the final rule is expected to reduce burdens, PHMSA certifies that it does not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, among other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under Section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[12]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A (*Department of Transportation Tribal Consultation Policies and Procedures*).[13] E.O. 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal government and Tribes.

PHMSA assessed the impact of the final rule and determined that it will not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's

[8] 66 FR 28355 (May 22, 2001).

[9] 64 FR 43255 (Aug. 10, 1999); 74 FR 24693 (May 22, 2009).

[10] 67 FR 53461 (Aug. 16, 2002).

[11] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

[12] DOT, *Implementing Procedures for Considering Environmental Impacts* (Aug. 28, 2025), available at *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[13] 65 FR 67249 (Nov. 9, 2000).

regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) require that PHMSA provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking will not create, amend, or rescind any existing information collections. However, this rulemaking eliminates the need for persons to renew a special permit, resulting in a decrease in paperwork burden for special permit holders. PHMSA estimates the reduction in information collection burden as follows:

OMB Control No. 2137–0051: Rulemaking, Special Permits, and Preemption Requirements.

Decrease in Annual Number of Respondents: 10.

Decrease in Annual Responses: 10.

Decrease in Annual Burden Hours: 14.

Decrease in Annual Burden Cost: $0.

Please direct your requests for a copy of this information collection to Steven Andrews, Office of Hazardous Materials Standards (PHH–12), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE, 2nd Floor, Washington, DC 20590–0001.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) requires agencies to consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American businesses to export and compete internationally.[14] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of the final rule and has determined that its regulatory amendments will not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

E.O. 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [15] PHMSA has considered the effects of the final rule and has determined that its regulatory amendments would not materially affect the cybersecurity risk profile for affected entities.

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, or on DOT's website at *http://www.dot.gov/privacy.*

N. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) directs Federal agencies to use voluntary consensus standards in their regulatory activities unless doing so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specification of materials, test methods, or performance requirements) that are developed or adopted by voluntary consensus standard bodies. This rulemaking involves a voluntary consensus standard.

List of Subjects

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements, Definitions and abbreviations.

49 CFR Part 173

Hazardous materials transportation, Incorporation by reference, Training, Packaging and containers, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

■ 1. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 section 4; Pub. L. 104–134, section 31001; Pub. L. 114–74 section 4 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97.

■ 2. In § 171.7, revise paragraphs (g)(2) and (dd)(3) to read as follows:

§ 171.7 Reference material.

* * * * *

(g) * * *

(2) ANSI/ASHRAE Standard 34–2024, Designation and Safety Classification of Refrigerants, copyright 2024, including addenda approved through August 30, 2024; into §§ 173.306; 173.307.

* * * * *

(dd) * * *

(3) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), 9th Revised Edition, ST/SG/AC.10/30/Rev.9 (2021); into §§ 172.401; 173.306; 173.307.

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 3. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 4. In § 173.306:

[14] 77 FR 26413 (May 4, 2012).

[15] 86 FR 26633 (May 17, 2021).

■ a. Revise paragraphs (e)(1)(i) through (iii), and paragraphs (e)(1)(v) and (e)(1)(vi);
■ b. Add paragraph (e)(1)(ix); and
■ c. Revise paragraph (e)(2)(i) introductory text.

The revisions and addition read as follows:

§ 173.306 Limited quantities of compressed gases.

* * * * *

(e) * * *

(1) * * *

(i) Each pressure vessel may not contain more than 5,000 pounds of Group A1 refrigerant gas as specified in ANSI/ASHRAE Standard 15 (IBR, *see* § 171.7 of this subchapter), not more than 5,000 pounds of a non-toxic, flammable refrigerant gas in Category 1B as classified by the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (IBR, *see* § 171.7 of this subchapter) or a Group A2L refrigerant gas as specified in ANSI/ASHRAE Standard 34 (IBR, *see* § 171.7 of this subchapter), or not more than 50 pounds of refrigerant other than those specified in this paragraph.

(ii) Machines or components thereof having two or more charged vessels may not contain an aggregate of more than 2,000 pounds of Group I refrigerant, an aggregate of more than 2,000 pounds of a non-toxic, flammable refrigerant gas in Category 1B as classified by GHS or a Group A2L as specified in ANSI/ASHRAE Standard 34, or more than 100 pounds of refrigerant other than those specified above.

(iii) Each pressure vessel must be equipped with a safety device meeting the requirements of ANSI/ASHRAE Standard 15.

* * * * *

(v) Pressure vessels must be manufactured, inspected, and tested in accordance with ANSI/ASHRAE Standard 15, or when over 6 inches internal diameter, in accordance with Section VIII of the ASME Code (IBR, *see* § 171.7 of this subchapter).

(vi) All parts subject to refrigerant pressure during shipment must be tested in accordance with ANSI/ASHRAE Standard 15.

* * * * *

(ix) Machines or components thereof containing a Division 2.1 gas must be transported:

(A) On a motor vehicle utilizing an open flat-bed trailer;

(B) On an open flat-bed rail car; or

(C) In a well-ventilated closed transport vehicle (such as a trailer or rail car).

* * * * *

(2) * * *

(i) *Packaging.* Reconditioned (used) refrigerating machines (UN2857, Div. 2.2 or UN3358, Div. 2.1) may be excepted from the marking requirements of § 172.302(c) of this subchapter and transported by motor vehicle when they conform to the requirements prescribed in paragraph (e)(1) of this section, are secured or permanently attached to the motor vehicle, and are:

* * * * *

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15818 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171 and 174

[Docket No. PHMSA–2025–0099 (HM–268K)]

RIN 2137–AG13

Hazardous Materials: Removing Burdensome Rail Reporting Requirements

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule reduces undue regulatory burdens by eliminating or replacing various rail transportation requirements that are either obsolete, overly burdensome, or conflict with other requirements in the Hazardous Materials Regulations.

DATES: This final rule is effective September 3, 2026.

FOR FURTHER INFORMATION CONTACT: Alexander Wolcott, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration (PHMSA), 2nd Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, 202–366–8553, *alexander.wolcott@dot.gov.*

I. PHMSA Action

A. What action is PHMSA taking in this final rule?

PHMSA is making several revisions to 49 CFR parts 171 and 174 of the Hazardous Materials Regulations (HMR) to eliminate or replace various rail requirements that are either obsolete, overly burdensome, or conflict with other requirements.

In Section 171.7, PHMSA is removing references to several outdated publications issued by the Association of American Railroads (AAR) Bureau of Explosives (BOE). Many of these publications have not been updated in decades and are no longer relevant to the Nation's modern supply chain. PHMSA is removing these obsolete publications from the table and making other conforming changes to §§ 174.55, 174.101, 174.112, 174.115, and 174.290 to remove subsequent references to the same publications.

In Section 174.200, PHMSA is deleting outdated requirements for rail carrier reporting to the AAR BOE. PHMSA finds removing these outdated reporting requirements would not adversely impact safety because rail carriers would still be able to make a determination that local conditions make the acceptance, transportation, or delivery of hazardous materials unusually hazardous.

In Section 174.67, PHMSA is removing certain outdated and unnecessary requirements from § 174.67, including removing the references to dirt and cinders in paragraph (b), amending paragraph (d) to provide flexibility in protecting open tank cars during transloading, and removing paragraph (n) because it is redundant with § 174.57.

B. Does this action apply to me?

Effective 30 days after publication of this final rule, PHMSA is making revisions to 49 CFR 171.7, 174.20, 174.55, 174.67, 174.101, 174.112, 174.115 and 174.290 that will eliminate or replace outdated and obsolete regulations that apply to rail offerors and carriers.

C. Why is PHMSA taking this action?

PHMSA is taking this action in response to commenter feedback and to eliminate or replace outdated rail requirements found in parts 171 and 174 of the HMR. PHMSA has determined that these changes will not have any adverse impact on safety as technological advances in the rail industry over the last 50 years have rendered them obsolete.

II. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published a notice of proposed rulemaking (NPRM), cited as *HM–268K,* to gather feedback on eliminating or replacing various rail transportation requirements that are either obsolete, overly burdensome, or

conflict with other requirements in the HMR.[1] Please refer to the NPRM for additional background and discussion of the proposed changes.

The following table alphabetically lists commenters to the NPRM:

Commenter	Comment identifier
Brotherhood of Locomotive Engineers and Trainmen (BLET)	PHMSA–2025–0099–0005
Dangerous Goods Advisory Council (DGAC)	PHMSA–2025–0099–0004
Institute of Makers of Explosives (IME)	PHMSA–2025–0099–0003
Sheet Metal, Air, Rail, Transportation-Transportation Division (SMART-TD)	PHMSA–2025–0099–0002

PHMSA received four sets of comments in response to the NPRM, including positive comments from IME and DGAC. Specifically, IME noted that it supports the proposals, and that it participated in the Railway Safety Advisory Committee (RSAC) meeting that found the Association of American Railroads (AAR) Bureau of Explosives (BOE) reporting requirements could be eliminated without any reduction in safety. IME also noted that many of the publications discussed in this rulemaking have not been updated in decades and are no longer relevant to the modern transportation supply chain. DGAC also supported these revisions, stating that continuing to include obsolete references or requirements in the HMR risks causing misinterpretation and confusion for the regulated community, which should of course be avoided when possible.

However, some commenters had questions or concerns about the NPRM as discussed below.

A. Comments on American Association of Railroads (AAR) Bureau of Explosives (BOE) Reporting

PHMSA received comments from SMART-TD and the BLET opposing the removal of the AAR BOE reporting requirement in 49 CFR 174.20. SMART-TD asserts that railroads should not be allowed unchecked discretion, stating that rail carriers operate as ''profit-at-all-cost enterprises'' rather than safety agencies. SMART-TD further states that, in many instances, rail carriers have a much higher risk tolerance than other groups, such as labor unions, emergency responders, and independent safety experts. This includes decisions regarding moving hazardous materials through extreme weather or in heavier and longer trains. Finally, SMART-TD states that removing the AAR BOE reporting requirement would be a step backward for transparency, leaving workers, regulators, and the public blind to critical safety decisions.

BLET also submitted comments opposing the removal of the AAR BOE reporting requirements, refuting PHMSA's claim that the RSAC consensus recommendations from May 25, 2017 included the removal of 49 CFR 174.20. BLET is also concerned that if the AAR BOE is not receiving these reports and there is no other organization taking that role, then there will be no way to document rail cars containing hazardous materials that should not be accepted or transported by the railroads.

PHMSA appreciates the commenters' insights into this topic; however, they are based on a misunderstanding of the requirements in 49 CFR 174.20. The commenters argued that removing 49 CFR 174.20 would reduce safety by allowing railroads unchecked discretion to operate during unsafe conditions. PHMSA disagrees. The existing text of 49 CFR 174.20 permits—but does not mandate—railroads to implement local or carrier restrictions when transportation is deemed unusually hazardous. Consequently, the implementation of such restrictions, and thus when such restrictions must be reported, is already entirely within the discretion of the railroads. Therefore, removing 49 CFR 174.20 will not alter the railroads' authority or decision-making processes regarding local or carrier restrictions.

Regarding transparency, the requirements in 49 CFR 174.20 have remained virtually unchanged since at least 1949. There will no longer be any official record of railroads utilizing their discretion to implement restrictions, but this reporting requirement has outlived its utility and been made obsolete by modern technology. This regulation was conceived well before the development of modern communication networks. Today, railroads are more than capable of communicating their internal restrictions between offerors and other carriers without the need of a third-party to publish the restrictions. Furthermore, PHMSA and the Federal Railroad Administration (FRA) have not relied on this data in recent memory, nor is the agency aware of any other entity that relies on this data.

Finally, in response to claims that the May 25, 2017 RSAC recommendations did not include the removal of 49 CFR 174.20, PHMSA and FRA reviewed the record and confirmed that the committee clearly recommended the removal of this section. The recommendation is found on page 16 of the document titled *Hazardous Materials Working Group Task 15–04 Proposed Regulatory Text.*[2] PHSMA has added a copy of the document to the rulemaking docket. Accordingly, PHMSA is removing 49 CFR 174.20 as proposed.

B. Comments on Removal of Documents Not Incorporated by Reference

PHMSA received comments from SMART-TD opposing the removal of various AAR BOE standards from the *Materials Not Incorporated by Reference* listed in 49 CFR 171.7. SMART-TD argued that, while these standards are dated, PHMSA should not remove the standards without providing replacements. Specifically, SMART-TD noted that one of the standards proposed for removal, *Emergency Handling of Hazardous Materials in Surface Transportation,* was the reference used by the crew of the train that derailed in East Palestine, Ohio. SMART-TD further stated that this standard is the reason that the crew properly determined the evacuation zone for the exact chemical their train was spilling, which protected the crew and the surrounding communities.

PHMSA is removing these references because they are either optional or obsolete. Most of these documents are cited only as non-mandatory examples of loading practices. Only two exceptions exist: *Pamphlet 6A,* which is an optional standard for certain munitions, and the 1989 *Emergency Handling* guide that has been replaced by the modern Emergency Response Guidebook (ERG). Since these documents no longer provide unique, mandatory regulatory value, their removal will not impact safety standards. Therefore, PHMSA is

[1] 90 FR 28556 (Jul. 1, 2025).

[2] FRA, Railroad Safety and Advisory Comm., *Committee Documents* (last accessed Dec. 15, 2025), available at: *https://rsac.fra.dot.gov/meetings?id=56*.

removing the documents not incorporated by reference as proposed.

C. Comments on Transloading Requirements

SMART-TD opposed the proposed change to 49 CFR 174.67 regarding tank car unloading. SMART-TD argued that PHMSA has downplayed the significance of the section, and that relaxing transloading standards would disproportionately increase the risk of major incidents, particularly in areas where local responders may be ill equipped to handle them.

PHMSA disagrees with the commenter's statement that the proposed language relaxes the transloading standards. PHMSA is not removing safety requirements. PHMSA is modernizing outdated terminology to allow for more effective safety measures. First, in paragraph (b), PHMSA proposed to replace the mention of ''cinders'' and ''dirt'' and to instead simply use the word ''debris,'' because the modern railroad industry has long since stopped relying on coal-fired steam locomotives. This revision keeps in place the requirement to keep the area around the manhole covers clear from any kind of debris, rather than it being limited to just cinders and dirt. Similarly, in paragraph (d), PHMSA proposed to remove the mention of asbestos, metal, or burlap covers to protect against sparks, and to replace the language with a general requirement to protect the manhole opening from sparks when unloading. Finally, as stated in the NPRM, paragraph (n) was removed entirely because it was redundant to the language in 49 CFR 174.57. Therefore, PHMSA is making the revisions to 49 CFR 174.67 as proposed.

III. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation as set forth in the Federal Hazardous Materials Transportation Laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [3] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This final rule is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B and determined that this final rule will result in cost savings by reducing regulatory burdens and regulatory uncertainty for the railroad industry. PHMSA estimates that cost savings will focus on those related to removing unnecessary reporting requirements. PHMSA finds those cost savings will result in reduced costs for public to whom those entities generally transfer a portion of their compliance costs.

These changes amend requirements in the HMR that are either obsolete or unnecessarily burdensome. These changes, including the removal of outdated recommended industry standards, outdated reporting to the AAR BOE, and removal of the requirement to cover exposed manhole covers with asbestos when loading, will not impose any new direct costs on the rail industry or Federal regulatory agencies. The revision will expand regulatory flexibility by being less prescriptive on how open tank car manhole covers are protected and reduces reporting burden by removing the outdated AAR BOE reporting requirements. As a result, PHMSA finds this final rule will impose no new compliance, implementation, or oversight burdens.

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[4] PHMSA finds the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . . [or] that undermine[s] the national interest.'' [5]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[6] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserted a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from, *inter alia,* the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [7] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

[3] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

[4] 90 FR 9065 (Feb. 6, 2025).

[5] 90 FR 10583 (Feb. 25, 2025).

[6] 90 FR 8433 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

[7] 66 FR 28355 (May 22, 2001).

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[8] E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation Laws contain an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and Tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses items covered in Paragraph 2 above and will preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Though the final rule may operate to preempt some State requirements, it will not impose any regulation that has substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. The preemptive effect of the regulatory amendments in this final rule is limited to the minimum level necessary to achieve the objectives of the Federal Hazardous Materials Transportation Laws. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to notice-and-comment rulemaking under the APA unless the agency head certifies that the final rule in the rulemaking will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act.[9] DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[10] This final rule was developed in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. Because the final rule is expected to reduce burdens, PHMSA certifies it does not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, among other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under Section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[11]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A (*Department of Transportation Tribal Consultation Policies and Procedures*).[12] E.O. 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined that it will not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) requires that PHMSA provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. PHMSA has analyzed this final rule and will revise the approved information collections under the following OMB Control Numbers: OMB Control No. 2137–0559,

[8] 64 FR 43255 (Aug. 10, 1999); 74 FR 24693 (May 22, 2009).

[9] 67 FR 53461 (Aug. 16, 2002).

[10] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

[11] DOT, PHMSA, *Implementing Procedures* (Aug. 28, 2025), available at: *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[12] 65 FR 67249 (Nov. 9, 2000).

Rail Carrier and Tank Car Tanks Requirements, Rail Tank Car Tanks—Transportation of Hazardous Materials by Rail. This final rule removes 49 CFR 174.20(b), which requires reporting to the AAR BOE regarding any restrictions over any portion of its lines. PHMSA addressed the comments to the removal of this information collection in Section II of this final rule. PHMSA currently accounts for 34 offerors submitting 1.5 reports a year. Each report takes 20 minutes resulting in a reduction of 17 hours of annual burden.

Please direct your requests for a copy of this information collection to Steven Andrews, Office of Hazardous Materials Standards (PHH–12), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE, 2nd Floor, Washington, DC 20590–0001.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) requires agencies to consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally.[13] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of the final rule and has determined that its regulatory amendments will not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

E.O. 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [14] PHMSA has considered the effects of the final rule and has determined that its regulatory amendments would not materially affect the cybersecurity risk profile for affected entities.

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov*, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, or on DOT's website at *http://www.dot.gov/privacy.*

List of Subjects

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Reporting and recordkeeping requirements, Definitions and abbreviations.

49 CFR Part 174

Railroad safety, Hazardous materials transportation, Radioactive materials.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

■ 1. The authority citation for Part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 section 4; Pub. L. 104–134, section 31001; Pub. L. 114–74 section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97.

■ 2. In § 171.7, amend ''Table 1 to 49 CFR 171.7—Materials Not Incorporated by Reference'' by revising the ''Bureau of Explosives'' entry in the table to read as follows:

§ 171.7 Reference material.

* * * * *

TABLE 1 TO 49 CFR 171.7—MATERIALS NOT INCORPORATED BY REFERENCE

Source and name of material	49 CFR reference
* * * * * * *	
Bureau of Explosives, Hazardous Materials Systems (BOE), Association of American Railroads, American Railroads Building, 50 F Street NW, Washington, DC 20001:	
Fetterley's Formula (The Determination of the Relief Dimensions for Safety Valves on Containers in which Liquefied gas is charged and when the exterior surface of the container is exposed to a temperature of 1,200 °F.)	173.315
* * * * * * *	

* * * * *

PART 174—CARRIAGE BY RAIL

■ 3. The authority citation for part 174 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 33 U.S.C. 1321; 49 CFR 1.81 and 1.97.

§ 174.20 [Removed and Reserved].

■ 4. Remove and reserve § 174.20.

■ 5. In § 174.55, revise paragraph (a) to read as follows:

§ 174.55 General requirements.

(a) Each package containing a hazardous material being transported by

[13] 77 FR 26413 (May 4, 2012).

[14] 86 FR 26633 (May 17, 2021).

rail in a freight container or transport vehicle must be loaded so that it cannot fall or slide and must be safeguarded in such a manner that other freight cannot fall onto or slide into it under conditions normally incident to transportation. When this protection cannot be provided by using other freight, it must be provided by blocking and bracing.

* * * * *

■ 6. In § 174.67:
■ a. Revise paragraph (b)(3);
■ b. Revise paragraph (d); and
■ c. Remove and reserve paragraph (n).
The revisions read as follows:

§ 174.67 Tank car unloading.

* * * * *

(b) * * *

(3) *Interior type.* All debris must be carefully removed from around the cover before the yoke is unscrewed.

* * * * *

(d) When unloading through the bottom outlet of a car equipped with an interior manhole type cover, and in each case where unloading is done through the manhole (unless a special cover with a safety vent opening and a tight connection for the discharge outlet is used), the manhole must be protected against the entrance of sparks or other sources of ignition of vapor.

* * * * *

■ 7. In § 174.101, revise paragraphs (o)(2) and (3) to read as follows:

§ 174.101 Loading Class 1 (explosive) materials.

* * * * *

(o) * * *

(2) Each truck body or trailer must be secured on the rail car so that it will not permanently change position or show evidence of failure or impending failure of the method of securing the truck body or trailer under impact from each end of at least 13 km (8.1 miles) per hour. Its efficiency must be determined by actual test, using dummy loads equal in weight and general character to the material to be shipped.

(3) Lading must be loaded, blocked, and braced within or on the truck body or trailer so that the lading will not change position under impact from each end of at least 13 km (8.1 miles) per hour.

* * * * *

■ 8. In § 174.112, revise paragraphs (b) and (c)(3) to read as follows:

§ 174.112 Loading Division 1.3 materials and Division 1.2 (explosive) materials (Also see § 174.101).

* * * * *

(b) Except as provided in § 174.101(b), (n), or (o), Division 1.3 materials and Division 1.2 (explosive) materials must be transported in a closed car or container car which is in good condition, and into which sparks cannot enter. The car does not require the car certificates prescribed in § 174.104(c) through (f). If the doors are not tight, they must be stripped to prevent the entrance of sparks. Wood floored cars must be equipped with spark shields (see § 174.104). Packages of Division 1.3 materials and Division 1.2 (explosive) materials must be blocked and braced to prevent their shifting and possible damage due to shifting of other freight during transportation.

* * * * *

(c) * * *

(3) Packages of Division 1.2 materials and Division 1.3 (explosive) materials are blocked and braced within the truck body, trailer, or container to prevent their shifting and possible damage due to shifting of other freight during transportation (ends, sidewalls, or doors of the truck body, trailer, or container may not be relied on to prevent the shifting of heavy loads).

■ 9. In § 174.115, revise paragraphs (a) and (b)(3) to read as follows:

§ 174.115 Loading Division 1.4 (explosive) materials.

(a) Division 1.4 (explosive) materials may be loaded into any closed car in good condition, or into any container car in good condition. Car certificates are not required. Packages of Division 1.4 (explosive) materials must be blocked and braced to prevent their shifting and possible damage due to shifting of other freight during transportation.

* * * * *

(b) * * *

(3) Packages of Division 1.4 (explosive) materials are blocked and braced within the truck body, trailer, or container to prevent their shifting and possible damage due to shifting of other freight during transportation. Ends, side walls, or doors of the truck body, trailer, or container may not be relied on to prevent shifting of heavy loads.

■ 10. In § 174.290, revise paragraph (e) to read as follows:

§ 174.290 Materials extremely poisonous by inhalation shipped by, for, or to the Department of Defense.

* * * * *

(e) Bombs, projectiles, and cannon ammunition being transported by rail must be loaded, blocked, and braced as shown in Department of Defense specifications. When a shipment is loaded in a gondola car it must be securely blocked and braced and not loaded higher than the sides of the car.

* * * * *

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15815 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 172

[Docket No. PHMSA–2025–0092 (HM–268D)]

RIN 2137–AG06

Hazardous Materials: Reducing Undue Paperwork Burdens to Domestic Carriers

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule removes undue regulatory burdens by providing domestic carriers and facility operators the option to maintain electronic copies of emergency response information rather than requiring a hard copy printed on paper.

DATES: This final rule is effective September 3, 2026.

FOR FURTHER INFORMATION CONTACT: Arthur Pollack, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration (PHMSA), 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–8553, *arthur.pollack@dot.gov.*

I. PHMSA Action

A. What action is PHMSA taking in this Final Rule?

PHMSA is revising 49 CFR 172.602 to provide domestic carriers and facility operators the option to maintain electronic copies of emergency response information rather than requiring a hard copy printed on paper.

B. Does this action apply to me?

Effective 30 days after publication of this final rule, carriers of hazardous materials and facility operators where a hazardous material is received, stored or handled during transportation will have the option to maintain emergency

response information in an electronic format rather than requiring a hard copy printed on paper. Carriers and facility operators are responsible for ensuring the reliability of their chosen method. A lack of cellular signal, device power loss, or device failure will not excuse compliance with the hazardous materials regulations (HMR).

C. Why is PHMSA taking this action?

PHMSA is taking this action in response to commenter feedback and to modernize the HMR to keep pace with modern technology by allowing domestic carriers and facility operators to maintain emergency response information using electronic means in lieu of hard copies. This action may reduce regulatory burdens for companies that choose to utilize this alternative form of compliance.

II. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published a notice of proposed rulemaking (NPRM), cited as *HM–268D,* to gather feedback on modernizing the HMR to provide domestic carriers and facility operators the option to maintain electronic copies of emergency response information rather than requiring a hard copy printed on paper.[1] Please refer to the NPRM for background and discussion of the proposed change.

The following table alphabetically lists commenters to the NPRM:

Commenter name	Docket No.
Alliance for Chemical Distribution (ACD)	PHMSA–2025–0092–0009
Association of American Railroads and the American Short Line and Regional Railroad Association	PHMSA–2025–0092–0012
Brotherhood of Locomotive Engineers and Trainmen (BLET)	PHMSA–2025–0092–0008
Commercial Vehicle Safety Alliance (CVSA)	PHMSA–2025–0092–0010
Council on Safe Transportation of Hazardous Articles, Inc. (COSTHA)	PHMSA–2025–0092–0004
Dangerous Goods Advisory Council (DGAC)	PHMSA–2025–0092–0006
National Tank Truck Carriers	PHMSA–2025–0092–0003
Offen Petroleum LLC	PHMSA–2025–0092–0002
Sheet Metal, Air, Rail, Transportation—Transportation Division (SMART–TD)	PHMSA–2025–0092–0007
Transportation Trades Department, AFL–CIO (TTD)	PHMSA–2025–0092–0011
William Forbes	PHMSA–2025–0092–0005

The NPRM drew a range of reactions from various stakeholders. Supporters argued that the proposal would modernize regulatory frameworks to reflect current operational realities where drivers already utilize electronic devices for compliance. Several commenters emphasized the significant financial benefits, noting that the industry spends tens of thousands of dollars printing paper copies that are frequently rendered obsolete, and that the proposal would reduce violations associated with outdated paperwork. Regarding safety, the National Tank Trunk Carriers commented that its members have consistently reported that paper emergency response information is rarely consulted by first responders who rely on their own protocols or information contained directly on the cargo tank, and that paper documents can be rendered inaccessible if a vehicle catches fire. For example, DGAC added that electronic formats allow the most recent version of the Emergency Response Guidebook (ERG) to be uploaded, ensuring that drivers have the most current emergency response instructions. Furthermore, CVSA supported the proposal for reducing administrative burdens on inspectors and industry alike. However, commenters such as COSTHA and ACD recommended that emergency response information be downloaded locally to devices to ensure accessibility in areas lacking cellular connectivity. In response to these comments, PHMSA notes that this final rule merely provides the option to maintain electronic copies of emergency response information. There is no requirement at this time to move to an electronic-only system. Therefore, regulated entities, to maintain compliance, should continue to maintain paper copies or have electronic copies downloaded to a device if the geographic areas in which they are operating present concerns about network connectivity.

Some commenters had additional questions or raised concerns and opposition. BLET and SMART–TD stated that relying solely on electronic formats is unsafe because railroads traverse remote areas where cellular service is unreliable or nonexistent. They assert that electronic devices can lose power or become damaged during an incident, making paper a critical redundancy. They also emphasize that train crews are the first people on the scene and need immediate access to a physical manifest to assess personal safety before first responders arrive. Lastly, TTD argued that electronic communication technology is ''not mature enough'' to replace printed communication completely, citing the lack of internet access in remote areas. They contend that electronic formats should only be permitted in addition to paper copies, rather than replacing the paper copies entirely.

PHMSA acknowledges these concerns but disagrees with the contention that electronic formats should be restricted to a supplemental role or that they are inherently unsafe due to connectivity limitations. PHMSA emphasizes that the amendment establishes a performance-based requirement—mandating that emergency response information be immediately available (*i.e.,* to first responders and inspectors) at all times—regardless of the medium employed. The carrier has an obligation to ensure the reliability of the method chosen; any carrier whose emergency response information is not immediately available during an incident due to a lack of cellular signal, power loss, or device failure is in violation of the HMR. Therefore, carriers and facility operators choosing to use electronic devices must ensure their systems remain accessible in all operating environments, including those discussed above, effectively eliminating concerns regarding remote areas or technical maturity.

For these reasons, PHMSA is publishing this final rule to modernize 49 CFR 172.602 as proposed. PHMSA finds these revisions will not have any adverse impact on safety.

III. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of

[1] Jul. 1, 2025 (90 FR 28563).

Transportation as set forth in the Federal Hazardous Materials Transportation Laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [2] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This final rule is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B and determined that this final rule will result in cost savings by reducing regulatory burdens and regulatory uncertainty for hazardous materials shippers and carriers. The final rule will eliminate the need to print and maintain paper copies of emergency response information when the paper copies can be replaced with reliable electronic copies, producing cost savings for the transportation industry and the public to whom those entities may generally transfer a portion of their compliance costs. In comments to the docket, COSTHA indicated that two of its members estimated that allowance of electronic emergency response information could eliminate approximately $33,000 to $70,000 in costs for obtaining paper copies every ERG cycle. PHMSA, however, lacks information to extrapolate these potential cost savings nationwide.

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[3] PHMSA finds the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . . [or] that undermine[s] the national interest.'' [4]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[5] The President has declared a national emergency to address America's inadequate energy development, production, transportation, refining, and generation capacity and asserted a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from, *inter alia,* the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [6] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009. E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation laws contain an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and Tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses items covered in Paragraph 1 above and will preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Though the final rule may operate to preempt some State requirements, it will not impose any regulation that has substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and

[2] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

[3] 90 FR 9065 (Feb. 6, 2025).

[4] 90 FR 10583 (Feb. 25, 2025).

[5] 90 FR 8433 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

[6] 66 FR 28355 (May 22, 2001).

responsibilities among the various levels of government. The preemptive effect of the regulatory amendments in this final rule is limited to the minimum level necessary to achieve the objectives of the Federal Hazardous Materials Transportation laws. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to notice-and-comment rulemaking under the APA unless the agency head certifies that the final rule will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act.[7] DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[8] This final rule was developed in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. Because the final rule will reduce burdens, PHMSA certifies that it does not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, among other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under Section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[9]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A (*Department of Transportation Tribal Consultation Policies and Procedures*).[10] E.O. 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined that it will not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded that the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) requires that PHMSA provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking will not create, amend, or rescind any existing information collections.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) requires agencies to consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally.[11] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of the final rule and has determined that its regulatory amendments will not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

E.O. 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [12] PHMSA has considered

[7] 67 FR 53461 (Aug. 16, 2002).

[8] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

[9] DOT, PHMSA, *Implementing Procedures* (Aug. 28, 2025), available at: *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[10] 65 FR 67249 (Nov. 9, 2000).

[11] 77 FR 26413 (May 4, 2012).

[12] 86 FR 26633 (May 17, 2021).

the effects of the final rule and has determined that its regulatory amendments will not materially affect the cybersecurity risk profile for affected entities.

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, and may be viewed on DOT's website at *http://www.dot.gov/privacy*.

List of Subjects in 49 CFR Part 172

Education, Hazardous materials transportation, Hazardous waste, Incorporation by reference, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, TRAINING REQUIREMENTS, AND SECURITY PLANS

■ 1. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96, and 1.97.

■ 2. In § 172.602, revise paragraph (b)(1) to read as follows:

§ 172.602 Emergency response information.

* * * * *

(b) * * *

(1) Printed legibly in English (either in hard copy printed on paper or in electronic format);

* * * * *

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15808 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 172

[Docket No. PHMSA–2025–0098 (HM–268J)]

RIN 2137–AG12

Hazardous Materials: Reduce Training Burdens for America's Farmers

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule makes an inflationary adjustment to the monetary threshold for farmers to be eligible for an exception from security plan and in-depth security training requirements.

DATES: This final rule is effective September 3, 2026.

FOR FURTHER INFORMATION CONTACT: Jose Cajar, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration (PHMSA), 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–8553, *jose.cajar@dot.gov.*

I. PHMSA Action

A. What action is PHMSA taking in this final rule?

PHMSA is making an inflationary adjustment to the monetary threshold for farmers to be eligible for the exception from the security plan requirements in 49 CFR 172.800(c). Specifically, farmers with less than $825,000 in 2025 dollars annually in gross receipts will be excepted from security plan requirements in 49 CFR part 172, subpart I. Farmers who are exempt from the security plan requirements in 49 CFR 172.800(c) are also exempt from the in-depth security training requirements for hazardous materials employees in 49 CFR 172.704(a)(5). Indexing to 2025 dollars will ensure that the threshold automatically accounts for future inflationary changes.

B. Does this action apply to me?

Effective 30 days after publication of this final rule, farmers with less than $825,000 in 2025 dollars annually in gross receipts from the sale of agricultural commodities are not subject to the security plan requirements in 49 CFR 172.800(c). PHMSA notes that the Notice of Proposed Rulemaking (NPRM) inadvertently styled the effect of the proposed revision as limited to an exception from the in-depth security training requirements.[1] This final rule clarifies that the actual scope of the rulemaking pertains to both the exception in 49 CFR 172.800(c) for security plan requirements and the in-depth training requirements associated with a security plan found at 49 CFR 172.704(a)(5).

C. Why is PHMSA taking this action?

PHMSA is taking this action based on positive commenter feedback and to advance the goals expressed in Executive Order (E.O.) 12866 (*Regulatory Planning and Review*).[2] E.O. 12866 requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' Raising the threshold for eligibility for relief from the security plan ($500,000 in 2005 to $825,000 in 2025 dollars) will provide relief to small farmers that have been unnecessarily burdened by this provision not being adjusted for inflation over time. As outlined in the final Regulatory Impact Analysis (RIA), PHMSA estimates this change would result in annualized cost savings of $5.7 million. A copy of the final RIA is available for review in the rulemaking docket. PHMSA does not expect the change to have any adverse impact on safety as it simply makes an inflationary adjustment to the exception from the security plan and in-depth security training requirements for small farmers.

II. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published an NPRM, cited as *HM–268J,* to gather feedback on revising the Hazardous Materials Regulations to raise the monetary threshold for farmers to be required to have a security plan.[3] Please refer to the NPRM for background and discussion of the proposed change. PHMSA received one comment from the Dangerous Goods Advisory Council in support of the proposal. PHMSA did not receive any negative comments in response to the NPRM. Therefore, PHMSA is revising 49 CFR 172.800(c) to except farmers who generate less than $825,000 in 2025 dollars annually in gross receipts from the sale of agricultural commodities or products from the security plan requirements in 49 CFR part 172, subpart I.

[1] 90 FR 28528 (Jul. 1, 2025).

[2] 58 FR 51735 (Oct. 4, 1993).

[3] 90 FR 28528 (Jul. 1, 2025).

III. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation as set forth in the Federal Hazardous Materials Transportation Laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

E.O. 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [4] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B also specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This final rule is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B and determined that this final rule will result in an estimated annualized cost savings of $5.7 million by reducing regulatory burdens and regulatory uncertainty for small farmers whose income threshold exceeds $500,000 by increasing the exception threshold to $825,000. In addition, farmers who no longer meet the new threshold of $825,000 in 2025 dollars would also no longer need to provide in-depth security awareness training to their employees on the implementation of the security plan. As outlined in the final RIA, PHMSA estimates that this change would result in annualized cost savings of $5.7 million (2024 dollars) at three percent and seven percent discount rates. A copy of the final RIA is available for review in the rulemaking docket.

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[5] PHMSA estimates this final rule would generate annualized cost savings of $5.7 million (2024 dollars) at three percent and seven percent discount rates. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 indicative of a regulation that is ''unlawful . . . [or] that undermine[s] the national interest.'' [6]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[7] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserted a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from (inter alia) the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [8] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[9] E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation Laws contain an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses items covered in Paragraph 2 above and will preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Though the final rule may operate to preempt some State requirements, it will not impose any regulation that has

[4] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

[5] 90 FR 9065 (Feb. 6, 2025).

[6] 90 FR 10583 (Feb. 25, 2025).

[7] 90 FR 8433 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

[8] 66 FR 28355 (May 22, 2001).

[9] 64 FR 43255 (Aug. 10, 1999); 74 FR 24693 (May 22, 2009).

substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. The preemptive effect of the regulatory amendments in this final rule is limited to the minimum level necessary to achieve the objectives of the Federal Hazardous Materials Transportation Laws. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to notice-and-comment rulemaking under the APA unless the agency head certifies that the changes in the rulemaking will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act.[10] DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[11] PHMSA developed this final rule in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. The final rule is expected to reduce burdens on farmers. PHMSA does not expect the final rule to impact safety as it simply makes an inflationary adjustment to the exception from the security plan and in-depth security training requirements for small farmers. Because the final rule is expected to reduce burdens, PHMSA certifies the final rule does not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, among other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under Section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[12]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A (*Department of Transportation Tribal Consultation Policies and Procedures*).[13] Executive Order 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined that it will not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded that the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) requires that PHMSA provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking will not create, amend, or rescind any existing information collections.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) requires agencies to consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally.[14] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of the final rule and has determined that its regulatory amendments will not cause unnecessary obstacles to foreign trade.

[10] 67 FR 53461 (Aug. 16, 2002).

[11] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

[12] DOT, PHMSA, *Implementing Procedures* (Aug. 28, 2025), *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[13] 65 FR 67249 (Nov. 9, 2000).

[14] 77 FR 26413 (May 4, 2012).

L. Cybersecurity and Executive Order 14028

E.O. 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [15] PHMSA has considered the effects of the final rule and has determined that its regulatory amendments would not materially affect the cybersecurity risk profile for affected entities.

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, or on DOT's website at *http://www.dot.gov/privacy.*

List of Subjects in 49 CFR Part 172

Hazardous materials transportation, Hazardous waste, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, AND TRAINING REQUIREMENTS

■ 1. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96, and 1.97.

■ 2. In § 172.800, paragraph (c) is revised to read as follows:

§ 172.800 Purpose and applicability.

* * * * *

(c) *Exceptions.* Transportation activities of a farmer, who generates less than $825,000 in 2025 dollars annually in gross receipts from the sale of agricultural commodities or products, are not subject to this subpart if such activities are:

(1) Conducted by highway or rail;

(2) In direct support of their farming operations; and

(3) Conducted within a 150-mile radius of those operations.

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15814 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 172 and 173

[Docket No. PHMSA–2025–0090 (HM–268B)]

RIN 2137–AG04

Hazardous Materials: Reducing Costs to Domestic Shippers and Carriers of Limited Quantities

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT)

ACTION: Final rule.

SUMMARY: This final rule removes undue regulatory burdens by allowing regulated entities to use a reduced sized marking for limited quantity shipments of hazardous materials by highway, rail, or vessel.

DATES: This final rule is effective September 3, 2026.

FOR FURTHER INFORMATION CONTACT: Jose Cajar, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration (PHMSA), 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–8553, *jose.cajar@dot.gov.*

I. PHMSA Action

A. What action is PHMSA taking in this Final Rule?

Currently, 49 CFR 172.315 specifies the marking requirements for limited quantities of hazardous materials, with paragraph (a)(2) of this section detailing the minimum size requirements. PHMSA is revising 49 CFR 172.315(a)(2) to allow regulated entities to use a reduced sized limited quantity marking on a package shipping label for certain shipments of hazardous materials in modes other than aircraft. PHMSA is also revising 49 CFR 173.25(a)(6) to specifically state that this marking is not authorized on an overpack.

B. Does this action apply to me?

Effective 30 days after publication of this final rule, persons subject to the limited quantities requirements in 49 CFR 172.315(a) will be allowed to use a reduced sized marking on packages containing limited quantities of hazardous materials transported by modes other than aircraft.

C. Why is PHMSA taking this action?

PHMSA is taking this action in response to commenter feedback and to reduce undue regulatory burdens on certain limited quantity shipments of hazardous materials. This final rule gives affected entities regulatory flexibility by authorizing the use of a reduced size limited quantity marking on certain packages. PHMSA expects this action will reduce costs and provide shippers and carriers of hazardous materials more options when transporting consumer products.

II. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published a notice of proposed rulemaking (NPRM), cited as *HM–268B,* to gather feedback on revising the Hazardous Materials Regulations (HMR) to authorize reduced sized limited quantity markings.[1] Please refer to the NPRM for background and discussion of the proposed change.

The following table alphabetically lists commenters to the NPRM:

Commenter name	Docket No.
Amazon.com, Inc. (Amazon)	PHMSA–2025–0090–0009
Council on Safe Transportation of Hazardous Articles, Inc. (COSTHA)	PHMSA–2025–0090–0006
Dangerous Goods Advisory Council	PHMSA–2025–0090–0008
Household & Commercial Products Association	PHMSA–2025–0090–0007
Medical Device Transport Council	PHMSA–2025–0090–0005
Nuclear Energy Institute	PHMSA–2025–0097–0002
Sporting Arms and Ammunition Manufacturers' Institute	PHMSA–2025–0090–0004

[15] 86 FR 26633 (May 17, 2021).

[1] 90 FR 28571 (Jul. 1, 2025).

All commenters supported the proposed amendments to reduce costs to domestic shippers and carriers of limited quantities of hazardous materials transported by modes other than aircraft. However, Amazon and COSTHA had additional questions or suggestions related to the NPRM proposal.

Amazon expressed support for the proposal but requested additional amendments to 49 CFR parts 172, 173, and 176 to remove the shipping paper requirement for vessels. PHMSA did not include these additional amendments in the NPRM and cannot finalize them at this time. PHMSA may consider including these proposals in a future rulemaking.

COSTHA expressed support for the proposal but requested clarification on whether the quarterly reporting requirement in DOT–SP 21015 would also be incorporated into the HMR. COSTHA noted that numerous members found this reporting requirement to be administratively burdensome and unrelated to the original underlying safety basis for DOT–SP 21015. In this final rule, PHMSA is clarifying that the quarterly reporting requirement found in DOT–SP 21015 was only a condition of the special permit and is not required as part of this regulatory provision.

Having considered the comments received, PHMSA is revising 49 CFR 172.315(a) to allow for a reduced size limited quantity marking that is capable of communicating to carriers that the package contains hazardous materials shipped under a limited quantity exception and by the authorized mode of transportation. In addition, PHMSA is revising 49 CFR 173.25(a)(6) to specifically state that the reduced sized limited quantity marking is not authorized on overpacks. PHMSA does not expect these revisions to have any adverse impact on safety.

III. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation set forth in the Federal Hazardous Materials Transportation Laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [2] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This NPRM is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B and determined that this final rule will result in cost savings by reducing regulatory burdens and regulatory uncertainty for hazardous materials shippers and carriers. The final rule will eliminate the need for a separate limited quantity label, as the hazard communication information will be embedded in the shipping label, producing cost savings for the transportation industry and the public to whom those entities generally transfer a portion of their compliance costs. These cost savings are not quantified because PHMSA lacks comprehensive data for limited quantity shipments across all surface modes of transportation.

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[3] PHMSA finds the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . . [or] that undermine[s] the national interest.'' [4]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[5] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserted a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from (inter alia) the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [6] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[7] E.O. 13132 requires agencies to

[2] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

[3] 90 FR 9065 (Feb. 6, 2025).

[4] 90 FR 10583 (Feb. 25, 2025).

[5] 90 FR 8433 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

[6] 66 FR 28355 (May 22, 2001).

[7] 64 FR 43255 (Aug. 10, 1999); 74 FR 24693 (May 22, 2009).

assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation laws contain an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and Tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses items covered in Paragraph 2 above and will preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Though the final rule may operate to preempt some State requirements, it will not impose any regulation that has substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. The preemptive effect of the regulatory amendments in this final rule is limited to the minimum level necessary to achieve the objectives of the Federal Hazardous Materials Transportation laws. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to notice-and-comment rulemaking under the APA unless the agency head certifies that the final rule in the rulemaking will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act.[8] DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[9] PHMSA developed this final rule in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. Because the final rule is expected to reduce burdens, PHMSA certifies that it does not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, among other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under Section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[10]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A (*Department of Transportation Tribal Consultation Policies and Procedures*).[11] Executive Order 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined that it will not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded that the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) require that PHMSA provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking will not create, amend, or rescind any existing information collections. However, this rulemaking eliminates the need for persons to renew a special permit, resulting in a decrease in paperwork burden for special permit holders. PHMSA estimates the inventory reduction for this OMB control number as follows:

OMB Control No. 2137–0051: Rulemaking, Special Permits, and Preemption Requirements

Decrease in Annual Number of Respondents: 8.

Decrease in Annual Responses: 8.

[8] 67 FR 53461 (Aug. 16, 2002).

[9] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

[10] PHMSA, *Implementing Procedures, https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[11] 65 FR 67249 (Nov. 9, 2000).

Decrease in Annual Burden Hours: 12.

Decrease in Annual Burden Cost: $0.

Please direct your requests for a copy of this information collection to Steven Andrews, Office of Hazardous Materials Standards (PHH–12), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE, 2nd Floor, Washington, DC 20590–0001.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) requires agencies to consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally.[12] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of the final rule and has determined that its regulatory amendments will not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

E.O. 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [13] PHMSA has considered the effects of the final rule and has determined that its regulatory amendments would not materially affect the cybersecurity risk profile for affected entities.

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, or on DOT's website at *http://www.dot.gov/privacy.*

List of Subjects

49 CFR Part 172

Hazardous materials transportation, Hazardous waste, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Training, Packaging and containers, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, TRAINING REQUIREMENTS, AND SECURITY PLANS

■ 1. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96, and 1.97.

■ 2. In § 172.315, add paragraph (a)(2)(iii) to read as follows:

§ 172.315 Limited quantities.

* * * * *

(a) * * *

(2) * * *

(iii) *Reduced size marking on shipping labels.* Except for the shipment of radioactive materials and hazardous materials transported by air or international vessels, the shipper may place a reduced size limited quantity marking on the package shipping label regardless of the size of packaging. Each marking must be a minimum of 25 mm on each side and the width of the border forming the square-on-point must be readily visible. The square-on-point must be durable, legible, readily visible, and displayed on a background of sharply contrasting color. Each shipping label must be capable of electronically communicating to carriers that the package contains hazardous materials shipped under a limited quantity exception and the authorized modes of transportation.

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 3. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96, and 1.97.

■ 4. In § 173.25, revise paragraph (a)(6) to read as follows:

§ 173.25 Authorized packagings and overpacks.

(a) * * *

(6) For limited quantities, the overpack is marked with a limited quantity marking prescribed in § 172.315 of this subchapter, unless a limited quantity marking representative of the hazardous material in the overpack is visible. The reduced size marking (25 mm x 25 mm) is not authorized for use on the outside of an overpack.

* * * * *

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15805 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 172 and 173

[Docket No. PHMSA–2025–0104 (HM–268P)]

RIN 2137–AG18

Hazardous Materials: Adoption of Department of Transportation Special Permit 21478

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT)

[12] 77 FR 26413 (May 4, 2012).

[13] 86 FR 26633 (May 17, 2021).

ACTION: Final rule.

SUMMARY: This final rule removes undue regulatory burdens by adopting the provisions of U.S. Department of Transportation (DOT) special permit (SP) 21478 to allow empty intermediate bulk containers (IBCs) that only contain the residue of a hazardous material to be transported without shipping papers, placards, and United Nations (UN) identification (ID) numbers.

DATES: This final rule is effective September 3, 2026.

FOR FURTHER INFORMATION CONTACT: Noah Jacobson, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration (PHMSA), 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–8553, *noah.jacobson@dot.gov.*

I. PHMSA Action

A. What action is PHMSA taking in this final rule?

PHMSA is adopting the provisions of DOT SP 21478 into the Hazardous Materials Regulations (HMR: 49 CFR parts 171–180) by revising 49 CFR 173.29 to add a new subparagraph (d) that authorizes the transportation of ''empty'' IBCs only containing a residue of a hazardous material in a manner similar to what is already allowed for empty non-bulk packaging in 49 CFR 173.29(c). PHMSA is also making conforming revisions to 49 CFR 172.331, 172.504, and 172.514. These revisions include amending 49 CFR 172.514 to make clear that IBCs shipped in accordance with the conditions of the empty packaging exception are not subject to placarding. The new provisions will require a document (in paper or electronic form) to accompany the IBCs that denotes the phrase ''Residue IBC(s)'' and indicates the number of IBCs containing hazardous materials for each Class or Division of material transported on a transport vehicle.

B. Does this action apply to me?

Effective 30 days after publication of this final rule, holders of DOT SP 21478 will no longer need a special permit to transport ''empty'' IBCs in accordance with 49 CFR 173.29.

C. Why is PHMSA taking this action?

PHMSA is taking this action in response to commenter feedback and to provide relief to stakeholders from certain requirements in the HMR for the transportation of ''empty'' IBCs containing only the residue of hazardous materials. This final rule will allow the transportation of empty IBCs in a manner similar to what is already permitted for non-bulk packagings. Specifically, the relief provided for an ''empty'' non-bulk packaging in § 173.29(c) states that non-bulk packaging containing only the residue of hazardous materials covered by Table 2 of § 172.504—a table of comparatively lower hazard Classes and Divisions of materials—are excepted from certain hazard communication requirements of the HMR. These packages do not need to be included in determining the need for placarding and are not subject to the shipping paper requirements when collected and transported by a for-hire or private carrier for reconditioning, remanufacture, or reuse.

PHMSA issued DOT–SP 21478 to grant relief from the requirement to offer for transportation and transport IBCs containing only residue of hazardous materials in a similar manner to that offered to non-bulk packagings. PHMSA has authorized this widely-utilized special permit for years with a proven track record for safety. PHMSA is also taking this action as part of its ongoing review of special permits that are appropriate for adoption into the HMR based on their safety record and positive impact on stakeholders.

II. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published a notice of proposed rulemaking (NPRM), cited as *HM–268P,* to gather feedback on adopting DOT SP 21478 into the HMR.[1] Please refer to the NPRM for background and discussion of the proposed change.

The following table alphabetically lists commenters to the NPRM:

Commenter name	Docket No.
AECOM Technical Services, Inc.	PHMSA–2025–0104–0011
Alliance for Chemical Distribution	PHMSA–2025–0104–0008
American Fuel & Petrochemical Manufacturers	PHMSA–2025–0104–0010
Commercial Vehicle Safety Alliance (CVSA)	PHMSA–2025–0104–0009
Dangerous Goods Advisory Council	PHMSA–2025–0104–0007
Industrial Packaging Association of North America	PHMSA–2025–0104–0006
Institute of Makers of Explosives	PHMSA–2025–0104–0005
Reusable Industrial Packaging Association	PHMSA–2025–0104–0003
William Forbes	PHMSA–2025–0104–0004

A majority of NPRM commenters submitted feedback in favor of the proposed revisions. However, some commenters had additional questions or suggestions related to the NPRM proposal.

William Forbes and CVSA commented that the quantity limits in the proposal are unenforceable and may not maintain safety. Both commenters state that enforcement personnel will have no practical means to determine whether the residue quantity limits are being met. PHMSA acknowledges these concerns but notes that the quantity limits as proposed can be effectively verified through established oversight practices such as routine inspections and documentation reviews.[2] These enforcement tools have a proven track record of ensuring compliance and mitigating potential safety risks. PHMSA also notes that by limiting the capacity of the IBCs, the safety concerns surrounding the actual quantities of residue are further mitigated. In addition, more than 40 entities have been approved to transport hazardous material residues under DOT SP 21478 since its issuance in 2021, and PHMSA has never received any reports of safety incidents related to its use. This operational history provides strong

[1] 90 FR 28566 (Jul. 1, 2025).

[2] PHMSA evaluated the safety hazards associated with the hazard communication exceptions and determined that there is an equivalent level of safety between transportation of ''empty'' IBCs and ''empty'' non-bulk packages. PHMSA also notes that, comparatively, the typical quantities of residue in these IBCs are less than the quantities that the Environmental Protection Agency (EPA) considers for a container to be empty under its Resource Conservation and Recovery Act regulations for residues of hazardous waste. EPA defines this amount as 0.3 percent or less of material by weight of the total capacity for a container greater than 119 gallons—the cutoff for a packaging to be considered non-bulk. *See* 40 CFR 261.7(b)(1)(iii)(B).

evidence that the permit conditions are both enforceable and effective in maintaining an appropriate level of safety.

CVSA expressed additional concerns that the NPRM no longer requires shipping papers, placards, and identification numbers to be displayed on the transport vehicle for residue IBCs. CVSA highlighted that under the NPRM, IBCs containing hazardous materials that are prohibited from being shipped together according to 49 CFR 177.848—which governs the segregation of hazardous materials—could inadvertently be transported together. CVSA also notes that shipping papers serve as a practical and effective means for verifying compliance with segregation requirements. Consequently, CVSA believes that eliminating the requirement for shipping papers on the transport vehicle introduces a significant safety risk by decreasing the ability of inspectors and emergency responders to verify proper segregation of hazardous materials.

PHMSA acknowledges CVSA's concerns regarding the elimination of the requirement for a traditional shipping paper under part 172 to accompany transport vehicles containing residue IBCs. However, PHMSA has determined that the proposed revisions to 49 CFR 173.29 provide an equally effective mechanism for communicating necessary hazard information while reducing unnecessary regulatory burden. As proposed, the driver must maintain—in either paper or electronic form—a document that accompanies the IBCs and includes the phrase ''Residue IBC(s)'' along with the number of IBCs containing hazardous materials for each hazard class or division transported. This documentation ensures that inspectors and emergency responders can quickly identify the type and quantity of hazardous materials present, thereby enabling verification of applicable segregation requirements without imposing the full shipping paper requirements of part 172. PHMSA has determined that this approach maintains safety by ensuring critical hazard communication while providing regulated entities with greater flexibility in meeting documentation requirements.

For these reasons, PHMSA concludes that the revisions as proposed will maintain appropriate levels of safety and authorize reasonable flexibilities. As such, PHMSA is adopting the provisions of DOT SP 21478 into 49 CFR 173.29 and making conforming revisions in 49 CFR 172.331, 172.504, and 172.514 in this final rule. PHMSA does not expect these revisions to have substantial adverse impact on safety.

III. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation as set forth in the Federal Hazardous Materials Transportation laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866: Regulatory Planning and Review

Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [3] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This final rule is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B and determined that this final rule will result in cost savings by reducing regulatory burdens and regulatory uncertainty for affected entities by providing relief from undue regulatory requirements to those offering and transporting empty IBCs containing only hazardous materials residue or from the need to apply for a relevant special permit. PHMSA expects that cost savings will result in reduced costs for the public to whom those entities generally transfer a portion of their compliance costs.

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[4] PHMSA finds the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . . [or] that undermine[s] the national interest.'' [5]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[6] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserted a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from, *inter alia,* the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [7] Because this final rule is not a significant action under E.O.

[3] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

[4] 90 FR 9065 (Feb. 6, 2025).

[5] 90 FR 10583 (Feb. 25, 2025).

[6] 90 FR 8433 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

[7] 66 FR 28355 (May 22, 2001).

12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[8] E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation laws contain an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses items (1), (2), and (3) above and may preempt state, local, and Tribal requirements not meeting the ''substantively the same'' standard. Though the final rule may operate to preempt some State requirements, it would not impose any regulation that has substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. The preemptive effect of the regulatory amendments in this final rule is limited to the minimum level necessary to achieve the objectives of the Federal Hazardous Materials Transportation Laws. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to notice-and-comment rulemaking under the APA unless the agency head certifies that the final rule in the rulemaking will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act.[9] DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[10] PHMSA developed this final rule in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. Because the final rule is expected to reduce burdens, PHMSA certifies that it does not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, among other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under Section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[11]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A (*Department of Transportation Tribal Consultation Policies and Procedures*).[12] E.O. 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined it will not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR

[8] 64 FR 43255 (Aug. 10, 1999): 74 FR 24693 (May 22, 2009).

[9] 67 FR 53461 (Aug. 16, 2002).

[10] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

[11] DOT, *Implementing Procedures for Considering Environmental Impacts* (Aug. 28, 2025), available at *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[12] 65 FR 67249 (Nov. 9, 2000).

1320.8(d) require that PHMSA provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking will not create, amend, or rescind any existing information collections. However, this rulemaking eliminates the need for persons to renew a special permit, resulting in a decrease in paperwork burden for special permit holders. PHMSA estimates the inventory reduction for this OMB control number as follows:

OMB Control No. 2137–0051: Rulemaking, Special Permits, and Preemption Requirements.

Decrease in Annual Number of Respondents: 11.

Decrease in Annual Responses: 11.

Decrease in Annual Burden Hours: 16.

Decrease in Annual Burden Cost: $0.

This final rule also creates a requirement for shippers using the new provisions in 49 CFR 173.29 to have a document—in paper or electronic form—in lieu of a shipping paper, accompanying the IBCs that denotes the phrase ''Residue IBC(s)'' and indicates the number of IBCs containing hazardous materials for each Class or Division of material transported on transport vehicle. PHMSA estimates that 44 respondents will ship 50 shipments per year under this provision resulting in 2,200 shipments per year. PHMSA estimates it will take 30 seconds each for offerors to create this certification resulting in 19 burden hours (2,200 responses × 30 seconds per response). PHMSA will place this information collection under OMB Control Number 2134–0034 ''Shipping Papers and Emergency Response Information.'' PHMSA estimates there is no additional burden associated with this information collection.

Please direct your requests for a copy of this information collection to Steven Andrews, Office of Hazardous Materials Standards (PHH–12), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE, 2nd Floor, Washington, DC 20590–0001.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) requires agencies to consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally.[13] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of the final rule and has determined that its regulatory amendments will not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

E.O. 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [14] PHMSA has considered the effects of the final rule and has determined that its regulatory amendments would not materially affect the cybersecurity risk profile for affected entities.

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, or on DOT's website at *http://www.dot.gov/privacy.*

[13] 77 FR 26413 (May 4, 2012).

[14] 86 FR 26633 (May 17, 2021).

List of Subjects

49 CFR Part 172

Education, Hazardous materials transportation, Hazardous waste, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, packaging and containers, radioactive materials, uranium, reporting, and recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, TRAINING REQUIREMENTS, AND SECURITY PLANS

■ 1. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96, and 1.97.

■ 2. In § 172.331, add paragraph (d) to read as follows:

§ 172.331 Bulk packagings other than portable tanks, cargo tanks, tank cars and multi-unit tank car tanks.

* * * * *

(d) Transport vehicles or freight containers used to transport empty IBCs in accordance with § 173.29(d) of this subchapter are not subject to identification number marking requirements.

■ 3. In § 172.504, revise paragraph (d) to read as follows:

§ 172.504 General placarding requirements.

* * * * *

(d) *Exceptions for empty packages.* (1) *Non-bulk.* Except for hazardous materials subject to § 172.505, a non-bulk packaging that contains only the residue of a hazardous material covered by Table 2 of paragraph (e) of this section need not be included in determining placarding requirements.

(2) *IBCs.* Transport vehicles or freight containers used to transport empty IBCs in accordance with § 173.29(d) of this subchapter are not subject to placarding requirements of this part.

* * * * *

■ 4. In § 172.514, revise paragraph (b) to read as follows:

§ 172.514 Bulk packagings.

* * * * *

(b) Each bulk packaging that is required to be placarded when it contains a hazardous material, must remain placarded when it is emptied, unless it—

(1) Is sufficiently cleaned of residue and purged of vapors to remove any potential hazard;

(2) Is refilled, with a material requiring different placards or no placards, to such an extent that any residue remaining in the packaging is no longer hazardous;

(3) Contains the residue of a hazardous substance in Class 9 in a quantity less than the reportable quantity, and conforms to § 173.29(b)(1) of this subchapter; or

(4) Is an empty IBC transported in accordance with § 173.29(d).

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 5. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 6. In § 173.29, redesignate current paragraphs (d) through (h) as paragraphs (e) through (i) and add new paragraph (d) to read as follows:

§ 173.29 Empty packagings.

* * * * *

(d) A steel, rigid plastic, or composite IBC not exceeding 2,100 L (550 gallons) containing only the residue of hazardous materials in packing group II or III of hazard Class or Division 3, 4.1, 5.1, 6.1, 8, and 9, is excepted from subpart C (shipping papers). Furthermore, transport vehicles and freight containers are not subject to the subpart F (placarding) of Part 172 of this subchapter and the marking requirements in § 172.331 (UN ID Number), provided the following conditions are met:

(1) Prior to shipment, the offeror must ensure that no more than 0.3 percent by weight of the total capacity of the IBC remains in the packaging;

(2) IBCs must be transported in a fully enclosed transport vehicle or freight container;

(3) Transportation is only authorized to a reconditioning, remanufacturing, requalification, disposal, or repair facility;

(4) A document (in paper or electronic form) must accompany the shipment of IBCs that denotes the phrase ''Residue IBC(s)'' and indicates the number of IBCs containing hazardous materials for each Class or Division of material transported;

(5) IBCs shall be marked and labeled in accordance with subpart D (marking) and subpart E (labeling) of Part 172 of this subchapter; and

(6) Transportation is authorized for only motor vehicle or rail.

* * * * *

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15820 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 173

[Docket No. PHMSA–2025–0094 (HM–268F)]

RIN 2137–AG08

Hazardous Materials: Reducing Burdens by Allowing Continued Use of Department of Transportation Special Permit Packagings

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule removes undue regulatory burdens by allowing for the continued use of packagings authorized under a manufacturing special permit for the useful life of the package. Manufacturing special permits typically authorize the manufacture, mark, sale, and use of the packaging authorized by the special permit.

DATES: This final rule is effective September 3, 2026.

FOR FURTHER INFORMATION CONTACT: Tony Horne, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration (PHMSA), 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–8553, *tony.horne@dot.gov.*

I. PHMSA Action

A. What action is PHMSA taking in this final rule?

PHMSA is revising 49 CFR 173.23 to allow for the continued use of a U.S. Department of Transportation (DOT) special permit (SP) packaging (*i.e.,* packaging associated with a manufacturing special permit) for which the SP has expired but the packaging remains otherwise safe and usable. Specifically, PHMSA is allowing DOT SP packagings to be used for the duration of their usable life regardless of the status of the grantee and whether the SP was not renewed—*e.g.,* when the original grantee has gone out of business but some of their packagings remain in commerce because a shipper has yet to use it for hazardous material shipment.

B. Does this action apply to me?

Effective 30 days after publication of this final rule, persons with a DOT SP packaging that is compliant with the requirements in 49 CFR 173.23 and the conditions of the most recent DOT SP on file with PHMSA may continue to use the packaging in hazardous materials service.

C. Why is PHMSA taking this action?

PHMSA is taking this action in response to commenter feedback and to allow the use of otherwise safe and usable packaging. Prohibiting the use of these packages solely because the original manufacturer (*i.e.,* the original special permit holder) has gone out of business or chose not to renew an SP is unnecessary. Authorizing the continued use of such packagings relieves an economic burden without compromising public safety.

II. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published a notice of proposed rulemaking (NPRM), cited as *HM–268F,* to gather feedback on revising the HMR to allow conditional continued use of packagings authorized under a manufacturing special permit for the duration of its useable life.[1] Please refer to the NPRM for background and discussion of the proposed change.

The following table alphabetically lists commenters to the NPRM:

Commenter name	Docket No.
Commercial Vehicle Safety Alliance (CVSA)	PHMSA–2025–0094–0013

[1] 90 FR 28571 (Jul. 1, 2025).

Commenter name	Docket No.
Compressed Gas Association, Inc	PHMSA–2025–0094–0005
Council on Safe Transportation of Hazardous Articles, Inc. (COSTHA)	PHMSA–2025–0094–0006
Dangerous Goods Advisory Council (DGAC)	PHMSA–2025–0094–0011
Industrial Packaging Association of North America	PHMSA–2025–0094–0012
Institute of Makers of Explosives	PHMSA–2025–0094–0009
International Vessel Operators Dangerous Goods Association (IVODGA)	PHMSA–2025–0094–0007
National Tank Truck Carriers	PHMSA–2025–0094–0003
PerVisum Ltd	PHMSA–2025–0094–0002
Sporting Arms and Ammunition Manufacturers' Institute	PHMSA–2025–0094–0004
William Forbes	PHMSA–2025–0094–0008

PHMSA received eleven comments, the majority of which supported the NPRM. Specifically, commenters noted that the structural integrity and safety of packagings do not degrade simply because the underlying manufacturing SP expires or is not renewed by the grantee. Stakeholders emphasized that the current regulatory framework creates an ''unnecessary burden'' that forces the premature disposal of ''perfectly functional packagings,'' resulting in unwarranted economic and environmental waste. Commenters noted that the proposal would also eliminate unnecessary administrative hurdles and provide critical certainty for shippers and carriers, thereby reducing confusion in port operations and preventing the refusal of safe shipments without compromising safety standards.

However, several commenters expressed concerns and asked for clarification on certain topics. In addition, one commenter suggested some changes to improve the proposal. PHMSA responds as follows:

A. Expired/Inactive Manufacturing Special Permits and Use of Packagings

With regard to the continued use of packagings conforming with manufacturing DOT SPs that have expired, CVSA and William Forbes commented that expired DOT SPs are not readily available online and difficult to locate. The commenters suggested that the inability to access the SPs would be a burden for industry to demonstrate shipment compliance and would create barriers for enforcement personnel to verify the terms of the DOT SP. Similarly, COSTHA and IVODGA shared concerns that carriers may deny shipments based on expired SPs. Those commenters requested that PHMSA provide clear guidance to carriers and enforcement personnel to avoid unnecessary disruptions.

PHMSA acknowledges the concerns raised by these commenters and reiterates the following. First, PHMSA notes that there are many measures in place that demonstrate responsibility for maintenance or availability of SPs by shippers and carriers. Two standard parts of every SP issued by PHMSA—Sections 8 (Special Provisions) and Section 10 (Modal Requirements)—require that a current copy of the SP be maintained at facilities where it is used and be carried aboard transport vehicles used to move SP packages. Moreover, in Section 11 (Compliance), hazmat employees who perform a function subject to an SP must receive training on the requirements and conditions of said SP in addition to the training requirements of the HMR. This is reinforced in the general requirements of the HMR in 49 CFR 171.2(c), which states that each person performing a function covered by a SP must perform that function in accordance with the SP. Furthermore, the training requirements in 49 CFR 172.704(b) mandate that each hazmat employee must be provided function-specific training concerning requirements of SPs issued by the agency. This demonstrates further that entities need to have a copy of the SP to use the packaging. Second, PHMSA also makes SPs available at its website through its SP search page, and this will be expanded to include expired manufacturing SPs. Thus, PHMSA finds that the availability of expired manufacturing SPs to the public will not be a compliance or enforcement concern or lead to the denial of shipments by carriers.

B. Life of the Packaging

CVSA and William Forbes commented that the ''life of the packaging'' should be defined because current manufacturing SPs do not include information regarding the lifespan. The commenters question whether enforcement personnel would be able to ascertain if a packaging that is used after the expiration or non-renewal of an SP is still within its usable lifespan and, therefore, in compliance with the HMR. The commenters suggest that all manufacturing SPs should define the lifespan of the packaging.

PHMSA acknowledges the concerns but disagrees with the premise. Except for a few package types—*e.g.,* a DOT 3HT cylinder—the HMR do not designate a lifespan (*i.e.,* a service life) for an authorized package, nor does PHMSA typically designate lifespans as a provision in manufacturing SPs. Rather, the service life depends generally on whether the packaging conforms in all respects to requirements of the HMR and, specifically—for a packaging subject to periodic evaluation—whether it can achieve requalification for continued service. This applies to SP packaging as well. Thus, the service life of an SP packaging is the duration of time from production until the packaging can no longer meet the required conditions or a service life as specified in the SP. As noted by commenters supporting the proposed change, the current rules create situations where packaging is rendered obsolete solely by permit expiration—rather than functional failure—forcing businesses to discard functional packaging and procure costly replacements, a cycle that not only destabilizes distribution networks and burdens customers, but also suppresses industry innovation while generating significant economic and environmental waste without any tangible improvement to safety.

COSTHA and IVODGA further requested that PHMSA confirm whether packagings manufactured prior to the expiration of a SP can be reused, and whether shipments that are already prepared and waiting in warehouses—prior to the SP expiration—remain authorized once the SP has expired.

PHMSA confirms that SP packagings manufactured during the life of the SP can be reused if they conform in all respects to the requirements of the SP and the HMR. In addition, shipments prepared prior to the SP expiration remain authorized for transport.

C. Safety Concerns

CVSA asked how PHMSA will handle packagings whose SP has been terminated or not renewed due to a

safety issue identified by the agency. They admit that, ''while uncommon, there have been instances in the past when the agency chose not to renew a special permit due to safety concerns.''

PHMSA's position remains that, if an SP was terminated due to safety issues, the permit will be removed from the PHMSA website and replaced with a termination letter, and the packaging will no longer be authorized for use. Termination of an SP is equivalent to the removal of any of its authorizations. Therefore, PHMSA finds this final rule will not have any impact on authorized shipments per se and should not cause any safety concerns.

D. Party Status

COSTHA, IVODGA, and PerVisum Ltd. requested clarification regarding the continuation of ''party status'' for SPs if the original applicant is no longer in business. In addition, PerVisum Ltd. asked whether older SPs would be amended to remove the statement ''See individual authorization letter'' on the line that indicates the grantee of the SP.

PHMSA clarifies that party status is not authorized for manufacturing SPs. Such a packaging may be used as provided in 49 CFR 173.22a. Once the manufacturing SP expires, manufacturing cannot continue but existing packagings may continue to be used so long as the packaging continues to conform to the provisions of the SP as well as all applicable HMR requirements. The change adopted in this final rule will allow for the continued use of a manufacturing SP for the duration of its usable life as discussed above, regardless of the status of the grantee.

PerVisum Ltd. asked whether the statement ''See individual authorization letter'' will be removed from older SPs. PerVisum Ltd. linked this question to a broader inquiry about whether ''Party Status'' would no longer be applied to these SPs under this rule. PHMSA is clarifying that party status is not issued for manufacturing SPs; therefore, the statement ''See individual authorization letter'' does not appear on any current manufacturing SPs.

E. Suggested Additional Conditions to the Proposed Change

DGAC supports the change allowing the continued use of SP packaging but provided several suggested conditions to include upon its adoption into a final rule: (1) a copy of the most recent SP must be maintained at each facility utilizing the packaging; (2) the packaging must be marked with the SP number; and (3) the packaging must be used and maintained in accordance with the provisions contained in the SP.

PHMSA appreciates the feedback offered by DGAC. The change adopted in this rulemaking requires conformance with the terms of the most recent version of the SP. As discussed earlier, the terms of manufacturing SPs currently include the requirements that a copy of the SP must be maintained at each facility using the packaging, and that the packaging must be marked with the SP number. Note that, in some instances, the manufacturing SP may include other markings in addition to the DOT SP number on the package. PHMSA notes that SPs also contain standard language in Section 11 (Compliance) stating that no person may use or apply the SP—including displaying its number—when the SP has expired or is otherwise no longer in effect. The action in this rulemaking supersedes that provision. Therefore, future manufacturing SPs issued will no longer contain the provision and persons using manufacturing SP packaging may disregard the instruction within the SP that prohibits continued use or application.

For the reasons discussed above, PHMSA is revising 49 CFR 173.23 to allow for the continued use of a SP packaging for which the SP has expired but the packaging remains otherwise safe and usable. Authorizing continued use of such packagings relieves an economic burden without compromising public safety. PHMSA finds this revision will not have an adverse impact on safety.

III. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation as set forth in the Federal Hazardous Materials Transportation Laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [2] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

Executive Order 12866 (*Regulatory Planning and Review*) and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Management and Budget (OMB) for review.[3] This rulemaking is not considered a significant regulatory action under Section 3(f) of E.O. 12866 and, therefore, was not formally reviewed by OMB.

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B and determined this final rule will result in cost savings by reducing regulatory burdens and regulatory uncertainty for affected entities by allowing use of packagings manufactured under a SP for the useful life of the packaging beyond expiration of the SP. PHMSA finds the cost savings are associated with the reduction in burdens for new SP applications (*e.g.,* renewals) and lost inventory. Those cost savings may also result in reduced costs for the public to whom those entities may generally transfer a portion of their compliance costs. In addition, the final rule will produce budget savings for the Federal Government, hence taxpayers, due to the reduction of SP applications that would otherwise need to be processed by PHMSA personnel.

The table below presents PHMSA's estimates of the costs and associated number of hours for SP applications, renewals, and for additional parties to join an existing SP. These estimates are based on prevailing compensation rates for specific occupations involved in developing and processing SP applications, and the number of hours

[2] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

[3] 58 FR 51735 (Oct. 4, 1993).

each occupation is estimated to commit to a SP application, renewal or additional party application. The rows marked ''private'' are the estimates for an SP applicant to apply, renew, or for another entity to join as a party to the SP. The rows marked ''government'' are the estimated costs for PHMSA to process SP applications, renewals, and additional party applications. PHMSA has not developed a comprehensive list of the SPs that would be affected by this rule and hence cannot estimate total cost savings.

Occupation title	Sector	New special permit		Special permit renewal		New special permit—additional parties	
		Hours	Cost	Hours	Cost	Hours	Cost
General and Operations Managers	Private	3.25	$310	2	$191	0.7	$62
Engineers	Private	25	2,091	3.75	314	5.0	418
Lawyers	Private	4	524	1.5	196	0.8	105
Office and Administrative Support Occupations	Private	1.75	63	1.75	63	0.4	13
Private Sector Subtotal		34	2,987	9	764	6.8	597
General and Operations Managers	Government	6	819	1	136	1.2	164
Engineers	Government	16	1,815	6	681	3.2	363
Lawyers	Government	4	580	2	290	0.8	116
Compliance Officers	Government	10	860	4	344	2.0	172
Government Subtotal		36	4,074	13	1,451	7.2	815
Grand Total		70	7,062	22	2,215	14	1,412

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[4] PHMSA finds the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . . [or] that undermine[s] the national interest.'' [5]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[6] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserted a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from (inter alia) the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [7] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[8] Executive Order 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation Laws contain an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and Tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses items covered in Paragraphs 2 and 5 above and would preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Though the final rule may operate to preempt some State requirements, it would not impose any regulation that has substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. The preemptive effect of the regulatory amendments in this final rule is limited to the minimum level necessary to achieve the objectives of the Federal Hazardous Materials Transportation laws. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

[4] 90 FR 9065 (Feb. 6, 2025).

[5] 90 FR 10583 (Feb. 25, 2025).

[6] 90 FR 8433 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

[7] 66 FR 28355 (May 22, 2001).

[8] 64 FR 43255 (Aug. 10, 1999); 74 FR 24693 (May 22, 2009).

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to notice-and-comment rulemaking under the APA unless the agency head certifies that the final rule will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act.[9] DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[10] This final rule was developed in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. Because the final rule will reduce burdens, PHMSA certifies that it does not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, amongst other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under Section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[11]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A (*Department of Transportation Tribal Consultation Policies and Procedures*).[12] Executive Order 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined that it will not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded that the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) requires that PHMSA provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking will not create, amend, or rescind any existing information collections.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) requires agencies to consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally.[13] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of the final rule and has determined that its regulatory amendments will not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

E.O. 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [14] PHMSA has considered the effects of the final rule and has determined that its regulatory amendments will not materially affect the cybersecurity risk profile for affected entities.

[9] 67 FR 53461 (Aug. 16, 2002).

[10] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

[11] DOT, PHMSA, *Implementing Procedures* (Aug. 28, 2025), available at: *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[12] 65 FR 67249 (Nov. 9, 2000).

[13] 77 FR 26413 (May 4, 2012).

[14] 86 FR 26633 (May 17, 2021).

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, or on DOT's website at *http://www.dot.gov/privacy.*

List of Subjects 49 CFR Part 173

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGING

■ 1. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96, and 1.97.

■ 2. In § 173.23, add paragraph (j) to read as follows:

§ 173.23 Previously authorized packaging.

* * * * *

(j) Notwithstanding the prohibition of use of an expired manufacturing special permit (as defined in 49 CFR 107.1) in accordance with 49 CFR 107.109(b), a packaging having been manufactured in accordance with a special permit which has expired and has yet to be adopted as an authorized packaging for broad and general use in this subchapter, may continue to be used in hazardous materials transportation service for its useful life provided the packaging continues to conform to applicable requirements of this subchapter and the terms of the most recent version of the special permit.

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15810 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 173

[Docket No. PHMSA–2025–0091 (HM–268C)]

RIN 2137–AG05

Hazardous Materials: Reducing Burdens on Domestic Companies Using Battery-Powered Equipment in Trades

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule modernizes the Materials of Trade (MOT) exception in the Hazardous Materials Regulations (HMR) by increasing the maximum allowable quantities of lithium batteries that can be transported as MOTs. This increase removes an undue regulatory burden which constrains the ability of construction, landscaping, mowing, tree service, food service, and entertainment companies to perform their trade.

DATES: This final rule is effective September 3, 2026.

FOR FURTHER INFORMATION CONTACT: Arthur Pollack, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration (PHMSA), 1200 New Jersey Avenue SE, Washington, DC 20590–0001, 202–366–8553, *arthur.pollack@dot.gov.*

I. PHMSA Action

A. What action is PHMSA taking in this final rule?

This final rule removes undue regulatory burdens by increasing the maximum allowable quantities of lithium batteries that can be transported as MOTs. This allowance applies to domestic companies in sectors such as construction, landscaping, mowing, tree service, food service, and entertainment—enabling them to carry the power sources required to perform their trade safely and more efficiently.

B. Does this action apply to me?

Effective 30 days after publication of this final rule, lithium batteries transported under conditions meeting the definition of an MOT under 49 CFR 171.8 may take advantage of the increased quantity limits outlined in 49 CFR 173.6.

C. Why is PHMSA taking this action?

PHMSA is taking this action in response to commenter feedback and to modernize 49 CFR 173.6 to update the quantity limits for lithium batteries under MOTs. The HMR currently limits the aggregate gross weight of materials of trade—other than certain diluted mixtures of Class 9 materials—in a motor vehicle to 200 kg (440 pounds). This revision increases this allowance for lithium batteries by authorizing up to 30 kg (66 pounds) per battery, a 500 kg (1102 pounds) gross vehicle limit, and no limit for batteries installed in equipment, while including safety provisions to prevent short circuits, shifting damage, and accidental activation. This action will reduce regulatory burdens for companies that transport batteries and battery-powered equipment in support of a trade without any compromise in safety because of the safety provisions included in the revision. Finally, this action advances the goals of multiple Executive Orders and provides annualized cost savings to American businesses—please see a more detailed discussion in the Executive Order (E.O.) 12866 discussion in ''Section III. Regulatory Analysis and Notices.''

II. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published a notice of proposed rulemaking (NPRM), cited as *HM–268C,* to gather feedback on modernizing the HMR to authorize increased quantities of lithium batteries under the MOTs exception.[1] Please refer to the NPRM for background and discussion of the proposed change.

The following table alphabetically lists commenters to the NPRM:

[1] 90 FR 28578 (Jul. 1, 2025).

TABLE 1—LIST OF NPRM COMMENTERS

Commenter name	Docket No.
American Pyrotechnics Association (APA)	PHMSA–2025–0091–0004
Battery Council International (BCI)	PHMSA–2025–0091–0016
Commercial Vehicle Safety Alliance (CVSA)	PHMSA–2025–0014
Council on the Safe Transportation of Hazardous Articles, Inc. (COSTHA)	PHMSA–2026–0091–0011
Dangerous Good Advisory Council (DGAC)	PHMSA–2025–0091–0013
Infotrac Inc	PHMSA–2025–0091–0003
Medical Device Transport Council (MDTC)	PHMSA–2025–0091–0010
Outdoor Power Equipment Institute (OPEI)	PHMSA–2025–0091–0009
Pyro Shows, Inc	PHMSA–2025–0091–0005
Pyro Spectaculars, Inc	PHMSA–2025–0091–0007
Rechargeable Battery Association (PRBA)	PHMSA–2025–0091–0008
Utility Solid Waste Activities Group (USWAG)	PHMSA–2025–0091–0015
William Forbes	PHMSA–2025–0091–0012

A majority of respondents supported the proposal to amend the MOT exception to authorize the transportation of increased quantities of lithium batteries. Support for the rulemaking came from a diverse coalition of stakeholders, including battery and equipment manufacturers, pyrotechnics and entertainment associations, utility groups, and transportation safety councils. Organizations, including PRBA, OPEI, and BCI, argued that the current MOT quantity limits are outdated and overly restrictive, creating logistical and financial burdens that limit growth in their industries.

Specific trade sectors also highlighted unique operational needs. For instance, APA, Pyro Shows, Inc., and Pyro Spectaculars, Inc. stated that the rulemaking would facilitate the efficient transport of drones used to supplement professional fireworks displays. Similarly, USWAG and the MDTC noted that the increased limits are essential for the transport of equipment used in electrical grid maintenance and life-saving medical care, respectively. Infotrac Inc. and OPEI emphasized the practical relief this rulemaking would provide to landscaping and maintenance professionals who currently face difficulties transporting heavy equipment, such as robotic mowers and yard tractors, under fully regulated hazardous materials frameworks. Furthermore, safety organizations, such as COSTHA and DGAC, supported the proposal on the grounds that it provides necessary economic relief and operational efficiency while preserving essential safety frameworks, such as testing and labeling requirements.

A few commenters had additional questions or concerns regarding this action. First, several respondents asked to extend the MOTs lithium battery allowance to sodium ion batteries. PHMSA did not include that proposal in the NPRM and is not prepared to address this issue in the final rule. PHMSA will consider adding sodium ion batteries to the MOT provision in a future rulemaking. In addition, commenters asked PHMSA to increase the 30 kg (66 pound) limit for lithium batteries to accommodate portable power stations—*e.g.,* rechargeable devices providing household AC power, often marketed as battery packs or ''generators.'' PHMSA appreciates these comments, but the agency did not include this proposal in the NPRM and lacks sufficient data to support increasing the authorized weight limit in this proceeding. PHMSA may consider this request in a future rulemaking.

Second, various stakeholders recommended that PHMSA authorize prototype and low-production-run batteries as MOT. These stakeholders noted that the NPRM would require all batteries to meet the testing criteria in Section 38.3 of the UN Manual of Tests and Criteria, and that this requirement would prevent untested prototypes—which are typically exempt from standard testing requirements—from being transported as MOT. PHMSA notes that prototype batteries are generally transported for testing, development, or certification. These commercial shipments are outside the scope of the MOT exception, which only applies to activities that are ''in direct support of a principal business.'' Furthermore, prototype batteries do not have an established safety record and generally pose a heightened risk of fire or thermal runaway during transport. Applying the strict safety requirements of the UN Manual of Tests and Criteria is necessary to mitigate the elevated risk to public safety that accompanies these shipments.

Third, PRBA and BCI requested a revision to 49 CFR 173.6 to clarify that outer packaging is not required for lithium batteries that are adequately secured against shifting. This allowance currently exists for other receptacles and articles under the MOT provisions. PHMSA agrees that this revision promotes regulatory consistency and efficiency and is amending 49 CFR 173.6 to authorize explicitly the transport of lithium batteries without outer packaging if they are properly secured to prevent movement during transport.

Finally, CVSA and Mr. William Forbes submitted comments opposing the proposed revisions to the MOT provisions. CVSA maintains that the current 440-pound weight allowance is sufficient and that increasing the quantity of lithium batteries directly correlates to the severity of potential incidents. CVSA cites recent crashes and fires involving lithium batteries that have resulted in significant highway and port closures. CVSA also points to the petitioner's own admission—that small businesses often lack the expertise to handle these materials outside of MOT—to argue that granting regulatory relief to inexperienced operators is inherently unsafe. Sharing similar concerns, Mr. Forbes characterizes the proposed weight increase as ''astronomical'' and argues that it poses an ''inherent risk'' without sufficient safety data. Mr. Forbes contends that the rulemaking would place an undue burden on first responders charged with managing these incidents.

PHMSA acknowledges these concerns but disagrees that the current 440-pound allowance is sufficient to meet industry needs or that the proposed changes pose an unacceptable safety risk. The weight increase in this final rule is a modest and incremental adjustment—not an ''astronomical'' expansion—that balances the operational needs of small businesses with robust safety standards. PHMSA is also retaining all mandatory performance-based packaging and hazard communication requirements currently applicable to lithium batteries.

Compliance with these requirements ensures that the increased weight allowance will not present an unacceptable risk to public safety. Consequently, PHMSA concludes that the final rule will not place an undue burden on first responders and that the economic benefits of facilitating commerce for small businesses—including the estimated annualized cost savings of $14.4 million (2024 dollars) outlined in the final Regulatory Impact Analysis (RIA) that is available for review in the rulemaking docket—outweigh any marginal increase in risk.

For these reasons, PHMSA is publishing this final rule to modernize 49 CFR 173.6 to update the quantity limits for lithium batteries under MOT. PHMSA finds these revisions will not have any adverse impact on safety.

III. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation as set forth in the Federal Hazardous Materials Transportation Laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

E.O. 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [2] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This final rule is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B and determined this final rule will result in cost savings by reducing regulatory burdens and regulatory uncertainty for the construction, landscaping, food service, and entertainment industries by distinguishing the weight limits for lithium batteries from other Class 9 hazardous materials. PHMSA estimated that these changes will result in annualized cost savings of $14.4 million (2024 dollars) at three percent and seven percent discount rates. The annualized cost savings under the three and seven percent discount rates are the same given that the annual cost savings are constant over the 10-year analysis period. A copy of the final RIA is available for review in the rulemaking docket.

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[3] PHMSA finds the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . . [or] that undermine[s] the national interest.'' [4]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[5] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserted a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from (inter alia) the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [6] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[7] E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation laws contain an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and Tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

[2] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

[3] 90 FR 9065 (Feb. 6, 2025).

[4] 90 FR 10583 (Feb. 25, 2025).

[5] 90 FR 8433 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

[6] 66 FR 28355 (May 22, 2001).

[7] 74 FR 24693 (May 22, 2009).

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses items covered in Paragraph 1 and 2 above and will preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Though the final rule may operate to preempt some State requirements, it will not impose any regulation that has substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. The preemptive effect of the regulatory amendments in this final rule is limited to the minimum level necessary to achieve the objectives of the Federal Hazardous Materials Transportation laws. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to notice-and-comment rulemaking under the APA unless the agency head certifies that the final rule will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act.[8] DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[9] This final rule was developed in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. Because the final rule will reduce burdens, PHMSA certifies that it does not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, among other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[10]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A *(Department of Transportation Tribal Consultation Policies and Procedures*).[11] E.O. 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined that it will not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded that the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) require PHMSA to provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking will not create, amend, or rescind any existing information collections.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) requires agencies to consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally.[12] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the

[8] 67 FR 53461 (Aug. 16, 2002).

[9] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

[10] PHMSA, *Implementing Procedures* (Aug. 28, 2025), available at: *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[11] 65 FR 67249 (Nov. 9, 2000).

[12] 77 FR 26413 (May 4, 2012).

standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of this deregulatory action and has determined that its regulatory amendments will not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

E.O. 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [13] PHMSA has considered the effects of the final rule and has determined that its regulatory amendments will not materially affect the cybersecurity risk profile for affected entities.

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, and may be viewed on DOT's website at *http://www.dot.gov/privacy.*

List of Subjects

49 CFR Part 173

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 1. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96, and 1.97.

■ 2. Amend § 173.6 by:

■ a. Adding paragraph (a)(7)(iii);
■ b. Revising paragraph (b)(3);
■ c. Adding paragraph (b)(6);
■ d. Revising paragraph (c)(4);
■ e. Adding paragraph (c)(5); and
■ f. Revising paragraph (d).

The revisions to read as follows:

§ 173.6 Materials of trade exceptions.

(a) * * *

(7) * * *

(iii) Except when the cell or battery is contained in equipment, cells and batteries described in 173.185 of this part may not exceed 30 kg (66 pounds) net weight for each cell or battery and 500 kg (1102 pounds) aggregate net weight on a motor vehicle. Cells and batteries, including when contained in or packed with equipment, must be of the type proven to meet the criteria in part III, sub-section 38.3 of the UN Manual of Tests and Criteria (IBR; see § 171.7 of this subchapter).

* * * * *

(b) * * *

(3) Outer packagings are not required for receptacles (*e.g.,* cans and bottles), articles, or batteries that are secured against shifting in cages, carts, bins, boxes, or compartments or by other means.

* * * * *

(6) Cells and batteries, including cells and batteries contained in equipment, must be packaged or secured in a manner to prevent:

(i) Short circuits;

(ii) Damage caused by shifting or placement within the package, if applicable; and

(iii) Accidental activation of the equipment.

* * * * *

(c) * * *

(4) Cells or batteries, including when contained in or packed with equipment, in packages exceeding 30 kg (66 pounds) net weight of batteries must be labeled with the Class 9 label as specified in § 172.447 and marked with the four-digit UN identification number, as applicable.

(5) The operator of a motor vehicle that contains a material of trade must be informed of the presence of the hazardous material (including whether the package contains a reportable quantity) and must be informed of the requirements of this section.

(d) *Aggregate gross weight.* Except for a material of trade authorized by paragraphs (a)(1)(iii) and (a)(7)(iii) of this section, the aggregate gross weight of all materials of trade on a motor vehicle may not exceed 200 kg (440 pounds).

* * * * *

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15823 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

[13] 86 FR 26633 (May 17, 2021).

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 177

[Docket No. PHMSA–2025–0100 (HM–268L)]

RIN 2137–AG14

Hazardous Materials: Adoption of Department of Transportation Special Permits 12412 and 11646 Into the Hazardous Materials Regulations

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: PHMSA is amending the Hazardous Materials Regulations to adopt the provisions of U.S. Department of Transportation (DOT) special permit (SP) 12412 and DOT SP 11646. These amendments will provide greater regulatory flexibility and eliminate the need for special permit renewal requests, reducing paperwork burdens and facilitating commerce while maintaining an equivalent level of safety.

DATES: *Effective date:* This final rule is effective September 3, 2026.

FOR FURTHER INFORMATION CONTACT: Ryan Larson, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration (PHMSA), 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–8553, *ryan.larson@dot.gov.*

I. PHMSA Action

A. What action is PHMSA taking in this Final Rule?

PHMSA is adopting the provisions of DOT SPs 12412 and 11646 into the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180). The adoption of these special permits will authorize the discharge (*i.e.,* emptying) of certain hazardous materials from specified packaging types without first removing the packaging from the vehicles on which they are transported. These special permits have been in place for over 20 years and have a well-established safety record.

B. Does this action apply to me?

Effective 30 days after publication of this final rule, persons transporting the specified classes of materials in the specified packaging types by motor vehicle will no longer be required to remove those packages from their vehicles prior to discharging their contents. Furthermore, stakeholders will no longer need to expend the time and resources associated with obtaining a special permit.

C. Why is PHMSA taking this action?

PHMSA is taking this action in response to commenter feedback and to improve the affected entities' ability to provide abundant, reliable, and affordable products in response to residential, commercial, and industrial demand. PHMSA is also taking this action as part of its ongoing review of special permits that are appropriate for adoption into the HMR based on their safety record and positive impact on stakeholders.

II. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published a notice of proposed rulemaking (NPRM), cited as *HM–268L,* to gather feedback on adopting the provisions of DOT SPs 12412 and 11646 into the HMR.[1] Please refer to the NPRM for background and discussion of the proposed changes.

The following table alphabetically lists commenters to the NPRM:

Commenter name	Docket No.
Alliance for Chemical Distribution	PHMSA–2025–0100–0010
Dangerous Goods Advisory Council	PHMSA–2025–0100–0008
Household & Commercial Products Association (HCPA)	PHMSA–2025–0100–0005
Industrial Packaging Association of North America (IPANA)	PHMSA–2025–0100–0007
Rex Railsback	PHMSA–2025–0100–0002
William Forbes	PHMSA–2025–0100–0006

PHMSA received six sets of comments in response to the NPRM, five of which were supportive of adopting both DOT SPs 12412 and 11646 into the HMR. However, some supporters of the proposed revisions also provided recommendations concerning the implementation of these (and other related) special permits.

First, IPANA provided comments supporting the adoption of both special permits but added that PHMSA should consider referencing 49 CFR 177.837—which provides instructions for bonding and grounding containers (other than cargo tanks) prior to and during transfer of lading. PHMSA concurs with IPANA's comment to reference 49 CFR 177.837 to remind stakeholders of the existing requirements for the proper bonding and grounding of containers transferring Class 3 materials. As such, PHMSA is adding a reference to the bonding and grounding requirements in the new paragraphs (h)(1) and (h)(2) in 49 CFR 177.834.

Second, Rex Railsback provided comments suggesting that PHMSA should additionally adopt the provisions of DOT SP 21260, which authorizes the offloading of materials not covered by DOT SPs 12412 and 11646. Mr. Railsback noted that the adoption of DOT SP 21260 would improve compliance and safety by providing greater visibility in the HMR as compared to a special permit. PHMSA acknowledges the recommendation to adopt DOT SP 21260 into the HMR. However, DOT SP 21260 imposes stricter compliance requirements for high-hazard materials, including requiring packaging outlets to meet the same standards as cargo tanks. Because PHMSA did not propose such changes in the NPRM, further evaluation and stakeholder input is needed. PHMSA may consider adopting this recommendation in a future rulemaking.

Third, HCPA provided comments on a provision of DOT SP 12412 being adopted in this final rule as new paragraph 49 CFR 177.834(h)(2). This provision states that hypochlorite solutions and fluorosilicic acid may be loaded on the same vehicle and transported in separate Intermediate Bulk Containers (IBCs) provided certain safety precautions are taken, even though these two materials could create unsafe conditions if mixed. HCPA recommended that PHMSA consider expanding this exception to include additional materials, such as permitting certain acids to be transported on the same vehicle as alkaline materials, provided additional safety measures are in place. PHMSA acknowledges HCPA's comment regarding additional exceptions. However, PHMSA did not propose such changes in the NPRM. PHMSA declines to make such revisions in this final rule without further evaluation by subject matter experts and an opportunity for stakeholder comment.

Lastly, William Forbes opposed the proposed adoption of DOT SPs 12412 and 11646. Mr. Forbes commented that additional measures are needed to prevent the commercial use of IBCs to deliver gasoline to consumer vehicles. PHMSA acknowledges the safety concerns regarding the use of IBCs for mobile refueling operations. PHMSA notes that DOT SP 12412, as adopted in this final rule, does not authorize gasoline as one of the specified materials because gasoline is a Class 3 Packing Group II material. However, PHMSA recognizes that DOT SP 11646, as also adopted in this final rule, does not explicitly prohibit the discharge of gasoline from drums situated on a motor vehicle. Because PHMSA does not intend for the adoption of DOT SP 11646 to serve as justification for mobile refueling platforms, this final rule amends 49 CFR 177.834(h)(1) to specify that these provisions do not apply to petroleum distillate fuels. In addition, Mr. Forbes also expressed concern that this final rule will lead to IBCs and portable tanks replacing cargo tanks without equivalent safety controls. PHMSA acknowledges this concern regarding the substitution of these packagings for cargo tanks. However, PHMSA has not proposed any new materials for transport in these types of packaging; therefore, PHMSA does not anticipate any impact on the cargo tank market. On the contrary, this final rule will improve safety by reducing the hazards associated with removing fully loaded packagings from a motor vehicle prior to discharge. By adopting the special permits' provisions that allow for the discharge of contents from a motor vehicle, PHMSA is adopting specific safety controls that have established a successful safety record over many years of widespread use.

For these reasons, PHMSA is revising 49 CFR 177.834 to allow the unloading of certain hazardous materials from certain packagings while remaining on the motor vehicle but requiring safety

[1] 90 FR 28581 (Jul. 1, 2025).

controls, including attendance by a qualified person during unloading, not allowing the manifolding of multiple packages, and requiring that hoses are not attached to outlets during transportation.

III. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation as set forth in the Federal Hazardous Materials Transportation laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [2] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This final rule is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B and determined that this final rule will result in cost savings by reducing regulatory burdens and regulatory uncertainty for affected entities by reducing the time and manpower necessary for entities needing to unload these materials efficiently and safely without the need for special permits. PHMSA finds these cost savings will also result in reduced costs for the public to whom those entities generally transfer a portion of their compliance costs. In addition, the final rule will produce cost savings to the Federal Government, hence taxpayers, due to the reduction of special permit applications that would otherwise need to be processed by PHMSA personnel.

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[3] PHMSA finds the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . .[or] that undermine[s] the national interest.'' [4]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[5] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserted a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from, *inter alia,* the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [6] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) [7] and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[8] E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation laws contain an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses items covered in Paragraph (2) above and would preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Although the final rule may (when finalized) operate to preempt some State requirements, it would not impose any regulation that has substantial direct

[2] 58 FR 51735 (Oct. 4, 1993).

[3] 90 FR 9065 (Feb. 6, 2025).

[4] 90 FR 10583 (Feb. 25, 2025).

[5] 90 FR 8433 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

[6] 66 FR 28355 (May 22, 2001).

[7] 64 FR 43255 (Aug. 10, 1999).

[8] 74 FR 24693 (May 22, 2009).

effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. The preemptive effect of the regulatory amendments in this final rule is limited to the minimum level necessary to achieve the objectives of the Federal Hazardous Materials Transportation Laws. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to notice-and-comment rulemaking under the Administrative Procedure Act unless the agency head certifies that the final rule in the rulemaking will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) [9] obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act. DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[10] This final rule was developed in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. Because the final rule is expected to reduce burdens, PHMSA certifies that it does not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, among other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under Section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA does not anticipate any adverse environmental impacts from this rule, and PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[11]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (*Consultation and Coordination with Indian Tribal Governments*) and DOT Order 5301.1A (*Department of Transportation Tribal Consultation Policies and Procedures*).[12] E.O. 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined that it would not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule would not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) requires that PHMSA provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking would not create, amend, or rescind any existing information collections. However, this rulemaking eliminates the need for persons to renew a special permit, resulting in a decrease in paperwork burden for special permit holders. PHMSA estimates the reduction in information collection burden as follows:

OMB Control No. 2137–0051: Rulemaking, Special Permits, and Preemption Requirements

Decrease in Annual Number of Respondents: 77.

Decrease in Annual Responses: 77.

Decrease in Annual Burden Hours: 115.

Decrease in Annual Burden Cost: $0.

Please direct your requests for a copy of this information collection to Steven Andrews, Office of Hazardous Materials Standards (PHH–12), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE, 2nd Floor, Washington, DC 20590–0001.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) requires agencies to consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally.[13] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the

[9] 67 FR 53461 (Aug. 16, 2002).

[10] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

[11] DOT, PHMSA, *Implementing Procedures* (Aug. 28, 2025), available at: *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[12] 65 FR 67249 (Nov. 9, 2000).

[13] 77 FR 26413 (May 4, 2012).

United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of the final rule and has determined that its regulatory amendments would not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

E.O. 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [14] PHMSA has considered the effects of the final rule and determined that its regulatory amendments would not materially affect the cybersecurity risk profile for affected entities.

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, or on DOT's website at *http://www.dot.gov/privacy.*

List of Subjects in 49 CFR Part 177

Hazardous materials transportation, motor carriers, radioactive materials, reporting, and recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 177—CARRIAGE BY PUBLIC HIGHWAY

■ 1. The authority citation for part 177 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; sec. 112 of Pub. L. 103–311, 108 Stat. 1673, 1676 (1994); sec. 32509 of Pub. L. 112–141, 126 Stat. 405, 805 (2012); 49 CFR 1.81 and 1.97.

■ 2. In § 177.834, revise paragraph (h) to read as follows:

§ 177.834 General requirements.

* * * * *

(h) *Precautions concerning containers in transit; fueling road units.* Reasonable care should be taken to prevent undue rise in temperature of containers and their contents during transit. There must be no tampering with such container or the contents thereof nor any discharge of the contents of any container between point of origin and point of billed destination. Discharge of contents of any container, other than a cargo tank, IM portable tank, or packaging authorized in paragraphs (h)(1) and (h)(2) of this section, must not be made prior to removal from the motor vehicle. Nothing contained in this paragraph shall be so construed as to prohibit the fueling of machinery or vehicles used in road construction or maintenance.

(1) *Drums.* For the purpose of this section only, Class 3 (PG II and III other than petroleum distillate fuels), Division 6.1 (PG II and III), Class 8 (PG II and PG III), and Class 9 materials are authorized. For liquids authorized under this section, the following conditions apply—

(i) Product transfer must be through pumps mounted on the motor vehicle or with an injection system indirectly mounted on a motor vehicle;

(ii) The drums must be attended at all times during unloading operations by a qualified person. For the purposes of this requirement, ''attended'' and ''qualified'' have the meanings described in paragraphs (i)(3) and (i)(4) of this section, respectively;

(iii) Hoses shall not be attached to container outlets during transportation;

(iv) Drums shall not be manifolded together during transportation;

(v) Each reused drum must meet the requirements prescribed in § 173.28 or an active special permit, as applicable; and

(vi) For Class 3 materials, see § 177.837(b).

(2) *IBCs and DOT specification 57 portable tanks.* For liquids other than Class 3 (PG II); Class 3 (PG III with a flash point of less than 100 °F (38°C)); Division 5.1 (PG II); or Division 6.1 (PG II) authorized to be transported in metal, rigid plastic, and composite UN standard IBCs or DOT Specification 57 portable tanks, the following conditions apply—

(i) Transportation is limited to private or contract motor vehicle;

(ii) IBC design types authorized are UN 31A, 31B, 31N, 31H1, 31H2, and 31HZ1;

(iii) If the IBC or portable tank is pressurized, it must be equipped with a pressure relief device set to open at not higher than two-thirds of the test pressure or 9 psig for a metal IBC;

(iv) Except for hypochlorite solutions and fluorosilicic acid, two or more materials may not be loaded on the same vehicle if any mixture of the materials would cause an unsafe condition. Hypochlorite solutions and fluorosilicic acid may be loaded on the same vehicle and transported in separate IBCs provided—

(A) No more than two IBCs are transported on a motor vehicle;

(B) Each IBC has a capacity not exceeding 1703 L (450 gallons);

(C) The materials shall not be discharged at the same time; and

(D) The hazardous materials are used for water treatment purposes only.

(v) Packagings shall not be manifolded together or have discharge outlets permanently connected to any part of the vehicle, including its discharge system. Hoses shall not remain attached to IBCs or portable tanks (*e.g.,* discharge outlets) during transportation (movement) of the motor vehicle;

(vi) The packagings must be attended at all times during unloading operations by a qualified person. For the purposes of this requirement, ''attended'' and ''qualified'' have the meanings described in paragraphs (i)(3) and (4) of this section, respectively;

(vii) Each IBC or DOT specification 57 portable tank must be discharged by—

(A) Using a mechanical pump with a positive means of stopping the flow of liquid from the pump;

(B) Gravity; or

(C) Pressurizing the IBC or portable tank.

(viii) Before starting each transfer of product to a receiving system, the person performing that function must determine that each component of the discharge system (including the hose) is of sound quality, free of leaks, and that connections are secure. A hose or associated equipment that shows signs of leakage, significant bulging, or other defects may not be used;

(ix) Packages shall not be filled or refilled while on a motor vehicle unless filled or refilled on the private property of the shipper, filler, or refiller. Prior to refilling, each IBC and its service equipment must be visually inspected in accordance with the provisions of §§ 173.35(b) and 180.352 and each DOT specification 57 portable tank and its service equipment must be visually

[14] 86 FR 26633 (May 17, 2021).

inspected in accordance with the provisions of § 180.605;

(x) Prior to reentering transportation, all hazardous materials must be purged from the pump, if equipped, the piping, and the discharge hose, as far as practicable; or all free-flowing hazardous material must be removed from the pump, if equipped, piping and the discharge hose in accordance with § 173.33(e). Residue remaining in these devices after product draining is not subject to this requirement provided these devices are capped and secured during transportation;

(xi) If the IBC or portable tank is unloaded using a pump, or if it is pressurized for unloading, prior to using a new or repaired transfer hose assembly (hose and associated fittings), the hose assembly must be subjected to a pressure test. The pressure test must be performed at no less than the pressure the hose is expected to be subjected to during product transfer. This test must be performed with all hose and hose fittings arranged in the configuration to be employed during transfer operations. Burst pressure must be at least four times the service pressure of the pump; and

(xii) For Class 3 materials, see § 177.837(b).

* * * * *

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15816 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 180

[Docket No. PHMSA–2025–0103 (HM–268O)]

RIN 2137–AG17

Hazardous Materials: Adoption of Department of Transportation Special Permit 14175

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule removes undue regulatory burdens by adopting the provisions of U.S. Department of Transportation (DOT) special permit (SP) 14175 to authorize a 10-year requalification period and the ultrasonic examination (UE) testing method for DOT specification 3A and 3AA cylinders in flammable and non-flammable, nonpoisonous gas service. This adoption reflects advances in testing technology and will relieve stakeholders of the burden of performing more frequent cylinder requalification.

DATES: This final rule is effective September 3, 2026.

FOR FURTHER INFORMATION CONTACT: Ryan Larson, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration (PHMSA), 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–8553, *ryan.larson@dot.gov.*

I. PHMSA Action

A. What action is PHMSA taking in this final rule?

PHMSA is adopting the provisions of DOT SP 14175 into the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180) by adding new paragraph (b)(2) to 49 CFR 180.209. This change will authorize a 10-year requalification interval (rather than five years) when either UE testing or hydrostatic testing with visual inspection is used for DOT specification 3A and 3AA cylinder bundles in flammable and non-flammable, nonpoisonous gas service.

B. Does this action apply to me?

Effective 30 days after publication of this final rule, holders of DOT SP 14175 will no longer need a special permit to requalify DOT specification 3A or 3AA cylinder bundles used in flammable and non-flammable, nonpoisonous gas service using UE.

C. Why is PHMSA taking this action?

PHMSA is taking this action in response to commenter feedback and to provide relief to stakeholders by allowing longer requalification intervals for the specified cylinder types when used in certain types of service. Allowing for the use of a 10-year requalification interval with UE testing or hydrostatic testing with visual inspection will reduce costs and provide greater efficiencies while also maintaining safety. PHMSA is also taking this action as part of its ongoing review of special permits that are appropriate for adoption into the HMR based on their safety record and positive impact on stakeholders.

II. Summary of Comments Received in Response to the Notice of Proposed Rulemaking

PHMSA published a notice of proposed rulemaking (NPRM), cited as *HM–268O,* to gather feedback on adopting DOT SP 14175 into the HMR.[1] Please refer to the NPRM for background and discussion of the proposed changes.

The following table alphabetically lists commenters to the NPRM:

Commenter name	Docket No.
Compressed Gas Association (CGA)	PHMSA–2025–0103–0003
Dangerous Goods Advisory Council	PHMSA–2025–0103–0004

Both commenters supported adopting DOT SP 14175 into the HMR. However, CGA had additional questions or suggestions related to the NPRM proposal.

First, CGA argued that if UE and hydrostatic testing are treated as equals, the NPRM proposal to add text to Table 1 to Paragraph (a) in 49 CFR 180.209 and 49 CFR 180.209(b)(2) requiring UE to be performed by a valid Requalification Identification Number (RIN) holder for DOT 3A and 3AA cylinders is unnecessary. PHMSA concurs with CGA's comment that the proposed text requiring a valid RIN holder to perform UE could cause confusion since no similar requirement is stated for the other test methods—such as hydrostatic pressure testing. In addition, PHMSA notes that 49 CFR 180.205 already requires a valid RIN holder for all requalification functions. PHMSA is therefore removing the text in Table 1 to Paragraph (a) and Paragraph (b)(2) of 49 CFR 180.209

[1] 90 FR 28585 (July 1, 2025).

specific to valid RIN holders in this final rule.

Second, CGA noted that a prior rulemaking (HM–219D) authorized UE for certain cylinders based on a petition for rulemaking (P–1727) to incorporate by reference the UE testing procedures in CGA C–20 *Requalification Standard for Metallic, DOT and TC 3-series Gas Cylinders and Tubes Using Ultrasonic Examination, Second Edition*.[2] CGA noted that the HM–219D final rule failed to identify all DOT 3-series cylinders in Table 1 to Paragraph (a) in 49 CFR 180.209 as being eligible for UE and—unintentionally—only authorized UE for DOT 3T specification cylinders and exemption or special permit cylinders. PHMSA acknowledges CGA's comment that UE should be authorized for the additional DOT 3-series cylinders as was requested in the CGA petition P–1727. While PHMSA is not incorporating these revisions in this final rule, PHMSA will consider this suggestion in a future rulemaking.

Third, CGA suggested that PHMSA adopt provisions from additional special permits—such as DOT SP 20341—which authorize UE for additional cylinder types. CGA noted that in doing so, PHMSA should update the reference for UE from CGA C–20–2014 to the more recent CGA C–20–2021, as proposed in CGA petition P–1766. While PHMSA is not incorporating these revisions in this final rule, PHMSA will consider this suggestion in a future rulemaking.

For these reasons, PHMSA concludes that the revisions will maintain appropriate levels of safety and authorize reasonable flexibilities and is therefore adopting the provisions of DOT SP 14175 into 49 CFR 180.209 in this final rule. PHMSA does not expect these revisions to have substantial adverse impact on safety.

III. Regulatory Analysis and Notices

A. Legal Authority

This final rule is published under the authority of the Secretary of Transportation as set forth in the Federal Hazardous Materials Transportation laws (49 U.S.C. 5101 *et seq.*) and delegated to the PHMSA Administrator pursuant to 49 CFR 1.97.

B. Executive Order 12866; Regulatory Planning and Review

Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), as implemented by 49 CFR part 5, subpart B, requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' [3] In arriving at those conclusions, E.O. 12866 requires that agencies should consider ''both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify'' and ''maximize net benefits . . . unless a statute requires another regulatory approach.'' E.O. 12866 also requires that ''agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Pursuant to 49 CFR part 5, subpart B, PHMSA and other Operating Administrations must generally choose the ''least costly regulatory alternative that achieves the relevant objectives'' unless required by law or compelling safety need. In addition, 49 CFR part 5, subpart B specifies that regulations should generally ''not be issued unless their benefits are expected to exceed their costs.''

E.O. 12866 and 49 CFR part 5, subpart B also require that PHMSA submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) within the Executive Office of the President's Office of Management and Budget (OMB) for review. This final rule is not a significant regulatory action pursuant to E.O. 12866 and has not been designated as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA has complied with the requirements in E.O. 12866 as implemented by 49 CFR part 5, subpart B, and determined this final rule will result in cost savings by reducing regulatory burdens and regulatory uncertainty for affected entities by providing longer cylinder requalification intervals with an alternative test method that has proven to be more accurate and more efficient. PHMSA expects that cost savings will result in reduced costs for the public to whom those entities generally transfer a portion of their compliance costs.

C. Executive Orders 14192 and 14219

PHMSA has determined that this final rule is an E.O. 14192 (*Unleashing Prosperity Through Deregulation*) deregulatory action.[4] PHMSA finds the total costs of the rule on the regulated community will be less than zero. This final rule does not implicate any of the factors identified in section 2(a) of E.O. 14219 (*Ensuring Lawful Governance*) indicative of a regulation that is ''unlawful . . . [or] that undermine[s] the national interest.'' [5]

D. Energy-Related Executive Orders 13211, 14154, and 14156

PHMSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 14156 (*Declaring a National Energy Emergency*) and E.O. 14154 (*Unleashing American Energy*).[6] The President has declared a national emergency to address America's inadequate energy development production, transportation, refining, and generation capacity and asserted a Federal policy to unleash American energy by ensuring access to abundant supplies of reliable, affordable energy from, *inter alia,* the removal of ''undue burden[s]'' on the identification, development, or use of domestic energy resources. PHMSA finds this final rule to be consistent with E.O. 14156 and E.O. 14154 because it will not hinder or unduly burden the transportation or production of energy or energy-related products.

In addition, this final rule is not a ''significant energy action'' under E.O. 13211 (*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*), which requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' [7] Because this final rule is not a significant action under E.O. 12866, it will not have a significant adverse effect on supply, distribution, or energy use; accordingly, OIRA has not designated this final rule as a significant energy action.

E. Executive Order 13132: Federalism

PHMSA analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (*Federalism*) and the Presidential Memorandum (*Preemption*) published in the **Federal Register** on May 22, 2009.[8] E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and

[2] 89 FR 15636 (Mar. 4, 2024).

[3] 58 FR 51735 (Oct. 4, 1993); 91 FR 22431 (Apr. 27, 2026); DOT Order 2100.7 (*Ensuring Reliance Upon Sound Economic Analysis in Department of Transportation Policies, Programs, and Activities*); *see also* DOT Order 2100.6B (*Policies and Procedures for Rulemakings*).

[4] 90 FR 9065 (Feb. 6, 2025).

[5] 90 FR 10583 (Feb. 25, 2025).

[6] 90 FR 8433 (Jan. 29, 2025); 90 FR 8353 (Jan. 29, 2025).

[7] 66 FR 28355 (May 22, 2001).

[8] 64 FR 43255 (Aug. 10, 1999); 74 FR 24693 (May 22, 2009).

responsibilities among the various levels of government.'' The Federal Hazardous Materials Transportation Law contains an express preemption provision at 49 U.S.C. 5125(b) that preempts State, local, and Tribal requirements on certain covered subjects, unless the non-Federal requirements are ''substantively the same'' as the Federal requirements, including the following:

(1) The designation, description, and classification of hazardous material;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This final rule addresses items covered in Paragraph (5) above and will preempt State, local, and Tribal requirements not meeting the ''substantively the same'' standard. Although the final rule may operate to preempt some State requirements, it will not impose any regulation that has substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. The preemptive effect of the regulatory amendments in this final rule is limited to the minimum level necessary to achieve the objectives of the Federal Hazardous Materials Transportation Law. Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Final Regulatory Flexibility Analysis (FRFA) for a final rule that has been subject to notice-and-comment rulemaking under the APA unless the agency head certifies that the final rule in the rulemaking will not have a significant economic impact on a substantial number of small entities. E.O. 13272 (*Proper Consideration of Small Entities in Agency Rulemaking*) obliges agencies to establish procedures promoting compliance with the Regulatory Flexibility Act. DOT posts information on a dedicated web page to help small businesses understand and navigate Federal regulatory processes.[9] PHMSA developed this final rule in accordance with E.O. 13272 and DOT implementing guidance to ensure compliance with the Regulatory Flexibility Act. Because the final rule is expected to reduce burdens, PHMSA certifies that it does not have a significant impact on a substantial number of small entities.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any proposed or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, among other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under UMRA because it does not result in costs of $100 million or more (in 1996 dollars) per year for either State, local, or Tribal governments, or to the private sector.

H. National Environmental Policy Act

PHMSA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and has determined it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Under Section 9 of DOT Order 5610.1D, PHMSA may apply a categorical exclusion (CE) established in another Operating Administration's procedures. PHMSA followed the requirements outlined in DOT Order 5610.1D to apply the Federal Highway Administration's CE to this deregulatory action. PHMSA has determined no unusual circumstances are present under 23 CFR 771.117(b). PHMSA's Categorical Exclusion Determination memo for this action is available on PHMSA's website.[10]

I. Executive Order 13175

PHMSA analyzed this final rule according to the principles and criteria in E.O. 13175 (Consultation and Coordination with Indian Tribal Governments) and DOT Order 5301.1A (Department of Transportation Tribal Consultation Policies and Procedures).[11] Executive Order 13175 requires agencies to assure meaningful and timely input from Tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship or distribution of power between the Federal Government and Tribes.

PHMSA assessed the impact of the final rule and determined it would not significantly or uniquely affect Tribal communities or Indian Tribal governments. The rulemaking's regulatory amendments have a broad, national scope; therefore, this final rule will not significantly or uniquely affect Tribal communities, much less impose substantial compliance costs on Tribal governments or mandate Tribal action. For these reasons, PHMSA has concluded the funding and consultation requirements of E.O. 13175 and DOT Order 5301.1A do not apply.

J. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d) requires PHMSA to provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. This rulemaking would not create, amend, or rescind any existing information collections.

However, this rulemaking eliminates the need for persons to renew a special permit, resulting in a decrease in paperwork burden for special permit holders. PHMSA estimates the reduction in information collection burden as follows:

OMB Control No. 2137–0051: Rulemaking, Special Permits, and Preemption Requirements.

Decrease in Annual Number of Respondents: 30.

Decrease in Annual Responses: 30.

Decrease in Annual Burden Hours: 45.

Decrease in Annual Burden Cost: $0.

Please direct your requests for a copy of this information collection to Steven Andrews, Office of Hazardous Materials

[9] DOT, *Rulemaking Requirements Related to Small Entities* (last accessed Sept 3, 2024), available at: *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities.*

[10] DOT, *Implementing Procedures for Considering Environmental Impacts* (Aug. 28, 2025), available at *https://www.phmsa.dot.gov/planning-and-analytics/environmental-analysis-and-compliance/implementing-procedures.*

[11] 65 FR 67249 (Nov. 9, 2000).

Standards (PHH–12), Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE, 2nd Floor, Washington, DC 20590–0001.

K. Executive Order 13609 and International Trade Analysis

E.O. 13609 (*Promoting International Regulatory Cooperation*) [12] requires agencies consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally.[13] In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA engages with international standards setting bodies to protect the safety of the American public. PHMSA has assessed the effects of the final rule and has determined that its regulatory amendments would not cause unnecessary obstacles to foreign trade.

L. Cybersecurity and Executive Order 14028

E.O. 14028 (*Improving the Nation's Cybersecurity*) directed the Federal Government to improve its efforts to identify, to deter, and to respond to ''persistent and increasingly sophisticated malicious cyber campaigns.'' [14] PHMSA has considered the effects of the final rule and has determined that its regulatory amendments would not materially affect the cybersecurity risk profile for affected entities.

M. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy*. DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, or on DOT's website at *http://www.dot.gov/privacy*.

List of Subjects in 49 CFR Part 180

Hazardous materials transportation, Motor carriers, Motor vehicle safety, Packaging and containers, Reporting, and Recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR Chapter I as follows:

PART 180—CONTINUING QUALIFICATION AND MAINTENANCE OF PACKAGINGS

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 2. In § 180.209, revise paragraphs (a) and (b) to read as follows:

§ 180.209 Requirements for requalification of specification cylinders.

(a) *Periodic qualification of cylinders.* Each specification cylinder that becomes due for periodic requalification, as specified in the following table, must be requalified and marked in conformance with the requirements of this subpart. Requalification records must be maintained in accordance with § 180.215. Table 1 follows:

TABLE 1 TO PARAGRAPH (a)—REQUALIFICATION OF CYLINDERS [1]

Specification under which cylinder was made	Minimum test pressure (psig) [2]	Requalification period (years)
3	3000 psig	5.
3A, 3AA	5/3 times service pressure, except non-corrosive service (*see* § 180.209(g)), or UE [3].	5, 10, or 12 (*see* § 180.209(b), (f), (h), and (j)).
3AL	5/3 times service pressure	5 or 12 (*see* § 180.209(j) and (m) [4]).
3AX, 3AAX	5/3 times service pressure	5.
3B, 3BN	2 times service pressure (*see* § 180.209(g))	5 or 10 (*see* § 180.209(f)).
3E	Test not required	
3HT	5/3 times service pressure	3 (*see* §§ 180.209(k) and 180.213(c)).
3T	5/3 times service pressure or UE [3]	5.
4AA480	2 times service pressure (*see* § 180.209(g))	5 or 10 (*see* § 180.209(h)).
4B, 4BA, 4BW, 4B–240ET	2 times service pressure, except non-corrosive service (*see* § 180.209(g)).	5, 7, 10, or 12 (*see* § 180.209(e), (f), and (j)).
4D, 4DA, 4DS	2 times service pressure	5.
4E	2 times service pressure, except non-corrosive service (*see* § 180.209(g)).	5, 10, or 12 (*see* § 180.209(e)).
4L	Test not required	
8, 8AL		10 or 20 (*see* § 180.209(i)).
Exemption or special permit cylinder	See current exemption or special permit, or UE [3] as allowed by CGA C–20 (2014).	See current exemption or special permit.
Foreign cylinder (*see* § 173.301(j) of this subchapter for restrictions on use).	As marked on cylinder, but not less than 53 of any service or working pressure marking.	5 (*see* §§ 180.209(l) and 180.213(d)(2)).

[1] Any cylinder not exceeding two inches outside diameter and less than two feet in length is excepted from volumetric expansion test.
[2] For cylinders not marked with a service pressure, see § 173.301a(b) of this subchapter.

[12] 77 FR 26413 (May 4, 2012).

[13] 77 FR 26413 (May 4, 2012).

[14] 86 FR 26633 (May 17, 2021).

[3] Minimum test pressure is not applicable to those cylinders and tubes requalified using ultrasonic examination (UE).
[4] This provision does not apply to cylinders used for carbon dioxide, fire extinguisher, or other industrial gas service.

(b) *DOT 3A or 3AA cylinders.* (1) A cylinder conforming to specification DOT 3A or 3AA with a water capacity of 56.7 kg (125 lb.) or less that is removed from any cluster, bank, group, rack, or vehicle each time it is filled, may be requalified every ten years instead of every five years, provided the cylinder conforms to all of the following conditions:

(i) The cylinder was manufactured after December 31, 1945.

(ii) The cylinder is used exclusively for air; argon; cyclopropane; ethylene; helium; hydrogen; krypton; neon; nitrogen; nitrous oxide; oxygen; sulfur hexafluoride; xenon; chlorinated hydrocarbons, fluorinated hydrocarbons, liquefied hydrocarbons, and mixtures thereof that are commercially free from corroding components; permitted mixtures of these gases (*see* § 173.301(d) of this subchapter); and permitted mixtures of these gases with up to 30 percent by volume of carbon dioxide, provided the gas has a dew point at or below minus (52 °F) at 1 atmosphere.

(iii) [Reserved]

(iv) The cylinder is dried immediately after hydrostatic testing to remove all traces of water.

(v) The cylinder is not used for underwater breathing.

(vi) Each cylinder is stamped with a five-pointed star at least one-fourth of an inch high immediately following the test date.

(2) A cylinder conforming to specification DOT 3A or 3AA with a water capacity of 56.7 kg (125 lb.) or less that is not removed from any cluster, bank, group, rack, or vehicle each time it is filled, may be requalified by either hydrostatic testing and visual inspection described in § 180.205 or by ultrasonic examination (UE) every ten years instead of every five years, provided the cylinder conforms to all of the following conditions:

(i) The cylinder was manufactured after December 31, 1945.

(ii) The cylinder is used exclusively for air; argon; helium; oxygen; nitrogen; neon; tetrafluoromethane (CF4); hydrogen; deuterium; mixtures of hydrogen, argon, helium, oxygen, and/or nitrogen; mixtures of argon, xenon, and/or neon; mixtures of krypton and neon; mixtures of hydrogen, argon, helium, and/or nitrogen; and mixtures containing deuterium, provided all gas mixtures have a dew point at or below minus (52 °F) at 1 atmosphere.

(iii) Carbon dioxide in any concentration cannot be added to cylinders in the bundle.

(iv) Gases that are toxic and/or corrosive cannot be added to cylinders in the bundle.

(v) If requalified by hydrostatic pressure testing, the cylinder is dried immediately after testing to remove all traces of water.

(vi) The cylinder is not used for underwater breathing.

(vii) Each cylinder is stamped with a five-pointed star at least one-fourth of an inch high immediately following the test date.

(3) If, since the last required requalification, a cylinder has not been used exclusively for the gases specifically identified in paragraph (b)(1)(ii) of this section, but currently conforms with all other provisions of paragraph (b)(1) of this section, it may be requalified every 10 years instead of every five years, provided it is first requalified and examined as prescribed by § 173.302a(b)(2), (3) and (4) of this subchapter.

(4) Except as specified in paragraph (b)(3) of this section, if a cylinder, marked with a star, is filled with a compressed gas other than as specified in paragraph (b)(1)(ii) of this section, the star following the most recent test date must be obliterated. The cylinder must be requalified five years from the marked test date, or prior to the first filling with a compressed gas, if the required five-year requalification period has passed.

* * * * *

Issued in Washington, DC, on July 31, 2026, under the authority delegated in 49 CFR 1.97.

Paul J. Roberti,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2026–15819 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 260729–0180]

RIN 0648–BO27

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Framework Adjustment 72

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Interim final rule; request for comments.

SUMMARY: NMFS issues this interim final rule to implement Framework Adjustment 72 (Framework 72) to the Northeast Multispecies Fishery Management Plan (FMP), specifically to implement status determination criteria for Georges Bank yellowtail flounder, set catch limits for multispecies (groundfish) stocks, and revise the process for setting recreational measures for Atlantic cod and haddock. This action is necessary to respond to updated scientific information and to achieve the goals and objectives of the FMP. The measures are intended to help prevent overfishing, rebuild overfished stocks, achieve optimum yield, and ensure that management measures are based on the best scientific information available.

DATES: Effective August 4, 2026. Comments must be received by 5 p.m. EST on September 3, 2026.

ADDRESSES: A plain language summary of this interim final rule is available at: *https://www.regulations.gov/docket/NOAA-NMFS-2026-0859.* You may submit comments, identified by NOAA–NMFS–2026–0859, by the following method:

Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and type NOAA–NMFS–2026–0859 in the Search box (*note:* copying and pasting the FDMS Docket Number directly from this document may not yield search results). Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. You may submit anonymous comments by entering ''N/A'' in the required fields if you wish to remain anonymous.

Copies of Framework Adjustment 72, including the Supplemental Information Report (SIR), the Regulatory Impact Review, and supporting documents prepared by the New England Fishery Management Council (Council) in support of this action, are available from Dr. Cate O'Keefe, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950. The supporting documents are also accessible via the internet at: *http://www.nefmc.org/management-plans/northeast-multispecies* or *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Liz Sullivan, Fishery Policy Analyst, phone: 978–282–8493; email: *Liz.Sullivan@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Summary of Approved Measures

The Northeast Multispecies FMP specifies the management measures for 13 groundfish species. The FMP was prepared by the Council and is implemented by NMFS through regulations at 50 CFR part 648, consistent with the requirements of the Magnuson-Stevens Act. The groundfish fishery includes recreational and commercial components, and the members of the commercial fishery choose whether to fish as part of the sector program or the common pool. Annually, the commercial groundfish fishery has a value of approximately $40 million (ex-vessel revenue from the most recent complete fishing year). Recreational fisheries, including the recreational groundfish fishery, contribute substantial value to the regional and national economies.

This action implements Framework 72 to the Northeast Multispecies FMP. The New England Fishery Management Council reviewed the regulations included in this rulemaking and deemed them consistent with, and necessary to implement, Framework 72 in a March 16, 2026, letter from Council Chairman Daniel Salerno to Regional Administrator Michael Pentony. Under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act, or Act), on behalf of the Secretary of Commerce, the Greater Atlantic Regional Fisheries Office's Regional Administrator approves, disapproves, or partially approves measures that the Council proposes, based on consistency with the Act and other applicable law.

To help ensure that Framework 72 is implemented as early as possible in the 2026 fishing year, which began May 1, 2026, NMFS is implementing Framework 72 through this interim final rule, which is effective upon publication. NMFS is also affording the public the opportunity to comment on this action by accepting public comment until September 3, 2026. NMFS will review all of the comments received on this interim final rule. If substantive comments are received, and NMFS determines that changes to the rule are appropriate in response, NMFS will publish a new final rule.

NMFS has approved and is implementing all of the measures in Framework 72, as recommended by the Council. Framework 72:

- Incorporates status determination criteria (SDC) for Georges Bank (GB) yellowtail flounder provided by the most recent stock assessment;
- Sets shared United States/Canada quotas for GB yellowtail flounder and eastern GB cod and haddock for fishing year 2026;
- Sets specifications, including catch limits for 12 groundfish stocks: GB cod, GB haddock, and GB yellowtail flounder for fishing year 2026; and Southern New England/Mid-Atlantic (SNE/MA) yellowtail flounder, Cape Cod/Gulf of Maine (CC/GOM) yellowtail flounder, GB winter flounder, GOM winter flounder, SNE/MA winter flounder, redfish, white hake, ocean pout, and wolffish for fishing years 2026–2030; and
- Modifies the regulatory process for the Regional Administrator to set recreational measures for cod and haddock stocks that do not have a recreational sub-annual catch limit (ACL).

This action also makes minor, clarifying regulatory changes that are not part of Framework 72, under section 305(d) authority in the Magnuson-Stevens Act to make changes necessary to carry out the FMP. NMFS is making these changes in conjunction with the Framework 72 measures for expediency purposes. These changes are described below under the heading, Minor, Clarifying Regulatory Changes under Secretarial Authority.

Status Determination Criteria

In 2024, the Northeast Fishery Science Center (Center) completed a research track assessment of GB yellowtail flounder, which transitioned the assessment to a Woods Hole Assessment Model (WHAM). This replaced the previous empirical approach that had been used to set catch advice for past fishing years. The 2025 management track assessment produced revised SDCs for GB yellowtail flounder, including revised numeric estimates.

Framework 72 incorporates the previously revised SDCs for GB yellowtail flounder, and provides updated numerical estimates of these criteria, in accordance with the results and peer review recommendations of the 2025 stock assessments (tables 1 and 2). These replace the ''unknown'' SDCs for GB yellowtail flounder that had been incorporated into the FMP by Framework 53 (80 FR 25110, May 1, 2015).

Table 1 –Status Determination Criteria

Stock	Biomass Target (SSB_{MSY} or Proxy)	Minimum Biomass Threshold	Maximum Fishing Mortality Threshold (F_{MSY} or proxy)
GB Yellowtail Flounder			
Previous SDC	Unknown	Unknown	Unknown
Revised SDC	SSB_{MSY} Proxy	½ SSBmsy	F_{MSY}

SSB = spawning stock biomass; MSY = maximum sustainable yield; F = fishing mortality

Table 2 -- Numerical Estimates of Status Determination Criteria

Stock	Model/ Approach	B_{MSY} or Proxy (mt)	F_{MSY} or Proxy	MSY (mt)
GB Yellowtail Flounder				
Using previous SDC	empirical	unknown	unknown	unknown
Using revised SDC	WHAM	7,072	0.9	597

Fishing Year 2026 Shared United States/Canada Quotas

Management of Transboundary Georges Bank Stocks

Eastern GB cod, eastern GB haddock, and GB yellowtail flounder are shared stocks that are jointly managed with Canada under the United States/Canada Resource Sharing Understanding (Understanding). As part of the Understanding, the United States and Canada consider the most recent stock information and develop shared quotas that are allocated between the United States and Canada based on a formula that considers historical catch (10-percent weighting) and the current resource distribution (90-percent weighting). For historical information about the Understanding, see: *http://www.bio.gc.ca/info/intercol/tmgc-cogst/index-en.php.*

A new approach called the Integration of Science Advice for Transboundary Stocks (ISATS) process was followed to provide science advice to support the decision-making process for the management of the three transboundary stocks. ISATS includes a meeting of the stock assessment leads for both countries, where the outcomes of the United States and Canadian domestic assessments are compiled into a joint document, to be considered equally as the basis for informing catch advice. In 2025, the U.S. GB yellowtail flounder management track assessment was conducted after the ISATS process and results were considered directly.

For GB yellowtail flounder, the Council's Scientific and Statistical Committee (SSC) also recommends an acceptable biological catch (ABC) for the stock. The ABC is typically used to inform the development of the annual shared quota. Although the stock is jointly managed with Canada, the Council may not recommend catch limits that would exceed the SSC's recommendation. In 2025, the shared quota for GB yellowtail flounder was developed before the SSC had met to discuss the stock, and the SSC took this already-developed quota into consideration when making its recommendation to the Council. The SSC does not recommend ABCs for eastern GB cod and haddock because they are management units of the total GB cod and haddock stocks. The SSC recommends overall ABCs for the total GB cod and haddock stocks. The shared United States/Canada quota for eastern GB cod and haddock is included in these overall ABCs and must be consistent with the SSC's recommendation for the total GB stocks.

2026 United States/Canada Quotas

The United States and Canada developed shared quotas for 2026 based on the available domestic assessment information from both countries. The Council adopted these recommendations in Framework 72 (table 3), and this action approves them.

Table 3 -- 2026 Fishing Year United States/Canada Quotas (mt, live weight) and Percent of Quota Allocated to Each Country

Quota	Eastern GB Cod	Eastern GB Haddock	GB Yellowtail Flounder
Total Shared Quota	473	4,750	57
United States Quota	151 (32 percent)	998 (21 percent)	31 (54 percent)
Canadian Quota	322 (68 percent)	3,752 (79 percent)	26 (46 percent)

The 2026 U.S. quotas for the eastern GB cod represent an 84-percent increase, compared to 2025; the eastern GB haddock and GB yellowtail flounder quotas represent 36-percent and 68-percent decreases, respectively. A more detailed discussion of the 2026 catch advice for shared stocks, including a description of each country's quota share, is accessible online at: *https://www.nefmc.org/*.

The regulations implementing the United States/Canada Resource Sharing Understanding at 50 CFR 648.85(a) require deducting any overages of the U.S. quota for eastern GB cod, eastern GB haddock, or GB yellowtail flounder from the U.S. quota in the following fishing year. If catch information for the 2025 fishing year indicates that the U.S. fishery exceeded its quota for any of the shared stocks, NMFS will reduce the respective U.S. quotas for the 2026 fishing year in a future action, as close to May 1, 2026, as possible. If any fishery that is allocated a portion of the U.S. quota exceeds its allocation and causes an overage of the overall U.S. quota, the overage reduction would be applied only to that fishery's allocation in the following fishing year. This ensures that catch by one component of the overall fishery does not negatively affect another component of the overall fishery.

Catch Limits for Fishing Years 2026–2030

Summary of the Catch Limits

Specifications are adopted for multiple years. Any specifications for fishing years beyond 2026 are projections that will be considered and reaffirmed or adjusted in the annual framework for that fishing year. Previously, specifications have been adopted for 3 years, the Council's omnibus management flexibility amendment (Amendment 26 to the Northeast Multispecies FMP, 91 FR 27234, May 14, 2026) would increase this duration to up to 5 years. To reflect this, Framework 72 developed specifications for fishing years 2026–2030.

Tables 4 through 16 show the catch limits for the 2026–2030 fishing years. A brief summary of how these catch limits were developed is provided below. More details on the catch limits for each groundfish stock can be found in appendix II (Calculation of Northeast Multispecies Annual Catch Limits, FY 2026–FY 2030) to the Framework 72 SIR (see **ADDRESSES** for information on how to get this document).

Through Framework 72, the Council recommended catch limits, including overfishing limits (OFLs), for GB cod, GB haddock, GB yellowtail flounder for fishing year 2026, and CC/GOM yellowtail flounder, SNE/MA yellowtail flounder, GB winter flounder, GOM winter flounder, SNE/MA winter flounder, white hake, redfish, ocean pout, and Atlantic wolffish for the 2026–2030 fishing years, based on stock assessments or data updates completed in 2025. Specifications for the Atlantic cod stocks were set in Amendment 25 (Revised) (91 FR 39529, June 30, 2026). Framework 72 replaces the Amendment 25 (Revised) specifications for GB cod. Catch limits for other groundfish stocks were previously set by Framework 66 (89 FR 35755, May 2, 2024) and Framework 69 (91 FR 11141, March 9, 2026). Table 4 provides an overview of which catch limits change based on Framework 72, as well as when the stock was most recently assessed. Table 5 provides the percentage change in the 2026 catch limit compared to the 2025 fishing year.

All specifications projected for fishing year 2026 in previous frameworks or Amendment 25 (Revised) were considered for reaffirmation or adjustment, as warranted by the best scientific information available in the adopting framework/amendment, and any updates in this action. The previously projected and adopted specifications are reaffirmed, consistent with the considerations and determinations in the adopting frameworks and amendment, because no new or updated scientific information warranted changes to prior adopted specifications.

BILLING CODE 3510–22–P

Table 4 -- Changes to Catch Limits by Framework 72

Stock	Most Recent Assessment	Change in Framework 72
EGOM Cod	2024	Reaffirm 2026-2027 catch limits set by Amendment 25
WGOM Cod	2024	Reaffirm 2026-2027 catch limits set by Amendment 25
GB Cod	2024	New 2026 ABC
SNE Cod	2024	Reaffirm 2026-2027 catch limits set by Amendment 25
GB Haddock	2024	New 2026 ABC
GOM Haddock	2024	Reaffirm 2026-2027 catch limits set by Framework 69
GB Yellowtail Flounder	2025	New 2026 ABC
SNE/MA Yellowtail Flounder	2025	New 2026-2030 ABC
CC/GOM Yellowtail Flounder	2025	New 2026-2030 ABC
American Plaice	2024	Reaffirm 2026-2027 catch limits set by Framework 69
Witch Flounder	2024	Reaffirm 2026-2027 catch limits set by Framework 69
GB Winter Flounder	2025	New 2026-2030 ABC
GOM Winter Flounder	2025	New 2026-2030 ABC
SNE/MA Winter Flounder	2025	New 2026-2030 ABC
Redfish	2025	New 2026-2030 ABC
White Hake	2025	New 2026-2030 ABC
Pollock	2024	Reaffirm 2026-2027 catch limits set by Framework 69
N. Windowpane Flounder	2023	Reaffirm 2026 catch limit set by Framework 66
S. Windowpane Flounder	2023	Reaffirm 2026 catch limit set by Framework 66
Ocean Pout	2025*	New 2026-2030 ABC
Atlantic Halibut	2024	Reaffirm 2026-2027 catch limits set by Framework 69
Atlantic Wolffish	2025*	New 2026-2030 ABC

*Ocean pout and Atlantic wolffish received data updates, not full assessments.
N = northern; S = southern

Table 5 -- Fishing Years 2026-2030 Overfishing Limits and Acceptable Biological Catches (mt, live weight)

Stock	2025		Percent change from 2025	2026		2027		2028		2029		2030	
	OFL	U.S. ABC		OFL	U.S. ABC	OFL	U.S. ABC	OFL	U.S. ABC	OFL	U.S. ABC	OFL	U.S. ABC
EGOM Cod	n/a	n/a	n/a	50	39	39	30	-	-	-	-	-	-
WGOM Cod	n/a	n/a	n/a	603	460	769	586	-	-	-	-	-	-
GB Cod	n/a	n/a	n/a	473	151	-	-	-	-	-	-	-	-
SNE Cod	n/a	n/a	n/a	47	36	65	36	-	-	-	-	-	-
GB Haddock	8,034	2,180	103%	8,177	4,425	-	-	-	-	-	-	-	-
GOM Haddock	4,430	3,410	7%	4,709	3,634	4,700	3,631	-	-	-	-	-	-
GB Yellowtail Flounder	UNK	96	-68%	57	31	-	-	-	-	-	-	-	-
SNE/MA Yellowtail Flounder	345	40	-18%	46	33	56	33	56	33	56	33	56	33
CC/GOM Yellowtail Flounder	1184	915	90%	2,224	1,736	2,638	2,062	2,984	2,335	3,225	2,335	3,225	2,335
American Plaice	11,048	8,697	-20%	8,866	6,979	7,368	5,791	-	-	-	-	-	-
Witch Flounder	UNK	1,526	0%	UNK	1,526	UNK	1,526	-	-	-	-	-	-
GB Winter Flounder	2,100	1,490	15%	2,279	1,713	2,148	1,609	2,079	1,555	2,061	1,541	2,060	1,540
GOM Winter Flounder	1,072	804	-1%	1,064	798	1,064	798	1,064	798	1,064	798	1,064	798
SNE/MA Winter Flounder	1,536	627	-19%	961	507	1,009	532	1,055	556	1,101	556	1,101	556
Redfish	10,982	8,273	-32%	7,519	5,665	7,203	5,427	6,999	5,273	6,723	5,065	6,513	4,907
White Hake	2,591	1,921	-29%	1,943	1,362	1,760	1,230	1,640	1,143	1,618	1,126	1,698	1,184
Pollock	16,585	12,733	-12%	14,583	11,170	13,383	10,252	-	-	-	-	-	-
N. Windowpane Flounder	UNK	136	0%	UNK	136	-	-	-	-	-	-	-	-
S. Windowpane Flounder	284	213	0%	284	213	-	-	-	-	-	-	-	-
Ocean Pout	125	87	0%	125	87	125	87	125	87	125	87	125	87
Atlantic Halibut	UNK	35	0%	UNK	35	UNK	35	-	-	-	-	-	-
Atlantic Wolffish	124	93	0%	124	93	124	93	124	93	124	93	124	93

UNK = Unknown
Note: An empty cell indicates no OFL/ABC is adopted for that year. These catch limits would be set in a future action.

BILLING CODE 3510–22–C

Overfishing Limits and Acceptable Biological Catches

The OFL is calculated to set the maximum amount of fish that can be caught in a year, without constituting overfishing. The ABC is typically set lower than the OFL to account for scientific uncertainty. For GB cod, GB haddock, and GB yellowtail flounder, the total ABC is reduced by the amount of the Canadian quota (see table 1 for the Canadian and United States shares of these stocks). Additionally, although GB winter flounder, white hake, and Atlantic halibut are not jointly managed with Canada, there is some Canadian catch of these stocks. Because the total ABC must account for all sources of fishing mortality, expected Canadian catch of GB winter flounder (38 metric tons; mt), white hake (57 mt), and Atlantic halibut (71 mt) is deducted from the total ABC. The United States ABC is the amount available to the domestic fishery after accounting for Canadian catch (see table 3). For stocks without Canadian catch, the United States ABC is equal to the total ABC.

Annual Catch Limits

Development of Annual Catch Limits

The U.S. ABC for each stock is divided among the various fishery components to account for all sources of fishing mortality. For stocks with a recreational allocation, the U.S. ABC is typically first divided between the commercial and recreational fisheries, before being further divided into sub-components and sub-ACLs. An estimate of catch expected from state waters and the other sub-component (*e.g.,* Federal commercial non-groundfish fisheries and some recreational groundfish fisheries, if there is not a recreational allocation) is deducted from the U.S. ABC. The remaining portion of the U.S. ABC is distributed to the fishery components that receive an allocation for the stock. Components of the fishery that receive an allocation have a sub-ACL set by reducing their portion of the ABC (the sub-ABC) to account for management uncertainty and are subject to accountability measures (AM) if they exceed their respective catch limit during the fishing year. This process is described fully in appendix II of the Framework 72 SIR.

Sector and Common Pool sub-ACLs

For stocks allocated to sectors, the commercial groundfish sub-ACL is further divided into the non-sector (common pool) sub-ACL and the sector sub-ACL, based on the total vessel enrollment in sectors and the cumulative potential sector contributions (PSC) associated with those sectors. The sector and common pool sub-ACLs implemented in this action are based on fishing year 2026 PSCs and sector rosters. All permits enrolled in a sector, and the vessels associated with those permits, had until April 30, 2026, to withdraw from a sector and fish in the common pool for the 2026 fishing year. In addition to the enrollment delay, all permits that changed ownership after the roster deadline were permitted to join a sector (or change sector) through April 30, 2026.

Management Uncertainty Buffer for Sectors

As mentioned generally above, management uncertainty is accounted for in the setting of ACLs that are equal to or lower than the ABC recommended by the SSC. This difference between an ABC and ACL or sub-ACL is known as a management uncertainty buffer. Without changing the process for setting management uncertainty buffers, Amendment 23 (87 FR 75852, December 9, 2022) implemented a measure to adjust the management uncertainty buffer for the sector sub-ACL for each allocated groundfish stock to zero when appropriate. In years that the at-sea monitoring (ASM) coverage target is set at 100 percent, the management uncertainty buffer will default to zero for the sector sub-ACL for allocated stocks, unless the Council's consideration of the 100-percent coverage target warrants specifying a different management uncertainty buffer in order to prevent exceeding the sub-ACL. Based on Amendment 25 (Revised), this provision does not apply for SNE cod.

As established in Amendment 23, the ASM coverage target is dependent on the level of funding for ASM and observers, and NMFS must evaluate overall annual appropriations from Congress to finalize the ASM coverage target. NMFS provides the target as soon as it can each year so that sectors can establish their rosters and meet annual deadlines. On March 13, 2026, the Regional Administrator announced that the preliminary fishing year 2026 ASM coverage target of 100 percent, and nothing has changed since that announcement to require a lower ASM coverage target or to change the determination that the coverage target provides a basis for removing the management uncertainty buffer. Therefore, in this action, NMFS is removing the management uncertainty buffer for each allocated stock, other than SNE cod, for all sectors for the entirety of the 2026 fishing year. Because removal of the buffer is dependent on the annual determination of the ASM coverage target and consideration of its merit, the determination regarding the buffer in fishing years 2027 and beyond would be made in a future action.

In Framework 72, the Council recommended the removal of the management uncertainty buffer for the sector sub-ACL for white hake, if the ASM coverage target is 90 percent or higher, for each fishing year through 2030. The Council's goal is to mitigate the adverse economic impacts of the ACLs for this potentially constraining stock by increasing the sector sub-ACLs if the ASM coverage target is high enough to reduce uncertainty. While this measure is moot for fishing year 2026, given this year's 100-percent coverage target, it is approved for the future fishing years.

Table 6 provides the fishing year 2026 ACLs and sub-ACLs for all stocks with the management uncertainty buffer removed for sectors. Because the removal of the management uncertainty buffer for sectors is an annual decision, tables 7–10 show the ACLs and sub-ACLs for fishing years 2027–2030 with the buffer left in place, and these would be updated in a future action based on the coverage target for that fishing year.

The removal of the management uncertainty buffer for sectors alone is not likely to cause the ABC or OFL to be exceeded. The fishery remains accountable for remaining within the sub-ACLs allocated to it. Further, the revised management uncertainty buffer applies only to sectors and not to the common pool component of the fishery or other sub-ACLs or sub-components for any stocks. Therefore, the management uncertainty buffer continues to exist for the stock's ACL, but the sector-specific buffer is removed.

Sector Allocations for Fishing Year 2026

At the start of the 2026 fishing year, NMFS allocated annual catch entitlements (ACE) for the allocated stocks to each sector, based on preliminary sector rosters and the catch limits set by prior frameworks and default specifications for certain stocks. This rule updates the ACE allocated to sectors based on final sector rosters and the catch limits approved in Framework 72, including the revised GB cod ABC, and based on the catch limits for EGOM cod, WGOM cod, and SNE cod set by Amendment 25 (Revised). NMFS calculates a sector's allocation for each stock by summing its members' PSC for the stock and then multiplying that total

percentage by the commercial sub-ACL for that stock. The process for allocating ACE to sectors is more fully described in the final rule allocating ACE to sectors for the start of the 2026 fishing year (91 FR 22467, April 27, 2026) and is not repeated here. Table 11 shows the cumulative PSC by stock for each sector for fishing year 2026. Tables 12 and 13 show the ACEs allocated to each sector for fishing year 2026, in thousands of pounds and metric tons, respectively. NMFS has included the common pool sub-ACLs in tables 11 through 13 for comparison. NMFS uses final allocations, along with later adjustments including ACE transfers, reductions for overages, or increases for carryover, monitor sector catch.

Common Pool Total Allowable Catches

The common pool sub-ACL for each allocated stock (except for SNE/MA winter flounder) is further divided into trimester total allowable catches (TACs). Table 14 summarizes the common pool trimester TACs set in this action.

Incidental catch TACs are also specified for certain stocks of concern (*i.e.,* stocks that are overfished or subject to overfishing) for common pool vessels fishing in the special management programs (*i.e.,* special access programs (SAP) and the Regular B Days-at-Sea (DAS) Program), in order to limit the catch of these stocks under each program. Tables 15 and 16 summarize the Incidental Catch TACs for each stock and the distribution of these TACs to each special management program.

BILLING CODE 3510–22–P

Table 6 -- Catch Limits for the 2026 Fishing Year with management uncertainty buffer removed for sectors (mt, live weight)

Stock	Total ACL	Groundfish sub-ACL	Sector sub-ACL	Common Pool sub-ACL	Recreational sub-ACL	Midwater Trawl Fishery	Scallop Fishery	Small-Mesh Fisheries	State Waters sub-component	Other sub-component
	A to H	A+B+C	A	B	C	D	E	F	G	H
EGOM Cod	39	38	37	1.4					0	0.4
WGOM Cod	451	422	294	10.6	118				23	5.0
GB Cod	151	139	134	5					0	12.1
SNE Cod	34	25	6.5	0.2	18				6.1	3.2
GB Haddock	4,411	4,306	4,161	145		82			0	22.1
GOM Haddock	3,542	3,472	2,270	57	1,146	34			36	0
GB Yellowtail Flounder	31	25	23	1.9			4.8	0.6	0	0
SNE/MA Yellowtail Flounder	33	29	21	8.0			2.7		0.2	0.7
CC/GOM Yellowtail Flounder	1,732	1,679	1,594	85					17	35
American Plaice	6,967	6,933	6,712	220					0	35
Witch Flounder	1,523	1,477	1,426	52					7.6	38
GB Winter Flounder	1,710	1,668	1,587	81					0	43
GOM Winter Flounder	793	689	589	100					96	8.0
SNE/MA Winter Flounder	504	398	340	57					25	81
Redfish	5,661	5,633	5,559	74					28	0
White Hake	1,361	1,354	1,339	16					0	6.8
Pollock	11,164	9,880	9,771	109					670	614
N. Windowpane Flounder	127	94	na	94			27		0.0	6.8
S. Windowpane Flounder	205	30	na	30			71		6.4	98
Ocean Pout	83	52	na	52					0.9	30
Atlantic Halibut	34	23	na	23					9.1	1.6
Atlantic Wolffish	87	87	na	87					0	0

na: not allocated to sectors

Table 7 -- Catch Limits for the 2027 Fishing Year* (mt, live weight)

Stock	Total ACL	Groundfish sub-ACL	Sector sub-ACL	Common Pool sub-ACL	Recreational sub-ACL	Midwater Trawl Fishery	Scallop Fishery	Small-Mesh Fisheries	State Waters sub-component	Other sub-component
	A to H	A+B+C	A	B	C	D	E	F	G	H
EGOM Cod	29	28	27	1.0					0	0
WGOM Cod	555	519	356	14	150				30	6.4
SNE Cod	34	25	6.5	0	18				6.1	3.2
GOM Haddock	3,426	3,356	2,155	57	1,145	34			36	0
SNE/MA Yellowtail Flounder	32	28	20	8.0			2.7		0.2	0.7
CC/GOM Yellowtail Flounder	1,962	1,900	1,799	102					21	41
American Plaice	5,503	5,474	5,291	183					0	29
Witch Flounder	1,452	1,406	1,354	52					7.6	38
GB Winter Flounder	1,562	1,522	1,446	76					0	40
GOM Winter Flounder	763	660	560	100					96	8.0
SNE/MA Winter Flounder	511	399	339	60					27	85
Redfish	5,157	5,130	5,060	70					27	0
White Hake	1,169	1,163	1,148	14					0	6.2
Pollock	9,798	8,619	8,520	100					615	564
Ocean Pout	83	52	na	52					0.9	30
Atlantic Halibut	34	23	na	23					9.1	1.6
Atlantic Wolffish	87	87	na	87					0	0

na: not allocated to sectors

* Northeast multispecies stocks not included in table 8 do not have catch limits approved for fishing year 2027.

Table 8 -- Catch Limits for the 2028 Fishing Year* (mt, live weight)

Stock	Total ACL	Groundfish sub-ACL	Sector sub-ACL	Common Pool sub-ACL	Recreational sub-ACL	Midwater Trawl Fishery	Scallop Fishery	Small-Mesh Fisheries	State Waters sub-component	Other sub-component
	A to H	A+B+C	A	B	C	D	E	F	G	H
SNE/MA Yellowtail Flounder	32	28	20	8.0			2.7		0.2	0.7
CC/GOM Yellowtail Flounder	2,222	2,152	2,037	115					23	47
GB Winter Flounder	1,510	1,471	1,397	73					0	39
GOM Winter Flounder	763	660	560	100					96	8.0
SNE/MA Winter Flounder	534	417	354	63					28	89
Redfish	5,011	4,984	4,916	68					26	0
White Hake	1,086	1,080	1,067	13					0	5.7
Ocean Pout	83	52	na	52					0.9	30
Atlantic Wolffish	87	87	na	87					0	0

na: not allocated to sectors

* Northeast multispecies stocks not included in table 9 do not have catch limits approved for fishing year 2028.

Table 9 -- Catch Limits for the 2029 Fishing Year* (mt, live weight)

Stock	Total ACL	Groundfish sub-ACL	Sector sub-ACL	Common Pool sub-ACL	Recreational sub-ACL	Midwater Trawl Fishery	Scallop Fishery	Small-Mesh Fisheries	State Waters sub-component	Other sub-component
	A to H	A+B+C	A	B	C	D	E	F	G	H
SNE/MA Yellowtail Flounder	32	28	20	8.0			2.7		0.2	0.7
CC/GOM Yellowtail Flounder	2,222	2,152	2,037	115					23	47
GB Winter Flounder	1,496	1,457	1,385	73					0	39
GOM Winter Flounder	763	660	560	100					96	8.0
SNE/MA Winter Flounder	534	417	354	63					28	89
Redfish	4,813	4,788	4,722	66					25	0
White Hake	1,070	1,064	1,051	13					0	5.6
Ocean Pout	83	52	na	52					0.9	30
Atlantic Wolffish	87	87	na	87					0	0

na: not allocated to sectors

* Northeast multispecies stocks not included in table 10 do not have catch limits approved for fishing year 2029.

Table 10 -- Catch Limits for the 2030 Fishing Year* (mt, live weight)

Stock	Total ACL	Groundfish sub-ACL	Sector sub-ACL	Common Pool sub-ACL	Recreational sub-ACL	Midwater Trawl Fishery	Scallop Fishery	Small-Mesh Fisheries	State Waters sub-component	Other sub-component
	A to H	A+B+C	A	B	C	D	E	F	G	H
SNE/MA Yellowtail Flounder	32	28	20	8.0			2.7		0.2	0.7
CC/GOM Yellowtail Flounder	2,222	2,152	2,037	115					23	47
GB Winter Flounder	1,495	1,457	1,384	73					0	39
GOM Winter Flounder	763	660	560	100					96	8.0
SNE/MA Winter Flounder	534	417	354	63					28	89
Redfish	4,663	4,638	4,575	64					25	0
White Hake	1,125	1,119	1,105	14					0	5.9
Ocean Pout	83	52	na	52					0.9	30
Atlantic Wolffish	87	87	na	87					0	0

na: not allocated to sectors

* Northeast multispecies stocks not included in table 11 do not have catch limits approved for fishing year 2030.

Table 11 -- Cumulative PSC (Percentage) Each Sector Receives by Stock for Fishing Year 2026*

Sector Name	MRI Count	GOM Cod	GB Cod	GB Haddock	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail Flounder	CC/GOM Yellowtail Flounder	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter Flounder	Redfish	White Hake	Pollock
Fixed Gear Sector	57	0.62000717	10.25792369	1.24259115	0.17619979	0.00311343	0.18887310	1.57238276	0.44450414	1.08591699	0.01699226	1.77327761	0.94395076	0.47653149	0.97977059	2.60863991
Maine Coast Community Sector	106	15.94885074	2.01397400	3.17168036	11.79604427	1.94847294	2.52339179	6.30047816	14.56530224	11.41871079	0.80517724	7.74554413	2.23311628	8.65019418	12.96999516	12.49686948
Maine Permit Bank	11	1.16763878	0.13459891	0.04453992	1.13092467	0.01387887	0.03209022	0.32135234	1.16810532	0.72956401	0.00021876	0.42976628	0.01821182	0.82284529	1.65877337	1.69730934
Mooncusser Sector	50	7.47192323	11.96726174	3.80128147	4.24304695	0.01132542	0.17899416	3.56343252	2.10535812	2.86874751	0.00930313	3.67942183	1.64232498	5.59064064	11.80076808	11.32716779
NEFS 2	133	26.02830199	11.00087974	17.99505278	27.40462471	8.19788059	7.61395906	26.69106217	16.85359867	21.95247846	5.90409225	26.98443120	6.40221795	22.87697316	15.77437408	18.78214595
NEFS 4	58	11.22369265	8.64395731	6.05664032	8.90136427	2.17865699	2.28636971	6.45637353	9.44210523	8.82814321	0.69998003	7.46661225	1.03571448	6.69584842	8.27363096	7.27021345
NEFS 5	14	0.33003363	0.35527445	0.42505553	0.11113193	0.70261898	10.45259401	0.93038193	0.22772759	0.40234230	0.17313693	0.84861845	6.94037632	0.01320698	0.03510319	0.06578502
NEFS 6	3	0.16963046	0.53360157	0.55638243	0.15193770	0.06623920	0.00032990	0.02505514	0.88233972	0.47931410	0.08026514	0.07146897	0.01437919	1.11270423	0.52918199	0.31866944
NEFS 8	116	6.65297914	34.30912194	41.03722846	19.35767773	48.05429966	19.40070596	19.99264099	22.75902017	21.90247850	62.83531305	5.07586053	43.28190215	30.27162273	20.08199605	19.47967929
NEFS 10	20	1.68404030	0.17156341	0.10432012	0.71955891	0.00105448	0.56776009	3.09000624	0.30014145	0.59825049	0.01076853	5.72945588	0.43199226	0.01057219	0.02845475	0.07118722
NEFS 11	37	10.57507102	0.39824603	0.03379056	2.65819864	0.00088673	0.00741402	2.12569078	1.43053749	1.44767208	0.00094464	1.91417989	0.01815525	1.86086065	3.95193590	8.48161221
NEFS 12	24	3.70670785	0.66798830	0.15520526	1.33790932	0.00051986	0.03718095	9.30645281	1.54959068	1.79872863	0.00058498	12.24618426	0.33402058	0.54741701	0.89358498	1.39275565
NEFS 13	49	0.35715437	7.58727804	11.88362378	0.40261570	24.93349818	20.12537033	4.44508613	5.41212377	5.91254683	13.04076885	1.34454863	11.03191709	1.32307878	0.89876852	0.92729120
New Hampshire Permit Bank	4	1.15613548	0.00082824	0.00003422	0.03251254	0.00002041	0.00001804	0.02204140	0.02857641	0.00618240	0.00000326	0.06115152	0.00003695	0.01942462	0.08148499	0.11148994
Sustainable Harvest Sector 1	46	5.93238203	5.43174188	6.25409428	8.37426597	3.11903075	2.86979875	5.13276469	10.81183472	8.42817876	9.19071549	4.70474171	6.13584969	8.70682543	10.97973024	6.57751889
Sustainable Harvest Sector 2	24	2.04310071	1.98369974	2.47310986	5.38146428	0.93658054	2.20619521	4.13543718	5.21821849	5.11551537	0.63689915	4.59470291	3.33317999	5.79033276	5.17959776	3.64943094
Sustainable Harvest Sector 3	10	1.20890197	1.05247319	1.22785741	5.25046696	2.07060102	2.81711339	0.54817563	3.46256035	3.33110315	1.61668900	0.20015459	1.13823911	3.85915984	4.65042318	3.58302588
Common Pool	489	3.72344849	3.48958783	3.53751209	2.57005564	7.76132193	28.69184131	5.34118559	3.33835544	3.69412643	4.97814728	15.12987936	15.06441515	1.37176159	1.23242621	1.15920840
All Sectors	762	96.28	96.51	96.46	97.43	92.24	71.31	94.66	96.66	96.31	95.02	84.87	84.94	98.63	98.77	98.84

NEFS: Northeast Fishery Sector

* The data in this table are based on sector rosters for fishing year 2026.

Table 12 -- ACE (in 1,000 pounds), by Stock, for Each Sector for Fishing Year 2026*#

Sector Name	EGOM cod	WGOM Cod	GB Cod East	GB Cod West	SNE Cod	GB Haddock East	GB Haddock West	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail	CC/GOM Yellowtail Flounder	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter Flounder	Redfish	White Hake	Pollock
Fixed Gear Sector	1	25	32	0	2	27	91	9	0	0	58	68	35	1	27	8	59	29	569
Maine Coast Community Sector	14	77	6	0	0	70	232	606	1	2	234	2,230	373	30	119	20	1,075	388	2,724
Maine Permit Bank	1	6	0	0	0	1	3	58	0	0	12	179	24	0	7	0	102	50	370
Mooncusser Sector	6	60	37	0	2	84	278	218	0	0	132	322	94	0	56	15	695	353	2,469
NEFS 2	22	143	34	0	2	396	1,315	1,408	5	5	991	2,580	716	217	413	57	2,843	471	4,093
NEFS 4	10	70	27	0	1	133	443	457	1	1	240	1,446	288	26	114	9	832	247	1,584
NEFS 5	0	2	1	0	0	9	31	6	0	7	35	35	13	6	13	61	2	1	14
NEFS 6	0	2	2	0	0	12	41	8	0	0	1	135	16	3	1	0	138	16	69
NEFS 8	6	104	105	0	5	903	3,000	994	27	13	742	3,484	715	2,314	78	382	3,762	600	4,245
NEFS 10	1	8	1	0	0	2	8	37	0	0	115	46	20	0	88	4	1	1	16
NEFS 11	9	49	1	0	0	1	2	137	0	0	79	219	47	0	29	0	231	118	1,848
NEFS 12	3	18	2	0	0	3	11	69	0	0	345	237	59	0	187	3	68	27	304
NEFS 13	0	18	23	0	1	261	869	21	14	13	165	829	193	480	21	97	164	27	202
New Hampshire Permit Bank	1	5	0	0	0	0	0	2	0	0	1	4	0	0	1	0	2	2	24
Sustainable Harvest Sector 1	5	39	17	0	1	138	457	430	2	2	191	1,655	275	338	72	54	1,082	328	1,433
Sustainable Harvest Sector 2	2	14	6	0	0	54	181	276	1	1	154	799	167	23	70	29	720	155	795
Sustainable Harvest Sector 3	1	8	3	0	0	27	90	270	1	2	20	530	109	60	3	10	480	139	781
Common Pool	3	23	10	0	1	78	242	125	4	18	188	486	115	178	220	126	162	35	240
Sector Total	82	648	296	0	14	2,122	7,052	5,004	51	46	3,514	14,798	3,143	3,499	1,299	750	12,256	2,951	21,541

* The data in this table are based on fishing year 2026 sector rosters and represent the total allocations to each sector.
# Numbers are rounded to the nearest thousand pounds. In some cases, this table shows an allocation of 0, but that sector may be allocated a small amount of that stock in tens or hundreds of pounds.

Table 13 -- ACE (in mt), by Stock, for Each Sector for Fishing Year 2026*#

Sector Name	EGOM cod	WGOM Cod	GB Cod East	GB Cod West	SNE Cod	GB Haddock East	GB Haddock West	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail	CC/GOM Yellowtail	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter	Redfish	White Hake	Pollock
Fixed Gear Sector	0	11	14	0	1	12	41	4	0	0	26	31	16	0	12	4	27	13	258
Maine Coast Community Sector	6	35	3	0	0	32	105	275	0	1	106	1,011	169	13	54	9	488	176	1,235
Maine Permit Bank	0	3	0	0	0	0	1	26	0	0	5	81	11	0	3	0	46	22	168
Mooncusser Sector	3	27	17	0	1	38	126	99	0	0	60	146	42	0	26	6.6	315	160	1,120
NEFS 2	10	65	15	0	1	180	597	638	2	2	449	1,170	325	99	187	26	1,290	214	1,857
NEFS 4	4	32	12	0	1	60	201	207	1	1	109	656	131	12	52	4	377	112	719
NEFS 5	0	1	0	0	0	4	14	3	0	3	16	16	6	3	6	28	1	0	7
NEFS 6	0	1	1	0	0	6	18	4	0	0	0	61	7	1	0	0	63	7	32
NEFS 8	3	47	48	0	2	410	1,361	451	12	6	337	1,580	324	1,049	35	173	1,706	272	1,926
NEFS 10	1	4	0	0	0	1	3	17	0	0	52	21	9	0	40	2	1	0	7
NEFS 11	4	22	1	0	0	0	1	62	0	0	36	99	21	0	13	0	105	54	838
NEFS 12	1	8	1	0	0	2	5	31	0	0	157	108	27	0	85	1	31	12	138
NEFS 13	0	8	11	0	1	119	394	9	6	6	75	376	88	218	9	44	75	12	92
New Hampshire Permit Bank	0	2	0	0	0	0	0	1	0	0	0	2	0	0	0	0	1	1	11
Sustainable Harvest Sector 1	2	18	8	0	0	62	207	195	1	1	86	751	125	154	33	25	491	149	650
Sustainable Harvest Sector 2	1	6	3	0	0	25	82	125	0	1	70	362	76	11	32	13	326	70	361
Sustainable Harvest Sector 3	0	4	1	0	0	12	41	122	1	1	9	240	49	27	1	5	218	63	354
Common Pool	1	11	5	0	0	35	110	57	2	8	85	220	52	81	100	57	73	16	109
Sector Total	37	294	134	0	7	963	3,199	2,270	23	21	1,594	6,712	1,426	1,587	589	340	5,559	1,338	9,771

* The data in this table are based on fishing year 2026 sector rosters and represent the total allocations to each sector.
# Numbers are rounded to the nearest mt, but allocations are made in pounds. In some cases, this table shows a sector allocation of 0 mt, but that sector may be allocated a small amount of that stock in pounds.

Table 14 -- Fishing Years 2026-2030 Common Pool Trimester TACs (mt, live weight)

Stock	2026			2027			2028			2029			2030		
	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3
EGOM Cod	1.1	0.1	0.1	0.8	0.1	0.1									
WGOM Cod	5.8	2.3	2.4	7.4	3.0	3.1									
GB Cod	1.5	1.5	1.6												
SNE Cod	0.08	0.07	0.08	0.07	0.06	0.07									
GB Haddock	39.2	47.9	58.0												
GOM Haddock	15.4	14.8	26.7	15.3	14.8	26.7									
GB Yellowtail Flounder	0.4	0.6	1.0												
SNE/MA Yellowtail Flounder	1.7	2.2	4.1	1.7	2.2	4.1	1.7	2.2	4.1	1.7	2.2	4.1	1.7	2.2	4.1
CC/GOM Yellowtail Flounder	48.7	22.2	14.5	57.9	26.4	17.3	65.5	29.9	19.5	65.5	29.9	19.5	65.5	29.9	19.5
American Plaice	162.9	17.6	39.6	135.2	14.6	32.9									
Witch Flounder	28.5	10.4	13.0	28.5	10.4	13.0									
GB Winter Flounder	6.4	19.3	54.8	6.1	18.2	51.5	5.9	17.6	49.8	5.8	17.4	49.4	5.8	17.4	49.3
GOM Winter Flounder	36.9	37.9	25.0	36.9	37.9	25.0	36.9	37.9	25.0	36.9	37.9	25.0	36.9	37.9	25.0
Redfish	18.4	22.8	32.3	17.6	21.8	31.0	15.7	19.5	27.7	15.7	19.5	27.7	15.7	19.5	27.7
White Hake	6.0	4.9	4.9	5.4	4.4	4.4	26.0	21.2	21.2	25.0	20.4	20.4	24.2	19.7	19.7
Pollock	30.5	38.1	40.3	28.0	35.0	37.0	3.7	4.7	4.9	3.7	4.6	4.8	3.9	4.8	5.1

T = Trimester

Table 15 -- Common Pool Incidental Catch TACs for the 2026-2030 Fishing Years (mt, live weight)

Stock	Percentage of Common Pool sub-ACL	2026	2027	2028	2029	2030
EGOM Cod	1	0.01	0.01			
WGOM Cod	1	0.11	0.14			
GB Cod	1.68	0.08				
SNE Cod	1	0.00	0.00			
GB Yellowtail Flounder	2	0.04				
CC/GOM Yellowtail Flounder	1	0.85	1.02	1.15	1.15	1.15
American Plaice	5	11.01	9.14			
Witch Flounder	5	2.60	2.60			
SNE/MA Winter Flounder	1	0.57	0.60	0.63	0.63	0.63

Table 16 -- Fishing Years 2026-2030 Incidental Catch TACs for Each Special Management Program (mt, live weight)

Stock	Regular B DAS Program					Eastern United States/Canada Haddock SAP				
	2026	2027	2028	2029	2030	2026	2027	2028	2029	2030
EGOM Cod	0.01	0.01				n/a	n/a	n/a	n/a	n/a
WGOM Cod	0.11	0.14				n/a	n/a	n/a	n/a	n/a
GB Cod	0.05					0.03				
SNE Cod	0.00	0.00				n/a	n/a	n/a	n/a	n/a
GB Yellowtail Flounder	0.02					0.02				
CC/GOM Yellowtail Flounder	0.85	1.02	1.15	1.15	1.15	n/a	n/a	n/a	n/a	n/a
American Plaice	11.01	9.14				n/a	n/a	n/a	n/a	n/a
Witch Flounder	2.60	2.60				n/a	n/a	n/a	n/a	n/a
SNE/MA Winter Flounder	0.57	0.60	0.63	0.63	0.63	n/a	n/a	n/a	n/a	n/a

BILLING CODE 3510–22–C

Recreational Management Measures

Currently, the Regional Administrator sets recreational measures (open season, minimum fish size, and possession limit) for stocks that have a recreational sub-ACL (*i.e.,* WGOM cod, SNE cod, and GOM haddock) after consulting with the Council, consistent with regulations in the FMP and the Administrative Procedure Act. This process has been used to set recreational measures since 2013. Framework 72 provides for this process to be used for the two cod stocks and one haddock stock that do not have a recreational sub-ACL (*i.e.,* GB haddock, GB cod, and EGOM cod). This administrative change to recreational management measures setting is expected to result in more consistent development and

implementation of measures across stocks that have recreational fisheries, even if they do not have recreational-specific allocations. Framework 72 makes no changes to the current recreational measures for any cod or haddock stock.

Minor, Clarifying Regulatory Changes Under Secretarial Authority

This rule makes minor, clarifying changes in the regulations. Specifically, this action revises 50 CFR 648.89(b)(2)(ii) to add a single word to improve clarity of the text. Additionally, this action revises § 648.82(e)(1)(i) to remove references to the regulations detailing differential days-at-sea accounting that were removed in a previous action.

Classification

The NMFS Assistant Administrator has determined that this interim final rule is consistent with the FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

Executive Orders 12866 and 14192

This interim final rule has been determined to be not significant for purposes of Executive Order (E.O.) 12866. This rule is not an E.O. 14192 regulatory action because this rule is not significant under E.O. 12866.

Executive Order 13175

NMFS has determined that this action would not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Therefore, consultation with Tribal officials under E.O. 13175 is not required, and the requirements of section (5)(b) and (c) of E.O. 13175 also do not apply. A Tribal summary impact statement under section (5)(b)(2)(B) and (c)(2) of E.O. 13175 is not required and has not been prepared.

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on the implementation of Framework 72, as prior notice and comment would be contrary to the public interest. The delay caused by providing prior notice and opportunity for public comment would prevent affected entities from being able to take advantage of an overall increase in fishing capacity during the extremely important summer season.

The Northeast multispecies fishing year started on May 1, 2026. Absent implementation of this rule to adjust Northeast multispecies catch allocations for 2026, the fishery will continue to be constrained to low rollover specifications from 2025, many of which are further reduced to 75 percent of the 2025 specifications. Implementing Framework 72 immediately and without prior notice and the opportunity for public comment is necessary to achieve optimum yield in the northeast multispecies fishery. The Magnuson-Stevens Fishery Conservation and Management Act requires conservation and management measures to comply with ten National Standards, the first one of which mandates preventing overfishing while achieving optimum yield on a continuing basis. Thus, in the groundfish sector fishery, catch allocations for all Northeast multispecies stocks are implemented annually on the basis of the best scientific information available. The specifications for fishing year 2026 include the allocations for each species adjusted by Framework 72 and the removal of the management uncertainty buffer for all stocks. These allocations reflect a balance of interests consistent with the national standards to comprise the greatest benefit to the nation and provide the increased fishing opportunity to fishery participants that is necessary for optimizing fishing operations.

Because specifications were not implemented at the beginning of this fishing year, May 1, 2026, pursuant to the Northeast multispecies fishery management plan regulations, default specifications were automatically reduced to 75 percent of the previous year's specifications for the Northeast multispecies stocks that did not have previously set specifications for 2026. Those reduced specifications remain in place until they are replaced through implementation of new specifications for this fishing year or October 31, whichever is earlier. Default specifications are set conservatively at only a portion of the previous fishing year's specifications and are intended to be only temporary stopgap measures until the current year's specifications can be implemented based on the most recent stock assessments and updated fishery information from preceding years.

In addition to an overall increase in catch allocations, this year's specifications also include an additional increase in catch allocations through the removal of the management uncertainty buffer for sectors. The management uncertainty buffer is not necessary in fishing year 2026 based on the 100-percent fishery monitoring coverage target, as specified in 50 CFR 648.90(a)(4)(i)(B). Based on an analysis of the catch limits in Framework 72 being implemented at the beginning of the fishing year, sector groundfish revenues are expected to increase up to $1.8 million from immediate removal of the management uncertainty buffer alone. Until Framework 72 is in effect, the buffers remain in place and sector participants cannot access the benefits from this measure.

The changes to the quotas for various stocks for this fishing year are especially beneficial to fishery participants, while maintaining all the conservation goals. This is because the current default quota for GB haddock has been a particularly constraining stock for the fishery, and the new quota will increase by 103 percent compared to the fishing year 2025 allocation. Under the Sector program, which accounts for 98 percent of the commercial fishery's catch, the current default for GB haddock has been restricting fishing operations across all stocks because sector vessels cannot fish in a stock area without an allocation for every species within that stock area. A lack of allocation for one species halts a vessel's fishing in that area for any species, unless the vessel owners pay to lease additional quota.

The restrictive GB haddock default limits require fishermen who have exhausted their allocation to pay for quota today that they will be able to otherwise access at no cost once Framework 72's higher GB haddock quota is in effect. The lease payments they are making today will generally not be recoverable even after allocations are increased. After the higher allocations are implemented, a sector may want or need to lease allocation back to another member or sector because the original lease was not ultimately necessary. However, lease prices for GB haddock and other species' catch limits often decrease after the implementation of increased catch limits, so leasing back to another member or sector would result in a net loss of funds for the sector member or sector. Also, if a fisherman cannot afford to pay for additional quota or a fisherman attempts to avoid these higher and potentially unnecessary costs by not fishing, they lose opportunities to fish until after Framework 72 is in effect. In these cases, this in effect acts as a temporary fishing closure for such fishermen, and these missed fishing opportunities cannot be replaced.

Thus, while the new specifications include decreased catch limits, in

addition to the limits that are being increased, the overall impact of the specifications provides stable and unfluctuating catch limits at the earliest available opportunity. While the decreased limits could potentially constrain some fishing activity, the greater availability of a higher value stock (*i.e.,* GB haddock) means the more constrained stocks may be limited only to when caught in pursuit of the higher value or more available stock. Due to GB haddock's value and availability, faster implementation of this fishing year's specifications allows more time for fishing under more accurate and beneficial market conditions.

Finally, losing fishing opportunities during the summer months redirects some fishing effort from warmer and generally calmer weather into colder and more hazardous weather. This is particularly challenging for smaller vessels, for which summer may be the only season in which they are able to participate in the fishery. Also, providing more days in a fishing year from which a fisherman can choose to fish generally provides a greater potential for choosing days with safer conditions. Implementing the 2026 fishing year quotas as soon as possible provides certainty and the greatest amount of time possible within this fishing year for participation.

For these reasons, there is good cause to waive the prior notice and opportunity for public comment for this rule.

For these same reasons, there is good cause under 5 U.S.C. 553(d)(3) for the measures in this final rule to become effective immediately upon publication. In addition, many of these measures relieve a restriction, pursuant to 5 U.S.C. 553(d)(1). Most of the allocations implemented through this rule are an increase over the current limits and setting the management uncertainty buffer at zero increases the allocation for all stocks. Therefore, the increased specifications and removal of the uncertainty buffer increases fishing opportunity for industry, thereby relieving current restrictions.

Although the rule will decrease the catch limit for a few stocks, it would be contrary to the public interest to implement allocation adjustments at different times. Implementing new catch limits, whether increasing or decreasing, in a piecemeal manner, would create confusion and add to the already ongoing difficult disruption to business planning and quota leasing markets arising from the current default specifications. And because the regulated community is expecting these decreases, sectors are already managing to the lower quotas. There is therefore no advantage to the regulated community for delaying implementation; fishery participants do not need to prepare to come into compliance and will not be able to maximize fishing opportunity for the stocks with quotas that are decreasing. In addition, there is potential danger of overfishing these stocks, which could then lead to the need for more restrictive conservation methods in future fishing years. Delaying the effective date of the lower quotas therefore offers no advantage for sector preparation, and immediate implementation does not disadvantage the non-fishing industry public in any way.

Stakeholder and industry groups have been aware of and have participated in the public meetings on Framework 72's development. Stakeholders voiced their strong support to have Framework 72 effective without delay. Public comments submitted in response to the Amendment 25 (Revised) proposed rule from industry groups, individual fishermen, and non-governmental organizations also urged quick implementation of both Amendment 25 (Revised) and Framework 72. Commenters noted that immediate implementation of both would provide economic and conservation benefits while averting the adverse economic and conservation impacts on fishery participants, fishing communities, and Northeast multispecies stocks that would result if these rulemakings were delayed. (Amendment 25 (Revised) was implemented on June 30, 2026 (91 FR 39529)). NMFS also has received correspondence citing a critical need for immediately implementing the new catch limits in Framework 72.

NMFS is inviting public comments on this interim final rule. NMFS will consider responding to any comments in a subsequent final rule, if warranted.

Regulatory Flexibility Act

Because prior notice and opportunity for public comment are not required for this rule by 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* are inapplicable.

Paperwork Reduction Act

This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping, and reporting requirements.

Dated: July 29, 2026.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons stated in the preamble, NMFS amends 50 CFR part 648 as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.82, revise paragraph (e)(1)(i) to read as follows:

§ 648.82 Effort-control program for NE multispecies vessels.

* * * * *

(e) * * *

(1) * * *

(i) *Common pool vessels.* For a common pool vessel, Category A DAS shall accrue in 24-hr increments. For example, a vessel that fished from 6 a.m. to 10 p.m. would be charged 24 hr of Category A DAS, not 16 hr; a vessel that fished for 25 hr would be charged 48 hr of Category A instead of 25 hr.

* * * * *

■ 3. In § 648.89, revise paragraphs (b)(2)(ii) and (g) to read as follows:

§ 648.89 Recreational and charter/party vessel restrictions.

* * * * *

(b) * * *

(2) * * *

(ii) *Transiting.* If the minimum size specified for cod and haddock differ between stock areas, vessels in possession of cod or haddock that meet the minimum size specified for fish caught in one stock area, as specified in § 648.88, may transit a different stock area with that cod and haddock, provided all bait and hooks are removed from fishing rods, and any cod and haddock on board has been gutted and stored.

* * * * *

(g) *Regional Administrator authority for cod and haddock recreational measures.* The Regional Administrator, after consultation with the NEFMC, may adjust recreational measures for cod and haddock stocks that do not have a recreational allocation to set consistent measures with other stock areas, as appropriate. Appropriate measures, including adjustments to fishing seasons, minimum fish sizes, or possession limits, may be implemented in a manner consistent with the Administrative Procedure Act, with the final measures published in the **Federal**

Register prior to the start of the fishing year when possible. Separate measures may be implemented for the private and charter/party components of the recreational fishery.

* * * * *

[FR Doc. 2026–15784 Filed 8–3–26; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 91, No. 148
Tuesday, August 4, 2026

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2026–6934; Airspace Docket No. 26–AWA–3]

RIN 2120–AA66

Establishment of Class C Airspace and Removal of Class D Airspace; Wilmington International Airport, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class C airspace and remove Class D airspace at Wilmington International Airport (ILM), NC. The FAA is proposing this action to enhance the efficient management of air traffic operations and reduce the potential for midair collision in the Wilmington, NC, terminal area. The Class C airspace would replace the existing Class D airspace at ILM. In addition, the non-regulatory Terminal Radar Service Area (TRSA) would be removed.

DATES: Comments must be received on or before October 5, 2026.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2026–6934 and Airspace Docket No. 26–AWA–3 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W58–213, West Building, 5th Floor, Washington, DC 20590.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W58–213 of the West Building, 5th Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W58–213 of the West Building, 5th Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11K, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/*. You may also contact the Rules and Regulations Group, Policy Directorate, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Ashley Toth, Rules and Regulations Group, Policy Directorate, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the airspace structure as necessary to enhance the safe and efficient flow of air traffic within the Wilmington, NC, terminal area.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy*.

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Avenue, College Park, GA, 30337.

Incorporation by Reference

Class C airspace areas and Class D airspace areas are published in paragraphs 4000 and 5000, respectively,

of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11K, dated August 4, 2025, and effective September 15, 2025. These updates would be published in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11K, which lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points, is publicly available as listed in the **ADDRESSES** section of this document.

Background

Wilmington International Airport (ILM) is located 3 miles northeast of the city of Wilmington, NC. The ILM Airport Traffic Control Tower (ATCT) consists of a combined tower and Terminal Radar Approach Control (TRACON) facility that operates from 0600 to 2300 local time, daily. Currently, Class D airspace, extending from surface to and including 2,500 feet mean sea level (MSL), surrounds the airport. When the ILM ATCT is closed, the ILM Class D airspace reverts to a Class E surface area. The Class D is effective during the specific dates and times established in advance by a Notice to Airmen (NOTAM), and thereafter as continuously published in the Chart Supplement.

A TRSA overlies the contiguous Class D airspace area in approximately a 20 nautical mile (NM) radius of ILM, within the TRACON's delegated airspace.

The airspace surrounding ILM is complex and congested due to runway configuration, geography, proximity to other airports, restricted airspace, navigational aids, flight training, tourists, skydiving, and military operations. Those factors coupled with the standard arrivals and departures into ILM make the TRSA airspace a web of intersecting flight paths. Participation in TRSA services is voluntary to pilots operating under visual flight rules (VFR). There are significant numbers of VFR pilots, which are not in contact with air traffic control (ATC), operating throughout the ILM terminal area. VFR pilots are often observed loitering or maneuvering in the departure corridors, along the final approach courses, or overhead the Class D. Without being in communication with ATC, air traffic controllers are unaware of the VFR pilots' intentions. Heading and altitude changes made by nonparticipating VFR aircraft are unpredictable, and this often requires controllers to take action to avoid possible conflicts with other aircraft under their control. With the current airspace configuration, there is no requirement for VFR pilots to contact ATC outside of the ILM Class D airspace area.

Class C Airspace and Terminal Radar Service Areas (TRSA)

Class C airspace areas are designated under 14 CFR part 71 rulemaking and can be used to improve aviation safety, reduce the risk of midair collisions in the terminal area, and enhance the management of air traffic operations therein. Operating requirements within Class C airspace keep ATC informed of all aircraft operating within the Class C airspace. Pilots are required to establish two-way radio communications with ATC prior to entering Class C airspace, and they must maintain communications with ATC while operating in Class C airspace. In addition, pursuant to 14 CFR part 91, no person may operate an aircraft in Class C airspace unless the aircraft is equipped with an operational transponder and Automatic Dependent Surveillance—Broadcast (ADS–B) Out.

TRSAs are not officially designated by airspace rulemaking action. They are not incorporated in 14 CFR part 71, nor are there any TRSA-specific operating rules in 14 CFR part 91. TRSAs are established around designated airports where ATC provides radar vectoring, sequencing, and separation services on a full-time basis for all instrument flight rules (IFR) and participating VFR aircraft. Pilots operating under VFR are encouraged to contact ATC to avail themselves of TRSA services. However, VFR pilot participation in TRSA services is voluntary. The limitations of the TRSA (*i.e.,* voluntary participation by VFR pilots) often fails to prevent nonparticipating VFR aircraft coming in direct conflict with higher-performance jets landing or departing ILM.

Need for Class C Airspace at ILM

Pursuant to FAA Order JO 7400.2, paragraph 16–2–1, to qualify for Class C airspace, an airport must be served by an operational ATCT and a radar approach control and meet one of the following criteria: (1) an annual instrument operations count of 75,000 at the primary airport; or (2) an annual instrument operations count of 100,000 and the primary and secondary airports; or (3) an annual count of 250,000 enplaned passengers at the primary airport.

ILM qualifies as a candidate for Class C airspace based on its annual enplaned passenger count. ILM's enplaned passenger count for calendar year (CY) 2024 (the latest year for which validated figures are available) was 737,065. This figure represents a 59.33% increase over CY 2021 numbers. Other factors considered are traffic volume, airspace complexity, and the potential for midair collision in the terminal area.

The existing TRSA does not adequately support the volume and diversity of aircraft operating in the congested ILM terminal area. Currently, there is no requirement for VFR pilots to establish radio contact with ATC outside of the existing ILM Class D airspace areas. Since participation in TRSA services is voluntary on the part of VFR pilots, the TRSA does not provide ATC with an adequate level of flight information or control required to segregate IFR and VFR aircraft operating in this complex airspace environment. VFR aircraft that are not in contact with ATC routinely operate in the area, and in so doing they cross ILM arrival and departure corridors and/or make unexpected heading and/or altitude changes. These aircraft frequently operate at altitudes that may conflict with aircraft arriving or departing ILM. As a result, IFR aircraft must alter their flight paths or altitudes to avoid them, thereby disrupting the orderly flow of ILM arrivals and departures.

Additionally, air traffic controller workload is increased due to the need for additional vectoring or altitude changes of ILM arrivals and departures to ensure separation from the non-participating VFR aircraft that are not communicating with ATC. Under this proposal, designation of Class C airspace would ensure that those VFR aircraft operating in the vicinity of the ILM arrival and departure corridors would be required to establish contact with ATC, making controllers aware of pilots' intentions and promoting increased safety and efficiency.

Benefits of Class C Airspace

All pilots would benefit from the enhanced safety provided by Class C services, which include the separation of aircraft, traffic advisories, and safety alerts. Class C airspace enhances safety by the requirement that two-way radio communication must be established with ATC prior to a pilot entering Class C airspace and maintained for the duration of flight in Class C airspace. The requirements for operating within Class C airspace will allow air traffic controllers to be aware of the intentions of VFR pilots and provide the opportunity to safely separate VFR and IFR traffic with more precision. Nonparticipating VFR aircraft will need to remain clear of the Class C airspace which will decrease the number of ILM arrivals and departures encountering nonparticipating VFR aircraft, thereby

reducing the potential for a midair collision. It also decreases the workload for air traffic controllers by minimizing the need to vector arrivals and departures to avoid conflicts with nonparticipating VFR aircraft due to the operating requirements for Class C airspace. Furthermore, it would minimize disruptions to the orderly flow of arrivals and departures to ensure pilots can fly stabilized approaches during a critical phase of flight.

Pre-NPRM Public Input

In 2024, the FAA approved the formation of an Ad Hoc Committee (Committee) to seek input and recommendations from representatives of affected aviation users for the FAA to consider in designing a proposed Class C airspace area at ILM. The Committee consisted of a diverse sampling of local aviation operators and organizations, including representatives from the Aircraft Owners and Pilots Association, pilots from the local airports and flight schools, the airlines, flight training, general aviation, military, business aviation, the ILM airport itself, and others.

Ad Hoc Committee Recommendations

The Committee met throughout 2024 and submitted its report to the FAA in February 2025. The initial Class C airspace design presented to the Committee would have extended from the surface to and including 4,100 feet MSL within a 5 NM radius of ILM; and the airspace would have extended from 1,300 feet MSL to and including 4,100 feet MSL within a 10 NM radius of ILM. However, based on the input and discussions from the meetings, the Committee recommended that the FAA include a 1 NM cutout from the outer shelf on the southern side of the ILM Class C surface area to accommodate Pilots Ridge Airport (03NC), NC, operations outside or beneath Class C airspace.

The Committee proposed the modification because it would allow users of 03NC to easily ingress and egress the airport without any negative impact on other airspace users. This modification does not present any undue challenges due to the location of 03NC at the outer edge of the proposed ILM Class C airspace. Additionally, the proposed cutout is located between the approach and departure corridors for both runways at ILM.

The Committee also considered a possible option to remove a slice of the Class C airspace along a line parallel to, and 1 NM north of 03NC, but it was not ultimately recommended by the Committee. This option was rejected because it would remove the outer shelf of the Class C where it would bisect the approach corridor for Runway 35 at a point where ATC vectors larger aircraft onto the final approach course and would create the potential for additional conflict with nonparticipating VFR aircraft.

After thorough review and analysis, the FAA concurred with the Committee's sole recommendation for modifying the proposal, *i.e.,* to include the cutout for 03NC. The design ensures all aircraft traversing the airspace centered around ILM receive positive control from ATC. It will ensure aircraft receiving radar services are not in conflict with nonparticipating VFR aircraft, especially high-performance jets in critical phases of flight. The design will prevent nonparticipating VFR aircraft from impacting operations while safely transitioning through the area. Finally, this design decreases risk and improves safety and efficiency for passengers and aviation professionals while still allowing access to 03NC.

Informal Airspace Meeting

As announced in the **Federal Register** (90 FR 40048; August 18, 2025), the FAA held an informal airspace meeting on October 1, 2025. The meeting was held virtually via the Zoom platform and was simultaneously broadcast on the FAA's YouTube channel. A total of 56 people logged into the Zoom meeting with 10 concurrent streamers on YouTube. The purpose of the meeting was to provide interested airspace users with an opportunity to present their views and offer recommendations regarding the proposed establishment of Class C airspace at ILM. The meeting began with a presentation describing the current ILM TRSA airspace and air traffic safety concerns and a review of graphical depictions of the updated Class C airspace proposal.

Next, the panelists participated in a live question-and-answer session with meeting attendees. Several questions were asked about whether the proposed airspace would limit general aviation aircraft's ability to transit the airspace as they currently do. General questions were asked about the flow of traffic in and around the area of ILM, how to obtain safety data, clarification on the proposed airspace design and modification process, and ADS–B requirements for Class C. No comments or recommendations were received from the informal airspace meeting.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to establish Class C airspace and remove the existing Class D airspace area at ILM. The latitude/longitude coordinates for the ILM airport reference points (ARP) would be updated to reflect the current Airport Master Records data. Also, the existing ILM TRSA would be removed from aeronautical charts and replaced by the Class C airspace area. The FAA is proposing this action to enhance the safe and efficient use of airspace and reduce the risk of midair collision in the ILM terminal area (see the attached chart).

The proposed Class C airspace area would consist of one area, described as follows. The Class C airspace would extend from the surface to and including 4,100 feet MSL within a 5 NM radius of ILM; and the airspace that would extend from 1,300 feet MSL to and including 4,100 feet MSL within a 10 NM radius of ILM, excluding that airspace within a 1 NM radius of Pilots Ridge Airport.

As previously stated, the ILM Class D airspace area and the ILM TRSA would be removed if the proposed Class C airspace is implemented.

Regulatory Impact Analysis

E.O. 12866 (''Regulatory Planning and Review'') and E.O. 13563 (''Improving Regulation and Regulatory Review'') require agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' This rule is not a significant regulatory action as defined in Section 3(f) of E.O. 12866. This rule is not an E.O. 14192 regulatory action because this rule is not significant under E.O. 12866.

The airspace surrounding ILM is heavily trafficked, measured by the increase in enplanements since 2022. Currently, the airspace at ILM is class D with an overlying TSA, and serves commercial air carriers, general aviation aircraft, and military aircraft. ILM TRACON's traffic flow is dynamic and is routinely impacted by seasonal conditions, pilot training, Med-Evac, law enforcement, military operations, and the hourly activation and deactivation of military airspace. Beach traffic and pilot training increase significantly in the summer months. ILM has three flight schools based at the airport, and three flight schools are based at nearby airports that regularly use ILM for flight training requirements.

Nearby operations also include the Novant Health Regional Medical Center Heliport. The Novant Health Regional Medical Center, located 4 miles south of ILM, operates 4 Med-Evac helicopters.

In addition, there are three nearby private airports, including Pilots Ridge Airport, Topsail Airpark, and Stag Air Park. The current, outdated ILM Airspace was last modified in 1993 through a rulemaking that amended the Class D airspace.[1] The airspace no longer meets ILM's need for maintaining a safe and efficient airspace given the growth since 2022.

The FAA proposes establishing Class C airspace at ILM to replace the Class D airspace. The FAA's proposal adopts the Ad Hoc Committee's recommendation to include a 1 NM cutout from the outer shelf on the southern side of the ILM Class C surface area to accommodate Pilots Ridge Airport (03NC), NC, operations outside or beneath Class C airspace.

The FAA determined that this proposed rule would enhance the efficient management of air traffic operations and reduce the potential for midair collision in the ILM terminal area. The proposal would reduce air traffic controller workloads by lessening the need for additional vectoring of arrivals and departures to avoid conflicts with unknown VFR aircraft and minimize disruptions to the orderly flow of arrivals and departures to ensure pilots can fly stabilized approaches during a critical phase of flight. Pilots would also benefit from the enhanced safety provided by Class C services, including separation, traffic advisories, and safety alerts.

Class C airspace areas are designated under 14 CFR part 71 rulemaking to improve aviation safety by reducing the risk of midair collisions in the terminal area and enhancing the management of air traffic operations therein. Class C airspace is designed to keep ATC informed of all aircraft operating within the Class C airspace. Pilots are required to establish two-way radio communications with ATC prior to entering Class C airspace, and they must maintain communications while operating in Class C airspace. In addition, pursuant to 14 CFR part 91, no person may operate an aircraft in Class C airspace unless the aircraft is equipped with an operational transponder and ADS–B Out. VFR operators would only need to make minor adjustments to accommodate the proposed Class C airspace by flying under or around it. Therefore, the FAA expects the proposal would result in minimal cost to VFR operators. The FAA requests comments on the benefits and costs of this proposal to inform the final rule.

[1] *Amendment to Class D Airspace Areas,* 58 FR 54953 (Oct. 25, 1993).

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) of 1980, (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) and the Small Business Jobs Act of 2010 (Pub. L. 111–240), requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term ''small entities'' comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The proposed rule would replace Class D airspace with Class C airspace at ILM. The FAA is proposing this action to enhance the efficient management of air traffic operations and reduce the potential for midair collision in the ILM terminal area. The change would affect general aviation operators using the proposed Class C airspace. Operators flying VFR would need to comply with Class C operating and equipage requirements or make small adjustments to their flight paths to avoid the modified Class C airspace, if preferred or needed. Some VFR operators are already avoiding the existing Class D airspace to avoid heavy traffic. If an agency determines a rulemaking will not result in a significant economic impact on a substantial number of small entities, the head of the agency may so certify under section 605(b) of the RFA. Therefore, as provided in section 605(b) and based on the foregoing, the FAA proposes to certify this rulemaking would not result in a significant economic impact on a substantial number of small entities. FAA requests comments on this proposed certification.

International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

The FAA has determined this proposal does not create an unnecessary obstacle to foreign commerce.

Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or Tribal government or the private sector to incur direct costs without the Federal government having first provided the funds to pay those costs. The FAA has determined the rule will not result in the expenditure of $193,000,000 or more ($100,000,000 adjusted for inflation using the most current Implicit Price Deflator for the Gross Domestic Product) by State, local, or Tribal governments, in the aggregate, or the private sector, in any one year.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined there is no new requirement for information collection associated with this proposed rule.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1G, ''*FAA National Environmental Policy Act Implementing Procedures*'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11K, Airspace Designations and Reporting

Points, dated August 4, 2025, and effective September 15, 2025, is amended as follows:

Paragraph 4000 Subpart C—Class C Airspace

* * * * *

ASO NC C Wilmington, NC [New]

Wilmington International Airport, NC

(Lat. 34°16′27″ N, long. 77°54′17″ W)

Pilots Ridge Airport, NC

(Lat. 34°06′26″ N, long. 77°54′25″ W)

That airspace extending upward from the surface to and including 4,100 feet MSL within a 5-mile radius of the Wilmington International Airport; and that airspace extending upward from 1,300 feet MSL to and including 4,100 feet MSL within a 10-mile radius of the Wilmington International Airport, excluding that airspace within a 1-mile radius of Pilots Ridge Airport.

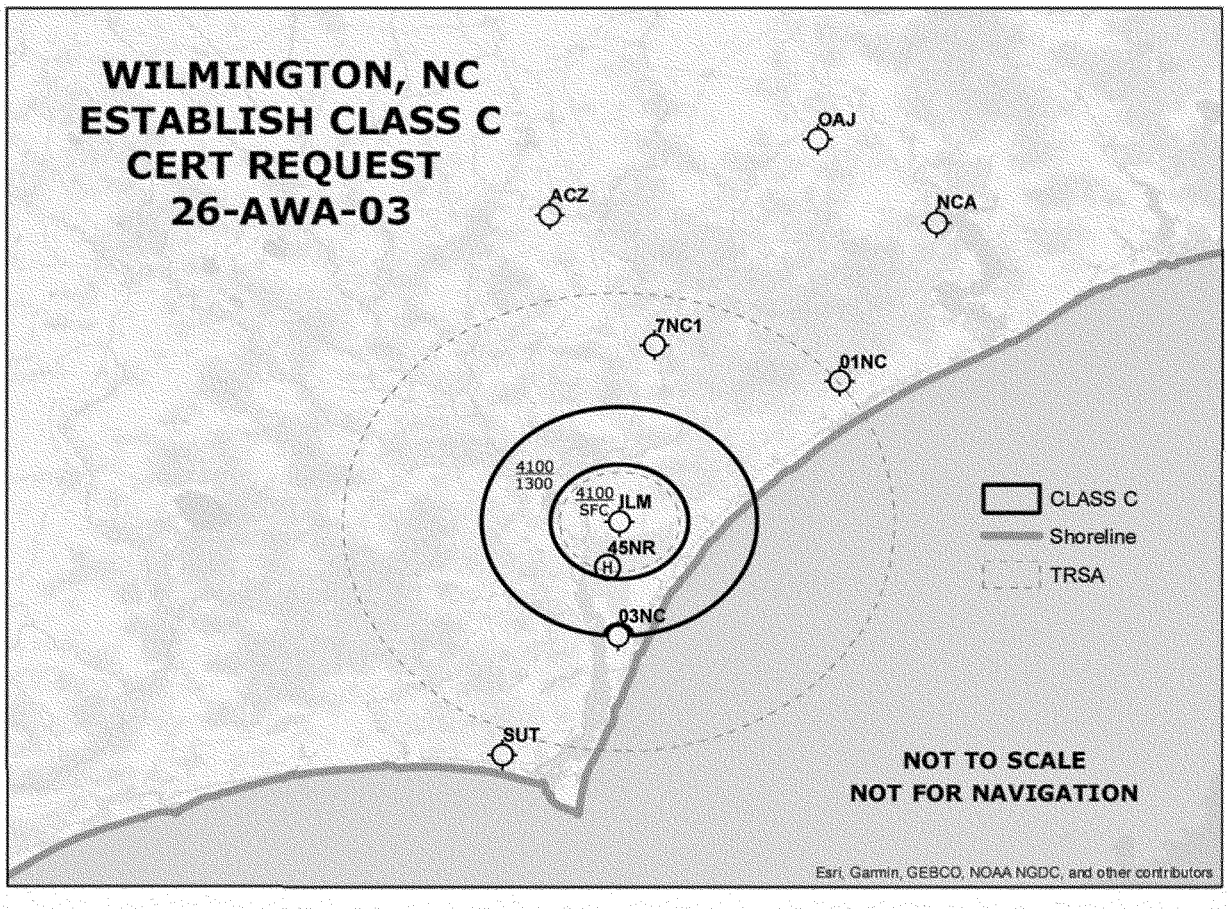
* * * * *

Paragraph 5000 Subpart D—Class D Airspace

* * * * *

ASO NC D Wilmington, NC [Removed]

* * * * *



Issued in Washington, DC, on July 31, 2026.

Alex W. Nelson,

Manager, Rules and Regulations Group.

[FR Doc. 2026–15758 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 1

[File No. R607005]

Petition for Rulemaking of Matheus Garcia Pereira

AGENCY: Federal Trade Commission.

ACTION: Receipt of petition; request for comment.

SUMMARY: Please take notice that the Federal Trade Commission (''Commission'') received a petition for rulemaking from Matheus Garcia Pereira and has published that petition online at *https://www.regulations.gov.* The Commission invites written comments concerning the petition. Publication of this petition is pursuant to the Commission's Rules of Practice and Procedure and does not affect the legal status of the petition or its final disposition.

DATES: Comments must identify the petition docket number and be filed by September 3, 2026.

ADDRESSES: You may view the petition, identified by docket number FTC–2026–1024, and submit written comments concerning its merits by using the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit sensitive or confidential information. You may read background documents or comments received at *https://www.regulations.gov* at any time.

FOR FURTHER INFORMATION CONTACT: Office of the Secretary (phone: 202–326–2514, email: *ElectronicFilings@ftc.gov*), Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to section 18(a)(1)(B) of the Federal Trade Commission Act, 15 U.S.C. 57a(1)(B), and FTC Rule 1.31(f), 16 CFR 1.31(f), notice is hereby given that the above-captioned petition has been filed with the Secretary of the Commission

and has been placed on the public record for a period of 30 days. Any person may submit comments in support of or in opposition to the petition. All timely and responsive comments submitted in connection with this petition will become part of the public record.

This petition requests to issue an interpretive rule regarding consumer freedom of choice: the destructive impact of deceptive information on market fairness and competition. The Commission will not consider the petition's merits until after the comment period closes. It may grant or deny the petition in whole or in part, and it may deem the petition insufficient to warrant commencement of a rulemaking proceeding. The purpose of this document is to facilitate public comment on the petition to aid the Commission in determining what, if any, action to take regarding the request contained in the petition. This document is not intended to start, stop, cancel, or otherwise affect rulemaking proceedings in any way.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other State identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2).

Authority: 15 U.S.C. 46; 15 U.S.C. 57a; 5 U.S.C. 601 note.

April J. Tabor,

Secretary.

[FR Doc. 2026–15824 Filed 8–3–26; 8:45 am]

BILLING CODE 6750–01–P

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Part 1120

[Docket No. ATBCB–2026–0004]

RIN 3014–AA51

Revision of Freedom of Information Act Regulations

AGENCY: Architectural and Transportation Barrier Compliance Board.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board or Board) is issuing this Notice of Proposed Rulemaking (NPRM) to update its regulations under the Freedom of Information Act (FOIA). The Board proposes to replace its existing FOIA regulations with this proposed rule, which streamlines the language of several procedural provisions; updates procedures consistent with current technology; incorporates changes required by amendments to the FOIA under the OPEN Government Act of 2007 and the FOIA Improvement Act of 2016, and developments in case law; and conforms to Department of Justice guidelines for agency FOIA regulations.

DATES: Submit comments by September 3, 2026. Comments received by mail will be considered timely if they are postmarked on or before that date. The electronic Federal Docket Management System (*https://www.regulations.gov*) will accept comments until Midnight Eastern Time at the end of that day.

ADDRESSES: You may submit comments, identified by docket number (ATBCB–2026–0004) by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: docket@access-board.gov.*
- *Mail:* Office of General Counsel, U.S. Access Board, 1331 F Street NW, Suite 1000, Washington, DC 20004–1111.

Instructions: All submissions must include the docket number, ATBCB–2026–0004. All comments received will be posted without change, including any personal information provided, to *http://www.regulations.gov* and will be available for public viewing.

FOR FURTHER INFORMATION CONTACT: Frances Spiegel, Attorney Advisor, (202)-0041, *foia@access-board.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction and Legal Authority

This proposed rule will update the Access Board's regulations under the Freedom of Information Act (FOIA), 5 U.S.C. 552. The Board proposes to replace its existing FOIA regulations with this proposed rule, which streamlines the language of several procedural provisions; incorporates changes required by amendments to the FOIA under the OPEN Government Act of 2007, Public Law 110–175, 121 Stat. 2524, and the FOIA Improvement Act of 2016, Public Law 114–185, 130 Stat. 538 (enacted June 30, 2016); and conforms to Department of Justice's guidelines for agency FOIA regulations.

The Board's FOIA regulations, 36 CFR part 1120—Public Availability of Information, were initially published in 1980, and revised in 1987 and 1990. *See* 45 FR 80976 (Dec. 8, 1980); 52 FR 43195 (Nov. 10, 1987); 55 FR 2521 (Jan. 25, 1990). While the Board has always administered its FOIA program consistent with the FOIA legislation and administrative directives, the Board now updates its FOIA regulations to reflect these changes.

II. Content of the Revised Regulation

The format and content of the Access Board's proposed updated FOIA regulation is consistent with the Department of Justice's guidance for agencies on FOIA regulations. *See* U.S. Dept. of Justice, Guidance for Agency FOIA Regulations (June 26, 2019), *available at https://www.justice.gov/oip/oip-guidance/guidance-agency-foia-regulations.* In addition to achieving consistency with statutory and administrative authorities that dictate the substance of agency FOIA regulations, the content has been updated to reflect changes in the Access Board's FOIA procedures due to advances in technology since the original regulation was published. The contents of each section are discussed below.

§ 1120.1 General Provisions

This section indicates that the regulation should be read in conjunction with the statutory text of the FOIA and the Uniform Freedom of Information Fee Schedule and Guidelines published by the Office of Management and Budget. It also points requesters to the agency's Privacy Act regulation for procedures to request records about themselves from an agency system of records.

§ 1120.2 Proactive Disclosure of Agency Records

This section indicates that records that are required to be made available

for public inspection by the FOIA are available on the agency's website.

§ 1120.3 Requirements for Making Requests

This section provides requesters with the information they need to make a FOIA request to the Access Board. Here the Board describes general information, including methods of submitting a request, how to find contact information for agency FOIA personnel, and additional requirements for requests for records pertaining to a third party. In addition, the section explains to requesters how to adequately describe records so that agency personnel can locate them with a reasonable amount of effort, and advises that agency personnel are available to help individuals formulate a sufficiently detailed request.

§ 1120.4 Responsibility for Responding to Requests

This section describes responsibility within the agency for responding to FOIA requests and explains the circumstances under which the Access Board will seek a consultation from another agency regarding whether information in requested records is exempt from disclosure, and when the Access Board will refer records directly to another agency for processing and response to the requester.

§ 1120.5 Timing of Responses to Requests

This section describes the statutory timeframes with which the Access Board must comply when responding to FOIA requests. It also states the Access Board's general practices for aggregating requests and undertaking expedited processing. The Access Board will approve requests for expedited processing where a requester demonstrates a ''compelling need,'' as defined by 5 U.S.C. 552(a)(6)(E)(v), and in other cases as determined by the agency. The statutory definition of ''compelling need'' includes circumstances where a lack of expedited processing could reasonably be expected to pose an imminent threat to the life or physical safety of an individual or where there is an urgent need to inform the public about a federal government activity and the request is made by a person primarily engaged in disseminating information. The Access Board envisions approving expedited processing in other cases only in rare circumstances that present a significant and substantiated level of urgency, similar to the level of urgency described in the statutory definition of ''compelling need.''

§ 1120.6 Responses to Requests

This section describes how FOIA office personnel communicate with requesters, in what instances tracking numbers are required to be assigned, and the actions the Access Board will take when it grants or denies a request. The section specifies the decisions that constitute adverse determinations or denials and describes the information that will be provided to a requester when the agency denies a request in whole or in part. Further, it states how information withheld under a FOIA exemption must be marked.

§ 1120.7 Confidential Commercial Information

This section describes the procedures that the agency will use when confidential commercial information contained in Access Board records is the subject of a FOIA request, and the steps that individuals who submit confidential commercial information to the Access Board should take to protect their interests.

Through this NPRM, the Access Board provides the public with notice and the opportunity to comment on proposed regulations establishing designation and predisclosure notification procedures for confidential commercial information, as required by Executive Order 12600 (June 23, 1987). *See* 52 FR 23781 (June 25, 1987).

This proposed section explains how individuals who submit confidential commercial information to the Access Board should mark it to alert agency FOIA personnel of the potential for protection from disclosure under FOIA Exemption 4, 5 U.S.C 552(b)(4). It describes the circumstances under which the agency will inform individuals or entities that information they submitted has been identified as responsive to a FOIA request, what the notification will include, and when the agency will not send a notice to a submitter.

In this section, the Access Board details how a submitter objects to disclosure of information that the submitter believes is exempt from disclosure under the FOIA. This section also affirms that the agency will consider the submitter's objections and describes the notice that will be provided to a submitter if the Access Board ultimately decides to disclose the information. Other notification requirements include notice to a submitter if the requester files a lawsuit seeking to compel disclosure, and notification to the requester in various circumstances: when a submitter is notified of a FOIA request for confidential commercial information, when the agency has notified the submitter of its intent to disclose the information, and when a submitter has filed a lawsuit to prevent disclosure.

§ 1120.8 Administrative Appeals

This section explains the procedures for appealing an adverse FOIA decision to the Access Board, specifying the format and content of the appeal. The section describes how the agency will adjudicate appeals, and what information will be contained in an appeal decision. Mediation services offered by the Office of Government Information Services of the National Archives and Records Administration (NARA) as a non-exclusive alternative to litigation are discussed in this section. Finally, this section clarifies that typically a requester must first submit a timely administrative appeal before seeking judicial review.

§ 1120.9 Preservation of Records

This section affirms that the Access Board will retain records related to FOIA requests for the length of time consistent with Federal law and the General Records Schedule 14 issued by NARA. It further states that records will not be disposed of or destroyed while they are the subject of a pending request, appeal, or lawsuit under the FOIA.

§ 1120.10 Fees

This section specifies the fees that may be charged to different categories of requesters for the processing of FOIA requests and under what circumstances. The fees and fee provisions stated in this section are consistent with the Uniform Freedom of Information Act Fee Schedule and Guidelines issued by the Office of Management and Budget (OMB). These Guidelines, originally published in 1987 and updated in 2020, provide general principles for how agencies should set fee schedules and make fee determinations, and define statutory fee terms, for consistency in administering the FOIA throughout the Federal government. *See* 52 FR 10012 (March 27, 1987); 85 FR 81955 (Dec. 17, 2020).

In November of 1987, the Access Board published an interim final rule amending its FOIA regulations to incorporate OMB's original 1987 Guidelines on fees, and a final rule in January 1990. *See* 52 FR 43195 (Nov. 10, 1987); 55 FR 2521 (Jan. 25, 1990). At that time, the Board set its search fee at $14.00 per hour, review fee at $20.00 per hour, and duplication fee at $0.20 per page. Consistent with OMB's guidelines, the search and review fees

were based on the prevailing basic rate of pay plus 16 percent for the employees who then undertook that work, and the duplication fee was based on the actual cost of duplication.

The Board now revises the search and review fees to reflect the change in salaries of government employees over the past nearly 40 years since the existing fees were set. The Access Board proposes the following fee schedule for search and review (basic pay plus 16 percent for benefits):

- Search or review by clerical personnel will be charged at a salary rate equivalent to a GS–9/step 5;
- Search or review by professional/managerial personnel will be charged at a salary rate equivalent to a GS–14/step 5; and
- Search or review by senior executive personnel and Board members will be charged at a salary rate equivalent to an EX-Level IV.

For simplicity, and to provide a fee schedule that is fair to requesters, the Access Board proposes to round down search and review time to the nearest hour. The Access Board proposes shifting its fee schedule from set dollar amounts to amounts based on the prevailing rate of pay at the specified general schedule and step for each personnel category to provide a schedule that will allow the agency to charge the full direct costs incurred as federal salaries change over time.

The Board proposes to maintain its duplication fee at $0.20 per page. This is a reasonable estimate of the Access Board's current cost of providing photocopies, which are rarely requested.

In addition to providing the fee schedule, this section provides information on restrictions on charging fees, notice requirements of anticipated fees, charges for other services, interest charges, aggregating of requests when it appears that a request has been divided to avoid fees, when advance payments are required, circumstances under which the fee schedule does not apply, and requirements for waiver or reduction of fees.

§ 1120.11 Other Rights and Services

This final section clarifies that nothing in this FOIA regulation should be construed as providing any person with a right to any service or record to which that individual is not entitled under the FOIA statute.

III. Regulatory Process Matters

Regulatory Review (E.O. 12866): The Office of Management and Budget has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, § 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by that Office.

Regulatory Flexibility Act: In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Access Board certifies that this regulation will not have a significant economic impact on a substantial number of small entities. This rule will affect those who make requests for access to information under the provisions of the FOIA. Under the FOIA, agencies may recover only the direct costs of searching for, reviewing, and duplicating the records processed for requesters, and only for certain classes of requester and when particular conditions are satisfied. In satisfying these conditions, the Access Board typically does not charge fees for processing FOIA requests. While the Access Board has not updated its FOIA regulation since 1990, it has nevertheless been following the current statutory requirements of the FOIA and related administrative directives as reflected in DOJ's FOIA regulations template. Thus, other than the proposed fee schedule, this rulemaking simply serves to codify existing practice, which is already required by law and administrative authorities.

Unfunded Mandates Reform Act of 1995: This rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Paperwork Reduction Act: This regulation contains no information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act. *See* 44 U.S.C. 3501, *et seq.*

List of Subjects in 36 CFR Part 1120

Administrative practice and procedure; Freedom of Information Act; Privacy.

Approved by vote of the Access Board on July 29, 2026.

Christopher Kuczynski,

General Counsel.

For the reasons stated in the preamble, the Access Board proposes to amend 36 CFR part 1120, as follows:

PART 1120—PUBLIC AVAILABILITY OF INFORMATION

■ 1. The authority citation continues to read as follows:

Authority: 5 U.S.C. 552, the Freedom of Information Act, as amended.

■ 2. Revise and republish part 1120 to read as follows:

PART 1120—PROCEDURES FOR DISCLOSURE OF RECORDS UNDER THE FREEDOM OF INFORMATION ACT

§ 1120.1 General provisions.

(a) This part contains the rules that the Architectural and Transportation Barriers Compliance Board (''U.S. Access Board,'' ''Access Board,'' or ''agency'') follows in processing requests for records under the Freedom of Information Act (''FOIA''), 5 U.S.C. 552. The rules in this part should be read in conjunction with the text of the FOIA and the Uniform Freedom of Information Fee Act Schedule and Guidelines published by the Office of Management and Budget (''OMB Guidelines''). Requests made by individuals for records about themselves under the Privacy Act of 1974, 5 U.S.C. 552a, are processed under 36 CFR 1121 as well as under this part.

§ 1120.2 Proactive disclosure of agency records.

Records that are required by the FOIA to be made available for public inspection in an electronic format may be accessed through the Access Board's website at *www.access-board.gov.* .

§ 1120.3 Requirements for making requests.

(a) *General information.*

(1) Requests for records must be submitted in writing. The Access Board has a central FOIA office that processes all records requests for the agency. To make a request for Access Board records, a requester should send an email to *foia@access-board.gov* or submit a request to the Access Board through the *FOIA.gov*portal (*www.foia.gov*). Alternatively, requesters may send requests to FOIA Officer, U.S. Access Board, 1331 F Street NW, Suite 1000, Washington, DC 20004.

(2) The agency's FOIA Officer and FOIA Public Liaison are available to assist requesters. Contact information for these individuals is available on the agency's website at *www.access-board.gov.*

(3) A requester who is making a request for records about himself or herself must comply with verification of identity procedures specified by the FOIA officer.

(4) Where a request for records pertains to a third party, a requester may receive greater access by submitting either a notarized authorization signed

by that individual or a declaration made in compliance with the requirements set forth in 28 U.S.C. 1746 by that individual authorizing disclosure of the records to the requester, or by submitting proof that the individual is deceased (*e.g.,* a copy of a death certificate or an obituary). As an exercise of administrative discretion, the agency can require a requester to supply additional information if necessary in order to verify that a particular individual has consented to disclosure.

(b) *Description of records sought.* Requesters must describe the records sought in sufficient detail to enable agency personnel to locate them with a reasonable amount of effort. To the extent possible, requesters should include specific information that may assist the agency in identifying the requested records, such as the date, title or name, author, recipient, subject matter of the record, case number, file designation, or reference number. In general, requesters should include as much detail as possible about the specific records or the types of records that they are seeking. Before submitting their requests, requesters may contact the agency's FOIA officer or FOIA Public Liaison to discuss the records they are seeking and to receive assistance in describing the records. If after receiving a request the agency determines that it does not reasonably describe the records sought, the agency shall inform the requester what additional information is needed or why the request is otherwise insufficient. If a request does not reasonably describe the records sought, the agency's response to the request may be delayed.

§ 1120.4 Responsibility for responding to requests.

(a) *In general.* Except in the instances described in paragraph(c) of this section, the agency's FOIA office is responsible for responding to the request. Only the agency's Chief FOIA Officer or designee are authorized to grant or to deny any requests for agency records.

(b) *Re-routing of misdirected requests.* Where a request for records is received by agency personnel other than FOIA office personnel, the receiving personnel shall route the request to the FOIA office for processing.

(c) *Consultation, referral, and coordination.* When reviewing records located in response to a request, FOIA office personnel shall assess whether another agency of the Federal Government is better able to determine whether the record is exempt from disclosure under the FOIA. As to any such record, the agency shall proceed in one of the following ways:

(1) *Consultation.* When records originated with the Access Board, but contain within them information of interest to another agency or other Federal Government office, FOIA office personnel should typically consult with that other agency or office prior to making a release determination.

(2) *Referral.*

(i) When FOIA office personnel conclude that a different agency or other Federal Government office is best able to determine whether to disclose the record, the Access Board will typically refer the responsibility for responding to the request regarding that record, as long as the referral is to an agency or office that is subject to the FOIA. Ordinarily, the agency or office that originated the record will be presumed to be best able to make the disclosure determination. However, if the Access Board and the originating agency or office jointly agree that the Access Board is in the best position to respond regarding the record, then the record may be handled as a consultation.

(ii) Whenever the Access Board refers any part of the responsibility for responding to a request to another agency or office, it shall document the referral, maintain a copy of the record that it refers, and notify the requester of the referral and inform the requester of the name of the agency or office to which the record was referred.

(3) *Coordination.* The standard referral procedure is not appropriate where disclosure of the identity of the agency to which the referral would be made could harm an interest protected by an applicable exemption, such as the exemptions that protect personal privacy or national security interests. In such instances, in order to avoid harm to an interest protected by an applicable exemption, the agency should coordinate with the originating agency to seek its views on the disclosability of the record. The release determination for the record that is the subject of the coordination should then be conveyed to the requester by the Access Board.

(d) *Agreements regarding consultations and referrals.* The Access Board may establish agreements with other agencies to eliminate the need for consultations or referrals with respect to particular types of records.

§ 1120.5 Timing of responses to requests.

(a) *In general.* The FOIA office will typically respond to requests according to their order of receipt. In instances involving misdirected requests that are re-routed pursuant to § 1120.4(b), the response time will commence on the date that the request is received by the FOIA office, but in any event not later than 10 working days after the request is first received by an agency employee.

(b) *Multitrack processing.* The FOIA office may designate additional processing tracks that distinguish between simple and more complex requests based on the estimated amount of work or time needed to process the request. Among the factors the FOIA office may consider are the number of pages involved in processing the request and the need for consultations or referrals. If multitrack processing has been established for the fiscal year at the time a request is filed, the FOIA officer shall advise the requester of the track into which the request falls and, when appropriate, shall offer the requester an opportunity to narrow the request so that it can be placed in a different processing track. Requests that are granted expedited processing in accordance with the standards set forth in paragraph (e) of this section shall be placed in a separate track for expedited processing regardless of whether multitrack processing has otherwise been established.

(c) *Unusual circumstances.* Whenever the statutory time limit for processing a request cannot be met because of ''unusual circumstances,'' as defined in the FOIA, and the agency extends the time limit on that basis, the agency shall notify the requester in writing of the unusual circumstances involved and of the date by which processing of the request can be expected to be completed. Where the extension exceeds 10 working days, the agency shall, as described by the FOIA, provide the requester with an opportunity to modify the request or arrange an alternative time period for processing. The agency shall make available its FOIA officer and its FOIA Public Liaison for this purpose. The agency will notify the requester of the availability of the Office of Government Information Services to provide dispute resolution services.

(d) *Aggregating requests.* For the purposes of satisfying unusual circumstances under the FOIA, the agency may aggregate requests in cases where it reasonably appears that multiple requests, submitted either by a requester or by a group of requesters acting in concert, constitute a single request that would otherwise involve unusual circumstances. The agency shall not aggregate multiple requests that involve unrelated matters.

(e) *Expedited processing.*

(1) The Access Board will process requests and appeals on an expedited basis when the requester demonstrates a

compelling need, and in other cases as determined by the agency. A compelling need exists when:

(i) lack of expedited processing could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(ii) there is an urgency to inform the public about an actual or alleged Federal Government activity, if the request is made by a person who is primarily engaged in disseminating information.

(2) A request for expedited processing may be made at any time.

(3) A requester who seeks expedited processing must submit a statement, certified to be true and correct, explaining in detail the basis for making the request for expedited processing. For example, under paragraph (e)(1)(ii) of this section, a requester who is not a full-time member of the news media must establish that the requester is a person whose primary professional activity or occupation is information dissemination, though it need not be the requester's sole occupation. Such a requester also must establish a particular urgency to inform the public about the government activity involved in the request—one that extends beyond the public's right to know about government activity generally. The existence of numerous articles published on a given subject can be helpful in establishing the requirement that there be an ''urgency to inform'' the public on the topic. As a matter of administrative discretion, the agency may waive the formal certification requirement.

(4) The agency shall notify the requester within 10 calendar days of the receipt of a request for expedited processing of its decision whether to grant or deny expedited processing. If expedited processing is granted, the request shall be given priority, placed in the processing track for expedited requests, and shall be processed as soon as practicable. If a request for expedited processing is denied, any appeal of that decision shall be acted on expeditiously.

§ 1120.6 Responses to requests.

(a) *In general.* The agency will communicate with requesters primarily via electronic mail and telephone, unless a physical mailing address is the only contact information provided.

(b) *Tracking numbers.* The FOIA office shall assign a request an individualized tracking number if it will take longer than 10 working days to process.

(c) *Grants of requests.* Once the agency makes a determination to grant a request in full or in part, it shall notify the requester in writing. The agency also shall inform the requester of any fees charged under § 1120.10 and shall disclose the requested records to the requester promptly upon payment of any applicable fees. The agency shall inform the requester of the availability of the FOIA Public Liaison to offer assistance.

(d) *Adverse determinations of requests.* The agency shall notify the requester of an adverse determination denying a request in any respect in writing. Adverse determinations, or denials of requests, include decisions that: the requested record is exempt, in whole or in part; the request does not reasonably describe the records sought; the information requested is not a record subject to the FOIA; the requested record does not exist, cannot be located, or has been destroyed; or the requested record is not readily reproducible in the form or format sought by the requester. Adverse determinations also include denials involving fees or fee waiver matters or denials of requests for expedited processing.

(e) *Content of denial.* The denial shall be signed by the agency's Chief FOIA Officer, or designee, and shall include:

(1) The name and title or position of the person responsible for the denial;

(2) A brief statement of the reasons for the denial, including any FOIA exemption applied by the agency in denying the request;

(3) An estimate of the volume of any records or information withheld, such as the number of pages or some other reasonable form of estimation, although such an estimate is not required if the volume is otherwise indicated by deletions marked on records that are disclosed in part or if providing an estimate would harm an interest protected by an applicable exemption;

(4) A statement that the denial may be appealed under § 1120.8(a), and a description of the requirements set forth therein; and

(5) A statement notifying the requester of the assistance available from the Agency's FOIA Public Liaison and the dispute resolution services offered by the Office of Government Information Services.

(f) *Markings on released documents.* Markings on released documents must be clearly visible to the requester. Records disclosed in part shall be marked to show the amount of information deleted and the exemption under which the deletion was made unless doing so would harm an interest protected by an applicable exemption. The location of the information deleted shall also be indicated on the record, if technically feasible.

§ 1120.7 Confidential commercial information.

(a) *Definitions.*

(1) *Confidential commercial information* means commercial or financial information obtained by the agency from a submitter that may be protected from disclosure under Exemption 4 of the FOIA, 5 U.S.C. 552(b)(4).

(2) *Submitter* means any person or entity, including a corporation, State, or foreign government, but not including another Federal Government entity, that provides information, either directly or indirectly to the Federal Government.

(b) *Designation of confidential commercial information.* A submitter of confidential commercial information must use good faith efforts to designate by appropriate markings, either at the time of submission or within a reasonable time thereafter, any portion of its submission that it considers to be protected from disclosure under Exemption 4. These designations shall expire 10 years after the date of the submission unless the submitter requests and provides justification for a longer designation period.

(c) *When notice to submitters is required.*

(1) The agency shall promptly provide written notice to a submitter of confidential commercial information whenever records containing such information are requested under the FOIA if, after reviewing the request, the responsive records, and any appeal by the requester, the agency determines that it may be required to disclose the records, provided:

(i) The requested information has been designated in good faith by the submitter as information considered protected from disclosure under Exemption 4; or

(ii) The agency has a reason to believe that the requested information may be protected from disclosure under Exemption 4, but has not yet determined whether the information is protected from disclosure under that exemption or any other applicable exemption.

(2) The notice shall either describe the commercial information requested or include a copy of the requested records or portions of records containing the information. In cases involving a voluminous number of submitters, notice may be made by posting or publishing the notice in a place or manner reasonably likely to accomplish it.

(d) *Exceptions to submitter notice requirements.* The notice requirements of this section shall not apply if:

(1) The agency determines that the information is exempt under the FOIA;

(2) The information has been lawfully published or has been officially made available to the public;

(3) Disclosure of the information is required by a statute other than the FOIA or by a regulation issued in accordance with the requirements of Executive Order 12600 of June 23, 1987; or

(4) The designation made by the submitter under paragraph (b) of this section appears obviously frivolous, except that, in such a case, the agency shall give the submitter written notice of any final decision to disclose the information and must provide that notice within a reasonable number of days prior to a specified disclosure date.

(e) *Opportunity to object to disclosure.*

(1) The agency will specify a reasonable time period within which the submitter must respond to the notice referenced above. If a submitter has any objections to disclosure, it should provide the agency a detailed written statement that specifies all grounds for withholding the particular information under any exemption of the FOIA. In order to rely on Exemption 4 as basis for nondisclosure, the submitter must explain why the information constitutes a trade secret or commercial or financial information that is privileged or confidential.

(2) A submitter who fails to respond within the time period specified in the notice shall be considered to have no objection to disclosure of the information. Information received by the agency after the date of any disclosure decision will not be considered by the agency. Any information provided by a submitter under this subpart may itself be subject to disclosure under the FOIA.

(f) *Analysis of objections.* The agency will consider a submitter's objections and specific grounds for nondisclosure in deciding whether to disclose the requested information.

(g) *Notice of intent to disclose.* Whenever the agency decides to disclose information over the objection of a submitter, the agency will provide the submitter written notice, including:

(1) A statement of the reasons why each of the submitter's disclosure objections was not sustained;

(2) A description of the information to be disclosed; and

(3) A specified disclosure date, which shall be a reasonable time subsequent to the notice.

(h) *Notice of FOIA lawsuit.* Whenever a requester files a lawsuit seeking to compel the disclosure of confidential commercial information, the agency will promptly notify the submitter.

(i) *Requester notification.* The agency will notify a requester whenever it provides the submitter with notice and an opportunity to object to disclosure; whenever it notifies the submitter of its intent to disclose the requested information; and whenever a submitter files a lawsuit to prevent the disclosure of the information.

§ 1120.8 Administrative appeals.

(a) *Requirements for making an appeal.* A requester may appeal any adverse determinations. Appeals can be submitted by email to *FOIA@access-board.gov* or by regular mail to: Chief FOIA Officer, Office of General Counsel, U.S. Access Board, 1331 F Street NW, Suite 1000, Washington, DC 20004. Examples of adverse determinations are provided in § 1120.6(d). The requester must make the appeal in writing and to be considered timely it must be postmarked, or in the case of electronic submissions, transmitted, within 90 calendar days after the date of the response. The appeal should clearly identify the agency's determination that is being appealed and the assigned request number. To facilitate handling, the requester should mark both the appeal letter and envelope, or subject line of the electronic transmission, ''Freedom of Information Act Appeal.''

(b) *Adjudication of appeals.*

(1) The agency's Chief FOIA Officer or designee will adjudicate appeals.

(2) An appeal ordinarily will not be adjudicated if the request becomes a matter of FOIA litigation.

(c) *Decisions on appeals.* A decision on an appeal must be made in writing. A decision that upholds the initial determination will contain a statement that identifies the reasons for the affirmance, including any FOIA exemptions applied. The decision will provide the requester with notification of the statutory right to file a lawsuit and will inform the requester of the mediation services offered by the Office of Government Information Services of the National Archives and Records Administration as a non-exclusive alternative to litigation. If the initial decision is modified on appeal, the requester will be notified of that determination in writing. The FOIA office will thereafter further process the request in accordance with that appeal determination and respond directly to the requester.

(d) *Engaging in dispute resolution services provided by OGIS.* Mediation is a voluntary process. If the agency agrees to participate in the mediation services provided by the Office of Government Information Services, it will actively engage as a partner to the process in an attempt to resolve the dispute.

(e) *When appeal is required.* Before seeking review by a court of the agency's adverse determination, a requester generally must first submit a timely administrative appeal.

§ 1120.9 Preservation of records.

The agency shall preserve all correspondence pertaining to the requests that it receives under this subpart, as well as copies of all requested records, until disposition or destruction is authorized pursuant to title 44 of the United States Code or the General Records Schedule 14 of the National Archives and Records Administration. Records shall not be disposed of or destroyed while they are the subject of a pending request, appeal, or lawsuit under the FOIA.

§ 1120.10 Fees.

(a) *In general.* The Access Board shall charge for processing requests under the FOIA in accordance with the provisions of this section and with the OMB Guidelines. In order to resolve any fee issues that arise under this section, the FOIA office may contact a requester for additional information. The agency shall ensure that searches, review, and duplication are conducted in the most efficient and the least expensive manner. The Access Board ordinarily will collect all applicable fees before sending copies of records to a requester. Requesters must pay fees by check or money order made payable to the Treasury of the United States.

(b) *Definitions.* For purposes of this section:

(1) *Commercial use request* is a request that asks for information for a use or a purpose that furthers a commercial, trade, or profit interest, which can include furthering those interests through litigation. The agency's decision to place a requester in the commercial use category will be made on a case-by-case basis based on the requester's intended use of the information.

(2) *Direct costs* are those expenses that an agency incurs in searching for and duplicating (and, in the case of commercial use requests, reviewing) records in order to respond to a FOIA request. For example, direct costs include the salary of the employee performing the work (*i.e.,* the basic rate of pay for the employee, plus 16 percent of that rate to cover benefits) and the cost of operating computers and other

electronic equipment, such as photocopiers and scanners. Direct costs do not include overhead expenses such as the costs of space, and of heating or lighting a facility.

(3) *Duplication* is reproducing a copy of a record, or of the information contained in it, necessary to respond to a FOIA request. Copies can take the form of paper, audiovisual materials, or electronic records, among others.

(4) *Educational institution* is any school that operates a program of scholarly research. A requester in this fee category must show that the request is made in connection with the requester's role at the educational institution. The Access Board may seek assurance from the requester that the request is in furtherance of scholarly research and will advise requesters of their placement in this category.

Example 1.

A request from a professor of geology at a university for records relating to soil erosion, written on letterhead of the Department of Geology, would be presumed to be from an educational institution.

Example 2.

A request from the same professor of geology seeking drug information from the Food and Drug Administration in furtherance of a murder mystery he is writing would not be presumed to be an institutional request, regardless of whether it was written on institutional stationery.

Example 3.

A student who makes a request in furtherance of the student's coursework or other school-sponsored activities and provides a copy of a course syllabus or other reasonable documentation to indicate the research purpose for the request, would qualify as part of this fee category.

(5) *Noncommercial scientific institution* is an institution that is not operated on a ''commercial'' basis, as defined in paragraph (b)(1) of this section and that is operated solely for the purpose of conducting scientific research the results of which are not intended to promote any particular product or industry. A requester in this category must show that the request is authorized by and is made under the auspices of a qualifying institution and that the records are sought to further scientific research and are not for a commercial use.

(6) *Representative of the news media* is any person or entity that actively gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. The term ''news'' means information that is about current events or that would be of current interest to the public. Examples of news media entities include television or radio stations that broadcast ''news'' to the public at large and publishers of periodicals that disseminate ''news'' and make their products available through a variety of means to the general public, including news organizations that disseminate solely on the internet. A request for records supporting the news-dissemination function of the requester shall not be considered to be for a commercial use. ''Freelance'' journalists who demonstrate a solid basis for expecting publication through a news media entity shall be considered as a representative of the news media. A publishing contract would provide the clearest evidence that publication is expected; however, the agency shall also consider a requester's past publication record in making this determination.

(7) *Review* is the examination of a record located in response to a request in order to determine whether any portion of it is exempt from disclosure. Review time includes processing any record for disclosure, such as doing all that is necessary to prepare the record for disclosure, including the process of redacting the record and marking the appropriate exemptions. Review costs are properly charged even if a record ultimately is not disclosed. Review time also includes time spent both obtaining and considering any formal objection to disclosure made by a confidential commercial information submitter under § 1120.7, but it does not include time spent resolving general legal or policy issues regarding the application of exemptions.

(8) *Search* is the process of looking for and retrieving records or information responsive to a request. Search time includes page-by-page or line-by-line identification of information within records and the reasonable efforts expended to locate and retrieve information from electronic records.

(c) *Charging fees.* In responding to FOIA requests, the Access Board will charge the following fees unless a waiver or reduction of fees has been granted under paragraph (k) of this section. The fee amounts provided below include the direct costs associated with a given fee type.

(1) *Search.*

(i) Requests made by educational institutions, noncommercial scientific institutions, or representatives of the news media are not subject to search fees. Search fees shall be charged for all other requesters, subject to the restrictions of paragraph (d) of this section. The agency may properly charge for time spent searching even if they do not locate any responsive records or if they determine that the records are entirely exempt from disclosure.

(ii) Search fees, including for electronic searches that do not require new programming, will be calculated based on the hourly rates (basic pay plus 16% for benefits) of the personnel conducting the search, rounded down to the nearest full hour, as follows:

(A) Searches by clerical personnel will be charged at a salary rate equivalent to a GS–9/step 5;

(B) Searches by professional/managerial personnel will be charged at a salary rate equivalent to a GS–14/step 5; and

(C) Searches by senior executive personnel and Board members will be charged at a salary rate equivalent to an EX-Level IV.

(iii) Requesters shall be charged the direct costs associated with conducting any search that requires the creation of a new computer program to locate the requested records. Requesters shall be notified of the costs associated with creating such a program and must agree to pay the associated costs before the costs may be incurred.

(iv) For requests that require the retrieval of records stored by the agency at a Federal records center operated by the National Archives and Records Administration (NARA), additional costs shall be charged in accordance with the Transactional Billing Rate Schedule established by NARA.

(2) *Duplication.* Duplication fees shall be charged to all requesters, subject to the restrictions of paragraph (d) of this section. The agency will honor a requester's preference for receiving a record in a particular form or format where it is readily reproducible by the agency in the form or format requested. Where photocopies are supplied, the agency will provide one copy per request at a cost of $0.20 per page. For copies of records produced on tapes, disks, or other media, the agency will charge the direct costs of producing the copy, including operator time. Where paper documents must be scanned in order to comply with a requester's preference to receive the records in an electronic format, the requester shall pay the direct costs associated with scanning those materials. For other forms of duplication, the agency will charge the direct costs.

(3) *Review.* Review fees shall be charged to requesters who make commercial use requests. Review fees shall be assessed in connection with the initial review of the record, *i.e.,* the

review conducted by the agency to determine whether an exemption applies to a particular record or portion of a record. No charge will be made for review at the administrative appeal stage of exemptions applied at the initial review stage. However, if a particular exemption is deemed to no longer apply, any costs associated with the re-review of the records in order to consider the use of other exemptions may be assessed as review fees. Review fees shall be charged at the same rates as those charged for a search under paragraph (c)(1)(ii) of this section.

(d) *Restrictions on charging fees.*

(1) No search fees will be charged for requests by educational institutions (unless the records are sought for a commercial use), noncommercial scientific institutions, or representatives of the news media.

(2) If the agency fails to comply with the FOIA's time limits in which to respond to a request, it may not charge search fees, or, in the instances of requests from requesters described in paragraph (d)(1) of this section, may not charge duplication fees, except as described in paragraphs (d)(2)(i) through (iii) of this section.

(i) If the agency has determined that unusual circumstances as defined by the FOIA apply and the agency provided timely written notice to the requester in accordance with the FOIA, a failure to comply with the time limit shall be excused for an additional 10 days.

(ii) If the agency has determined that unusual circumstances as defined by the FOIA apply, and more than 5,000 pages are necessary to respond to the request, the agency may charge search fees, or, in the case of requesters described in paragraph (d)(1) of this section, may charge duplication fees if the following steps are taken. The agency must have provided timely written notice of unusual circumstances to the requester in accordance with the FOIA and the agency must have discussed with the requester via written mail, email, or telephone (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request in accordance with 5 U.S.C. 552(a)(6)(B)(ii). If this exception is satisfied, the agency may charge all applicable fees incurred in the processing of the request.

(iii) If a court has determined that exceptional circumstances exist as defined by the FOIA, a failure to comply with the time limits shall be excused for the length of time provided by the court order.

(3) Except for requesters seeking records for a commercial use, the agency will provide without charge:

(i) The first 100 pages of duplication (or the cost equivalent for other media); and

(ii) The first two hours of search.

(4) When, after first deducting the 100 free pages (or its cost equivalent) and the first two hours of search, a total fee calculated under paragraph (c) of this section is $25.00 or less for any request, no fee will be charged.

(5) No fees will be charged if the costs of routine collection and processing of the fee are likely to equal or exceed the amount of the fee.

(e) *Notice of anticipated fees in excess of $25.00.*

(1) When the agency determines or estimates that the fees to be assessed in accordance with this section will exceed $25.00, the agency will notify the requester of the actual or estimated amount of the fees, including a breakdown of the fees for search, review or duplication, unless the requester has indicated a willingness to pay fees as high as those anticipated. If only a portion of the fee can be estimated readily, the agency will advise the requester accordingly. If the requester is a noncommercial use requester, the notice will specify that the requester is entitled to the statutory entitlements of 100 pages of duplication at no charge and, if the requester is charged search fees, two hours of search time at no charge, and will advise the requester whether those entitlements have been provided.

(2) In cases in which a requester has been notified that the actual or estimated fees are in excess of $25.00, the request will not be considered received and further work will not be completed until the requester commits in writing to pay the actual or estimated total fee, or designates some amount of fees the requester is willing to pay, or in the case of a noncommercial use requester who has not yet been provided with the requester's statutory entitlements, designates that the requester seeks only that which can be provided by the statutory entitlements. The requester must provide the commitment or designation in writing, and must, when applicable, designate an exact dollar amount the requester is willing to pay. The agency is not required to accept payments in installments.

(3) If the requester has indicated a willingness to pay some designated amount of fees, but the agency estimates that the total fee will exceed that amount, the agency will toll the processing of the request when it notifies the requester of the estimated fees in excess of the amount the requester has indicated a willingness to pay. The agency will inquire whether the requester wishes to revise the amount of fees the requester is willing to pay or modify the request. Once the requester responds, the time to respond will resume from where it was at the date of the notification.

(4) The Access Board's FOIA officer and FOIA Public Liaison is available to assist any requester in reformulating a request to meet the requester's needs at a lower cost.

(f) *Charges for other services.* Although not required to provide special services, if the agency chooses to do so as a matter of administrative discretion, the direct costs of providing the service will be charged. Examples of such services include certifying that records are true copies, providing multiple copies of the same document, or sending records by means other than first class mail.

(g) *Charging interest.* The agency may charge interest on any unpaid bill starting on the 31st day following the date of billing the requester. Interest charges will be assessed at the rate provided in 31 U.S.C. 3717 and will accrue from the billing date until payment is received by the agency. The Access Board will follow the provisions of the Debt Collection Act of 1982 (Pub. L. 97–365, 96 Stat. 1749), as amended, and its administrative procedures, including the use of consumer reporting agencies, collection agencies, and offset.

(h) *Aggregating requests.* When the agency reasonably believes that a requester or a group of requesters acting in concert is attempting to divide a single request into a series of requests for the purpose of avoiding fees, the agency may aggregate those requests and charge accordingly. The agency may presume that multiple requests of this type made within a 30-day period have been made in order to avoid fees. For requests separated by a longer period, the agency will aggregate them only where there is a reasonable basis for determining that aggregation is warranted in view of all the circumstances involved. Multiple requests involving unrelated matters shall not be aggregated.

(i) *Advance payments.*

(1) For requests other than those described in paragraphs (i)(2) or (i)(3) of this section, the Access Board will not require the requester to make an advance payment before work commences or is continued on a request. Payment owed for work already completed (*i.e.,* payment before copies are sent to a requester) is not an advance payment.

(2) When the agency determines or estimates that a total fee to be charged

under this section will exceed $250.00, it may require that the requester make an advance payment up to the amount of the entire anticipated fee before beginning to process the request. The agency may elect to process the request prior to collecting fees when it receives a satisfactory assurance of full payment from a requester with a history of prompt payment.

(3) Where a requester has previously failed to pay a properly charged FOIA fee within 30 calendar days of the billing date, the agency may require that the requester pay the full amount due, plus any applicable interest on that prior request, and may require that the requester make an advance payment of the full amount of any anticipated fee before the agency begins to process a new request or continues to process a pending request or any pending appeal. Where the agency has a reasonable basis to believe that a requester has misrepresented the requester's identity in order to avoid paying outstanding fees, it may require that the requester provide proof of identity.

(4) In cases in which the agency requires advance payment, the request shall not be considered received and further work will not be completed until the required payment is received. If the requester does not pay the advance payment within 30 calendar days after the date of the agency's fee determination, the request will be closed.

(j) *Other statutes specifically providing for fees.* The fee schedule of this section does not apply to fees charged under any statute that specifically requires an agency to set and collect fees for particular types of records. In instances where records responsive to a request are subject to a statutorily-based fee schedule program, the agency shall inform the requester of the contact information for that program.

(k) *Requirements for waiver or reduction of fees.*

(1) Requesters may seek a waiver of fees by submitting a written application demonstrating how disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

(2) The agency will furnish records responsive to a request without charge or at a reduced rate when it determines, based on all available information, that disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester. In deciding whether this standard is satisfied, the agency will consider the factors described in paragraphs (k)(2)(i) through (iii) of this section:

(i) Disclosure of the requested information would shed light on the operations or activities of the government. The subject of the request must concern identifiable operations or activities of the Federal Government with a connection that is direct and clear, not remote or attenuated.

(ii) Disclosure of the requested information would be likely to contribute significantly to public understanding of those operations or activities. This factor is satisfied when the following criteria are met:

(A) Disclosure of the requested records must be meaningfully informative about government operations or activities. The disclosure of information that already is in the public domain, in either the same or a substantially identical form, would not be meaningfully informative if nothing new would be added to the public's understanding.

(B) The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. A requester's expertise in the subject area as well as the requester's ability and intention to effectively convey information to the public must be considered. The agency will presume that a representative of the news media will satisfy this consideration.

(iii) The disclosure must not be primarily in the commercial interest of the requester. To determine whether disclosure of the requested information is primarily in the commercial interest of the requester, the agency will consider the following criteria:

(A) Whether the requester has any commercial interest that would be furthered by the requested disclosure. A commercial interest includes any commercial, trade, or profit interest. Requesters must be given an opportunity to provide explanatory information regarding this consideration.

(B) If there is an identified commercial interest, whether that is the primary interest furthered by the request. A waiver or reduction of fees is justified when the requirements of paragraphs (k)(2)(i) and (ii) of this section are satisfied and any commercial interest is not the primary interest furthered by the request. The agency ordinarily will presume that when a news media requester has satisfied the requirements of paragraphs (k)(2)(i) and (ii) of this section, the request is not primarily in the commercial interest of the requester. Disclosure to data brokers or others who merely compile and market government information for direct economic return will not be presumed to primarily serve the public interest.

(3) Where only some of the records to be released satisfy the requirements for a waiver of fees, a waiver shall be granted for those records.

(4) Requests for a waiver or reduction of fees should be made when the request is first submitted and should address the criteria referenced above. A requester may submit a fee waiver request at a later time so long as the underlying record request is pending or on administrative appeal. When a requester who has committed to pay fees subsequently asks for a waiver of those fees and that waiver is denied, the requester shall be required to pay any costs incurred up to the date the fee waiver request was received.

§ 1120.11 Other rights and services.

Nothing in this part shall be construed to entitle any person, as of right, to any service or to the disclosure of any record to which such person is not entitled under the FOIA.

[FR Doc. 2026–15782 Filed 8–3–26; 8:45 am]

BILLING CODE 8150–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571 and 585

[Docket No. NHTSA–2025–0051]

RIN 2127–AM74

Federal Motor Vehicle Safety Standards; Child Restraint Anchorage Systems; Child Restraint Systems

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking; response to petitions for reconsideration, technical corrections.

SUMMARY: This NPRM responds to petitions for reconsideration of the January 7, 2025 final rule amending Federal Motor Vehicle Safety Standard (FMVSS) No. 225. NHTSA proposes granting the requests to extend the 3-year phase-in period to a 4-year phase-in period to comply with updated requirements in FMVSS No. 225 and to

extend the lead time for small-volume manufacturers to comply fully with the updated requirements by the end of the proposed phase-in period. The agency also proposes granting the request to extend the sunset of the tether anchorage exemption for convertibles by two years. NHTSA proposes denying the request to allow tether routing over adjustable or removable head restraints to meet the tether anchorage location requirements. NHTSA is also proposing to make several technical corrections, and clarify certain test procedures.

DATES: Comments must be received by September 3, 2026.

Proposed Compliance Dates: NHTSA proposes adopting a 4-year phase-in period to comply with the updated requirements in FMVSS No. 225 and proposes extending the lead time for small-volume manufacturers to comply fully with the updated requirements by the end of the proposed phase-in period. The agency also proposes extending the sunset date of the tether anchorage exclusions for convertibles by two years. NHTSA proposes to permit early compliance.

ADDRESSES: You may submit comments to the docket number identified in the heading of this document by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Suite W58–213, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays. To be sure someone is there to help you, please call (202) 366–9826 or (202) 366–9317 before coming.
- *Fax:* 202–493–2251.

Regardless of how you submit your comments, please mention the docket number of this document.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *www.regulations.gov,* or the street address listed above. Follow the online instructions for accessing the dockets.

Confidential Business Information: If you claim that any of the information in your comment (including any additional documents or attachments) constitutes confidential business information within the meaning of 5 U.S.C. 552(b)(4) or is protected from disclosure pursuant to 18 U.S.C. 1905, please see the detailed instructions given under the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Privacy Act: Please see the Privacy Act heading under the Regulatory Analyses section of this document.

FOR FURTHER INFORMATION CONTACT: For technical issues, you may contact Cristina Echemendia, Office of Crashworthiness Standards, at *cristina.echemendia@dot.gov.* For legal issues, you may contact John Piazza, Office of Chief Counsel, at *john.piazza@dot.gov.* You can reach these officials by phone at 202–366–1810. Address: National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue, SE, West Building, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
II. Petitions for Reconsideration and NHTSA's Response
  a. Extend 3-Year Phase-In to 4-Year Phase-In
  b. Extend Lead Time and Phase-In for Small Volume Manufacturers
  c. Extend the Sunset Date of Tether Anchorage Exemption for Convertible Vehicles
  d. Allow Tether Strap Routing Over Adjustable or Removable Head Restraints To Meet New Tether Anchor Location Requirement
  e. Extend Permissible Vertical Measurement To Locate Lower Anchorage Markings
  f. Clarify Test Procedure to Position Clearance Angle Tool in Some Vehicles
III. Corrections and Clarifications to Regulatory Text
  a. Figure Reference in S6.2.2 of FMVSS No. 225
  b. Test Procedure To Position Anchorage Depth Tool in FMVSS No. 225
  c. Compliance Date in S5.9(c) of FMVSS No. 213b
  d. Location of Tether Marking for Flexible Tether Anchorages That Are Also Routing Devices
  e. Force Direction S11(a)(1) and (2)
  f. 49 CFR 585.140 Reporting Requirements for Vehicles Produced by More Than One Manufacturer
  g. Clarification of Length Measurement of Tether Hardware Assemblies
IV. Costs and Benefits
V. Proposed Compliance Dates
VI. Regulatory Analyses and Notices

I. Background

On January 7, 2025, NHTSA published a final rule (90 FR 1288) amending FMVSS No. 225, ''Child restraint anchorage systems,'' to improve ease-of-use of the lower and tether anchorages and improve correct use of child restraint systems in motor vehicles.

NHTSA's regulations allow any interested person to petition the Administrator for reconsideration of a rule.[1] Under NHTSA's regulations, petitions for reconsideration must provide an explanation why compliance with the rule is not practicable, is unreasonable, or is not in the public interest. Petitions must be received within 45 days of the publication of the final rule. The Administrator may, consistent with 5 U.S.C. 553, issue a final decision on reconsideration without further proceedings or may provide opportunity for comment.

NHTSA received petitions for reconsideration of the January 7, 2025 final rule from Alliance for Automotive Innovation (Alliance) and Mercedes-Benz Research & Development North America, Inc (Mercedes-Benz).[2]

In this notice of proposed rulemaking (NPRM), NHTSA proposes granting Mercedes-Benz's request to change the 3-year phase-in period to a 4-year phase-in period and granting Alliance's requests to amend the phase-in schedule for small volume manufacturers [3] and to extend the sunset of the tether anchorage exemption for convertibles by 2 years. NHTSA proposes denying Mercedes-Benz's requests to allow tether routing over adjustable or removable head restraints to meet the new tether location requirement and to extend the permissible vertical transverse plane measurement to locate lower anchorage markings. The agency is also proposing minor technical corrections to the regulatory text and is providing clarification on the use of the clearance angle tool requested by Mercedes-Benz.

NHTSA seeks comment on all aspects of this NPRM.

II. Petitions for Reconsideration and NHTSA's Response

a. Extend 3-Year Phase-In to 4-Year Phase-In

The January 7, 2025 final rule established a three-year phase-in

[1] 49 CFR 553.35, 553.37.

[2] Petitions are docketed at: *https://www.regulations.gov/docket/NHTSA-2024-0089/document.*

[3] Small Volume Manufacturers are those that produce fewer than 5,000 vehicles annually for sale in the United States.

schedule to comply with the updated FMVSS No. 225 requirements, as follows: 20 percent of applicable vehicles produced from September 1, 2028 to August 31, 2029, 50 percent from September 1, 2029 to August 31, 2030, and 100 percent beginning September 1, 2030. Mercedes-Benz petitioned the agency to change the three-year phase-in schedule to a four-year phase-in schedule to meet the updated requirements in FMVSS No. 225. In support of its petition, Mercedes-Benz stated that a four-year phase-in schedule ''would lessen the burden for manufacturers to redesign the body-in-white and seat structure for vehicles currently in mid-life cycle.'' [4]

Based on information provided by Mercedes-Benz, NHTSA tentatively concludes that to meet the updated FMVSS No. 225 requirements, several vehicle models would require structural redesign in mid-life cycle. This would involve an iterative process for redesigning structural components of the vehicle and seats, and the seat foam, and validating the design to the updated requirements. Changes to the structural and seat foam design would also necessitate changes to production tooling that could add to manufacturing delays. All of this involves non-trivial lead time, and this challenge is magnified when the changes occur off-cycle.

Accordingly, NHTSA proposes extending the phase-in schedule from a three-year phase-in to a four-year phase-in as requested by Mercedes-Benz. This extension would ease the burden of redesigning vehicles by reducing costs and providing additional time to plan and implement the necessary changes to the affected vehicles. This additional phase-in year would reduce potential tooling costs by allowing manufacturers the opportunity to make required changes to subject vehicles during their regular design update cycles. The proposed phase-in schedule to comply with the FMVSS No. 225 updated requirements, which is in accordance with the petitioner's request, is as follows:

- 20 percent of applicable vehicles produced from September 1, 2028 to August 31, 2029;
- 50 percent from September 1, 2029 to August 31, 2030;
- 75 percent from September 1, 2030 to August 31, 2031; and
- 100 percent of applicable vehicles on and after September 1, 2031.

NHTSA explained in the January 2025 final rule that the intent of the phase-in schedule was to provide sufficient time for vehicle manufacturers to accommodate significant vehicle system changes into manufacturers' normal course of vehicle redesign. Providing an additional year to the phase-in schedule would allow manufacturers to meet the requirements of this final rule with minimal cost impacts consistent with the intent of the January 2025 final rule.

b. Extend Lead Time and Phase-In for Small Volume Manufacturers

Alliance petitioned NHTSA to provide additional lead time for small volume manufacturers (SVM) [5] to comply with the updated requirements. Specifically, Alliance's petition asked that the phase-in schedule for SVMs be removed and replaced with 100% compliance by September 1, 2030 to minimize additional manufacturing costs.

Alliance stated the additional lead time is necessary to address the regulatory burden unique to SVMs, explaining that because of their small volume and unique product lifecycles, SVMs encounter more planning constraints and do not benefit from phase-in schedules like larger vehicle manufacturers may. In support of its petition, Alliance explained that modifications to the seating system, the overall vehicle architecture, or both will be necessary to meet the new requirements. Alliance stated that SVMs typically do not have a larger parent company that can benefit from base-vehicle platforms shared across multiple models or brands to spread overall development and manufacturing costs. Alliance added that given lower sales volumes, the relative investment to redesign SVM vehicles is often more substantial per model line compared to larger vehicle manufacturers. Further, Alliance stated that financial capital and human resource constraints for SVMs are often very different from those of large volume vehicle manufacturers.

NHTSA proposes granting Alliance's request to extend the lead time for SVMs. The agency understands that SVMs might need more time to make vehicle design changes and that such changes may trigger added costs due to SVMs' longer design cycles. Given the unique design cycles of SVMs, NHTSA is proposing to eliminate the phase-in period to meet the updated requirements in FMVSS No. 225 and instead require SVMs to comply by the proposed compliance date. The petitioner requested September 1, 2030 as the compliance date for SVMs, but because the agency is proposing to grant Mercedes-Benz's request and extend the phase-in period for non-SVMs by one year (to 2031), NHTSA is proposing September 1, 2031 as the compliance date for SVMs, with no phase-in.

This proposal is consistent with the general lead time concerns addressed in the January 7, 2025 final rule, which acknowledged that design changes such as body structure reinforcement and re-design, changes to the seat and anchorages, and in some cases development of new attachment schemes would be necessary for production vehicles to meet the updated requirements. Specifically, NHTSA extended the lead time in the final rule to provide sufficient time for vehicle manufacturers to accommodate any vehicle system changes into manufacturers' normal course of vehicle redesign while also mitigating cost impacts.

c. Extend the Sunset Date of Tether Anchorage Exemption for Convertible Vehicles

The FMVSS No. 225 standard established in 1999 excluded convertibles from having to provide tether anchorages in rear seating positions.[6] This exclusion was created in response to comments to the 1997 NPRM,[7] where GM and Mitsubishi stated that vehicle manufacturers have technical problems installing tether anchorages in convertibles because the vehicles have folding roofs, a stowage area behind the seat back for the top and its mechanism, and less rear seat space. NHTSA agreed that many convertibles could have design problems and determined that it could not at that time readily separate those convertibles from those without technical problems.

The 2015 NPRM requested comments on the feasibility of installing tether anchorages in convertibles because several convertible vehicle models in the market have demonstrated that they can accommodate tether anchorages.[8] Specifically, the agency found that among 35 convertible vehicle models from the 2013 vehicle fleet, 10 were equipped with lower anchorages and tether anchorage in two rear designated seating positions (DSPs), 14 were equipped with only the lower

[4] Mercedes-Benz used the term ''body-in-white'' in their petition. This is an automotive and manufacturing term that in general means the bare structural skeleton of a vehicle. More formally, Body-in-White (BIW) refers to the stage where a car's sheet metal components (like the frame, roof, and side panels) have been welded together but have not yet been painted or fitted with parts like the engine, suspension, seats, electronics, or bumpers.

[5] Per Alliance's description, SVMs sell fewer than 5,000 vehicles per year in the United States.

[6] 64 FR 10786 (Mar. 5, 1999).

[7] 62 FR 7858 (Feb. 20, 1997).

[8] 80 FR 3744 (Jan. 23, 2015).

anchorages at two rear DSPs, and 11 were not equipped with any anchorages. The 2025 final rule established that convertibles manufactured after September 1, 2031 would be required to be equipped with tether anchorages.

Alliance petitioned the agency to extend the sunset date of the tether anchorage exclusions for convertibles from September 1, 2031 to September 1, 2033. Alliance explained that the design changes for convertible vehicles often occur after the architecture for coupe models has been established, causing these models to follow a longer design cycle, and requiring additional time to minimize the burden of modifying an already developed vehicle architecture. Alliance added that the implementation of the top tether anchorage is challenging because of the unique design of convertible models, which is more complex than coupe variants because of the roof mechanism and the low clearance available to install the anchorage.

NHTSA proposes to grant Alliance's request to extend the sunset date of the tether anchorage exclusions to September 1, 2033. The agency understands that convertibles may present unique design challenges and that these models might follow longer design cycles. NHTSA tentatively concludes that extending the sunset date for the exemption for convertibles will help accomplish the final rule's intent of increasing tether availability while also minimizing costs. NHTSA requests comment on the proposal for a two-year extension of the sunset date of the exemption for convertibles from tether anchorage requirements.

NHTSA also proposes to extend the sunset date of the exception for lower anchorages in rear designated seating positions where interference with the transmission or suspension components prevent the location of the lower anchorages anywhere in the specified zones in S5.1(e) of FMVSS No. 225. This provision mostly affects convertible vehicles and aligning the sunset dates for the exception of both the tether anchorages and the lower anchorages in convertibles will help streamline the design development of child restraint anchorage systems in these vehicles.

d. Allow Tether Strap Routing Over Adjustable or Removable Head Restraints To Meet New Tether Anchor Location Requirement

The 2025 final rule adopted a new requirement for DSPs with either adjustable, removable, or no head restraint to locate the tether anchorage outside a specified zone. This zone is defined by a 325-millimeter (mm) radius sphere centered on the R-point [9] and horizontally truncated 230 mm below the sphere's center. This measurement was adopted to ensure sufficient space exists between the tether anchorage and the tether attachment on the child restraint for a caregiver to tighten the tether strap. The 2025 final rule excluded DSPs with fixed head restraints from the tether anchorage location requirements specified by the 325-mm sphere centered on the R-point. This exclusion was made because DSPs with fixed head restraints require the tether to be routed over the fixed head restraint. This extended tether routing length provides sufficient space to effectively tighten the tether strap. In addition, because there is no interference of fixed head restraints during tether routing and tightening, the zone where tether anchorages cannot be located, defined by the 325-mm radius sphere, is unnecessary for DSPs with fixed head restraints.

Mercedes-Benz petitioned NHTSA to allow for tether strap routing over adjustable or removable head restraints if such tether strap routing meets the required minimum wraparound distance of 325 mm from R-Point to the tether anchorage location.[10] Mercedes-Benz stated that the tether strap routing over adjustable or removable head restraints ''should be included and described in the Operator's Manual.'' Mercedes-Benz argued that this belt length is sufficient and allows for easy tether fixation but is not currently permitted in the final rule. In support of its request, Mercedes-Benz stated, in a meeting with NHTSA,[11] that NHTSA's own research indicates that routing the tether under or over an adjustable head restraint did not have an effect on head excursion. Mercedes-Benz added that to meet the new tether anchorage location requirements, Mercedes-Benz's body-in-white and seat structures must be redesigned to move the tether anchorage rearward by 75 mm.[12] Mercedes-Benz explained their current design includes structural reinforcements for this anchorage and that redesigning this area will incur significant time and development costs.

On July 25, 2025, NHTSA received a joint letter from Volkswagen Group of America (Volkswagen) and Porsche Cars North America (Porsche) in support of Mercedes-Benz's petition for reconsideration to allow tether strap routing over adjustable head restraints if such tether strap routing meets a required minimum wraparound distance of 325 millimeters from R-point to the tether anchor location.[13] Volkswagen and Porsche also requested that the 325-millimeter radius sphere, with its center at the R-point, that is used for establishing a zone where tether anchorages cannot be located, be truncated 155 millimeters below the sphere's center instead of the current 230 millimeters below the sphere's center. Volkswagen and Porsche noted that this modification to the final rule regulatory text would permit tether anchorage locations in current sport utility vehicles (SUVs) that otherwise would be prohibited by the January 7, 2025 final rule. Volkswagen and Porsche also noted that the tether anchorages at their current location in SUVs have not hindered attaching and tightening the tether.

NHTSA has tentatively decided to deny Mercedes-Benz's request to allow routing the tether strap over adjustable or removable head restraints. The January 7, 2025 final rule already considered and responded to comments raising concerns that relocating tether anchorages might require tooling and manufacturing changes. In response to these comments, the agency provided an extended lead time followed by a phase-in period to comply with the updated requirements so that those changes could be made during regular vehicle design updates to mitigate cost.

The NHTSA-funded research that Mercedes-Benz referred to in the July 23, 2025 meeting is a study conducted by the University of Michigan Transportation Research Institute (UMTRI).[14] The results of this study suggest that there is not a particular method of routing the tether that provides the greatest safety benefit in terms of reduced head excursion.

[9] R-point refers to the shoulder reference point, which is a location for evaluating occupant restraint systems, seat design, and compliance with safety standards. The ISO Standard 6549, titled ''Road vehicles—Procedure for H- and R-point determination'' specifies the use of a three-dimensional manikin, known as an H-point (hip point) machine, to physically measure several reference points in a vehicle seat.

[10] Mercedes provided an illustration in its petition (Figure 1). The petition can be found here: *https://www.regulations.gov/document/NHTSA-2024-0089-0007*.

[11] A memorandum summarizing NHTSA's July 23, 2025 meeting with Mercedes-Benz is in the docket, NHTSA–2025–0051 that can be accessed on *www.regulations.gov*.

[12] Mercedes provided illustration in their petition (Figure 2).

[13] Volkswagen and Porsche letter is in the docket for this final rule at NHTSA–2025–0051.

[14] Klinich, K.D., Manary, M.A., & Orton, N.R. (2017, December). Effect of tether routing and anchor location on child restraint kinematics (Report No. DOT HS 812 467) Washington, DC National Highway Traffic Safety Administration (*available at https://deepblue.lib.umich.edu/bitstream/handle/2027.42/149101/UMTRI-2013-27.pdf?sequence=1&isAllowed=y*).

Rather, the lowest head excursions were associated with routing and tether locations that involved the shortest amount of tether webbing between the tether anchor and the attachment point on the child restraint, provided the tether could be adequately tightened. UMTRI noted in another NHTSA-funded study, however, that tether routing over the head restraint could result in the tether slipping to the side of the head restraint in oblique and side impact crashes, resulting in greater head excursions.[15]

The current best practice followed by child passenger safety technicians is to route the tether strap under adjustable head restraints or to remove the head restraint for practical and safety considerations.[16] Most manufacturers, including Mercedes-Benz, Volkswagen, and Porsche, currently recommend in their owner's manual to route the tether under adjustable head restraint or to remove the head restraint.

The January 2025 final rule explained that because some head restraints that protrude or tilt to the front could interfere with the installation of some CRS models, it is typically advised to remove or move the head restraint to a higher position to eliminate this interference. If the vehicle was designed to meet the tether location requirement while routing the tether over the head restraint and the head restraint is removed because of CRS-head restraint interference, it is possible that the tether anchorage would not be at a sufficient distance from the back of the CRS that would permit tightening the tether. As explained in the final rule, NHTSA determined that because adjustable or removable head restraints are likely to be used with a tether routed under the head restraint, it is important to have the tether anchorage beyond the 325 mm truncated sphere from the R-point to ensure tethers can be tightened easily. Routing the tether over a head restraint placed in its highest position to avoid interference with a child restraint would increase the tether strap length resulting in higher head excursions and a greater risk of head injuries.

Another safety concern with routing the tether over a head restraint placed in a high position to avoid interference with a child restraint is that there are no strength requirements for the head restraint to withstand tether loads; therefore, the head restraint may not remain sufficiently fixed in position relative to the seat back. The head restraint might shift to a lower position or separate from the seat back, resulting in tether slack and higher head excursions.

For these reasons, which were discussed generally in the January 2025 final rule, NHTSA has decided tentatively to deny Mercedes-Benz's request to allow tether routing over adjustable/removable head restraints to meet the tether location requirement.

NHTSA also does not propose, as requested by Volkswagen and Porsche, to truncate the 325-millimeter sphere at 155 millimeters below the center of the sphere to continue to permit tether anchorage locations in the seatbacks of their current SUVs. Volkswagen and Porsche did not provide specific data showing that this allowance in the location of the tether anchorages would allow tightening the tether of child restraints in a variety of vehicle designs. In a NHTSA-funded study, UMTRI evaluated nine vehicle models with tether anchorages located on the seatback and found that seven of these vehicles (78 percent) met the January 2025 final rule specifications for tether anchorage location.[17] The remaining two vehicles needed only minor modifications (one to two centimeters) to the tether anchorage location on the seat back to meet the January 2025 final rule specifications. If the 325-millimeter sphere, truncated at 155 millimeters below the center of the sphere was applied to these two vehicles, and the tether anchorage was placed at the outside edge of this boundary, the tether anchorage would be too close to the head restraint (less than 165 mm) and would likely be difficult to tighten. Therefore, NHTSA concludes tentatively that Volkswagen and Porsche's requested modification to the allowable location zone for the tether anchorages would not ensure that the tether strap of child restraints can be sufficiently tightened in all vehicles.

The January 7, 2025 final rule specifications for allowable tether anchorage locations using the 325 millimeter sphere centered at the R-point of the seat and truncated 230 millimeters below the R-point harmonize with the requirements in the Australian Design Rule 34/02 ''Child Restraint Anchorages and Child Restraint Anchor Fittings.'' [18] The January 2025 final rule tether anchorage location requirements were designed to prevent possible conflicts with the June 2016 Insurance Institute for Highway Safety (IIHS) Vehicle LATCH Hardware Evaluation Rating Guidelines [19] such that tether anchorages located on the seatback that meet the January 2025 final rule requirements could also obtain higher IIHS scores.

Based on the diagrams presented in the Volkswagen-Porsche letter, the tether anchor location on the seatback would need only minor adjustments to meet the January 2025 final rule specifications for tether anchorage location. NHTSA concludes tentatively the additional one-year phase-in period would allow the manufacturers to make any needed vehicle changes within their normal design cycle to meet the tether anchorage location requirements specified in the January 7, 2025 final rule.

e. Extend Permissible Vertical Measurement To Locate Lower Anchorage Markings

Before the January 2025 final rule, FMVSS No. 225 required lower anchors that are not visible to be marked with a circle that is not less than 13 mm in diameter located on the seatback area at a vertical distance between 50 and 100 mm above the anchorage or on the seat cushion at a horizontal distance 100 ±25 mm forward of the anchorage. This is illustrated in figure 22 of FMVSS No. 225.

The January 2025 final rule updated the requirements for lower anchor markings and their location. The final rule required all lower anchorages to be marked, regardless of whether they are visible, with a circle not less than 13 mm in diameter displaying the International Standards Organization (ISO) lower anchorage symbol (figure 24 of FMVSS No. 225). The final rule also expanded the permissible location of the marking on the seat cushion to

[15] Klinich, K.D., Boyle, K., Orton, N.R., Manary, M.A., & Ebert, S. (2016, January). *Investigation of clearance criterion between tether anchor and head restraint.* Ann Arbor: University of Michigan Transportation Research Institute. Report will be docketed alongside this final rule (*available at https://www.regulations.gov/document/NHTSA-2024-0089-0002*) (*citing* Hauschild, H.W., Humm, J.R., Pintar, F.A., Yoganandan, N., Kaufman, B., Kim, J., Maltese, M.R., Arbogast, K.B. (2016). Protection of children in forward-facing child restraint systems during oblique side impact sled tests: Intrusion and tether effects. Traffic Injury Prevention, available at *https://www.tandfonline.com/doi/full/10.1080/15389588.2016.1194982*).

[16] Child passenger safety technician guide: *https://cdn.nsc.org/cpsboard/technician_guide_final.pdf.*

[17] Klinich, K.D., Boyle, K., Orton, N.R., Manary, M.A., & Ebert, S. (2016, January). *Investigation of clearance criterion between tether anchor and head restraint.* Ann Arbor: University of Michigan Transportation Research Institute. The report has been placed in the docket for this final rule and is also available at *https://www.regulations.gov/document/NHTSA-2024-0089-0002.*

[18] *https://www.legislation.gov.au/F2012L00703/latest/text.*

[19] See *https://www.iihs.org/media/8f828313-d122-4d27-a3b0-f2b8ec60065d/tQhxoA/Ratings/Protocols/archive/LATCH_rating_guidelines_0616.pdf.*

accommodate seat contours where the marking can be visible when positioned behind the lower anchor. Specifically, the final rule specified that, if the manufacturer chooses to locate the marking on the seat cushion, it must be placed at a horizontal distance between 100 mm forward and 50 mm rearward of the horizontal centerline of the lower anchorage bar. The final rule did not change the location requirements for markings placed on the seatback. The final rule placed an illustration of the updated marking location requirements in Figure 19 of the standard.[20] The final rule placed the current requirements in S9.5.1 and the updated requirements in S9.5.2.

Mercedes-Benz requested that NHTSA extend the permissible Vertical Transverse Plane (the ''a'' measurement in Figure 19 of the standard, reproduced in Figure 1 below) to locate the lower anchorage marking symbol on the seat back of the vehicle from the specified 50 to 100 mm range to a range from negative 50 to 100 mm. Mercedes-Benz stated that this change would allow the markings to be located on the molded anchorage rod fixture while still being easily visible to CRS installers.[21]

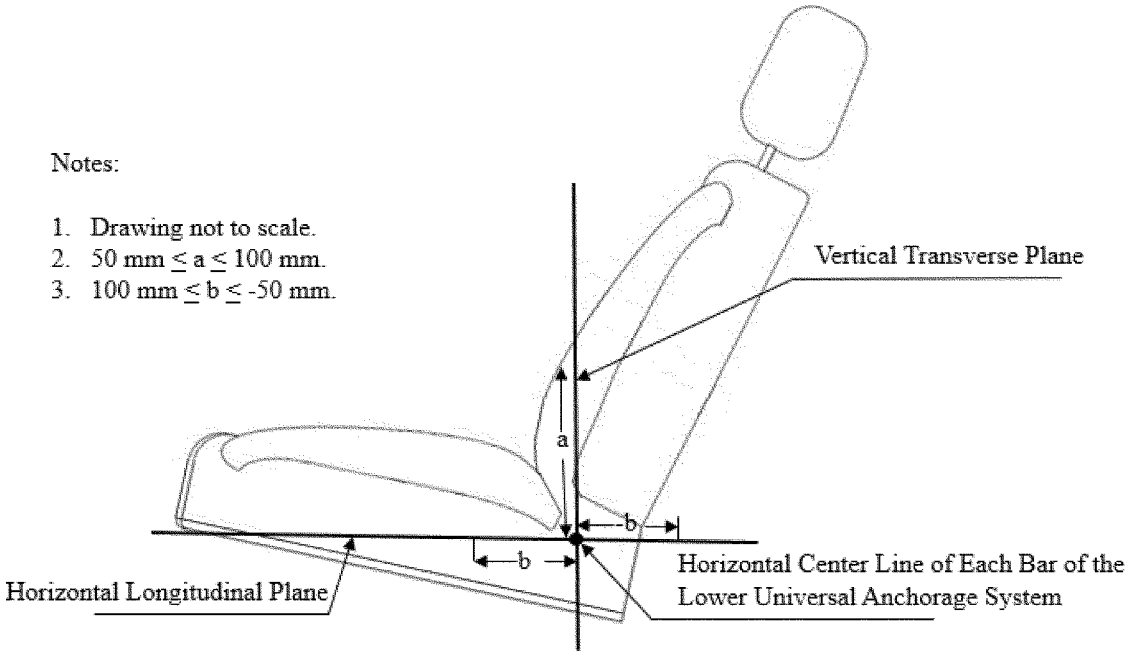


Figure 1. Placement of Symbol on the Seat Back and Seat Cushion of Vehicle (current Fig. 19 in FMVSS No. 225)

NHTSA is denying Mercedes' request as unnecessary. In the June 27, 2003 final rule that is the source of the current requirements in S9.5.1,[22] the agency changed the original requirement, which consisted of only a vertical placement distance for the marking (seat back), to one that also allowed a horizontal placement for the marking on the seat pan. The 2003 final rule implemented this change in response to comments from Mitsubishi and the Alliance, who asked where the ''seat back'' begins for the purpose of marking the lower anchorages on highly contoured seats. Specifically, Mitsubishi stated that the bottom cushion of some of its seats curves toward the vertical and supports a portion of an occupant's lower back before a separate seat back begins. To address this issue, the 2003 final rule adopted the location requirements from Transport Canada Regulation 210.2, ''Lower Universal Anchorage Systems for Restraint Systems and Booster Cushions,'' which had vertical (seat back) and horizontal (seat pan) allowable locations for the marking. In support of this decision, the agency explained that these location requirements provide greater clarity in relation to where the markings should be while also permitting the markings to be located either on the seat back or the seat cushion, and thus allowing more flexibility to manufacturers with atypical seat designs.

Though NHTSA changed some of the allowable distances for the markings in the January 7, 2025 final rule, the intent of the 2003 final rule was maintained. The 2025 final rule continues to permit markings to be placed on the seat back or the seat pan. The different allowable distances already provided by the final rule should provide flexibility to manufacturers with atypical seat designs in relation to where to place the lower anchorage markings. In the example Mercedes-Benz provided in its petition, the marking would be within the allowable seat pan ''b'' locations. Therefore, NHTSA denies Mercedes-

[20] Prior to the 2025 final rule, figure 19 contained an illustration of an optional tether anchorage test applicable for vehicles manufactured before 2004. This figure is no longer applicable to currently manufactured vehicles and was replaced with the illustration of the location of lower anchorage markings.

[21] Mercedes provided illustration in their petition (Figure 4). The petition can be found here: *https://www.regulations.gov/document/NHTSA-2024-0089-0007.*

[22] 68 FR 38208.

Benz's request to change the seat back ''a'' distance. In support of this decision, NHTSA notes that for atypical seats with an extra bolster in the seat bight region (the area where a seat cushion intersects with the seatback) that helps transition the seat pan to the seat back, the bolster may be considered as part of the seat back or seat pan location to locate the marking within the ''a'' or ''b'' locations illustrated in Figure 19 of FMVSS No. 225.

In light of the request from Mercedes, NHTSA proposes to modify the regulatory text for both the current requirements (S9.5.1(a)(3)) and the updated requirements (S9.5.2(a)(3)) to clarify the permissible marking locations. NHTSA is also proposing to amend Figure 19 to FMVSS No. 225 so that the ''b'' measurement is specified as a continuous interval (Figure 2) instead of broken into positive and negative segments (Figure 1).

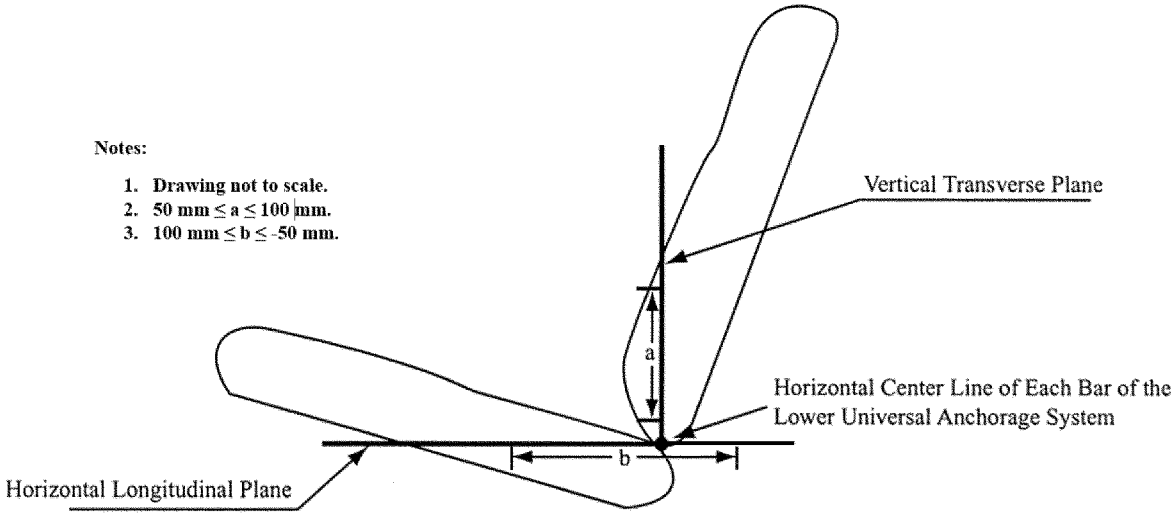


Figure 2. Corrected Placement of Symbol on the Seat Back and Seat Cushion of Vehicle (the proposed revision of Figure 19 in FMVSS No. 225)

f. Clarify Test Procedure to Position Clearance Angle Tool in Some Vehicles

A 2012 LATCH Usability study performed by UMTRI identified three vehicle lower anchorage hardware characteristics serving as predictors for correct CRS use, which include anchorage depth, anchorage attachment force, and anchorage clearance angle.[23] Anchorage depth refers to how deeply the lower anchorages are embedded in the vehicle seat (usually in the seat bight or seatback). Attachment force refers to the force needed to attach a child restraint's lower anchorage connector to a lower anchorage in a vehicle. Clearance angle refers to the clearance around a lower anchorage from parts that interfere with the ability to maneuver the CRS lower anchorage connector. UMTRI showed that subjects were 19 times more likely to install the CRS correctly if the vehicle met all three usability criteria than if none of the criteria were met.

Based on this study, NHTSA proposed in the 2015 NPRM[24] to adopt the three characteristics measured by three different tools per the following:

- *Attachment force:* Less than 178 N (40 lb).
- *Clearance Angle:* Greater than 54 degrees when applying a 66.7 N (15 lb) vertical force to the tool.
- *Anchorage Depth:* Less than 2 cm.

Commenters to the 2015 NPRM expressed concerns on the repeatability of the usability measurements. NHTSA conducted repeatability and reproducibility studies where the proposed tools were updated to ensure better repeatability. Results of the studies and tool updates showed that the clearance angle and anchorage depth measurements were repeatable, but the attachment force measurement was not repeatable. Therefore, the 2025 final rule adopted only the clearance angle and anchorage depth measurements into FMVSS No. 225.

One of the repeatability improvements developed for the 2025 final rule clearance angle tool was adding a pulley bridge to position a weight that would apply a constant 66.7 N (15 lb) vertical force, as commenters were concerned about the difficulty of applying manually and keeping a constant vertical force to make the clearance angle measurement.

Mercedes-Benz petitioned NHTSA to ''evaluate the Clearance Angle Tool (CAT) in a smaller two-door sport/coupe vehicle.'' Mercedes-Benz explained that it is not clear from the final rule how the ''pulley bridge'' should be placed in vehicles with integrated headrests on the front and rear seat.[25] In addition to its CAT concerns, Mercedes-Benz petitioned NHTSA to allow the use of the IIHS Clearance Angle Tool.

NHTSA acknowledges that the regulatory text in FMVSS No. 225 does not specify how to position the pulley bridge of the clearance angle tool on the vehicle. However, NHTSA's research test procedure[26] describes how to position the pulley bridge as follows:

[23] Klinich et al., ''LATCH Usability in Vehicles,'' UMTRI–2012–7, April 2012. Link: *https://deepblue.lib.umich.edu/handle/2027.42/90856.*

[24] 80 FR 3744 (Jan. 23, 2015).

[25] Mercedes provided an illustration in its petition (Figure 5).

[26] The VRTC Test Procedure can be found in Appendix D–1 of docketed technical report titled ''Evaluation of LATCH Usability Tools Update:''

Continued

Place the pulley bridge so it rests on the tops of the rear and front seatbacks above the lower anchor. Use the leveling feet to position the bridge so it is horizontal within ±5 degrees about its longitudinal axis. If necessary, change the front seatback angle to help level the pulley bridge.

In response to the concerns raised by Mercedes-Benz, NHTSA experimented with other vehicles in which there may be similar difficulty placing the pulley bridge on the rear and front seat backs. NHTSA found that placing a metal bar on the windowsill of the front row windows can help position the pulley bridge on those vehicles where it is not possible to place the pulley bridge on the front seat. This approach showed that, for vehicles with this configuration, the front seat can be moved, removed, or reclined in such a way so as not to interfere with the placement of the pulley bridge. In response to petitioner's concerns and to assist with future testing, NHTSA will docket an updated research test procedure [27] to include information explaining how other vehicle structures and other structures could be used to position the pulley bridge if the front and rear seats cannot be used.

NHTSA is not codifying this step in the regulatory text of FMVSS No. 225 because the agency believes it is more appropriate to include this detailed information in the test procedure to help entities understand how to position the pulley bridge in the required position to make the clearance angle measurement appropriately.

In addition, NHTSA denies Mercedes-Benz's request to align or allow use of the IIHS clearance angle tool for measuring the clearance angle in FMVSS No. 225. The 2015 NPRM proposed using a clearance angle tool based on the IIHS tool and NHTSA received comments expressing concerns about the repeatability and reproducibility of that tool's measurements. Specifically, General Motors stated that it was difficult to apply the vertical force due to interference with the seat back, and Fiat Chrysler Automobiles U.S.[28] commented that an operator would have difficulty maintaining 67 N (15 lbf) of vertical force to make the measurement. As explained in the January 2025 final rule, NHTSA added a pulley bridge (with adjustable feet to make it level) to apply a 67 N (15 lbf) force vertically to remove the difficulty of applying the specified load manually and address concerns raised by commenters.

III. Corrections and Clarifications to Regulatory Text

a. Figure Reference in S6.2.2 of FMVSS No. 225

Paragraph S6.2.2 of the January 7, 2025 final rule regulatory text referenced Figure 3 regarding the allowable tether anchorage zone under the vehicle seat, which is defined by a ''vertical plane 120 mm rearward of the H Point.'' However, Figure 3 in the standard shows the allowable tether anchorage location zone before the January 7, 2025 amendments and is not relevant to the updated allowable tether anchorage zone under the vehicle seat. The agency proposes to correct the figure reference in S6.2.2 to Figure 10, which shows the updated tether anchorage location zone and shows the new allowable tether zone under the vehicle seat.

b. Test Procedure to Position Anchorage Depth Tool in FMVSS No. 225

Paragraph S11(c) of FMVSS No. 225 describes the test procedure to measure the anchorage depth with the depth tool. However, this section lacks clarity on determining the view angles and positioning of the depth tool on the seat pan (see Figure 3). The research test procedure docketed [29] along with the 2025 final rule details the procedure with the desired clarity. Accordingly, NHTSA proposes to amend S11(c) of FMVSS No. 225 to align with this research test procedure.

Specifically, NHTSA proposes changing the sentence ''To measure the anchorage depth, subtract 30 degrees from the measured seat pan angle to calculate the view angle.'' to ''To measure the anchorage depth, the tool view angle is determined by subtracting the measured seat pan angle from 30 degrees.'' NHTSA also proposes changing the sentence ''Adjust the depth tool base to be within ±2 degrees of the view angle (30 degrees minus seat pan angle) to set the tool-parallel to the seat pan angle.'' to ''Adjust the depth tool base to be parallel with the seat pan angle (within ±2 degrees) while maintaining the established tool view angle (30 degrees minus seat pan angle).''

https://downloads.regulations.gov/NHTSA-2024-0089-0002/attachment_5.pdf.

[27] The research test procedures are used for research testing and inform the laboratory test procedure developed for compliance testing. To investigate whether specific vehicles or products comply with the FMVSS, NHTSA's Office of Vehicle Safety Compliance (OVSC) contracts with labs to conduct compliance testing. OVSC laboratory test procedures are prepared for the limited purpose of use by contracted independent laboratories conducting compliance tests for the OVSC. OVSC laboratory test procedures are based generally on the regulatory test procedures in specific FMVSS but are prepared by the agency to give contracted labs specific instructions on how to conduct a specific test. The OVSC laboratory test procedures are simply agency guidance for contracted labs and do not constitute official agency action (*e.g.,* a rule). Compliance test procedures may differ from the research test procedures.

[28] FCA merged with French PSA Group to form Stellantis in 2021.

[29] Appendix D of the ''Evaluation of LATCH Usability Tools Update'' report (*available at https://downloads.regulations.gov/NHTSA-2024-0089-0002/attachment_5.pdf*).

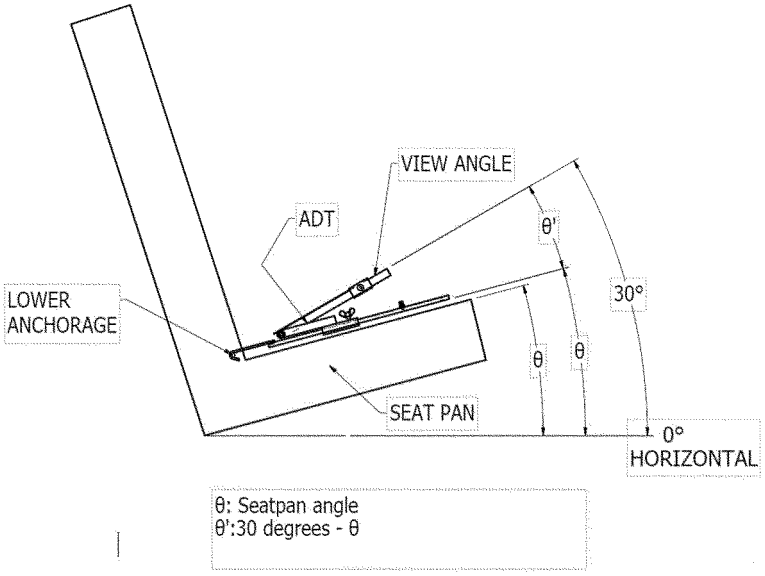


Figure 3. Anchorage Depth Angle Set Up

c. Compliance Date in S5.9(c) of FMVSS No. 213b

NHTSA proposes correcting the compliance date indicated in S5.9 (c) of FMVSS No. 213b. Currently the date for the new requirements for tether hardware assembly to have a maximum length indicates a compliance date of January 8, 2025. On March 3, 2025, the agency issued a final rule specifying a 3-year lead time for several requirements adopted in the January 7, 2025 final rule. However, this correction indicated a January 8, 2025 compliance date in S5.9(c) by mistake, when it should state January 8, 2028 to match the corrections made to other sections in FMVSS No. 213b. The agency is proposing to correct paragraph 5.9(c) to state a January 8, 2028 compliance date.

d. Location of Tether Marking for Flexible Tether Anchorages That Are Also Routing Devices

The 2025 final rule amended FMVSS No. 225 to require all vehicles to bear the ISO standardized marking near all tether anchorages provided in the vehicle to improve the ease with which consumers find lower anchorages and tether anchorages in the vehicle.

NHTSA also adopted requirements for the tether markings to be no more than 100 mm away from the tether anchorage. For vehicles with tether strap routing devices, NHTSA permits placing the required tether anchorage marking on a tag attached to the tether strap routing device.

The January 7, 2025 final rule specified location requirements for the tether anchorage markings such that they are aligned and within 100 mm from the tether anchorage (S6.4 of FMVSS No. 225). While S6.4 section offers the option of using tags to mark tether strap routing devices,[30] the regulatory text does not specify the location of the markings with respect to a flexible tether strap routing device that can be used as tether anchorages. The agency proposes correcting this omission by specifying the location of the marking with respect to the routing device that is consistent with the required location of the markings with respect to a rigid tether anchorage bar. The maximum distance of the marking from the routing device would remain the same as that from a rigid anchor (not more than 100 mm); however, the reference point on the routing device to measure the maximum distance of the marking is the intersection of the longitudinal [31] and lateral [32] centerline of the attachment of the routing device to the vehicle or vehicle seat in its nominal position,[33] as illustrated in Figure 4 of this preamble. In the case of routing devices that may have multiple attachment points, the center of those attachment points would be the reference to measure the distance to the marking.

[30] A tether routing device is a vehicle component, typically designed as a loop or guide, that redirects the tether strap of a child restraint system (CRS) toward a tether anchorage usually located on an adjacent designated seating position.

[31] Longitudinal means front to back with respect to the designated seating position.

[32] Lateral means side to side with respect to the designated seating position.

[33] By nominal position, is the position the anchorage naturally adopts when it is not being used, pulled, or pushed.

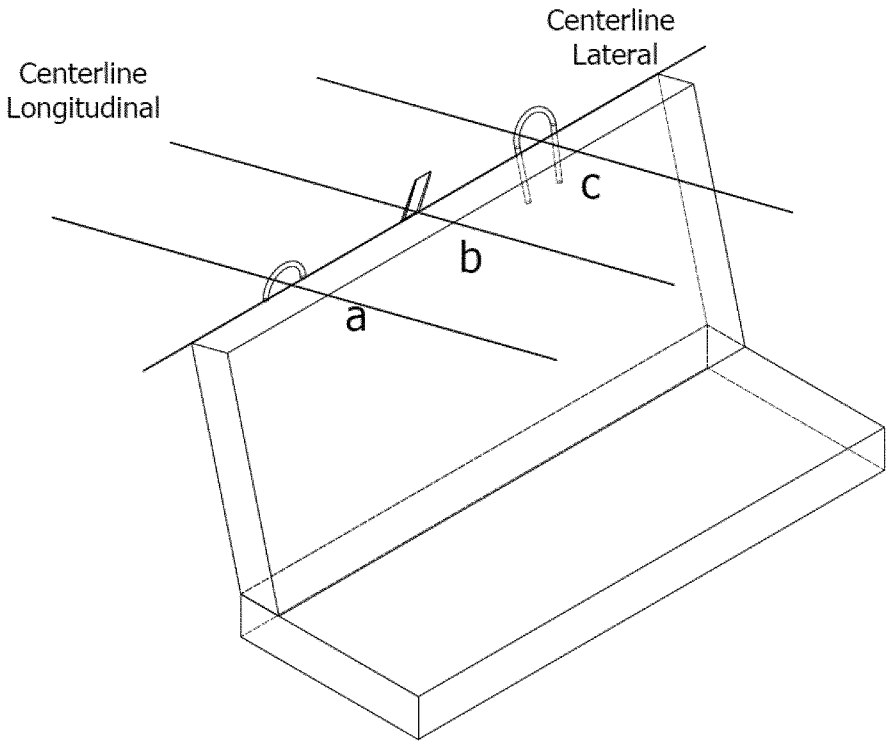


Figure 4. Longitudinal and Lateral Centerline Intersection of Routing Devices

e. Force Direction S11(a)(1) and (2)

Paragraphs S11(a)(1) and (2) of the regulatory text in the January 7, 2025 final rule specify the test procedure for applying forces to the lower anchorages to assess compliance with the strength requirements specified in S9.4.1(a) and (b), respectively. However, additional text introduced in the January 7, 2025 final rule is incorrect because it describes a horizontal preload force in S11(a)(1) and a preload perpendicular to the longitudinal centerline of the SFAD2 at point X of the test device in S11(a)(2). The preload force specified in S9.4.1(a) must be applied with an initial angle of 10 ± 5 degrees above the horizontal as described in S9.4.1.1. Also, the lateral load required in S9.4.1(b) is not perpendicular to the longitudinal plane but at a 75 ± 5 degree angle from the longitudinal plane. The agency proposes to correct the contradictory text in S11(a)(1) and (2) by deleting the added text.

f. 49 CFR 585.140 Reporting Requirements for Vehicles Produced by More Than One Manufacturer

Subpart O of 49 CFR 585 outlines the phase-in reporting requirements for FMVSS No. 225. Paragraph (b)(3) of § 585.140 addresses vehicles manufactured by more than one entity and currently references S13.2.1(c) of FMVSS No. 225. This reference is incorrect. The correct citation is S13.2.2. Accordingly, the agency proposes to amend § 585.140(b)(3) to replace the erroneous reference with the correct citation to S13.2.2.

g. Clarification on the Length Measurement of Tether Hardware Assemblies

NHTSA received a request for interpretation from Britax on October 27, 2025 [34] seeking confirmation of its understanding of the test procedure for evaluating compliance with S5.9(c) of FMVSS No. 213b, which specifies that the length of the child restraint tether hardware assembly (which consists of the tether hook and hardware to tighten and loosen the tether strap) shall not exceed 165 mm.

Britax noted that NHTSA's Laboratory Test Procedure does not specify a measurement method. Britax also noted that its V-shaped tether hardware assembly, which is common in its products, differs from the single-strap tether designs NHTSA studied primarily. Britax stated that because a single strap tether hardware assembly has the adjustment mechanism located along the tether webbing in a fixed location relative to the tether hook, determining compliance with S5.9(c) simply requires measuring the length from the far end of the adjustment mechanism to the end of the tether hook. On the other hand, Britax noted that its V-shaped tether hardware assembly, consisting of a tether hook, two permanent tether strap webbing attachment points on the back of the CRS and a mechanism designed to adjust the tether strap webbing, would not be able to comply with the requirement that the tether hardware assembly length be no more than 165 mm in all adjustment positions if the measurement is made from the adjustment mechanism to the tether hook.

Due to the unique nature of the V-shaped tether hardware assembly with varying distance between the adjustment mechanism and the tether hook, Britax stated that to determine compliance with S5.9(c), it measures the distance from the center of the CRS seat back to the end of the tether hook after the tether strap is tightened. Britax stated that this aligns with NHTSA's stated goal for the 165 mm limit, which

[34] Britax's letter can be found in the docket of this NPRM.

was to ensure all CRS tether straps can be tightened given the minimum tether anchorage distance from the seat back reference point, and that NHTSA was aware of and did not intend to outlaw the Britax design.

NHTSA is responding to Britax's request for interpretation in this NPRM. NHTSA disagrees with part of Britax's suggested measurement procedure—specifically, measuring the distance from the center of the CRS seat back to the end of the tether hook. This is not a correct interpretation of the requirement specified in the regulatory text. The regulatory text states that the length of the tether hardware assembly, which consists of a tether hook and a mechanism designed to tighten and loosen the tether strap, shall not exceed 165 mm. Because Britax's suggested measurement method does not include the adjustment mechanism, it does not conform to the regulatory text. NHTSA is therefore not proposing to include Britax's suggested measurement method in the regulation.

NHTSA, however, does agree with Britax's approach of tightening the tether strap prior to measuring the length of the hardware assembly. NHTSA acknowledges that the original regulatory text did not account clearly for an adjustable tether hardware assembly such as that in Britax's CRSs. NHTSA is therefore proposing two changes to the current regulatory text.

First, NHTSA is proposing to clarify in sections 5.9(b) and (c) of the FMVSS No. 213b what constitutes the tether hardware assembly. The current regulatory text indicates that the tether hardware assembly consists of ''a tether hook and a webbing tightening mechanism designed to tighten or loosen the tether strap.'' The agency is proposing to change this to ''a tether hook and a mechanism designed to tighten and loosen the tether strap, including any material between those components.'' This would more accurately describe the assembly because the CRS tether hardware sometimes has webbing or other materials attaching the tether hook to the tether adjustment mechanism.

Second, NHTSA is proposing to clarify that the length of an adjustable tether hardware assembly will be determined with the tether adjustment hardware as close to the tether hook as possible (''If the tether hardware assembly length is adjustable, its minimum adjusted length shall not exceed 165 mm'').

NHTSA notes that this proposed approach—tightening the tether strap prior to measuring the length of the tether hardware assembly—is the procedure NHTSA used in developing the January 2025 final rule. NHTSA documented in a technical report,[35] submitted to the docket with the January 7, 2025 final rule, the tether hardware measurements NHTSA conducted on several CRSs, including Britax models with V-shaped tethers.[36] All CRSs in that study except for the Britax CRSs had fixed-length tether hardware assemblies. To measure the length of the tether hardware assemblies for Britax's CRSs, NHTSA measured the V-shaped tether hardware assembly length with the tether strap pulled through the adjustment mechanism such that it resulted in the shortest distance possible between the tether hook and the adjustment mechanism, and the measurement was made from the end of the tether hook to the furthest point of the adjustment mechanism. The photographs in the technical report also illustrate the measurement method used for determining the length of the tether hardware assembly. This involved a fixture simulating a vehicle's tether anchorage, with a tape measure alongside it. The CRS tether hook is attached to the fixture's anchor to facilitate the measurement of the tether hardware against the tape measure. NHTSA's Office of Vehicle Safety Compliance is developing an updated laboratory test procedures manual, which may contain similar illustrations of the procedure.

NHTSA anticipates that Britax will be able to comply with the 165 mm requirement when evaluated using this procedure. All three Britax CRSs with V-shaped tether hardware assembly met the 165 mm requirement when evaluated by NHTSA using this method.[37] In addition, Britax, in its comments to the 2015 NPRM,[38] stated that its CRSs would be able to meet the 165 mm tether hardware length requirement.[39]

NHTSA seeks comment on these proposed amendments.

[35] Wietholder, K., & Smith, J. (2019, November). Evaluation of tether anchor zones for FMVSS No. 225 (Report No. DOT HS 812 842). Washington, DC: National Highway Traffic Safety Administration. Appendix B. (See docket NHTSA–2024–0089–0002 in *www.regulations.gov*).

[36] The three Britax child seats evaluated in the report ''Evaluation of Tether Anchor Zones for FMVSS No. 225'' (Boulevard E9LX615, Marathon E9LX11A, and Advocate E9BB9P8) all included a V-shaped tether.

[37] Wietholder, K., & Smith, J. (2019, November). Evaluation of tether anchor zones for FMVSS No. 225 (Report No. DOT HS 812 842). Washington, DC: National Highway Traffic Safety Administration. Appendix B. (See docket NHTSA–2024–0089–0002 in *www.regulations.gov*).

[38] 80 FR 3744.

[39] See Docket NHTSA–2014–0123–0012 in *www.regulations.gov* for Britax comments.

IV. Costs and Benefits

The proposed changes in compliance dates for FMVSS No. 225 would not result in additional costs; FMVSS No. 225 costs for these vehicles will simply be delayed.

NHTSA estimated the total cost of the updated requirements for anchorage markings and written instructions specified in the January 2025 final rule to be $1.73 million. This estimated cost would be delayed by the proposed changes in compliance dates. There may be additional cost savings associated with the proposed delay in the FMVSS No. 225 compliance dates because manufacturers have indicated to the agency that they may incur additional costs when making vehicle changes outside their planned design cycle and an extended compliance date would help reduce those costs.

NHTSA did not quantify benefits resulting from the January 2025 final rule. NHTSA stated only that if the updated requirements in the January 2025 final rule result in a 5 percent increase in correct installation using the lower anchorages and a 5 percent increase in tether use, it would save approximately 3 lives and prevent 6 moderate to higher severity injuries annually. Therefore, any benefits that could be delayed as a result of this proposal are speculative.

V. Proposed Compliance Dates

This NPRM proposes to amend the three-year phase-in period in the January 2025 final rule to a four-year phase in period to comply with the FMVSS No. 225 updated requirements. The proposed four-year phase-in for compliance with the FMVSS No. 225 updated requirements is as follows: 20 percent of applicable vehicles produced from September 1, 2028, to August 31, 2029, 50 percent from September 1, 2029, to August 31, 2030, 75 percent from September 1, 2030, to August 31, 2031 and 100 percent of applicable vehicles on and after September 1, 2031. This NPRM proposes amending the lead time for small-volume manufacturers to comply with the updated requirements in FMVSS No. 225 so that those manufacturers would now need to comply with the updated requirements starting on September 1, 2031.[40] This NPRM also proposes to extend the sunset date of the tether anchorage exclusions for convertibles to September 1, 2033. The rest of the proposed amendments and corrections would have a compliance date corresponding

[40] If the phase-in extension from a 3- to 4-year phase in is not adopted, the compliance date for SVM would be September 1, 2030.

to the compliance date of the section being amended.

VI. Regulatory Analyses and Notices

Executive Order 12866 and Executive Order 14192

NHTSA has considered the impact of this proposal under Executive Order (E.O.) 12866 and E.O. 14192. This rule has been determined to be not significant pursuant to E.O. 12866 and was not reviewed by the Office of Management and Budget (OMB) pursuant to that order.

The proposed update to FMVSS No. 225 is an E.O. 14192 deregulatory action.

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of proposed rulemaking or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations and small governmental jurisdictions), unless the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities. Agencies must also provide a statement of the factual basis for this certification.

I certify that this rulemaking action would not have a significant economic impact on a substantial number of small entities. NHTSA estimates that there are three small light vehicle manufacturers in the U.S. The estimated annual vehicle sales for these three manufacturers range from 25 to 100 vehicles with a sales price range $24,000 to $750,000 and estimated annual revenue between $2 million and $4 million. This proposed rule reduces design and cost burden for these small volume manufacturers by extending the full compliance date to September 1, 2031 without any phase-in.

Federalism

NHTSA has examined this NPRM pursuant to E.O. 13132 (64 FR 43255, Aug. 10, 1999) and concluded that no additional consultation with States, local governments or their representatives is mandated beyond the rulemaking process. The agency has concluded that the rulemaking would not have sufficient federalism implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement. This proposed rule would not have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

NHTSA rules can have preemptive effect in two ways. First, the National Traffic and Motor Vehicle Safety Act contains an express preemption provision stating that, if NHTSA has established a standard for an aspect of motor vehicle or motor vehicle equipment performance, a State may only prescribe or continue in effect a standard for that same aspect of performance if the State standard is identical to the Federal standard.[41] It is this statutory command by Congress that preempts any non-identical State legislative and administrative law addressing the same aspect of performance.

The express preemption provision described above is subject to a savings clause under which ''[c]ompliance with a motor vehicle safety standard prescribed under this chapter does not exempt a person from liability at common law.'' [42] Pursuant to this provision, State common law tort causes of action against motor vehicle manufacturers that might otherwise be preempted by the express preemption provision are generally preserved.

NHTSA rules can also preempt State law if complying with the FMVSS would render the motor vehicle manufacturers liable under State tort law. Because most NHTSA standards established by an FMVSS are minimum standards, a State common law tort cause of action that seeks to impose a higher standard on motor vehicle manufacturers will generally not be preempted. However, if and when such a conflict does exist—for example, when the standard at issue is both a minimum and a maximum standard—the State common law tort cause of action is impliedly preempted.[43]

Pursuant to E.O. 13132, NHTSA has considered whether this proposed rule could or should preempt State common law causes of action. The agency's ability to announce its conclusion regarding the preemptive effect of one of its rules reduces the likelihood that preemption will be an issue in any subsequent tort litigation. To this end, the agency has examined the nature (*e.g.,* the language and structure of the regulatory text) and objectives of this NPRM and finds that this proposed rule, like many NHTSA rules, prescribes only a minimum safety standard. Accordingly, NHTSA does not intend that this proposed rule preempt state tort law that would effectively impose a higher standard on motor vehicle manufacturers than that established by this proposed rule. Establishment of a higher standard by means of State tort law would not conflict with the minimum standard finalized in this document. Without any conflict, there could not be any implied preemption of a State common law tort cause of action.

National Environmental Policy Act

DOT has analyzed the environmental impacts of this notice of proposed rulemaking pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*). NHTSA has determined that this proposed rule is categorically excluded pursuant to 23 CFR 771.118(c)(4). Categorical exclusions (CE) are categories of actions that the agency has determined normally do not significantly affect the quality of the human environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS).[44] In analyzing the applicability of a categorical exclusion, the agency must also consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS.[45] The Department's Operating Administrations (OAs) may apply CEs established in another OA's procedures.[46] To do so, the Operating Administration ''must evaluate the action for extraordinary circumstances identified in the OA procedures in which the CE is established to determine if a normally excluded action may have a significant impact and coordinate with the originating OA to ensure that the CE is being applied correctly.'' [47] This proposed rule, which would amend certain requirements and compliance dates in FMVSS Nos. 213b and 225, is categorically excluded pursuant to 23 CFR 771.118(c)(4): ''Planning and administrative activities that do not involve or lead directly to construction, such as: Training, technical assistance and research; promulgation of rules, regulations, directives, or program guidance; approval of project concepts; engineering; and operating assistance to transit authorities to continue existing service or increase service to meet routine demand.'' NHTSA has

[41] 49 U.S.C. 30103(b)(1).

[42] 49 U.S.C. 30103(e).

[43] *See Geier* v. *American Honda Motor Co.,* 529 U.S. 861 (2000).

[44] *See* DOT Order 5610.1D § 9.

[45] *Id.* § 9(b).

[46] *Id.* § 9(f).

[47] *Id.*

coordinated with the Federal Transit Administration (FTA) to ensure that this CE is being applied correctly. NHTSA does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

Paperwork Reduction Act

Under the procedures established by the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), a Federal agency must request and receive approval from OMB before it collects certain information from the public and a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. This proposed rule would not have any requirements that are considered to be information collection requirements as defined by the OMB in 5 CFR part 1320.

Unfunded Mandates Reform Act (UMRA)

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) requires Federal agencies to assess the effects of regulatory actions that may result in the expenditure by a State, local, or Tribal government, in the aggregate, or by the private sector of $206 million (the value equivalent of $100 million in 1995, adjusted for inflation to 2025) or more in any one year. This proposed rule does not contain Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local and Tribal governments, or the private sector of $206 million or more in any one year. Thus, the analytical requirements of the UMRA do not apply to this action.

Executive Order 12778 (Civil Justice Reform)

With respect to the review of the promulgation of a new regulation, section 3(b) of Executive Order 12988, ''Civil Justice Reform'' (61 FR 4729, February 7, 1996) requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) specifies clearly the preemptive effect; (2) specifies clearly the effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct, while promoting simplification and burden reduction; (4) specifies clearly the retroactive effect, if any; (5) defines key terms adequately; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. This document is consistent with that requirement.

NHTSA has reviewed this rulemaking and determined that this rulemaking action conforms to the applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform. The issue of preemption is discussed above in connection with E.O. 13132. NHTSA notes further that there is no requirement that an individual submit a petition for reconsideration or pursue other administrative proceedings before they may file suit in court.

National Technology Transfer and Advancement Act

Under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104–113), ''all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.'' Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by voluntary consensus standards bodies, such as the International Organization for Standardization (ISO) and the Society of Automotive Engineers (SAE). The NTTAA directs this agency to provide Congress, through OMB, explanations when we decide not to use available and applicable voluntary consensus standards. There are no voluntary consensus standards developed by voluntary consensus standards bodies pertaining to this proposed rule.

Promoting International Regulatory Cooperation

The policy statement in section 1 of E.O. 13609 provides that the regulatory approaches taken by foreign governments may differ from those taken by the United States to address similar issues, and that in some cases the differences between them might not be necessary and might impair the ability of American businesses to export and compete internationally. It further recognizes that in meeting shared challenges involving health, safety, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation and can reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

NHTSA has analyzed this rule under the policies and agency responsibilities of E.O. 13609 and has determined this rulemaking will have no effect on international regulatory cooperation.

Executive Order 13175

E.O. 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. NHTSA has assessed the impact of this proposed rule on Indian tribes and determined that this rule would not have Tribal implications that require consultation under E.O. 13175.

E-Government Act Compliance

NHTSA is committed to complying with the E-Government Act, 2002 to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes. The E-Government Act of 2002 (Pub. L. 107–347, sec. 208, 116 Stat. 2899, 2921, Dec. 17, 2002), requires Federal agencies to conduct a privacy impact assessment for new or substantially changed technology that collects, maintains, or disseminates information in an identifiable form. No new or substantially changed technology would collect, maintain, or disseminate information as a result of this proposed rule. Accordingly, NHTSA has not conducted a privacy impact assessment.

Plain Language Requirement

E.O. 12866 and E.O. 13563 requires each agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

- Have we organized the material to suit the public's needs?
- Are the requirements in the rule clearly stated?
- Does the rule contain technical language or jargon that isn't clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rule easier to understand?

NHTSA has considered these questions and attempted to use plain language in promulgating this proposed rule. Please inform the agency if you can suggest how NHTSA can improve its use of plain language.

Regulatory Identifier Number (RIN)

DOT assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading at the beginning of this notice may be used to find this action in the Unified Agenda.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, or other entity). For information on DOT's compliance with the Privacy Act, see *https://www.transportation.gov/privacy.*

Public Participation

How do I prepare and submit comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the docket number indicated in this document in your comments.

Your comments must not be more than 15 pages long. (49 CFR 553.21). We established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments.

If you are submitting comments electronically as a PDF (Adobe) file, NHTSA asks that the documents be submitted using the Optical Character Recognition (OCR) process, thus allowing NHTSA to search and copy certain portions of your submissions.

Please note that pursuant to the Data Quality Act, for substantive data to be relied upon and used by the agency, it must meet the information quality standards set forth in the OMB and DOT Data Quality Act guidelines. Accordingly, we encourage you to consult the guidelines in preparing your comments. OMB's guidelines may be accessed at *https://www.transportation.gov/regulations/dot-information-dissemination-quality-guidelines.*

How can I be sure that my comments were received?

If you wish the Docket to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, the Docket will return the postcard by mail.

How do I submit confidential business information?

You should submit a redacted ''public version'' of your comment (including redacted versions of any additional documents or attachments) to the docket using any of the methods identified under **ADDRESSES**. This ''public version'' of your comment should contain only the portions for which no claim of confidential treatment is made and from which those portions for which confidential treatment is claimed has been redacted. See below for further instructions on how to do this.

You also need to submit a request for confidential treatment directly to the Office of Chief Counsel. Requests for confidential treatment are governed by 49 CFR part 512. Your request must set forth the information specified in part 512. This includes the materials for which confidentiality is being requested (as explained in more detail below); supporting information, pursuant to § 512.8; and a certificate, pursuant to § 512.4(b) and part 512, Appendix A.

You are required to submit to the Office of Chief Counsel one unredacted ''confidential version'' of the information for which you are seeking confidential treatment. Pursuant to § 512.6, the words ''ENTIRE PAGE CONFIDENTIAL BUSINESS INFORMATION'' or ''CONFIDENTIAL BUSINESS INFORMATION CONTAINED WITHIN BRACKETS'' (as applicable) must appear at the top of each page containing information claimed to be confidential. In the latter situation, where not all information on the page is claimed to be confidential, identify each item of information for which confidentiality is requested within brackets: ''[ ].''

You are also required to submit to the Office of Chief Counsel one redacted ''public version'' of the information for which you are seeking confidential treatment. Pursuant to § 512.5(a)(2), the redacted ''public version'' should include redactions of any information for which you are seeking confidential treatment (*i.e.,* the only information that should be unredacted is information for which you are not seeking confidential treatment).

NHTSA is currently treating electronic submission as an acceptable method for submitting confidential business information to the agency under part 512. Please do not send a hardcopy of a request for confidential treatment to NHTSA's headquarters. The request should be sent to Dan Rabinovitz in the Office of the Chief Counsel at *Daniel.Rabinovitz@dot.gov* or you may contact him for a secure file transfer link. Manufacturers or any companies that already have a Confidential Business Information (CBI) Portal account or an Enterprise Account with NHTSA should use the CBI Portal for their submission. If you submit a CBI request, please also email a courtesy copy of the request to John Piazza at *john.piazza@dot.gov.*

Will the agency consider late comments?

We will consider all comments received before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that the docket receives after that date. If the docket receives a comment too late for us to consider in developing a final rule (assuming that one is issued), we will consider that comment as an informal suggestion for future rulemaking action.

How can I read the comments submitted by other people?

You may read the comments received by the docket at the address given above under **ADDRESSES**. The hours of the docket are indicated above in the same location. You may also see the comments on the internet. To read the comments on the internet, go to *https://www.regulations.gov.* Follow the online instructions for accessing the dockets.

Please note that even after the comment closing date, we will continue to file relevant information in the docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material. You can arrange with the docket to be notified when others file comments in the docket. See *www.regulations.gov* for more information.

List of Subjects

49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

49 CFR Part 585

Reporting and recordkeeping requirements.

In consideration of the foregoing, NHTSA proposes to amend 49 CFR part 571 and 49 CFR part 585 as set forth below.

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

■ 1. The authority citation for part 571 of title 49 continues to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117 and 30166; delegation of authority at 49 CFR 1.95.

■ 2. Amend § 571.213b by revising paragraphs S5.9 (b) and (c) to read as follows:

§ 571.213b Standard No. 213b; Child restraint systems; Mandatory applicability beginning December 5, 2026.

* * * * *

S5.9 * * *

(b) In the case of each child restraint system that has components for attaching the system to a tether anchorage, those components shall include a tether hook that conforms to the configuration and geometry specified in figure 11 to this section. For child restraints manufactured on or after January 8, 2028, the tether hook or the tether strap shall be permanently marked with either pictogram shown in figure 16 to this section. If the mark is on the tether strap or on a tag attached to the tether strap, the mark must be located within 25 mm of the tether hardware assembly (which consists of a tether hook and a mechanism designed to tighten and loosen the tether strap, including any material between those components).

(c) In the case of each child restraint system that has components, including belt webbing, for attaching the system to an anchorage of a child restraint anchorage system (lower anchorage or tether anchorage), the belt webbing shall be adjustable so that the child restraint can be tightly attached to the vehicle. For child restraints manufactured on or after January 8, 2028, the length of the tether hardware assembly, which consists of a tether hook and a mechanism designed to tighten and loosen the tether strap, including any material between those components, shall not exceed 165 mm. If the tether hardware assembly length is adjustable, its minimum adjusted length shall not exceed 165 mm.

* * * * *

■ 3. Amend § 571.225 by:
■ a. Revising the introductory text of paragraph S5;
■ b. Revising introductory text of S5.1 and S5.2;
■ c. Revising paragraphs S6.2.2, S6.4(a)(3), S9.5.1, S9.5.1(a)(2), S9.5.1(a)(3), S9.5.1(a)(4);
■ d. Adding paragraph S9.5.1(a)(5);
■ e. Revising paragraphs S9.5.2, S9.5.2(a)(2), S9.5.2(a)(3), S9.5.2(a)(4);
■ f. Adding paragraph S9.5.2(a)(5);
■ g. Revising paragraphs S11(a)(1), S11(a)(2), S11(c), the introductory text of paragraphs S13, S13.1, S13.1.2, S13.1.3, and S13.1.4;
■ h. Adding paragraphs S13.1.5, S13.3, S13.3.1, and S13.3.2; and
■ i. Revising Figure 19.

The amendments read as follows:

§ 571.225 Standard No. 225; Child restraint anchorage systems

* * * * *

S5 *General exceptions.* Vehicles manufactured before September 1, 2033, must meet the requirements of S5.1. Vehicles manufactured on or after September 1, 2033, must meet the requirements of S5.2.

S5.1 Vehicles manufactured before September 1, 2033.

* * * * *

S5.2 Vehicles manufactured on or after September 1, 2033.

* * * * *

S6.2.2 Subject to S6.2.2.2, the part of each tether anchorage to which a tether hook attaches must be located within the shaded zone shown in figures 3 through 7 to this section of the designated seating position for which it is installed. The zone is defined with reference to the seating reference point (*see* § 571.3). (For purposes of the figures, ''H Point'' means seating reference point.) A tether anchorage may be recessed in the seat back, provided that it is not in the strap wrap-around area at the top of the vehicle seat back. For the area under the vehicle seat, the forwardmost edge of the shaded zone is defined by a vertical plane 120 mm rearward of the ''H Point,'' as shown in figure 10 to this section.

* * * * *

S6.4 * * *

(a) * * *

(3) The nearest edge of the marking shall be located not more than 100 mm away from the tether anchorage bar as shown in figure 27 to this section or from the intersection of the longitudinal and lateral centerlines of the routing device, when the routing device is not in use and not pulled away from its attachment to the vehicle. No other attachment feature to secure occupant items (*i.e.,* cargo hooks or similar) shall be nearer to the marking than the distance from the marking to the tether anchorage. Vehicles with routing devices per S6.2.2.2 may use tags attached to the routing device.

* * * * *

S9.5.1 *Requirements for lower anchors.* Subject to the phase-in specified in S13, lower anchorages must meet the requirements in S9.5.1(a) or (b).

(a) * * *

(2) That is either solid or open, with or without words, symbols, or pictograms, provided that if words, symbols or pictograms are used, their meaning is explained to the consumer in writing, such as in the vehicle's owner's manual;

(3) That is located such that its center is in the vertical plane that passes through the center of the bar (±25 mm) and is parallel to the vehicle longitudinal centerline; and

(4) That is located such that its center is (as illustrated in figure 22 to this section):

(i) on the seat back between 50 and 100 mm above the horizontal longitudinal plane that intersects the horizontal centerline of the bar; or

(ii) on the seat cushion between 125 mm and 75 mm forward of the vertical transverse plane that intersects the horizontal centerline of the bar.

(5) The circle may be on a tag.

* * * * *

S9.5.2 *Requirements for lower anchors.* Subject to the phase-in specified in S13, lower anchorages must meet the requirements in S9.5.2(a) and (b), as applicable.

(a) * * *

(2) Contains the pictogram shown in figure 24 to this section;

(3) That is located such that its center is in the vertical plane that passes through the center of the bar (±25 mm) and is parallel to the vehicle longitudinal centerline; and

(4) That is located such that its center is (as illustrated in figure 19 to this section):

(i) on the seat back between 50 and 100 mm above the horizontal longitudinal plane that intersects the horizontal centerline of the bar; or

(ii) on the seat cushion between 100 mm forward of, and 50 mm rearward of, the vertical transverse plane that intersects the horizontal centerline of the bar.

(5) The symbol may be on a tag.

* * * * *

S11 * * *

(a) * * *

(1) *Forward force direction.* Place SFAD 2 in the vehicle seating position and attach it to the two lower anchorages of the child restraint anchorage system. Do not attach the tether anchorage. A rearward force of 135 ±15 N is applied to the center of the lower front crossbar of SFAD 2 to press the device against the seat back as the fore-aft position of the rearward extensions of the SFAD is adjusted to remove any slack or tension. Apply a preload force of 500 N at point X (illustrated in Figure 17 of this standard) of the test device. Increase the pull force as linearly as practicable to a full force application of 11,000 N in not less than 24 seconds and not more than 30 seconds and maintain at an 11,000 N level for 1 second.

(2) *Lateral force direction.* Place SFAD 2 in the vehicle seating position and attach it to the two lower anchorages of the child restraint anchorage system. Do not attach the tether anchorage. A rearward force of 135 ± 15 N is applied to the center of the lower front crossbar of SFAD 2 to press the device against the seat back as the fore-aft position of the rearward extensions of the SFAD is adjusted to remove any slack or tension. Apply a preload force of 500 N at point X of the test device. Increase the pull force as linearly as practicable to a full force application of 5,000 N in not less than 24 seconds and not more than 30 seconds and maintain at a 5,000 N level for 1 second.

* * * * *

(c) *Anchorage depth.* The seat back angle, if adjustable, is set at the manufacturer's nominal design seat back angle. If the position is not specified, set the seat back at the first detent rearward of 25° from the vertical. To measure the anchorage depth, the tool view angle is determined by subtracting the measured seat pan angle from 30 degrees. With the anchorage depth tool (*see* figure 28 to this section) on a flat surface, adjust the view bar to read the view angle. Slide the zeroing strip along the view bar so that it is barely touching the top of the depth tool hook. Move the view bar forward, so the end of the zeroing strip is aligned with the zero-scribe line. For hidden anchorages, slide the anchorage depth tool so that it reads 0 mm at the rear edge of the slider. For visible anchorages, align the depth gauge to 25 mm so that negative values can be read. Attach the depth tool centered to the lower anchorage. Adjust the depth tool base to be parallel with the seat pan angle (within ±2 degrees) while maintaining the established tool view angle (30 degrees minus seat pan angle). Move the entire slider bar forward until the zeroing strip contacts the vehicle seat back or any other vehicle part.

* * * * *

S13 *Phase-in schedule.* The S13 phase-in schedule details when listed requirements become inactive and are replaced by newer requirements. Requirements in Standard No. 225 (this section) not listed in S13 shall be in effect before, during, and after the S13 phase-in. Manufacturers producing fewer than 5,000 vehicles annually for sale in the United States are not subject to the S13.1 phase-in schedule and are instead subject to S13.3.

S13.1 *Vehicle certification information.* At any time during the production years ending August 31, 2029, August 31, 2030 and August 31, 2031, each manufacturer shall, upon request from the Office of Vehicle Safety Compliance, provide information identifying the vehicles (by make, model and vehicle identification number) that have been certified as complying with the child restraint anchorage usability requirements of this standard. Manufacturers shall specify the number of vehicles meeting each phase-in percentage. The manufacturer's designation of a vehicle as a certified vehicle is irrevocable.

* * * * *

S13.1.2 *Phase-in year 1.* Vehicles manufactured on or after September 1, 2028, and before September 1, 2029. The total number of individual vehicles complying with S6.1.2, S6.2.2, S6.4, S9.2 (except for S9.2.2(a)), S9.5.2, and S12.2 of this standard shall be not less than 20 percent of a vehicle manufacturer's total production for this time period. The remainder of a vehicle manufacturer's total production for this time period is subject to S6.1.1, S6.2.1, S9.2.1, S9.2.2, S9.2.3, S9.5.1, and S12.1 of this standard.

S13.1.3 *Phase-in year 2.* Vehicles manufactured on or after September 1, 2029, and before September 1, 2030. The total number of individual vehicles complying with S6.1.2, S6.2.2, S6.4, S9.2 (except for S9.2.2(a)), S9.5.2, and S12.2 of this standard shall be not less than 50 percent of a vehicle manufacturer's total production for this time period. The remainder of a vehicle manufacturer's total production for this time period is subject to S6.1.1, S6.2.1, S9.2.1, S9.2.2, S9.2.3, S9.5.1, and S12.1 of this standard.

S13.1.4 *Phase-in year 3.* Vehicles manufactured on or after September 1, 2030 and before September 1, 2031. The total number of individual vehicles complying with S6.1.2, S6.2.2, S6.4, S9.2 (except for S9.2.2(a)), S9.5.2, and S12.2 of this standard shall be not less than 75 percent of a vehicle manufacturer's total production for this time period. The remainder of a vehicle manufacturer's total production for this time period is subject to S6.1.1, S6.2.1, S9.2.1, S9.2.2, S9.2.3, S9.5.1, and S12.1 of this standard.

S13.1.5 *Phase-in year 4 and beyond.* Vehicles manufactured on or after September 1, 2031. The total number of vehicles complying with S6.1.2, S6.2.2, S6.4, S9.2 (except for S9.2.2(a)), S9.5.2, and S12.2 shall be not less than 100 percent of a vehicle manufacturer's total production.

* * * * *

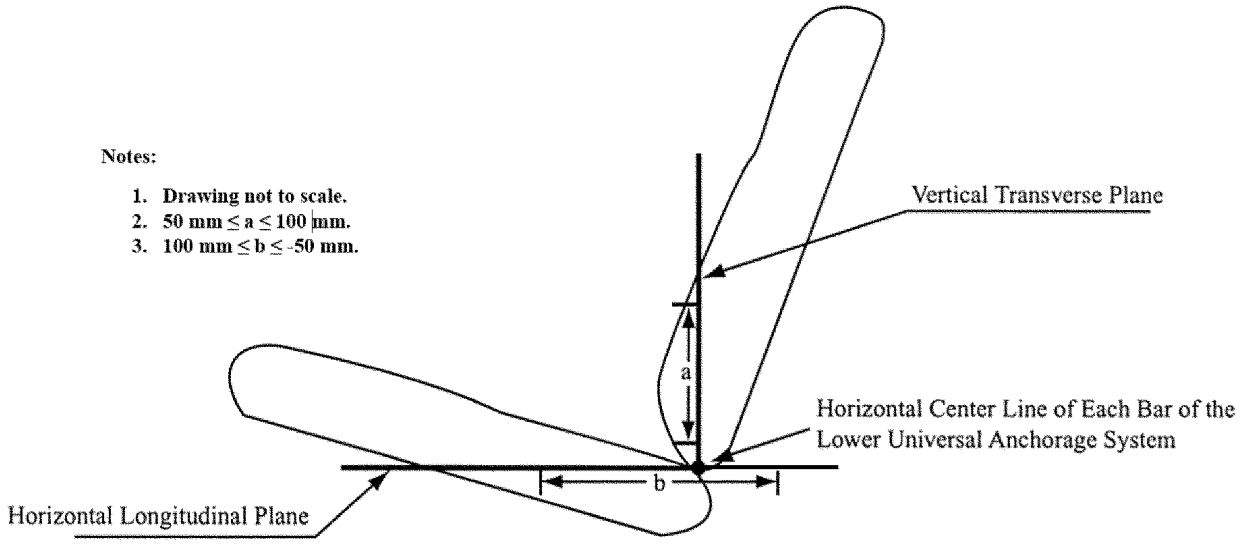
S13.3 *Manufacturers producing fewer than 5,000 vehicles annually for sale in the United States.*

S13.3.1 *Applicable unless vehicle is certified to S13.3.2.* Vehicles manufactured before September 1, 2031 are subject to S6.1.1, S6.2.1, S9.2.1, S9.2.2, S9.2.3, S9.5.1, and S12.1 of this standard.

S13.3.2 *Mandatory applicability beginning September 1, 2031.* Vehicles manufactured on or after September 1, 2031 are subject to S6.1.2, S6.2.2, S6.4, S9.2 (except for S9.2.2(a)), S9.5.2, and S12.2 of this standard.

* * * * *

Figure 19 to § 571.225. Placement of Symbol on the Seat Back and Seat Cushion of Vehicle



* * * * *

PART 585—PHASE-IN REPORTING REQUIREMENTS

■ 4. The authority citation for part 585 continues to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117, and 30166; delegation of authority at 49 CFR 1.95.

■ 5. Amend § 585 subpart O by:

■ a. Revising paragraphs 585.140 (a), 585.140(b)(3), and 585.141.

The amendments read as follows:

* * * * *

§ 585.140 Reporting requirements.

(a) General reporting requirements. Within 60 days after the end of the production years ending August 31, 2029, August 31,2030 and August 31, 2031, each manufacturer shall submit a report to the National Highway Traffic Safety Administration concerning its compliance with the child restraint anchorage system requirements of Standard No. 225 (49 CFR 571.225) for applicable vehicles produced in that year. Each report shall:

* * * * *

(b) * * *

(3) *Vehicles produced by more than one manufacturer.* Each manufacturer whose reporting of information is affected by one or more of the express written contracts permitted by S13.2.2 of Standard No. 225 (49 CFR 571.225) must:

* * * * *

§ 585.141 Records.

Each manufacturer must maintain records of the Vehicle Identification Number for each vehicle for which information is reported under § 585.140 until December 31, 2033.

* * * * *

Issued in Washington, DC, under authority delegated in 49 CFR 1.95.

Jonathan Morrison,

Administrator.

[FR Doc. 2026–15743 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–59–P

Notices

Federal Register
Vol. 91, No. 148
Tuesday, August 4, 2026

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request Revision and Extension of a Currently Approved Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to request feedback from the general public on the ''Generic Clearance for the Collection of Qualitative Feedback on Agency Programs''. This collection was developed as part of a Federal Government-wide effort to streamline the process for seeking feedback from the public on service delivery. This notice announces our intent to submit this collection to OMB for approval and solicits comments on specific aspects for the proposed information collection.

DATES: Comments on this notice must be received by October 5, 2026 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–0261, by any of the following methods:

- *Email: omboffi cer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *E-fax:* (855) 838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: NASS OMB Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: NASS OMB Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Jody R. McDaniel, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–2707. Copies of this information collection and related instructions can be obtained without charge from NASS OMB Clearance Officer, at (202) 720–2206 or at *omboffi cer@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title of Collection: Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Programs.

OMB Control Number: 0535–0261.

Expiration Date of Current Approval: April 30, 2027.

Type of Request: Intent to revise and extend a currently approved information collection for a period of three years.

Abstract: The proposed information collection activities provides a means to obtain qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving the quality and timeliness of survey data and its analysis. The qualitative feedback will provide useful insights on perceptions and opinions but are not rigorous statistical surveys that yield quantitative results that can be generalized to the study population. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with data collection efforts, and focus attention on areas where communication, training or changes in operations might improve NASS surveys and publications. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders.

The information collections will target areas such as: timeliness, usefulness of summarized information, perceptions of products or services, accuracy of information, efficiency and ease of reporting data, and the ease and understandability of data collection instruments. Responses will be assessed to plan and inform efforts to improve or maintain the quality of data collected and reported to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with NASS surveys or data, or may reasonably be expected to have experience with the surveys or data in the near future;
- Information gathered will be used only internally for improving data collection efforts, products and services, and the summarization and publication of data, and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the study population.

This generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Estimate of Burden:

Respondents: Farmers, ranchers, agri-businesses and data users.

Estimated Number of Respondents: 120,000.

Below we provide projected average estimates for the next three years:

Average Number of Responses per Respondent: 1.

Total Responses: 120,000 (30,000 completed responses and 90,000 refusals).

Frequency of Responses: Once per request.

Average Minutes per Response: 5 to 20 minutes, depending on the survey.

Total Estimated Burden Hours: 8,375.

Comments: Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, technological or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, July 23, 2026.

Jody R. McDaniel,

Associate Administrator.

[FR Doc. 2026–15754 Filed 8–3–26; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request Revision and Extension of a Currently Approved Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to request a revision and extension of a currently approved information collection titled ''NASS Data Security Requirements for Accessing Confidential Data.'' NASS plans to collect information from the public to fulfill its data security requirements when providing access to restricted use data for the purpose of evidence building. NASS's data security agreements and other paperwork along with the corresponding security protocols allow NASS to maintain careful controls on confidentiality and privacy, as required by law.

DATES: Comments on this notice must be received by October 5, 2026 to be assured of consideration.

ADDRESSES:

You may submit comments, identified by docket number 0535–0274, by any of the following methods:

- *Email: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *E–fax:* (855) 838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: NASS OMB Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: NASS OMB Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT:

Jody R. McDaniel, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–2707. Copies of this information collection and related instructions can be obtained without charge from NASS OMB Clearance Officer, at (202) 720–2206 or at *ombofficer@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title of collection: NASS Data Security Requirements for Accessing Confidential Data.

OMB Control Number: 0535–0274.

Expiration Date of Current Approval: April 30, 2027.

Type of Request: Intent to revise and extend a currently approved information collection for a period of three years.

Abstract: Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (hereafter referred to as the Evidence Act) mandates that OMB establish a Standard Application Process (SAP) for requesting access to certain confidential data assets. Specifically, the Evidence Act requires OMB to establish a common application process through which agencies, the Congressional Budget Office, State, local, and Tribal governments, researchers, and other individuals, as appropriate, may apply for access to confidential data assets collected, accessed, or acquired by a statistical agency or unit. This new process will be implemented while maintaining stringent controls to protect confidentiality and privacy, as required by law.

Data collected, accessed, or acquired by statistical agencies and units is vital for developing evidence on conditions, characteristics, and behaviors of the public and on the operations and outcomes of public programs and policies. This evidence can benefit the stakeholders in the programs, the broader public, as well as policymakers and program managers at the local, State, Tribal, and National levels. The many benefits of access to data for evidence building notwithstanding, National Agricultural Statistics Service is required by law to maintain careful controls that allow it to minimize disclosure risk while protecting confidentiality and privacy.

The fulfillment of National Agricultural Statistics Service's data security requirements places a degree of burden on the public, which is outlined below.

The SAP Portal is a web-based application for the public to request access to confidential data assets from federal statistical agencies and units. The objective of the SAP Portal is to increase public access to confidential data for the purposes of evidence building and reduce the burden of applying for confidential data. Once an individual's application in the SAP Portal has received a positive determination, the data-owning agency(ies) or unit(s) will begin the process of collecting information to fulfill their data security requirements.

The paragraphs below outline the SAP Policy, the steps to complete an application through the SAP Portal, and the process for agencies to collect information fulfilling their data security requirements.

The SAP Policy

At the recommendation of the ICSP, the SAP Policy establishes the SAP to be implemented by statistical agencies and units and incorporates directives from the Evidence Act. The policy is intended to provide guidance as to the application and review processes using the SAP Portal, setting forth clear standards that enable statistical agencies and units to implement a common application form and a uniform review process. The SAP Policy renewal was submitted to the public for comment in June 2025 (90 FR 25380). The renewal policy was approved and has a current expiration date of 12–31–2028.

The SAP Portal

The SAP Portal is an application interface connecting applicants seeking data with a catalog of data assets owned by the federal statistical agencies and units. The SAP Portal is not a new data repository or warehouse; confidential data assets will continue to be stored in secure data access facilities owned and hosted by the federal statistical agencies and units. The SAP Portal will provide a streamlined application process across agencies, reducing redundancies in the application process. This single SAP Portal will improve the process for applicants, tracking and communicating the application process throughout its lifecycle. This reduces redundancies and burden on applicants that request access to data from multiple agencies. The SAP Portal will automate key tasks to save resources and time and will bring agencies into compliance with the Evidence Act statutory requirements.

Data Discovery

Individuals begin the process of accessing restricted use data by discovering confidential data assets through the SAP data catalog, maintained by federal statistical agencies at *www.sap.nsf.gov.* Potential applicants can search by agency, topic, or keyword to identify data of interest or relevance. Once they have identified data of interest, applicants can view metadata outlining the title, description or abstract, scope and coverage, and detailed methodology related to a specific data asset to determine its relevance to their research.

While statistical agencies and units shall endeavor to include metadata in the SAP data catalog on all confidential data assets for which they accept applications, it may not be feasible to include metadata for some data assets (*e.g.,* potential curated versions of administrative data). A statistical agency or unit may still accept an application even if the requested data asset is not listed in the SAP data catalog.

SAP Application Process

Individuals who have identified and wish to access confidential data assets will be able to apply for access through the SAP Portal. Applicants must create an account and follow all steps to complete the application. Applicants begin by entering their personal, contact, and institutional information, as well as the personal, contact, and institutional information of all individuals on their research team. Applicants proceed to provide summary information about their proposed project, to include project title, duration, funding, timeline, and other details including the data asset(s) they are requesting and any proposed linkages to data not listed in the SAP data catalog, including non-federal data sources. Applicants then proceed to enter detailed information regarding their proposed project, including a project abstract, research question(s), literature review, project scope, research methodology, project products, and anticipated output. Applicants must demonstrate a need for confidential data, outlining why their research question cannot be answered using publicly available information.

Submission for Review

Upon submission of their application, applicants will receive a notification that their application has been received and is under review by the data owning agency or agencies (in the event where data assets are requested from multiple agencies). At this point, applicants will also be notified that application approval does not alone grant access to confidential data, and that, if approved, applicants must comply with the data-owning agency's security requirements outside of the SAP Portal.

In accordance with the Evidence Act and the direction of the ICSP, agencies will approve or reject an application within a prompt timeframe. In some cases, agencies may determine that additional clarity, information, or modification is needed and request the applicant to ''revise and resubmit'' their application.

Data discovery, the SAP application process, and the submission for review are planned to take place within the web-based SAP Portal. As noted above, the renewal notice to collect information through the SAP Portal has been published separately (90 FR 25380).

Access to Restricted Use Data

In the event of a positive determination, the applicant will be notified that their proposal has been accepted. The positive or final adverse determination concludes the SAP Portal process. In the instance of a positive determination, the data-owning agency (or agencies) will contact the applicant to provide instructions on the agency's security requirements that must be completed to gain access to the confidential data. The completion and submission of the agency's security requirements will take place outside of the SAP Portal.

Collection of Information for Data Security Requirements

In the instance of a positive determination for an application requesting access to a National Agricultural Statistics Service (NASS) confidential data asset, NASS will contact the applicant(s) to initiate the process of collecting information to fulfill their security requirements. These include additional requirements necessary for the statistical agency or unit to place the applicant(s) in a trusted category that may include the applicant's successful completion of identity verification, confidentiality training, nondisclosure, inspection of the site the confidential data will be accessed, and data use agreements.

NASS's data security requirements include the collection of the following:

- *Security Briefing:* NASS personnel provide a Security Briefing to all applicants who were approved access to restricted data. The Briefing is provided prior to the applicant completing the three forms listed below and includes information on the Confidential Information Protection and Statistical Efficiency Act of 2018, Title III of Public Law 115–435, codified in 44 U.S.C. Ch. 35 and other applicable Federal laws that protect the restricted data.
- Completion of form *ADM–043, Certification and Restrictions on Use of Unpublished Data.* This form is required to be signed by researchers who have been approved to access unpublished NASS data (alternatively, some approved researchers complete on-line training in lieu of completing this form). The form contains excerpts of the various laws that apply to the unpublished data being provided to the researcher. The form explains the restrictions associated with the unpublished data and includes a place for the research to sign the form, thereby acknowledging the restrictions and agreeing to abide by them.
- Completion of *User Attestation Form.* Researchers approved to access unpublished NASS data are provided with the document *Handbook for Special Sworn Data Users of a NASS Data Lab* that explains the policies and procedures associated with accessing unpublished NASS data in a NASS Data Lab (including data enclaves). Each researcher approved to access unpublished NASS data is required to sign the *User Attestation Form* to acknowledge they were provided with the *Handbook for Special Sworn Data Users of a NASS Data Lab* and agree to abide by its provisions.

• Completion of *NASS Site Inspection Checklist.* Researchers approved to access unpublished NASS data do so using a secure data enclave environment accessible at their own location. A NASS employee performs a site inspection (either in-person or via a video call) of the researcher's location prior to the researcher being granted access to the unpublished data. During the site inspection, the NASS employee administers the form *NASS Site Inspection Checklist,* which asks questions pertaining to the suitability of the location for restricted data access and some of the policies associated with accessing the restricted data. The form also collects information about the computer the researcher will use to access the NASS data enclave.

Specifically, researchers will be required to complete the OF–306 (Declaration for Federal Employment) to support onboarding into USDA's human capital management system. This step is necessary to establish a formal relationship between NASS and the researcher and to ensure compliance with federal identity verification and personnel tracking requirements. The OF–306 collects administrative PII such as Social Security Number (SSN), date of birth, sex, and citizenship. This information will be submitted directly to REE Onboarding and will not be retained or processed by NASS. The collection and maintenance of this data are governed by USDA's Privacy Act System of Records Notice (SORN) OCFO/NFC–1—Systems for Personnel, Payroll, and Time & Attendance (89 FR 5481, January 29, 2024). The OF–306 is approved under OMB Control No. 3206–0182. As such, burden associated with completing the OF–306 is not included in this ICR.

In alignment with the Animal and Plant Health Inspection Service (APHIS) notice published on August 19, 2024 (89 FR 67058), the National Agricultural Statistics Service (NASS) has transitioned certain data collection activities previously conducted under OMB Control Number 0579–0500 to OMB Control Number 0535–0274. These activities involve co-owned data between NASS and the National Animal Health Monitoring System (NAHMS). This consolidation under a single control number is intended to streamline data collection processes, enhance data security protocols, and maintain compliance with confidentiality standards as outlined in the APHIS notice.

Estimate of Burden: The amount of time to complete the agreements and other paperwork, Security Briefing, and read the *Handbook for Special Sworn Data Users* that comprise NASS's security requirements will vary based on the confidential data assets requested and the access modality. To obtain access to NASS confidential data assets, it is estimated that the average time to complete and submit NASS's data security agreements and other paperwork, Security Briefing, and read the *Handbook for Special Sworn Data Users* is 145 minutes per applicant. This estimate does not include the time needed to complete and submit an application within the SAP Portal. All efforts related to SAP Portal applications occur prior to and separate from NASS's effort to collect information related to data security requirements.

The expected number of applications in the SAP Portal that receive a positive determination from NASS in a given year may vary. Overall, per year, NASS estimates it will collect data security information from 200 applicants that received a positive determination within the SAP Portal (note: an SAP Portal application may include access for more than one applicant) or other restricted use access approval. NASS estimates that the total burden for the collection of information for data security requirements over the course of the three-year OMB clearance will be about 1,452 hours and, as a result, an average annual burden of 484 hours.

Below we provide projected average estimates for the next three years:

Total Requests: 200.

Frequency of Request: Once per request.

Average Minutes per Request: 145 minutes.

Total Estimated Burden Hours: 484

Comments: Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, technological or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, July 23, 2026

Jody R. McDaniel,

Associate Administrator.

[FR Doc. 2026–15755 Filed 8–3–26; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

[Docket No. RUS–26–ELECTRIC–0232]

Notice of Funding Opportunity for the Powering Affordable Reliable Technology (PART) Energy Program 2026

AGENCY: Rural Utilities Service, U.S. Department of Agriculture (USDA).

ACTION: Notice of funding opportunity.

SUMMARY: The Rural Utilities Service (RUS or the Agency), a Rural Development (RD) agency of the United States Department of Agriculture (USDA) is soliciting Letters of Interest (LOI) for loan Applications, announcing the Application process for those loans, and providing deadlines for Applications from eligible entities under the Powering Affordable Reliable Technology (PART) Energy Program for fiscal year (FY) 2026. In future years this funding opportunity will only be announced on the Agency website and *grants.gov*, without a **Federal Register** notice. Therefore, in future years, neither the funding opportunity nor reference to the funding opportunity in *grants.gov* will appear in the **Federal Register**. Please make note of this change in location of the funding announcement in your records.

DATES: August 4, 2026.

ADDRESSES: Full funding notice is available on *grants.gov.* Program guidance is available at *https://www.rd.usda.gov/programs-services/electric-programs.*

FOR FURTHER INFORMATION CONTACT: Christopher A. McLean, Assistant Administrator, Electric Program, RUS, RD, USDA, 1400 Independence Avenue SW, STOP 1568, Washington, DC 20250–1560; Telephone: 202–690–4492; Email: *SM.RD.RUS.PART-Questions@usda.gov.*

SUPPLEMENTARY INFORMATION: The full text of the Notice of Funding Opportunity (NOFO) is available on the Agency website and on *grants.gov* using Funding Opportunity Number RUS–PART–2026 or Assistance Listing Number 10.757.

(Authority: 7 U.S.C. 901.)

Karl Elmshaeuser,

Administrator, Rural Utilities Service.

[FR Doc. 2026–15795 Filed 8–3–26; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–36–2025]

Foreign-Trade Zone (FTZ) 12; Authorization of Production Activity; Avant Technology, Inc.; (Solid-State Drives and Memory Modules); Pharr, Texas

On July 2, 2025, Avant Technology, Inc., submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 12, in Pharr, Texas.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (90 FR 30048, July 8, 2025). On July 31, 2026, the applicant was notified of the FTZ Board's decision that the proposed activity has been authorized on a limited basis, subject to the FTZ Act and the Board's regulations, including section 400.14, and subject to a one-year time period.

Dated: July 31, 2026.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2026–15804 Filed 8–3–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–95–2026]

Foreign-Trade Zone (FTZ) 80, Notification of Proposed Production Activity; CGT US Ltd.; (Automotive Upholstery); New Braunfels, Texas

CGT US Ltd. submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in New Braunfels, Texas within Subzone 80E. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on July 30, 2026.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.* The proposed finished product and materials/components would be added to the production authority that the Board previously approved for the operation, as reflected on the Board's website.

The proposed finished product is Supported Upholstery Coated with Polyvinyl Chloride Coverstock (duty free).

The proposed foreign-status materials/components include: Zinc Borate; Zinc-Based PVC Stabilizers; and Color Paste (duty rate ranges from 3.7% to 6.5%).

The request indicates that certain materials/components are subject to duties under section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable section 301 decision requires subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is September 14, 2026.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact John Frye at *John.Frye@trade.gov.*

Dated: July 30, 2026.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2026–15746 Filed 8–3–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 260731–0181]

XRIN 0694–XC159

Notice of Reduction of Tariffs on Patented Pharmaceuticals and Pharmaceutical Ingredients for Products of the United Kingdom Implemented by Presidential Proclamation 11020

AGENCY: Bureau of Industry and Security, Office of Strategic Industries and Economic Security, U.S. Department of Commerce.

ACTION: Notice.

SUMMARY: This notice revises the tariff rate on patented pharmaceuticals and associated pharmaceutical ingredients that are products of the United Kingdom from 10 percent to zero percent in accordance with Proclamation 11020 ''Adjusting Imports of Pharmaceuticals and Pharmaceutical Ingredients Into the United States.''

DATES: The duties set out in this notice are effective with respect to certain products that are entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. Eastern Time on July 31, 2026.

SUPPLEMENTARY INFORMATION:

Background

On April 2, 2026, The President issued Proclamation 11020 ''Adjusting Imports of Pharmaceuticals and Pharmaceutical Ingredients Into the United States,'' (Presidential Proclamation) on April 2, 2026, to adjust imports of patented pharmaceuticals and associated pharmaceutical ingredients, (Proclamation 11020 of April 2, 2026) (91 FR 18183).

The Presidential Proclamation directed the Secretary to publish a **Federal Register** Notice indicating that the tariff rate on patented pharmaceuticals and associated pharmaceutical ingredients that are products of the United Kingdom will be reduced to zero to the extent required by any future agreement between the United States and the United Kingdom on pharmaceutical pricing. On April 2, 2026, the United States and the United Kingdom announced the successful conclusion of the pharmaceutical pricing agreement as outlined in the ''Arrangement Between the Government of the United States of America and the Government of the United Kingdom of Great Britain and Northern Ireland on Pharmaceutical Pricing'' *https://ustr.gov/sites/default/files/files/Press/Releases/2026/U.S.-UK%20Pharma%20Pricing%20Arrangement%20-%204.2.2026.pdf.* Furthermore, the requirements of section IV.1.a of the Arrangement are currently being met. Therefore, the tariff rate for patented pharmaceuticals and associated pharmaceutical ingredients that are products of the United Kingdom is now zero.

Modifications to the Harmonized Tariff Schedule of the United States

Effective with respect to goods entered for consumption, or withdrawn for consumption, on or after 12:01 a.m. eastern time on July 31, 2026, heading 9903.04.63 of the Harmonized Tariff

Schedule of the United States is amended by deleting ''+10%'' in each place that it appears and inserting ''+0%'' in lieu thereof.

Jessica Curyto,

Deputy Assistant Secretary for Technology Security.

[FR Doc. 2026–15799 Filed 7–31–26; 4:15 pm]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–875]

Van-Type Trailers and Subassemblies Thereof From Canada: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that van-type trailers and subassemblies thereof (van-type trailers) from Canada are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2024, through September 30, 2025. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable August 4, 2026.

FOR FURTHER INFORMATION CONTACT: Jun Jack Zhao or Maria Teresa Aymerich, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1396 or (202) 482–0499, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on January 26, 2026.[1] On May 15, 2026, Commerce postponed the preliminary determination of this investigation until July 29, 2026.[2]

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/frnotices.*

Scope of the Investigation

The products covered by this investigation are van-type trailers from Canada. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the *Preamble* to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] Commerce is preliminarily modifying the scope as it appeared in the *Initiation Notice* by adding an additional Harmonized Tariff Schedule of the United States (HTSUS) code. *See* the scope in Appendix I to this notice.

In the Preliminary Scope Decision Memorandum, Commerce established the deadline for parties to submit scope case and rebuttal briefs.[7] Commerce intends to issue a final scope decision with the final determinations of the LTFV and CVD investigations of van-type trailers from People's Republic of China (China).

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated constructed export prices in accordance with section 772(b) of the Act. Normal value is calculated in accordance with section 773 of the Act. Furthermore, pursuant to section 776(a) and (b) of the Act, Commerce has preliminarily relied upon facts otherwise available, with adverse inferences, with respect to Collins Manufacturing Company and GINCOR Werx. *See* ''Rate for Non-Responsive Companies,'' below.

Vanguard Refrigerated Trailer Co., Ltd.

Commerce selected Vanguard Refrigerated Trailer Co., Ltd. (Vanguard, or VRTC) as one of the mandatory respondents.[8] We preliminarily determine that Vanguard made no sales of subject merchandise with regard to the LTFV investigation of van-type trailers from Canada, as the record evidence indicates that the van-type trailers it shipped from Canada to the United States during the POI were comprised of Chinese-origin merchandise that falls within the scope of the ongoing LTFV and CVD investigations on van-type trailers from China. Accordingly, we have not calculated a company-specific dumping margin for Vanguard. For further discussion on this issue, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

Commerce calculated an individual estimated weighted-average dumping margin for Manac Inc., the only individually examined exporter/producer in this investigation. Because the only individually calculated dumping margin is not zero, *de minimis,* or based entirely on facts otherwise available, the estimated

[1] *See Van-Type Trailers and Subassemblies Thereof from Canada, the People's Republic of China, and Mexico: Initiation of Less-Than-Fair-Value Investigations,* 91 FR 3104 (January 26, 2026).

[2] *See Van-Type Trailers and Subassemblies Thereof from Canada and Mexico: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 91 FR 29454 (May 20, 2026).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Van-Type Trailers and Subassemblies Thereof from Canada,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

[5] *See Initiation Notice.*

[6] *See* Memorandum, ''Van-Type Trailers and Subassemblies Thereof from Canada, Mexico, and the People's Republic of China: Preliminary Scope Decision Memorandum,'' dated concurrently with this notice (Preliminary Scope Decision Memorandum).

[7] *Id.* at ''Public Comment'' section.

[8] *See* Memorandum, ''Respondent Selection,'' dated March 17, 2026.

weighted-average dumping margin calculated for Manac Inc. is the margin assigned to all other producers and exporters, pursuant to section 735(c)(5)(A) of the Act.

Rate for Non-Responsive Companies

The following two exporters and/or producers of van-type trailers from Canada did not respond to the quantity and value (Q&V) questionnaire: (1) Collins Manufacturing Company; and (2) GINCOR Werx (collectively, the non-responsive companies). We find that, by not responding to the Q&V questionnaire, these companies withheld necessary information that was requested of them, failed to provide information within the deadlines established and significantly impeded this proceeding. Thus, in reaching our preliminary determination, pursuant to sections 776(a)(1) and (2)(A)–(C) of the Act, we are basing the dumping rate for these two companies facts available.

In addition, we preliminary determine that an adverse inference is warranted, pursuant to section 776(b) of the Act. By failing to submit responses to Commerce's Q&V questionnaire, these two companies did not cooperate to the best of their ability in this investigation. Accordingly, we preliminarily find that an adverse inference is warranted to ensure that the non-responsive companies will not obtain a more favorable result than had they fully complied with our request for information. For more information on the application of adverse facts available (AFA), *see* ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Decision Memorandum.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Weighted-average dumping margin (percent)
Manac Inc	4.29
Di-Mond Sales, Inc	4.29
Innovative Trailer Design Industries, Inc	4.29
Morgan Canada Corporation	4.29
Collins Manufacturing Company	*44.86
GINCOR Werx	*44.86
All Others	4.29

*Based on facts available with adverse inferences.

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) the cash deposit rate for the respondents listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

Additionally, because the scope of the LTFV investigation on van-type trailers from China includes Chinese van-type trailers and subassemblies processed in third countries,[9] Chinese subassemblies and/or van-type trailers containing Chinese subassemblies imported through third countries are subject to the suspension of liquidation and cash deposit requirements noted above.[10]

In the LTFV and CVD investigations of van-type trailers from China, and in the instant investigation, the petitioner has requested clarification that Chinese subassemblies and/or van-type trailers containing Chinese subassemblies imported from Canada are subject to China CVD duties.[11] Thus, in the LTFV and CVD investigations of van-type trailers from China, Commerce has established a Canadian third-country case number in the Automated Commercial Environment (ACE).[12] Accordingly, for Chinese subassemblies and/or van-type trailers containing Chinese subassemblies imported through Canada, importers should report such entries under third country case numbers C–122–218 and A–122–219. For van-type trailers containing Chinese subassemblies imported through Canada, only the Chinese subassembly portion of the merchandise is subject to China CVD duties. Importers, producers, or exporters of subject merchandise from other third countries should file a request through ACCESS for Commerce to establish a case number for that specific country in ACE. CBP may also submit a request, through the ACE AD/CVD Portal Inquiry System, for Commerce to establish specific third-country case numbers.

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose its calculations performed to interested parties in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

Non-scope case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. A timeline for the submission of case briefs and written

[9] *See* Appendix I.

[10] *See Van-Type Trailers and Subassemblies Thereof from People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination,* 91 FR 34222, Appendix I (June 5, 2026) (*Van-Type Trailers from China CVD Prelim*); *see also Van-Type Trailers and Subassemblies Thereof from the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value,* 91 FR 35957, Appendix I (June 15, 2026) (*Van-Type Trailers from China LTFV Prelim*) where Commerce reached the same conclusion.

[11] *See Van-Type Trailers from China CVD Prelim,* 91 FR at 34223; *Van-Type Trailers from China LTFV Prelim,* 91 FR at 35958; and Petitioner's Letter, ''Comments in Advance of the Preliminary Determination,'' dated July 23, 2026, at 2–4.

[12] *See Van-Type Trailers from China CVD Prelim,* 91 FR at 34223; *see also Van-Type Trailers from China LTFV Prelim,* 91 FR at 35958.

comments will be notified to interested parties at a later date. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[13] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[14]

As provided under 19 CFR 351.309(c)(2)(iii) and (d)(2)(iii), we request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[15] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[16]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On July 27, 2026, pursuant to 19 CFR 351.210(e), Manac requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[17] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

U.S. International Trade Commission (ITC) Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act, and 19 CFR 351.205(c).

Dated: July 29, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation consists of certain van-type trailers and subassemblies thereof, whether finished or unfinished, whether assembled or unassembled, regardless of the number of axles, for carriage of goods. Van-type trailers are typically, but not limited to, rectangular cuboid trailers with a fully enclosed cargo space consisting of a front nose (with or without a refrigeration unit), side walls (with or without doors), movable rear panels (whether roll-up doors, swing doors, or another configuration), a floor and subframe, an affixed or removable roof, a suspension and axle system, wheels and tires, brakes, a lighting and electrical system, landing gear, and coupling for towing behind a truck tractor or a connection system for training behind another van-type trailer. Covered van-type trailers are those with a gross vehicle weight rating of greater than 26,000 pounds.

Subject merchandise includes, but is not limited to, the following subassemblies:

- Van-type trailer subframes, or sections of van-type trailer frames, typically consisting of welded crossmembers and slider rails for attaching the running gear;
- Nose wall, side wall, and roof subassemblies, whether insulated or non insulated, and with or without top, bottom, or side rails;
- Rear door frame, whether for swing or roll-up doors, with or without installed doors, bumpers, bumper plates, or reinforcing plates for liftgate;
- Door assemblies, whether for rear swing doors, roll-up doors, side doors or any other configuration, with or without lockrods, handles, hinges, or hinge pins;
- Rear impact guard subassemblies, typically consisting of a fabricated horizontal structural component (such as a guard tube) and uprights for connection to the underside of the rear frame;
- Coupler assembly for connection to truck tractor's fifth wheel, typically consisting of main beams and cross members, support plates, and front nose wrap, and with or without kingpin installed;
- Running gear subassemblies or axle assemblies for connection to the subframe, which may or may not include suspension(s), wheel end components, slack adjusters, dressed axles, brake chambers, locking pins, wheels, and tires; and
- Landing gear subassemblies, typically consisting of two landing legs, a cross channel, braces, bracketing, a cross shaft, and a crank handle.

These subassemblies are subject to the investigation, whether entered alone or with other subassemblies and whether assembled or unassembled and whether finished or unfinished. The absence of any subassembly from an otherwise finished or unfinished van-type trailer does not remove the van-type trailer from coverage.

[13] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

[14] *See* 19 CFR 351.309(c)(2) and (d)(2).

[15] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[16] *See APO and Service Procedures.*

[17] *See* Manac's Letter, ''Request for Postponement of Final Determination,'' dated July 27, 2026.

Subject merchandise also includes components entered with (*i.e.,* on the same bill of lading as) van-type trailers and subassemblies, such as, but not limited to: hub and drum assemblies, brake assemblies (either drum or disc), bare axles, brake chambers, suspensions and suspension components, wheel end components, landing gear legs, wheels, tires, brake control systems, electrical harnesses and lighting systems, lift gate systems, tire inflation systems, or refrigeration units (with or without evaporators or fuel tanks) whether assembled or unassembled, whether as part of a kit or not, and whether or not accompanied by additional components that constitute as part of an unfinished and/or unassembled van-type trailer and subassemblies thereof that are subject to the investigation.

Processing of finished and unfinished van-type trailers and subassemblies, such as trimming, cutting, grinding, notching, punching, drilling, painting, coating, staining, finishing, assembly, or any other processing either in the country of manufacture of the in-scope product or in a third country does not remove the product from the scope. Inclusion of other components not identified as comprising the finished or unfinished van-type trailer does not remove the product from the scope.

Specifically excluded are subassemblies covered by the scope of the antidumping and countervailing duty orders on certain chassis and subassemblies thereof from the People's Republic of China. *See Certain Chassis and Subassemblies Thereof from the People's Republic of China: Antidumping Duty Order,* 86 FR 36093 (July 8, 2021) and *Certain Chassis and Subassemblies Thereof from the People's Republic of China: Countervailing Duty Order and Amended Final Affirmative Countervailing Duty Determination,* 86 FR 24844 (May 10, 2021).

The finished and unfinished van-type trailers subject to the investigation are typically classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings: 8716.39.0040, 8716.39.0090 and 8716.90.5060. Imports of finished and unfinished subassemblies may also enter under HTSUS subheadings 7308.30.5050, 7308.90.9590, 7326.90.8688, 8708.29.1500, 8708.99.8180, 8716.90.5010. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise under investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Affiliation
V. Vanguard Refrigerated Trailer Co., Ltd.
VI. Application of Facts Available and Use of Adverse Inferences
VII. All-Others Rate
VIII. Discussion of the Methodology
IX. Currency Conversion
X. Recommendation

[FR Doc. 2026–15763 Filed 8–3–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–019]

Boltless Steel Shelving Units Prepackaged for Sale From the People's Republic of China: Final Results of the Expedited Second Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on boltless steel shelving units prepackaged for sale (boltless steel shelving) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable August 4, 2026.

FOR FURTHER INFORMATION CONTACT: Nathan James, AD/CVD, Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5305.

SUPPLEMENTARY INFORMATION:

Background

On October 21, 2015, Commerce published in the **Federal Register** the CVD order on boltless steel shelving from China.[1] On April 1, 2026, Commerce published the notice of initiation of the second sunset review of the *Order,* pursuant to section 751(c) of the Act and 19 CFR 351.218(c).[2]

On April 14, 2026, Commerce received a notice of intent to participate in this review from the domestic interested party, within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] The domestic interested party claims that it has interested party status within the meaning of section 771(9)(C) of the Act and 19 CFR 351.102(b)(29)(v) as a U.S. producer of the domestic like product.[4]

On April 30, 2026, Commerce received an adequate substantive response from the domestic interested party, within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[5] Commerce did not receive a substantive response from either the Government of China or a respondent interested party to this proceeding. On May 20, 2026, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from respondent interested parties.[6] As a result, Commerce conducted an expedited (120-day) sunset review of the *Order,* pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(B)(2) and (C)(2).

Scope of the Order

The product covered by the *Order* is boltless steel shelving. For a full description of the scope, *see* the Issues and Decision Memorandum.[7]

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of continuation or recurrence of subsidization and the countervailable subsidy rates likely to prevail if the *Order* were to be revoked, is contained in the accompanying Issues and Decision Memorandum.[8] A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), which is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/frnotices.*

Final Results of Sunset Review

Pursuant to sections 751(c) and 752(b) of the Act, Commerce determines that revocation of the *Order* would be likely

[1] *See Boltless Steel Shelving Units Prepackaged for Sale from the People's Republic of China: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 80 FR 63745 (October 21, 2015) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 91 FR 16181 (April 1, 2026).

[3] *See* Domestic Interested Party's Letter, ''Five-Year (2nd Sunset) Review of the Countervailing Duty Order on Boltless Steel Shelving Units Prepackaged for Sale from the People's Republic of China—Petitioner's Notice of Intent to Participate,'' dated April 14, 2026.

[4] *Id.* at 4.

[5] *See* Domestic Interested Party's Letter, ''Five-Year (2nd Sunset) Review of the Countervailing Duty Order on Boltless Steel Shelving Units Prepackaged for Sale from the People's Republic of China—Petitioner's Substantive Response to the Notice of Initiation,'' dated April 30, 2026 (Substantive Response).

[6] *See* Commerce's Letter, ''Sunset Reviews Initiated on April 1, 2026,'' dated May 20, 2026.

[7] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Second Sunset Review of the Countervailing Duty Order on Boltless Steel Shelving Units Prepackaged for Sale from the People's Republic of China,'' dated concurrently with this notice (Issues and Decision Memorandum).

[8] *Id.*

to lead to continuation or recurrence of countervailable subsidies at the following net countervailable subsidy rates:

Producer/Exporter	Subsidy rate (percent)
Ningbo ETDZ Huixing Trade Co., Ltd	12.40
Nanjing Topsun Racking Manufacturing Co., Ltd	15.05
Dalian Huameilong Metal Products Co., Ltd	80.39
Dongguan Yuan Er Sheng Machinery Source Hardware Co., Ltd	80.39
Dong Rong Metal Products Co., Ltd	80.39
Global Storage Equipment Manufacturer Limited	80.39
Intradin (Shanghai) Import & Export Co., Ltd	80.39
Jinhua Development District Hongfa Tool, Ltd	80.39
Kunshan Jisheng Metal & Plastic Co., Ltd	80.39
Nanjing Huade Warehousing Equipment Manufacturing Co., Ltd	80.39
Nanjing Whitney Metal Products Co., Ltd	80.39
Nanjing Yodoly Logistics Equipments Manufacturing Co., Ltd	80.39
Ningbo Decko Metal Products Trade Co., Ltd	80.39
Ningbo Haifa Metal Works Co., Ltd	80.39
Ningbo HaiFa Office Equipment Co., Ltd	80.39
Ningbo TLT Metal Products Co., Ltd	80.39
All Others	13.73

Notification Regarding Administrative Protective Orders

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials, or conversion to judicial protective, orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act, and 19 CFR 351.221(c)(5)(ii).

Dated: July 29, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Legal Framework
VI. Discussion of the Issues
1. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
2. Net Countervailable Subsidy Rates Likely To Prevail
3. Nature of the Subsidies
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2026–15742 Filed 8–3–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–946]

Prestressed Concrete Steel Wire Strand From the People's Republic of China: Final Results of the Expedited Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on prestressed concrete steel wire strand (PC strand) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of the Sunset Review'' section of this notice.

DATES: Applicable August 4, 2026.

FOR FURTHER INFORMATION CONTACT: Peter Zukowski, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0189.

SUPPLEMENTARY INFORMATION:

Background

On July 7, 2010, Commerce published the *Order* on PC strand from China.[1] On April 1, 2026, Commerce published the notice of initiation of the third sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.218(c)(2).[2] On April 16, 2026, Commerce received a notice of intent to participate from Insteel Wire Products Company, Sumiden Wire Products Corporation, and Wire Mesh Corp. (collectively, the domestic interested parties), within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] The domestic interested party claimed interested party status under section 771(9)(C) of the Act and 19 CFR 351.102(b)(29)(v) as producers of the domestic like product.

On May 1, 2026, Commerce received an adequate substantive response from the domestic interested parties within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] Commerce did not receive a substantive response from any government or respondent interested party to this proceeding. On May 20, 2026, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.[5] As a result, Commerce conducted an expedited (120-day) sunset review of the *Order*, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(B)(2) and (C)(2).

Scope of the Order

The product covered by this *Order* is PC strand from China. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.[6]

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of continuation or recurrence of subsidization and the countervailable subsidy rates likely to prevail if the *Order* were to be revoked, is provided in the Issues and Decision Memorandum. A list of the topics discussed in the Issues and Decision Memorandum is attached as an

[1] *See Pre-Stressed Concrete Steel Wire Strand from the People 's Republic of China: Notice of Amended Final Affirmative Countervailing Duty Determination and Notice of Countervailing Duty Order,* 75 FR 38977 (July 7, 2010) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews, 91* FR 16181 (April 1, 2026).

[3] *See* Domestic Industry's Letter, ''Domestic Industry's Notice of Intent to Participate,'' dated April 16, 2026.

[4] *See* Domestic Industry's Letter, ''Domestic Industry's Substantive Response,'' dated May 1, 2026.

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated April 1, 2026,'' dated May 20, 2026.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Sunset Review of the Countervailing Duty Order on Prestressed Concrete Steel Wire Strand from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), which is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed at *https://access.trade.gov/frnotices.*

Final Results of Sunset Review

Pursuant to sections 751(c) and 752(b) of the Act, we determine that revocation of the *Order* would be likely to lead to continuation or recurrence of countervailable subsidies at the following net countervailable subsidy rates:

Producers/Exporters	Net countervailable subsidy rate (percent *ad valorem*)
Fasten Group Corporation, Fasten Group Import & Export Co., Ltd., Jiangyin Hongsheng Co., Ltd., Jiangyin Fasten Steel Products Co., Ltd., Jiangyin Hongyu Metal Products Co., Ltd., and Jiangyin Walsin Steel Cable Co., Ltd. (collectively, the Fasten Companies)	9.42
Xinhua Metal Products Company, Xinyu Iron and Steel Joint Stock Limited Company, and Xingang Iron and Steel Joint Stock Limited Liability Company (collectively, the Xinhua Companies)	45.85
All Others	27.64

Administrative Protective Order (APO)

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

Commerce is issuing and publishing these final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act, and 19 CFR 351.218.

Dated: July 30, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
  2. Net Countervailable Subsidy Rates Likely To Prevail
  3. Nature of the Subsidies
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2026–15749 Filed 8–3–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List; Note Regarding Format of Review Requests

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

Background

Each year during the anniversary month of the publication of an antidumping duty (AD) or countervailing duty (CVD) order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (the Act), may request, in accordance with 19 CFR 351.213, that the U.S. Department of Commerce (Commerce) conduct an administrative review of that AD or CVD order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting date.

Commerce asks that requests for review of multiple companies include an appendix listing, in alphabetical order, the company names for which a review is requested. *See infra* for additional details regarding this request.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review (POR). We intend to release the CBP data under administrative protective order (APO) to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 35 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. Commerce invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

1. In general, Commerce finds that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating AD rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of a review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this AD proceeding (*i.e.,* investigation, administrative review, new shipper review, or changed circumstances review).

2. For any company subject to a review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection.

3. Parties are requested to: (a) identify which companies subject to review previously were collapsed; and (b)

provide a citation to the proceeding in which they were collapsed.

4. Further, if companies are requested to complete a Quantity and Value Questionnaire for purposes of respondent selection, in general, each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of a proceeding where Commerce considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[1] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation, pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial Section D responses.

Opportunity to Request a Review: Not later than the last day of August 2026,[2] interested parties may request an administrative review of the following orders, findings, or suspended investigations, with anniversary dates in August for the following periods:

Antidumping Duty Proceedings	
CANADA: Utility Scale Wind Towers, A–122–867	8/1/25–7/31/26
GERMANY:	
Seamless Line and Pressure Pipe, A–428–820	8/1/25–7/31/26
Sodium Nitrite, A–428–841	8/1/25–7/31/26
INDIA: Finished Carbon Steel Flanges, A–533–871	8/1/25–7/31/26
INDONESIA: Utility Scale Wind Towers, A–560–833	8/1/25–7/31/26
ITALY: Finished Carbon Steel Flanges, A–475–835	8/1/25–7/31/26
JAPAN:	
Brass Sheet & Strip, A–588–704	8/1/25–7/31/26
Tin Mill Products, A–588–854	8/1/25–7/31/26
MALAYSIA:	
Polyethylene Retail Carrier Bags, A–557–813	8/1/25–7/31/26
Silicon Metal, A–557–820	8/1/25–7/31/26
MEXICO:	
Light-Walled Rectangular Pipe and Tube, A–201–836	8/1/25–7/31/26
Standard Steel Welded Wire Mesh, A–201–853	8/1/25–7/31/26
REPUBLIC OF KOREA:	
Dioctyl Terephthalate (DOTP), A–580–889	8/1/25–7/31/26
Large Power Transformers, A–580–867	8/1/25–7/31/26
Light-Walled Rectangular Pipe And Tube, A–580–859	8/1/25–7/31/26
Low Melt Polyester Staple Fiber, A–580–895	8/1/25–7/31/26
Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe, A–580–909	8/1/25–7/31/26
Utility Scale Wind Towers, A–580–902	8/1/25–7/31/26
REPUBLIC OF TÜRKIYE: Certain Brake Drums, A–489–853	1/29/25–7/31/26
ROMANIA: Carbon And Alloy Seamless Standard, Line, And Pressure Pipe, (Under 4½ Inches), A–485–805	8/1/25–7/31/26
RUSSIA:	
Certain Cut-to-Length Carbon Steel Plate, A–821–808	8/1/25–7/31/26
Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe, A–821–826	8/1/25–7/31/26
SOCIALIST REPUBLIC OF VIETNAM:	
Frozen Fish Fillets, A–552–801	8/1/25–7/31/26
Seamless Refined Copper Pipe and Tube, A–552–831	8/1/25–7/31/26
Utility Scale Wind Towers, A–552–825	8/1/25–7/31/26
SPAIN:	
Ripe Olives, A–469–817	8/1/25–7/31/26
Utility Scale Wind Towers, A–469–823	8/1/25–7/31/26
TAIWAN: Low Melt Polyester Staple Fiber, A–583–861	8/1/25–7/31/26
THAILAND:	
Polyethylene Retail Carrier Bags, A–549–821	8/1/25–7/31/26
Steel Propane Cylinders, A–549–839	8/1/25–7/31/26
THE PEOPLE'S REPUBLIC OF CHINA:	

[1] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[2] Or the next business day, if the deadline falls on a weekend, Federal holiday or any other day when Commerce is closed.

Certain Brake Drums, A–570–174	1/29/25–7/31/26
Cast Iron Soil Pipe Fittings, A–570–062	8/1/25–7/31/26
Certain Metal Lockers and Parts Thereof, A–570–133	8/1/25–7/31/26
Certain Passenger Vehicle and Light Truck Tires, A–570–016	8/1/25–7/31/26
Certain Pea Protein, A–570–154	8/1/25–7/31/26
Certain Steel Nails, A–570–909	8/1/25–7/31/26
Certain Steel Wheels,[3] A–570–082	5/1/25–4/30/26
Certain Tungsten Shot, A–570–178	2/19/26–7/31/26
Floor-Standing, Metal-Top Ironing Tables And Parts Thereof, A–570–888	8/1/25–7/31/26
Hydrofluorocarbon Blends And Components Thereof, A–570–028	8/1/25–7/31/26
Laminated Woven Sacks, A–570–916	8/1/25–7/31/26
Light-Walled Rectangular Pipe And Tube, A–570–914	8/1/25–7/31/26
Certain Low Speed Personal Transportation Vehicles, A–570–176	11/1/24–7/31/26
Petroleum Wax Candles, A–570–504	8/1/25–7/31/26
Polyethylene Retail Carrier Bags, A–570–886	8/1/25–7/31/26
Sodium Nitrite, A–570–925	8/1/25–7/31/26
Stainless Steel Flanges, A–570–064	8/1/25–7/31/26
Steel Propane Cylinders, A–570–086	8/1/25–7/31/26
Tetrahydrofurfuryl Alcohol (THFA), A–570–887	8/1/5–7/31/26
Tow-Behind Lawn Groomers And Parts Thereof, A–570–939	8/1/25–7/31/26
UKRAINE:	
Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe, A–823–819	8/1/25–7/31/26
Silicomanganese, A–823–805	8/1/25–7/31/26
Countervailing Duty Proceedings	
CANADA: Utility Scale Wind Towers, C–122–868	1/1/25–12/31/25
INDIA: Finished Carbon Steel Flanges, C–533–872	1/1/25–12/31/25
MALAYSIA: Utility Scale Wind Towers, C–557–822	1/1/25–12/31/25
REPUBLIC OF KOREA:	
Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe, C–580–910	1/1/25–12/31/25
Stainless Steel Sheet And Strip In Coils, C–580–835	1/1/25–12/31/25
REPUBLIC OF TÜRKIYE: Certain Brake Drums, C–489–854	12/3/24–12/31/25
RUSSIA:	
Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe, C–821–827	1/1/25–12/31/25
Sodium Nitrite, C–821–837	1/1/25–12/31/25
SOCIALIST REPUBLIC OF VIETNAM: Utility Scale Wind Towers, C–552–826	1/1/25–12/31/25
SPAIN: Ripe Olives, C–469–818	1/1/25–12/31/25
THE PEOPLE'S REPUBLIC OF CHINA:	
Certain Brakes Drums, C–570–175	12/3/24–12/31/25
Cast Iron Soil Pipe Fittings, C–570–063	1/1/25–12/31/25
Certain Metal Lockers and Parts Thereof, C–570–134	1/1/25–12/31/25
Certain Low Speed Personal Transportation Vehicles, C–570–177	9/7/24–12/31/25
Certain Pea Protein, C–570–155	1/1/25–12/31/25
Certain Steel Wheels,[4] C–570–083	1/1/25–12/31/25
Certain Tungsten Shot, C–570–179	12/20/24–12/31/25
Laminated Woven Sacks, C–570–917	1/1/25–12/31/25
Light-Walled Rectangular Pipe and Tube, C–570–915	1/1/25–12/31/25
Passenger Vehicle and Light Truck Tires, C–570–017	1/1/25–12/31/25
Sodium Nitrite, C–570–926	1/1/25–12/31/25
Steel Propane Cylinders, C–570–087	1/1/25–12/31/25

Suspension Agreements

None.

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that Commerce conduct an administrative review. For both AD and CVD reviews, the interested party must specify the individual producers or exporters covered by an AD finding or an AD or CVD order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires Commerce to review those particular producers or exporters. If the interested party intends for Commerce to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Note that, for any party Commerce was unable to locate in prior segments, Commerce will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for Commerce to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

[3] Commerce inadvertently did not include certain steel wheels from the People's Republic of China in the *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List; Note Regarding Format of Review Requests,* 91 FR 23956 (May 4, 2026).

[4] Commerce inadvertently did not include certain steel wheels from the People's Republic of China in the *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List; Note Regarding Format of Review Requests,* 91 FR 23956 (May 4, 2026).

Commerce is instituting a new formatting request. Specifically, Commerce asks that requests for review of multiple companies also include an appendix listing, in alphabetical order, the company names for which a review is requested. The list should be limited solely to company names and formatted as a single column, with each company name identified on a separate line, except in the case of companies that Commerce previously determined should be collapsed into a single entity or found to be cross-owned with other companies. Companies that Commerce previously determined should be collapsed or found to be cross-owned with one another should be listed together as a group, on one line—or more, as needed, for the group—with the company names within each group listed alphabetically and separated by semicolons.

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (June 6, 2003), and *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), Commerce clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to AD findings and orders.[5]

Commerce no longer considers the non-market economy (NME) entity as an exporter conditionally subject to an AD administrative review.[6] Accordingly, the NME entity will not be under review unless Commerce specifically receives a request for, or self-initiates, a review of the NME entity.[7] In administrative reviews of AD orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate rate, Commerce will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity's entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity). Following initiation of an AD administrative review when there is no review requested of the NME entity, Commerce will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

All requests must be filed electronically in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) on Enforcement and Compliance's ACCESS website at *https://access.trade.gov*.[8] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request. Interested parties should note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[9]

Commerce will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of August 2026. If Commerce does not receive, by the last day of August 2026, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, Commerce will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period of the order, if such a gap period is applicable to the period of review.

Establishment of and Updates to the Annual Inquiry Service List

On September 20, 2021, Commerce published the final rule titled ''*Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*'' in the **Federal Register**.[10] On September 27, 2021, Commerce also published the notice entitled ''*Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions*'' in the **Federal Register**.[11] The *Final Rule* and *Procedural Guidance* provide that Commerce will maintain an annual inquiry service list for each order or suspended investigation, and any interested party submitting a scope ruling application or request for circumvention inquiry shall serve a copy of the application or request on the persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin.[12]

In accordance with the *Procedural Guidance,* for orders published in the **Federal Register** before November 4, 2021, Commerce created an annual inquiry service list segment for each order and suspended investigation. Interested parties who wished to be added to the annual inquiry service list for an order submitted an entry of appearance to the annual inquiry service list segment for the order in ACCESS and, on November 4, 2021, Commerce finalized the initial annual inquiry service lists for each order and suspended investigation. Each annual inquiry service list has been saved as a public service list in ACCESS, under each case number, and under a specific segment type called ''AISL-Annual Inquiry Service List.'' [13]

As mentioned in the *Procedural Guidance,* beginning in January 2022,

[5] *See* Enforcement and Compliance's website at *https://www.trade.gov/us-antidumping-and-countervailing-duties-home-page.*

[6] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[7] In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.

[8] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[9] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

[10] *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300 (September 20, 2021) (*Final Rule*).

[11] *See Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions,* 86 FR 53205 (September 27, 2021) (*Procedural Guidance*).

[12] *Id.*

[13] This segment has been combined with the ACCESS Segment Specific Information (SSI) field which will display the month in which the notice of the order or suspended investigation was published in the **Federal Register**, also known as the anniversary month. For example, for an order under case number A–000–000 that was published in the **Federal Register** in January, the relevant segment and SSI combination will appear in ACCESS as ''AISL-January Anniversary.'' Note that there will be only one annual inquiry service list segment per case number, and the anniversary month will be pre-populated in ACCESS.

Commerce will update these annual inquiry service lists on an annual basis when the *Opportunity Notice* for the anniversary month of the order or suspended investigation is published in the **Federal Register**.[14] Accordingly, Commerce will update the annual inquiry service lists for the above-listed AD and CVD proceedings. All interested parties wishing to appear on the updated annual inquiry service list must take one of the two following actions: (1) new interested parties who did not previously submit an entry of appearance must submit a new entry of appearance at this time; (2) interested parties who were included in the preceding annual inquiry service list must submit an amended entry of appearance to be included in the next year's annual inquiry service list. For these interested parties, Commerce will change the entry of appearance status from ''Active'' to ''Needs Amendment'' for the annual inquiry service lists corresponding to the above-listed proceedings. This will allow those interested parties to make any necessary amendments and resubmit their entries of appearance. If no amendments need to be made, the interested party should indicate in the area on the ACCESS form requesting an explanation for the amendment that it is resubmitting its entry of appearance for inclusion in the annual inquiry service list for the following year. As mentioned in the *Final Rule,*[15] once the petitioners and foreign governments have submitted an entry of appearance for the first time, they will automatically be added to the updated annual inquiry service list each year.

Interested parties have 30 days after the date of this notice to submit new or amended entries of appearance. Commerce will then finalize the annual inquiry service lists five business days thereafter. For ease of administration, please note that Commerce requests that law firms with more than one attorney representing interested parties in a proceeding designate a lead attorney to be included on the annual inquiry service list.

Commerce may update an annual inquiry service list at any time as needed based on interested parties' amendments to their entries of appearance to remove or otherwise modify their list of members and representatives, or to update contact information. Any changes or announcements pertaining to these procedures will be posted to the ACCESS website at *https://access.trade.gov.*

Special Instructions for Petitioners and Foreign Governments

In the *Final Rule,* Commerce stated that, ''after an initial request and placement on the annual inquiry service list, both petitioners and foreign governments will automatically be placed on the annual inquiry service list in the years that follow.'' [16] Accordingly, as stated above and pursuant to 19 CFR 351.225(n)(3), the petitioners and foreign governments will not need to resubmit their entries of appearance each year to continue to be included on the annual inquiry service list. However, the petitioners and foreign governments are responsible for making amendments to their entries of appearance during the annual update to the annual inquiry service list in accordance with the procedures described above.

Notification to Interested Parties

This notice is not required by statute but is published as a service to the international trading community.

Dated: July 30, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026–15800 Filed 8–3–26; 8:45 am]

BILLING CODE 3510–DS–P

[14] *See Procedural Guidance,* 86 FR at 53206.

[15] *See Final Rule,* 86 FR at 52335.

[16] *Id.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–867]

Van-Type Trailers and Subassemblies Thereof From Mexico: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that van-type trailers and subassemblies thereof (van-type trailers) from Mexico are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2024, through September 30, 2025. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable August 4, 2026.

FOR FURTHER INFORMATION CONTACT: Charles DeFilippo or Jacob Saude, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3797 or (202) 482–9081, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on January 26, 2026.[1] On May 20, 2026, Commerce postponed the preliminary determination of this investigation and the revised deadline is now July 29, 2026.[2]

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/frnotices.*

Scope of the Investigation

The products covered by this investigation are van-type trailers from Mexico. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the *Preamble* to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product

[1] *See Van-Type Trailers and Subassemblies Thereof from Canada, the People's Republic of China, and Mexico: Initiation of Less-Than-Fair-Value Investigations,* 91 FR 3104 (January 26, 2026) (*Initiation Notice*).

[2] *See Van-Type Trailers and Subassemblies Thereof from Canada and Mexico: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 91 FR 29454 (May 20, 2026).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Determination in the Less-Than-Fair Value Investigation of Van-Type Trailers and Subassemblies Thereof from Mexico'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

coverage (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[6] Commerce is preliminarily modifying the scope as it appeared in the *Initiation Notice* by adding an additional Harmonized Tariff Schedule of the United States (HTSUS) code. *See* the scope in Appendix I to this notice. In the Preliminary Scope Decision Memorandum, Commerce established the deadline for parties to submit scope case and rebuttal briefs.[7] Commerce intends to issue a final scope decision with the final determinations of the LTFV and CVD investigations of van-type trailers from People's Republic of China (China).

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated constructed export prices in accordance with section 772(b) of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

In this investigation, Commerce calculated estimated weighted-average dumping margins for Hyundai de Mexico S.A. de C.V. (HYMEX) and Utility Trailer Manufacturing de México, S. de R.L. de C.V. (Utility Mexico) that are not zero, *de minimis,* or based entirely on facts otherwise available. Commerce calculated the all-others rate using a weighted average of the estimated weighted-average dumping margins calculated for the examined respondents using each company's publicly-ranged values for the merchandise under consideration.[8]

Rate for Non-Responsive Companies

The following five exporters and/or producers of van-type trailers from Mexico did not respond to the quantity and value (Q&V) questionnaire: (1) Commercializadora Nimmka, S.A. de. C.V. d/b/a Atro Remolques y Carrociera (Commercializadora Nimmka); (2) BRD Trailers S.A. de C.V. d/b/a DeLucio (BRD Trailers); (3) Gallegos Trailers (Gallegos); (4) Industrias Kuzzy De Mexico S.A. de C.V. (Industrias Kuzzy); and (5) Manufacturas Industriales Gami S.A. de C.V. (Industriales Gami) (collectively, non-responsive companies). We find that, by not responding to the Q&V questionnaire, these companies withheld necessary information that Commerce requested of them, failed to provide information within the deadlines established and significantly impeded this proceeding. Thus, in reaching our preliminary determination, pursuant to sections 776(a)(1) and (2)(A)–(C) of the Act, we are basing the dumping rate for the non-responsive companies on facts available.

In addition, we preliminary determine that an adverse inference is warranted, pursuant to section 776(b) of the Act. By failing to submit responses to Commerce's Q&V questionnaire, the non-responsive companies did not cooperate to the best of their ability in this investigation. Accordingly, we preliminarily find that an adverse inference is warranted to ensure that the non-responsive companies will not obtain a more favorable result than had they fully complied with our request for information. For more information on the application of adverse facts available (AFA), *see* ''Application of Facts Available, Use of Adverse Inferences, and Corroboration'' in the Preliminary Decision Memorandum.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter Producer	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset(s)) (percent)
Hyundai de Mexico S.A. de C.V	10.19	[9] 8.35
Utility Trailer Manufacturing de México, S. de R.L. de C.V	3.21	[10] 2.43
Commercializadora Nimmka, S.A. de. C.V. d/b/a Atro Remolques y Carrociera	79.92 *	79.92
BRD Trailers S.A. de C.V. d/b/a DeLucio	79.92 *	79.92
Gallegos Trailers	79.92 *	79.92
Industrias Kuzzy De Mexico S.A. de C.V.	79.92 *	79.92
Manufacturas Industriales Gami S.A. de C.V.	79.92 *	79.92
All Others	8.72	[11] 7.10

* Rate is based on facts available with adverse inferences.

[5] *See Initiation Notice.*

[6] *See* Memorandum, ''Van-Type Trailers and Subassemblies Thereof from Canada, Mexico, and the People's Republic of China: Preliminary Scope Decision Memorandum,'' dated concurrently with this notice (Preliminary Scope Decision Memo).

[7] *Id.* at ''Public Comment'' section.

[8] With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents; (B) a simple average of the estimated weighted-average dumping margins calculated for the examined respondents; and (C) a weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents using each company's publicly-ranged U.S. sales values for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53662 (September 1, 2010), and accompanying Issues and Decision Memorandum at Comment1. As complete publicly ranged sales data were available, Commerce based the all-others rate on the publicly ranged sales data of the mandatory respondents. For a complete analysis of the data, *see* Memorandum, ''Preliminary Calculation of All-Others Rate,'' dated concurrently with this notice (All-Others Memorandum).

[9] The export subsidy rate for HYMEX is 1.84 percent and consists of the following programs: Program for the Manufacturing Industry, Maquiladora and Export Services Program (IMMEX); and Eighth Rule Permit. *See* Memorandum, ''Preliminary Determination Calculations for Hyundai de Mexico S.A. de C.V.,'' dated June 1, 2026.

[10] The export subsidy rate for Utility Mexico is 0.78 percent and consists of the following programs: Program for the Manufacturing Industry, Maquiladora and Export Services Program (IMMEX); and Eighth Rule Permit. *See* Memorandum, ''Preliminary Determination Calculations for Utility Trailer Manufacturing de Mexico, S. de R.L. de C.V.,'' dated June 1, 2026.

[11] *See* All-Others Memorandum.

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) The cash deposit rate for the respondents listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

Commerce normally adjusts cash deposits for estimated antidumping duties by the amount of export subsidies countervailed in a companion countervailing duty (CVD) proceeding, when CVD provisional measures are in effect. Accordingly, where Commerce preliminarily made an affirmative determination for countervailable export subsidies, Commerce has offset the estimated weighted-average dumping margin by the appropriate CVD rate. Any such adjusted cash deposit rate may be found in the ''Preliminary Determination'' section above. Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting estimated antidumping duty cash deposits unadjusted for countervailed export subsidies at the time that the provisional CVD measures expire.

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

Non-scope case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[12] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[13]

As provided under 19 CFR 351.309(c)(2)(iii) and (d)(2)(iii), we request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[14] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[15]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On July 23, 2026, pursuant to 19 CFR 351.210(e), HYMEX requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[16] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will

[12] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

[13] *See* 19 CFR 351.309(c)(2) and (d)(2).

[14] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[15] *See APO and Service Procedures.*

[16] *See* HYMEX's Letter, ''Request for Postponement of Final AD Determination,'' dated July 23, 2026.

make its final determination no later than 135 days after the date of publication of this preliminary determination.

U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: July 29, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation consists of certain van-type trailers and subassemblies thereof, whether finished or unfinished, whether assembled or unassembled, regardless of the number of axles, for carriage of goods. Van-type trailers are typically, but not limited to, rectangular cuboid trailers with a fully enclosed cargo space consisting of a front nose (with or without a refrigeration unit), side walls (with or without doors), movable rear panels (whether roll-up doors, swing doors, or another configuration), a floor and subframe, an affixed or removable roof, a suspension and axle system, wheels and tires, brakes, a lighting and electrical system, landing gear, and coupling for towing behind a truck tractor or a connection system for training behind another van-type trailer. Covered van-type trailers are those with a gross vehicle weight rating of greater than 26,000 pounds.

Subject merchandise includes, but is not limited to, the following subassemblies:

- Van-type trailer subframes, or sections of van-type trailer frames, typically consisting of welded crossmembers and slider rails for attaching the running gear;
- Nose wall, side wall, and roof subassemblies, whether insulated or non insulated, and with or without top, bottom, or side rails;
- Rear door frame, whether for swing or roll-up doors, with or without installed doors, bumpers, bumper plates, or reinforcing plates for liftgate;
- Door assemblies, whether for rear swing doors, roll-up doors, side doors or any other configuration, with or without lockrods, handles, hinges, or hinge pins;
- Rear impact guard subassemblies, typically consisting of a fabricated horizontal structural component (such as a guard tube) and uprights for connection to the underside of the rear frame;
- Coupler assembly for connection to truck tractor's fifth wheel, typically consisting of main beams and cross members, support plates, and front nose wrap, and with or without kingpin installed;
- Running gear subassemblies or axle assemblies for connection to the subframe, which may or may not include suspension(s), wheel end components, slack adjusters, dressed axles, brake chambers, locking pins, wheels, and tires; and
- Landing gear subassemblies, typically consisting of two landing legs, a cross channel, braces, bracketing, a cross shaft, and a crank handle.

These subassemblies are subject to the investigation, whether entered alone or with other subassemblies and whether assembled or unassembled and whether finished or unfinished. The absence of any subassembly from an otherwise finished or unfinished van-type trailer does not remove the van-type trailer from coverage.

Subject merchandise also includes components entered with (*i.e.,* on the same bill of lading as) van-type trailers and subassemblies, such as, but not limited to: hub and drum assemblies, brake assemblies (either drum or disc), bare axles, brake chambers, suspensions and suspension components, wheel end components, landing gear legs, wheels, tires, brake control systems, electrical harnesses and lighting systems, lift gate systems, tire inflation systems, or refrigeration units (with or without evaporators or fuel tanks) whether assembled or unassembled, whether as part of a kit or not, and whether or not accompanied by additional components that constitute as part of an unfinished and/or unassembled van-type trailer and subassemblies thereof that are subject to the investigation.

Processing of finished and unfinished van-type trailers and subassemblies, such as trimming, cutting, grinding, notching, punching, drilling, painting, coating, staining, finishing, assembly, or any other processing either in the country of manufacture of the in-scope product or in a third country does not remove the product from the scope. Inclusion of other components not identified as comprising the finished or unfinished van-type trailer does not remove the product from the scope.

Specifically excluded are subassemblies covered by the scope of the antidumping and countervailing duty orders on certain chassis and subassemblies thereof from the People's Republic of China. *See Certain Chassis and Subassemblies Thereof from the People's Republic of China: Antidumping Duty Order,* 86 FR 36093 (July 8, 2021) and *Certain Chassis and Subassemblies Thereof From the People's Republic of China: Countervailing Duty Order and Amended Final Affirmative Countervailing Duty Determination,* 86 FR 24844 (May 10, 2021).

The finished and unfinished van-type trailers subject to the investigation are typically classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings: 8716.39.0040, 8716.39.0090 and 8716.90.5060. Imports of finished and unfinished subassemblies may also enter under HTSUS subheadings 7308.30.5050, 7308.90.9590, 7326.90.8688, 8708.29.1500, 8708.99.8180, 8716.90.5010. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise under investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Affiliation
V. Application of Facts Available and Use of Adverse Inferences
VI. Discussion of the Methodology
VII. Currency Conversion
VIII. Adjustments to Cash Deposit Rates for Export Subsidies in the Companion Countervailing Duty Investigation
IX. Recommendation

[FR Doc. 2026–15764 Filed 8–3–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–898]

Large Diameter Welded Pipe From the Republic of Korea: Preliminary Results and Rescission, in Part, of Countervailing Duty Administrative Review; 2024

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies were provided to producers and exporters of large diameter welded pipe (welded pipe) from the Republic of Korea (Korea). The period of review (POR) is January 1, 2024, through December 31, 2024. In addition, Commerce is rescinding this review, in part, with respect to 16 companies. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable August 4, 2026.

FOR FURTHER INFORMATION CONTACT: Jonathan Schueler or Brandon James, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington,

DC 20230; telephone: (202) 482–9175 and (202) 482–7472.

SUPPLEMENTARY INFORMATION:

Background

On May 2, 2019, Commerce published a countervailing duty (CVD) order on LDWP from Korea.[1] On June 25, 2025, based on timely requests for review, in accordance with 19 CFR 351.221(c)(1)(i), Commerce initiated an administrative review of the *Order.*[2] On September 5, 2025, Commerce selected Hyundai Steel Pipe Co., Ltd. (HSP) and SeAH Steel Corporation (SeAH Steel) as the mandatory respondents in this review.[3]

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.[4] Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.[5] On February 18, 2026, Commerce extended the deadline for issuing these preliminary results by 90 days.[6] On June 10, 2026, Commerce extended the deadline for issuing these preliminary results by an additional 21 days, until June 29, 2026.[7]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[8] A list of topics included in the Preliminary Decision Memorandum is provided in Appendix I. The Preliminary Decision Memorandum is a public document and is on file electronically via ACCESS. ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/frnotices.*

Scope of the Order

The product covered by the *Order* is welded pipe from Korea. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Rescission of Administrative Review, In Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if all parties that requested the review withdraw their requests within 90 days of the date of publication of the notice of initiation. As noted above, Commerce received timely-filed withdrawal requests with respect to the following companies, and no other parties requested a review of these companies: (1) Hansol Metal Co., Ltd.; (2) Il Jin Nts Co., Ltd.; (3) Iljin Nts Co. Ltd.; (4) Kem Solutions Co., Ltd.; and (5) POSCO International Corporation.[9] Therefore, we are rescinding this administrative review with respect to these companies, pursuant to 19 CFR 351.213(d)(1).

Pursuant to 19 CFR 351.213(d)(3), it is Commerce's practice to rescind an administrative review of a countervailing duty order where it concludes that there were no suspended entries of subject merchandise during the POR.[10] Normally, upon completion of an administrative review, the suspended entries are liquidated at the CVD assessment rate calculated for the POR.[11] Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry that Commerce can instruct U.S. Customs and Border Protection (CBP) to liquidate at the CVD assessment rate calculated for the POR.[12] Commerce notified all interested parties of its intent to rescind this administrative review regarding the companies listed in Appendix II.[13] No party commented on this memorandum. In the absence of any suspended entries of subject merchandise from these companies during the POR, we are rescinding this administrative review for the companies listed in Appendix II, in accordance with 19 CFR 351.213(d)(3).

Methodology

Commerce is conducting this administrative review in accordance with 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[14] For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Rate for Non-Individually Examined Companies

There are nine companies for which a review was requested and Commerce does not intend to rescind review, which had reviewable entries, and which were not selected as mandatory respondents or found to be cross-owned with a mandatory respondent (*see* Appendix III). The Act does not address the establishment of a rate to apply to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce's regulation at 19 CFR 351.109(g) states that Commerce will determine the rate for non-selected companies by following the process set forth in 19 CFR 351.109(f)(1)–(2), which generally parallels the process for determining the all-others rate in an investigation under section 705(c)(5) of the Act. Section 705(c)(5)(A) of the Act

[1] *See Large Diameter Welded Pipe from the Republic of Korea: Countervailing Duty Order,* 84 FR 18773 (May 2, 2019) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* (90 FR 26967) (June 25, 2025) (*Initiation Notice*).

[3] *See* Memorandum, ''Respondent Selection,'' dated September 5, 2025.

[4] *See* Memorandum, ''Deadlines Affected by the Shutdown of the Federal Government,'' dated November 14, 2025.

[5] *See* Memorandum, ''Tolling of all Case Deadlines,'' dated November 24, 2025.

[6] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review,'' dated February 18, 2026.

[7] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review,'' dated June 10, 2026.

[8] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Countervailing Duty Order on Large Diameter Welded Pipe from the Republic of Korea; 2024,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[9] *See* American Line Pipe Producers Association's Letter, ''Partial Withdrawal of Request for Administrative Review,'' dated September 23, 2025.

[10] *See, e.g., Certain Non-Refillable Steel Cylinders from the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2024,* 90 FR 48043 (October 3, 2025).

[11] *See* 19 CFR 351.212(b)(2).

[12] *See, e.g., Shanghai Sunbeauty Trading Co.* v. *United States,* 380 F.Supp.3d 1328, 1337 (CIT 2019), at 12 (referring to section 751(a) of the Act, the U.S. Court of International Trade held that ''{w}hile the statute does not explicitly require that an entry be suspended as a prerequisite for establishing entitlement to a review, it does explicitly state the determined rate will be used as the liquidation rate for the reviewed entries. This result can only obtain if the liquidation of entries has been suspended''; *see also Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2018–2019,* 86 FR 36102, and accompanying Issues and Decision Memorandum at Comment 4; and *Solid Fertilizer Grade Ammonium Nitrate from the Russian Federation: Notice of Rescission of Antidumping Duty Administrative Review,* 77 FR 65532 (October 29, 2012) (noting that ''for an administrative review to be conducted, there must be a reviewable, suspended entry to be liquidated at the newly calculated assessment rate'').

[13] *See* Memorandum, ''Notice of Intent to Rescind Review, In Part,'' dated July 15, 2026.

[14] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

and 19 CFR 351.109(f) state that for companies not investigated, in general, we will determine an all-others rate by weight averaging the countervailable subsidy rates established for each of the companies individually investigated, excluding zero and *de minimis* rates or any rates based entirely on facts available.

Accordingly, to determine the rate for companies not selected for individual examination, Commerce's practice is to weight-average the net subsidy rates for the selected mandatory respondents, excluding rates that are zero, *de minimis,* or based entirely on facts available.[15] For these preliminary results, because the rate calculated for SeAH Steel is *de minimis*, we are preliminarily assigning to the companies under review that were not selected for individual examination a countervailable subsidy rate based on the rate calculated for HSP.

Preliminary Results of Review

In accordance with 19 CFR 351.221(b)(4)(i), we preliminarily determine the following net countervailable subsidy rates exist for the POR, January 1, 2024, through December 31, 2024:

Company	Subsidy rate (percent *ad valorem*)
Hyundai Steel Pipe Co., Ltd[16].	1.00.
SeAH Steel Corporation[17]	0.27 (*de minimis*).
Non-Selected Companies Receiving a Review-Specific Rate[18].	1.00.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties for these preliminary results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(3) of the Act, Commerce intends to verify the information relied upon in making its final results.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this review. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[19] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[20] All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the established deadline.

As provided under 19 CFR 351.309(c)(2)(iii) and (d)(2)(iii), we request that interested parties provide at the beginning of their briefs a public executive summary for each issue raised in their briefs.[21] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[22]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce will inform parties of the scheduled date for the hearing.[23]

Assessment Rates

Consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review.

For the companies with respect to which the review is being rescinded, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue rescission instructions to CBP no earlier than 35 days after the date of publication of this notice in the **Federal Register**.

Commerce intends to issue assessment instructions to CBP regarding HSP, SeAH Steel, and the companies listed in Appendix III no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.107(e), Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review, as follows: (1) the cash deposit rate for the companies listed above will be equal to the company-specific estimated individual countervailable subsidy rates determined in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) if both the producer and exporter of the subject

[15] *See, e.g., Certain Pasta from Italy: Final Results of the 13th (2008) Countervailing Duty Administrative Review,* 75 FR 37386, 37387 (June 29, 2010).

[16] As discussed in the Preliminary Decision Memorandum, Commerce has found the following company to be cross-owned with HSP: Hyundai Steel Company.

[17] As discussed in the Preliminary Decision Memorandum, Commerce has found the following company to be cross-owned with SeAH Steel: SeAH Steel Holdings Corporation.

[18] *See* Appendix III for a list of the non-selected companies under review.

[19] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

[20] *See* 19 CFR 351.309(c)(2) and (d)(2).

[21] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[22] *See APO and Service Procedures.*

[23] *See* 19 CFR 351.310(d).

merchandise have company-specific estimated subsidy rates assigned, and their rates differ, then the applicable cash deposit rate will be the higher of these two rates; (3) if either the producer or the exporter, but not both, of the subject merchandise has a company-specific estimated subsidy rate assigned, the applicable cash deposit rate will be that company's company-specific rate; and (4) the cash deposit rate for all other producers and exporters will be continue to be 9.29 percent, the all-others subsidy rate established in the investigation.[24] These cash deposit instructions, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless the deadline is extended, Commerce intends to issue the final results of this administrative review, which will include the results of Commerce's analysis of the issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: July 29, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Diversification of Korea's Economy
V. Subsidies Valuation
VI. Benchmarks and Interest Rates
VII. Analysis of Programs
VIII. Recommendation

Appendix II

Companies With No Reviewable Entries Rescinded From Review

1. Daiduck Piping Co., Ltd.
2. Dongbu Incheon Steel Co., Ltd.
3. EEW KHPC Co., Ltd.
4. Kiduck Industries Co., Ltd.
5. Kum Kang Kind. Co., Ltd.
6. Kumsoo Connecting Co., Ltd.
7. Samkang M&T Co., Ltd.
8. Seonghwa Industrial Co., Ltd.
9. SIN–E B&P Co., Ltd.
10. Steel Flower Co., Ltd.
11. WELTECH Co., Ltd.

[24] *See Order,* 84 FR at 18773.

Companies Withdrawn From Review Requests and Rescinded From Review

1. Hansol Metal Co., Ltd.
2. Il Jin Nts Co., Ltd.
3. Iljin Nts Co. Ltd.
4. Kem Solutions Co., Ltd.
5. POSCO International Corporation

Appendix III

Non-Selected Companies Under Review

1. AJU Besteel Co., Ltd.
2. Chang Won Bending Co., Ltd.
3. Dong Yang Steel Pipe Co., Ltd.
4. EEW Korea Co., Ltd.
5. Histeel Co., Ltd.
6. Husteel Co., Ltd.[25]
7. Hyundai RB Co., Ltd.; Shinchang Construction Co., Ltd.
8. Hyundai Steel Company[26]
9. Nexteel Co., Ltd.

[FR Doc. 2026–15802 Filed 8–3–26; 8:45 am]

BILLING CODE 3510–DS–P

[25] Subject merchandise both produced and exported by Husteel Co., Ltd. (Husteel) is excluded from the countervailing duty order. *See Order,* 84 FR at 18773. Thus, Husteel's inclusion in this administrative review is limited to entries for which Husteel was not both the producer and exporter of the subject merchandise.

[26] Subject merchandise both produced and exported by Hyundai Steel Company (Hyundai Steel) and subject merchandise produced by Hyundai Steel and exported by Hyundai Corporation are excluded from the countervailing duty order. *See Order,* 84 FR at 18773. Thus, Hyundai Steel's inclusion in this administrative review is limited to entries for which Hyundai Steel was not both the producer and exporter of subject merchandise.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–127]

Non-Refillable Steel Cylinders From the People's Republic of China: Final Results of the Expedited Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on non-refillable steel cylinders (non-refillable cylinders) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of the Sunset Review'' section of this notice.

DATES: Applicable August 4, 2026.

FOR FURTHER INFORMATION CONTACT: Peter Zukowski, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0189.

SUPPLEMENTARY INFORMATION:

Background

On May 11, 2021, Commerce published the *Order* on non-refillable cylinders from China.[1] On April 1, 2026, Commerce published the notice of initiation of the first sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.218(c)(2).[2] On April 15, 2026, Commerce received a notice of intent to participate from Worthington Enterprises, Inc. (the domestic interested party), within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] The domestic interested party claimed interested party status under section 771(9)(C) of the Act and 19 CFR 351.102(b)(29)(v) as a U.S. producer of the domestic like product.

On May 1, 2026, Commerce received an adequate substantive response from the domestic interested party within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] Commerce did not receive a substantive response from any government or respondent interested party to this proceeding. On May 20, 2026, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.[5] As a result, Commerce conducted an expedited (120-day) sunset review of the *Order,* pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(B)(2) and (C)(2).

Scope of the Order

The product covered by this *Order* is non-refillable cylinders from China. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.[6]

[1] *See Certain Non-Refillable Steel Cylinders from the People's Republic of China: Amended Final Antidumping Duty Determination and Antidumping and Countervailing Duty Orders,* 86 FR 25839 (May 11, 2021) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 91 FR 16181 (April 1, 2026).

[3] *See* Domestic Interested Party's Letter, ''Petitioners Notice of Intent to Participate,'' dated April 15, 2026.

[4] *See* Domestic Interested Party's Letter, ''Petitioner's Substantive Response to the Notice of Initiation,'' dated May 1, 2026.

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on April 1, 2026,'' dated May 20, 2026.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Countervailing Duty Order on Non-Refillable Steel Cylinders from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of continuation or recurrence of subsidization and the countervailable subsidy rates likely to prevail if the *Order* were to be revoked, is provided in the Issues and Decision Memorandum. A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), which is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed at *https://access.trade.gov/frnotices.*

Final Results of Sunset Review

Pursuant to sections 751(c) and 752(b) of the Act, we determine that revocation of the *Order* would be likely to lead to continuation or recurrence of countervailable subsidies at the following net countervailable subsidy rates:

Producers/Exporters	Net countervailable subsidy rate (percent *ad valorem*)
Ningbo Eagle Machinery & Technology Co., Ltd	25.91
Wuyi Xilinde Machinery Manufacture Co., Ltd	18.37
Jiangsu Kasidi Chemical Machinery Co., Ltd	186.18
Jinhua Sinoblue Machinery Manufacturing Co., Ltd	186.18
Ningbo Runkey CGA Cylinders Co., Ltd	186.18
Ninhua Group Co., Ltd	186.18
Shanghai Ronghua High-Pressure Vessel Co., Ltd	186.18
Zhejiang Ansheng Mechanical Manufacture Co., Ltd	186.18
Zhejiang Nof Chemical Co., Ltd	186.18
All Others	21.28

Administrative Protective Order (APO)

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

Commerce is issuing and publishing these final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act, and 19 CFR 351.218.

Dated: July 30, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Legal Framework
VI. Discussion of the Issues
1. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
2. Net Countervailable Subsidy Rates Likely To Prevail
3. Nature of the Subsidies
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2026–15747 Filed 8–3–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–135]

Chassis and Subassemblies Thereof From the People's Republic of China: Final Results of the Expedited First Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on chassis and subassemblies thereof from the People's Republic of China (China) would be likely to lead to continuation or recurrence of dumping, at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable August 4, 2026.

FOR FURTHER INFORMATION CONTACT: Blair Hood, Operations Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: 202–482–832.

SUPPLEMENTARY INFORMATION:

Background

On July 8, 2021, Commerce published the *Order* in the **Federal Register**.[1] On April 1, 2026, Commerce published the notice of initiation of this first sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On April 16, 2026, Commerce received a timely and complete notice of intent to participate in the sunset review for the domestic interested party[3] within the deadline specified in the 19 CFR 351.218(d)(1)(i).[4] The domestic interested party claimed interested party status within the meaning of section 771(9)(F) of the Act as a coalition of U.S. producers of the domestic like product.[5] On April 23, 2026, Commerce notified the U.S. International Trade Commission (ITC) that it had received a notice of intent to participate from the domestic interested party.[6]

On May 1, 2026, pursuant to 19 CFR 351.218(d)(3)(i), the domestic interested party filed a timely and adequate substantive response.[7] Commerce did not receive a substantive response from any respondent interested party. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce is conducting an expedited (120-day) sunset review of the *Order.*

Scope of the Order

The product covered by these *Order* is chassis and subassemblies thereof from China. For the full description of the scope of the *Order, see* the Issues and Decisions Memorandum.[8]

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including

[1] *See Certain Chassis and Subassemblies Thereof from the People's Republic of China: Antidumping Duty Order,* 86 FR 36093 (July 8, 2021) *(Order).*

[2] *See Initiation of Five-Year (Sunset) Reviews,* 91 FR 16181 (April 1, 2026).

[3] The domestic interested party is the Coalition of American Chassis Manufacturers comprised of the following: Cheetah Chassis Corporation, Hercules Enterprises, LLC, Pitts Enterprises, Inc., Pratt Industries, Inc. and Stoughton Trailers, LLC.

[4] *See* Domestic Interested Party's Letter, ''Chassis and Subassemblies Thereof from the People's Republic of China: Notice of Intent to Participate in Sunset Review,'' dated April 6, 2026.

[5] *Id.* at 2.

[6] *See* Commerce's Letter, ''Sunset Reviews Initiated on April 1, 2026,'' dated April 23, 2026.

[7] *See* Domestic Interested Party's Letter, ''Chassis and Subassemblies Thereof from the People's Republic of China: Substantive Response to Notice of Initiation,'' dated May 1, 2026.

[8] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Antidumping Duty Order on Chassis and Subassemblies Thereof from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice.

the likelihood of continuation or recurrence of dumping in the event of revocation of the *Order* and the magnitude of the margins likely to prevail if the *Order* were to be revoked, is provided in the accompanying Issues and Decision Memorandum.[9] A list of the topics discussed in the Issues and Decision Memorandum can be found in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be directly accessed at *https://access.trade.gov/frnotices.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1), 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail would be weighted-average dumping margins up to 188.05 percent.

Notification Regarding Administrative Protective Orders

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials, or conversion to judicial protective, orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218 and 19 CFR 351.221(c)(5)(ii).

Dated: July 30, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Legal Framework
VI. Discussion of the Issues
1. Likelihood of Continuation or Recurrence of Dumping
2. Magnitude of the Margins of Dumping Likely To Prevail
VII. Final Results of Sunset Review
VIII. Recommendation

[9] *Id.*

[FR Doc. 2026–15748 Filed 8–3–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF802]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to U.S. Army Corps of Engineers Bonneville Lock 1 Bridge Replacement Project on the Columbia River in Oregon

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of two incidental harassment authorizations.

SUMMARY: In accordance with regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued two consecutive incidental harassment authorizations (IHAs) to U.S. Army Corps of Engineers for authorization to take marine mammals incidental to Year 1 and Year 2 of the Bonneville Lock 1 Bridge Replacement Project (BLBR Project) on the Columbia River in Oregon.

DATES: The Year 1 IHA is effective from December 1, 2027, through November 30, 2028. The Year 2 IHA is effective for 1 year from the date of notification by the IHA-holder, not to exceed 1 year from the date of expiration of the Year 1 IHA.

ADDRESSES: Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/action/incidental-take-authorization-us-army-corps-engineers-bonneville-lock-1-bridge-replacement.* In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Austin Demarest, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

MMPA Background and Determinations

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Among the exceptions is section 101(a)(5)(D) of the MMPA (16 U.S.C. 1361 *et seq.*) which directs the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking by harassment of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and the public has an opportunity to comment on the proposed IHA.

Specifically, NMFS shall issue an IHA if it finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least [practicable] adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to here as ''mitigation''). NMFS must also prescribe requirements pertaining to the monitoring and reporting of such takings. The definitions of key terms, such as ''take,'' ''harassment,'' and ''negligible impact,'' can be found in the MMPA and the NMFS' implementing regulations (see 16 U.S.C. 1362; 50 CFR 216.103).

On June 26, 2026, a notice of NMFS' proposal to issue two consecutive IHAs to the U.S. Army Corps of Engineers (USACE) for take of marine mammals incidental to the BLBR Project on the Columbia River in Oregon was published in the **Federal Register** (91 FR 38676). In that notice, NMFS indicated the estimated numbers, types, and methods of incidental take proposed for each species or stock, as well as the mitigation, monitoring, and reporting measures that would be required should the two IHAs be issued. The **Federal Register** notice also included analysis to support NMFS' preliminary conclusions and determinations that each IHA, if issued, would satisfy the requirements of section 101(a)(5)(D) of the MMPA for issuance of the IHAs. The **Federal Register** notice included web links to a draft IHAs for review, as well as other supporting documents.

No comments were received during the public comment period. There are no changes to the specified activity, the species taken, the proposed numbers, type, or methods of take, or the mitigation, monitoring, or reporting measures in the proposed IHA. No new information that would change any of the preliminary analyses, conclusions, or determinations in the proposed IHAs has become available since that notice was published, and therefore, the preliminary analyses, conclusions, and determinations included in the notice of proposed IHAs are considered final.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of these two consecutive IHAs qualifies for categorical exclusion from further NEPA review.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency ensures that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take of endangered or threatened species.

No incidental take of ESA-listed species is authorized or expected to result from these activities. Therefore, NMFS has determined that consultation under section 7 of the ESA is not required for this action.

Authorization

Accordingly, consistent with the requirements of section 101(a)(5)(D) of the MMPA, NMFS has issued two consecutive IHAs to USACE for authorization to take marine mammals incidental to the BLBR Project on the Columbia River in Oregon.

Dated: July 30, 2026.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2026–15776 Filed 8–3–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF905]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public webinar of its Joint Herring Committee and Advisory Panel to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Tuesday, August 18, 2026, at 1:30 p.m. EDT. Webinar registration URL information: *https://nefmc-org.zoom.us/meeting/register/gYfhUTDqQWy0sc3ANOueQA.*

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Cate O'Keefe, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Atlantic Herring Committee and Advisory Panel will meet jointly to discuss Atlantic herring specifications for 2027–2031. They will also make recommendations to the Committee or Council as appropriate. Other business will be discussed if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Cate O'Keefe, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

(Authority: 16 U.S.C. 1801 *et seq.*)

Dated: July 31, 2026.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026–15788 Filed 8–3–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Navy

Certificate of Alternate Compliance for the Landing Craft Utility Vessel 1710 Class (LCU 1710 Through LCU 1721)

AGENCY: Department of the Navy, Department of Defense.

ACTION: Notice of issuance of certificate of alternate compliance.

SUMMARY: The U.S. Navy hereby announces that a Certificate of Alternate Compliance has been issued for Landing Craft Utility Vessel 1710 Class (LCU 1710 through LCU 1721). Due to the special construction and purpose of each vessel of this class, the Admiralty Counsel of the Navy has determined that each vessel of this class is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with the navigation lights provisions of the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS) without interfering with its special function as a naval ship. The intended effect of this notice is to warn mariners in waters where 72 COLREGS apply.

DATES: This Certificate of Alternate Compliance is effective August 4, 2026 and is applicable beginning November 14, 2025.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Jeffrey M. Larson, JAGC, U.S. Navy, Office of the Judge Advocate General, Admiralty and

Claims Division (Code 15A), 1322 Patterson Ave. SE, Suite 3000, Washington Navy Yard, DC 20374–5066, 202–685–5040, or *admiralty@us.navy.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose.

Executive Order (E.O.) 11964 (42 FR 4327; January 19, 1977) and 33 U.S.C. 1605 provide that the requirements of the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), as to the number, position, range, or arc of visibility of lights or shapes, as well as to the disposition and characteristics of sound-signaling appliances, shall not apply to a vessel or class of vessels of the Navy where the Secretary of the Navy shall find and certify that, by reason of special construction or purpose, it is not possible for such vessel(s) to comply fully with the provisions without interfering with the special function of the vessel(s). Notice of issuance of a Certificate of Alternate Compliance must be made in the **Federal Register**.

In accordance with 33 U.S.C. 1605, the Admiralty Counsel of the Navy, under authority delegated by the Secretary of the Navy, hereby finds and certifies that the LCU 1710 Class (LCU 1710—LCU 1721) are vessels of special construction or purpose, and that, with respect to the position of the following navigational lights, it is not possible to comply fully with the requirements of the provisions enumerated in the 72 COLREGS without interfering with the special function of the vessel:

Annex I, paragraph 2(a)(i), pertaining to the vertical position of the forward masthead light; Annex I, paragraph 2(a)(ii), pertaining to the vertical separation between forward and aft masthead lights; Annex I, paragraph 2(i)(iii), pertaining to equal spacing of vertically aligned lights; Annex I, paragraph 2(f), pertaining to the vertical positioning of all-round lights; Annex I, paragraph 2(i)(i), pertaining to the spacing and height of vertical light arrays; Annex I, paragraph 3(a), pertaining to the horizontal separation of masthead lights. The Admiralty Counsel of the Navy further finds and certifies that these navigational lights are in closest possible compliance with the applicable provisions of the 72 COLREGS.

(Authority: 33 U.S.C. 1605(c), E.O. 11964.)

Dated: July 31, 2026.

M.A. Tabach,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2026–15766 Filed 8–3–26; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL26–67–000]

PJM Interconnection, L.L.C.

AEP Appalachian Transmission Company, Inc.
AEP Indiana Michigan Transmission Company, Inc.
AEP Kentucky Transmission Company, Inc.
AEP Ohio Transmission Company, Inc.
AEP West Virginia Transmission Company, Inc.
Allegheny Electric Cooperative, Inc.
American Transmission Systems, Incorporated
Appalachian Power Company
Atlantic City Electric Company
Baltimore Gas and Electric Company
Commonwealth Edison Company
Commonwealth Edison Company of Indiana, Inc.
Dayton Power and Light Company
Delmarva Power & Light Company
Duke Energy Kentucky, Inc.
Duke Energy Ohio, Inc.
Duquesne Light Company
Essential Power Rock Springs, LLC
Hudson Transmission Partners, LLC
Indiana Michigan Power Company
Jersey Central Power & Light Company
Kentucky Power Company
Keystone Appalachian Transmission Company
Kingsport Power Company
Linden VFT, LLC
Mid-Atlantic Interstate Transmission, LLC
Monongahela Power Company
Neptune Regional Transmission System, LLC
NextEra Energy Transmission MidAtlantic Indiana, Inc.
Ohio Power Company
Ohio Valley Electric Corporation
Old Dominion Electric Cooperative
PECO Energy Company
PPL Electric Utilities Corporation
The Potomac Edison Company
Potomac Electric Power Company
Public Service Electric and Gas Company
Rockland Electric Company
Silver Run Electric, LLC
Trans-Allegheny Interstate Line Company
Transource West Virginia, LLC
UGI Utilities, Inc.
Virginia Electric and Power Company
Wabash Valley Power Association, Inc.
Wheeling Power Company; Notice Establishing Answer Period

On July 28, 2026, pursuant to Rule 212 of the Commission's Rules of Practice and Procedure,[1] PJM Interconnection, L.L.C. (PJM) and Indicated PJM Transmission Owners [2] (Indicated PJM TOs) each filed a motion to hold the show cause proceeding in Docket No. EL26–67–000 in abeyance for 90 days. PJM and Indicated PJM TOs each request that the Commission shorten the answer period for their respective motions to five days, such that answers to the motion would be due on or by Monday, August 3, 2026.

Upon consideration, notice is hereby given that answers in response to the motions for abeyance are due by 5:00 p.m. Eastern Time on Friday, August 7, 2026.

Dated: July 30, 2026.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2026–15779 Filed 8–3–26; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.212 (2025).

[2] The Indicated PJM Transmission Owners include: American Electric Power Service Corporation on behalf of its affiliates, Appalachian Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, Wheeling Power Company, AEP Appalachian Transmission Company, Inc., AEP Indiana Michigan Transmission Company, Inc., AEP Kentucky Transmission Company, Inc., AEP Ohio Transmission Company, Inc., and AEP West Virginia Transmission Company, Inc.; The Dayton Power and Light Company; Dominion Energy Services, Inc. on behalf of Virginia Electric and Power Company; Duke Energy Business Services, LLC for Duke Energy Kentucky, Inc. and Duke Energy Ohio, Inc.; Duquesne Light Company; East Kentucky Power Cooperative, Inc.; Exelon Corporation on behalf of its affiliates Atlantic City Electric Company, Baltimore Gas and Electric Company, Commonwealth Edison Company, Commonwealth Edison Company of Indiana, Inc., Delmarva Power & Light Company, PECO Energy Company, and Potomac Electric Power Company; FirstEnergy Service Company, on behalf of its affiliates American Transmission Systems, Incorporated, Jersey Central Power & Light Company, Mid-Atlantic Interstate Transmission LLC, The Potomac Edison Company, Monongahela Power Company, Keystone Appalachian Transmission Company, and Trans-Allegheny Interstate Line Company; PPL Electric Utilities Corporation; Public Service Electric and Gas Company; Rockland Electric Company; and the Southern Maryland Electric Cooperative.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP26–536–000]

Texas Gas Transmission, LLC; Notice of Schedule for the Preparation of an Environmental Assessment for the Dearborn County Lateral Project

On May 29, 2026, Texas Gas Transmission, LLC (Texas Gas) filed an application in Docket No. CP26–536–000 requesting a Certificate of Public Convenience and Necessity pursuant to Section 7(c) of the Natural Gas Act to construct and operate certain natural gas pipeline facilities. The proposed project is known as the Dearborn County Lateral Project (Project) and would entail Texas Gas constructing and operating a new interstate natural gas pipeline and associated aboveground facilities in Indiana, Kentucky, and Ohio to deliver up to 265,000 dekatherms per day of firm natural gas transportation service to Vistra Corp.'s Miami Fort Power Plant in Hamilton County, Ohio, supporting the plant's planned conversion from coal-fueled to natural-gas-fueled generation.

On June 12, 2026, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's environmental document for the Project.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the Project and the planned schedule for the completion of the environmental review.[1] The EA will be issued for a 30-day comment period.

Schedule for Environmental Review

Issuance of EA, January 15, 2027.

90-day Federal Authorization Decision Deadline[2], April 15, 2027.

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

The Dearborn County Lateral Project would consist of the following new facilities:

- an approximately 11.8-mile-long, 20-inch-diameter natural gas pipeline beginning in Dearborn County, Indiana and terminating in Hamilton County, Ohio;
- tie-in piping, a pig launcher, and associated infrastructure to connect the new lateral to the existing Texas Gas 26-inch-diameter Mainline System in Dearborn County, Indiana;
- a new measurement and flow control station and associated infrastructure in Dearborn County, Indiana; and
- a new pig receiver and associated infrastructure at the terminus of the pipeline in Hamilton County, Ohio.

Background

On June 26, 2026, the Commission issued a *Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Dearborn County Lateral Project* (Notice of Scoping). The Notice of Scoping was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. In response to the Notice of Scoping and the Commission's Notice of Application for the Project, the Commission received comments from county officials, state legislators, and some potentially affected landowners. The Boone County Fiscal Court expressed confusion regarding the rationale for routing the Project through Boone County, noting that the route appears circuitous and would require two crossings of the Ohio River, and requested that any construction within the county be conducted in the least impactful manner possible while stating its opposition to the use of eminent domain. The Commission also received letters of support for the Project from Ohio State Senator Louis W. Blessing III and Ohio State Representative Mike Odioso.

The primary issues raised by landowners relate to the routing of the Project across their private properties. Concerns include impacts on farming operations, maple syrup and honey production, woodland resources, groundwater and drinking-water springs, stocked ponds and outflow structures, farmland privacy, and property values. Commenters also raised concerns regarding the need for the Project; cumulative impacts; effects on soil, water, and vegetation resources; impacts on special-status species; the use of eminent domain; and the potential for increased trespassing along the right-of-way. All substantive environmental comments will be addressed in the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This service provides automatic notification of filings made to subscribed dockets, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov*.

Additional information about the Project is available from the FERC website (*www.ferc.gov*). Using the ''eLibrary'' link, select ''General Search'' from the eLibrary menu, enter the selected date range and ''Docket Number'' excluding the last three digits (*i.e.,* CP26–536), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

(Authority: 18 CFR 2.1.)

Dated: July 30, 2026.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2026–15780 Filed 8–3–26; 8:45 am]

BILLING CODE 6717–01–P

[1] For tracking purposes under the National Environmental Policy Act, the unique identification number for documents relating to this environmental review is EAXX–019–20–000–1784121744.

[2] The Commission's deadline applies to the decisions of other federal agencies, and state agencies acting under federally delegated authority, that are responsible for federal authorizations, permits, and other approvals necessary for proposed projects under the Natural Gas Act. Per 18 CFR 157.22(a), the Commission's deadline for other agency's decisions applies unless a schedule is otherwise established by federal law.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR26–73–000.

Applicants: Pickton Gas Storage, LLC.

Description: 284.123 Rate Filing: Petition for NGPA Section 311. Market Based Rate Approval to be effective 12/31/2026.

Filed Date: 7/30/26.

Accession Number: 20260730–5000.

Comment Date: 5 p.m. ET 8/20/26.

Docket Numbers: RP26–995–000.

Applicants: Tennessee Gas Pipeline Company, L.L.C.

Description: 4(d) Rate Filing: Negotiated Rate Agreement—WWM Logistics, LLC to be effective 8/1/2026.

Filed Date: 7/29/26.

Accession Number: 20260729–5053.

Comment Date: 5 p.m. ET 8/10/26.

Docket Numbers: RP26–996–000.

Applicants: NEXUS Gas Transmission, LLC.

Description: Compliance filing: Order No. 587–AB (Docket No. RM96–1–044) Compliance Filing to be effective 1/1/2027.

Filed Date: 7/30/26.

Accession Number: 20260730–5004.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–997–000.

Applicants: East Tennessee Natural Gas, LLC.

Description: Compliance filing: Order No. 587–AB (Docket No. RM96–1–044) Compliance Filing to be effective 1/1/2027.

Filed Date: 7/30/26.

Accession Number: 20260730–5005.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–998–000.

Applicants: Sabal Trail Transmission, LLC.

Description: Compliance filing: Order 587–AB (Docket RM96–1–044) Compliance Filing to be effective 1/1/2027.

Filed Date: 7/30/26.

Accession Number: 20260730–5006.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–999–000.

Applicants: Saltville Gas Storage Company L.L.C.

Description: Compliance filing: Order 587–AB (Docket RM96–1–044) Compliance Filing to be effective 1/1/2027.

Filed Date: 7/30/26.

Accession Number: 20260730–5007.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–1000–000.

Applicants: Southeast Supply Header, LLC.

Description: Compliance filing: Order No. 587–AB (Docket No. RM96–1–044) Compliance Filing to be effective 1/1/2027.

Filed Date: 7/30/26.

Accession Number: 20260730–5008.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–1001–000.

Applicants: Texas Eastern Transmission, LP.

Description: Compliance filing: Order No. 587–AB (Docket No. RM96–1–044) Compliance Filing to be effective 1/1/2027.

Filed Date: 7/30/26.

Accession Number: 20260730–5009.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–1002–000.

Applicants: Gulfstream Natural Gas System, L.L.C.

Description: Compliance filing: Order No. 587–AB (Docket No. RM96–1–044) Compliance Filing to be effective 1/1/2027.

Filed Date: 7/30/26.

Accession Number: 20260730–5010.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–1003–000.

Applicants: Viking Gas Transmission Company.

Description: Compliance filing: Conforming Displacement Agreement—Radiate Energy to be effective N/A.

Filed Date: 7/30/26.

Accession Number: 20260730–5012.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–1004–000.

Applicants: Garden Banks Gas Pipeline, LLC.

Description: Compliance filing: Order No. 587–AB. (Docket No. RM96–1–044) Compliance Filing to be effective 1/1/2027.

Filed Date: 7/30/26.

Accession Number: 20260730–5014.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–1005–000.

Applicants: Granite State Gas Transmission, Inc.

Description: 4(d) Rate Filing: Limited Section 4 Rate Change to be effective 9/1/2026.

Filed Date: 7/30/26.

Accession Number: 20260730–5020.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–1006–000.

Applicants: Mississippi Canyon Gas Pipeline, L.L.C.

Description: Compliance filing: Order No. 587–AB (Docket No. RM96–1–044) Compliance Filing to be effective 1/1/2027.

Filed Date: 7/30/26.

Accession Number: 20260730–5021.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–1007–000.

Applicants: NEXUS Gas Transmission, LLC.

Description: 4(d) Rate Filing: Negotiated Rates Various Releases eff 8–01–2026 to be effective 8/1/2026.

Filed Date: 7/30/26.

Accession Number: 20260730–5025.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–1008–000.

Applicants: Egan Hub Storage, LLC.

Description: Compliance filing: Order No. 587–AB (Docket No. RM96–1–044) Compliance Filing to be effective 1/1/2027.

Filed Date: 7/30/26.

Accession Number: 20260730–5068.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–1009–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: Compliance filing: Order 587–AB (Docket No. RM96–1–044) Compliance Filing to be effective 1/1/2027.

Filed Date: 7/30/26.

Accession Number: 20260730–5094.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–1010–000.

Applicants: Big Sandy Pipeline, LLC.

Description: Compliance filing: Order No. 587–AB (Docket No. RM96–1–044) Compliance Filing to be effective 1/1/2027.

Filed Date: 7/30/26.

Accession Number: 20260730–5096.

Comment Date: 5 p.m. ET 8/11/26.

Docket Numbers: RP26–1011–000.

Applicants: Bobcat Gas Storage.

Description: Compliance filing: Order No. 587–AB (Docket No. RM96–1–044) Compliance Filing to be effective 1/1/2027.

Filed Date: 7/30/26.

Accession Number: 20260730–5097.

Comment Date: 5 p.m. ET 8/11/26.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern Time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov.*

Dated: July 30, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–15770 Filed 8–3–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following Accounting Request filings:

Docket Numbers: AC26–97–000.

Applicants: GridLiance Heartland LLC.

Description: GridLiance Heartland LLC submits proposed journal entries to clear assets from Account 102 re purchase of certain jurisdictional transmission facilities from Logansport Municipal Utilities.

Filed Date: 7/29/26.

Accession Number: 20260729–5137.

Comment Date: 5 p.m. ET 8/19/26.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL26–94–000.

Applicants: Long Island Power Authority v. Neptune Regional Transmission System, LLC.

Description: Complaint of Long Island Power Authority v. Neptune Regional Transmission System, LLC.

Filed Date: 7/27/26.

Accession Number: 20260727–5198.

Comment Date: 5 p.m. ET 8/17/26.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1827–015.

Applicants: Cleco Power LLC.

Description: Notice of Non-Material Change in Status of Cleco Power LLC.

Filed Date: 7/24/26.

Accession Number: 20260724–5427.

Comment Date: 5 p.m. ET 8/14/26.

Docket Numbers: ER19–1217–009.

Applicants: Montana-Dakota Utilities Co.

Description: Notice of Non-Material Change in Status of Montana-Dakota Utilities Co.

Filed Date: 7/27/26.

Accession Number: 20260727–5327.

Comment Date: 5 p.m. ET 8/17/26.

Docket Numbers: ER23–1736–004.

Applicants: Big Plain Solar, LLC.

Description: Compliance filing: Revised Tariff Records Under ER23–1736–002 to be effective 1/1/2024.

Filed Date: 7/30/26.

Accession Number: 20260730–5103.

Comment Date: 5 p.m. ET 8/20/26.

Docket Numbers: ER25–561–003; ER21–2445–007; ER16–2226–008; ER23–2716–005; ER25–562–003; ER15–1019–017; ER22–2703–013

Applicants: Pattern Energy Management Services LLC, Fowler Ridge IV Wind Farm LLC, Winfield Solar I, LLC, Moraine Sands Wind Power, LLC, McHenry Battery Storage, LLC, Glacier Sands Wind Power, LLC, Crossover Wind LLC.

Description: Notice of Non-Material Change in Status of Crossover Wind LLC, *et al.*

Filed Date: 7/24/26.

Accession Number: 20260724–5428.

Comment Date: 5 p.m. ET 8/14/26.

Docket Numbers: ER25–3171–001.

Applicants: 1000 Mile Solar, LLC.

Description: Notice of Non-Material Change in Status of 1000 Mile Solar, LLC.

Filed Date: 7/24/26.

Accession Number: 20260724–5425.

Comment Date: 5 p.m. ET 8/14/26.

Docket Numbers: ER26–541–002.

Applicants: PVS 2, LLC.

Description: Compliance filing: Notice of Change in Status Reporting Passive Tax Equity Investor and Revised MBR to be effective 9/29/2026.

Filed Date: 7/30/26.

Accession Number: 20260730–5024.

Comment Date: 5 p.m. ET 8/20/26.

Docket Numbers: ER26–3331–000.

Applicants: New England Power Pool Participants Committee.

Description: 205(d) Rate Filing: Aug 2026 Membership Filing to be effective 8/1/2026.

Filed Date: 7/30/26.

Accession Number: 20260730–5003.

Comment Date: 5 p.m. ET 8/20/26.

Docket Numbers: ER26–3332–000.

Applicants: Southwest Power Pool, Inc.

Description: 205(d) Rate Filing: Tariff Clean-Up Filing Effective 20260701 to be effective 7/1/2026.

Filed Date: 7/30/26.

Accession Number: 20260730–5016.

Comment Date: 5 p.m. ET 8/20/26.

Docket Numbers: ER26–3333–000.

Applicants: Deseret Generation & Transmission Co-operative, Inc.

Description: 205(d) Rate Filing: Change in Status—Amendment to be effective 9/28/2026.

Filed Date: 7/30/26.

Accession Number: 20260730–5019.

Comment Date: 5 p.m. ET 8/20/26.

Docket Numbers: ER26–3334–000.

Applicants: Puget Sound Energy, Inc., Bonneville Power Administration.

Description: Notice of Cancellation of Trust Agreement between Puget Sound Energy, Inc. and Bonneville Power Administration.

Filed Date: 7/17/26.

Accession Number: 20260717–5266.

Comment Date: 5 p.m. ET 8/7/26.

Docket Numbers: ER26–3335–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Amendment to GIA, SA No. 7651; Project Identifier No. AF2–025 to be effective 9/29/2026.

Filed Date: 7/30/26.

Accession Number: 20260730–5036.

Comment Date: 5 p.m. ET 8/20/26.

Docket Numbers: ER26–3336–000.

Applicants: Tampa Electric Company.

Description: 205(d) Rate Filing: Rate Schedule No. 107 with FPL (Affected Sys Facilities Construction Agreement) to be effective 10/1/2026.

Filed Date: 7/30/26.

Accession Number: 20260730–5055.

Comment Date: 5 p.m. ET 8/20/26.

Docket Numbers: ER26–3337–000.

Applicants: Midcontinent Independent System Operator, Inc., American Transmission Company LLC.

Description: 205(d) Rate Filing: American Transmission Company LLC submits tariff filing per 35.13(a)(2)(iii: 2026–07–30_SA 4224 ATC–WPSC 1st Rev PCA to be effective 7/31/2026.

Filed Date: 7/30/26.

Accession Number: 20260730–5079.

Comment Date: 5 p.m. ET 8/20/26.

Docket Numbers: ER26–3338–000.

Applicants: Midcontinent Independent System Operator, Inc., American Transmission Company LLC.

Description: 205(d) Rate Filing: American Transmission Company LLC submits tariff filing per 35.13(a)(2)(iii: 2026–07–30_SA 4819 ATC–WPSC PCA to be effective 9/29/2026.

Filed Date: 7/30/26.

Accession Number: 20260730–5100.

Comment Date: 5 p.m. ET 8/20/26.

Docket Numbers: ER26–3339–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: Tariff Amendment: Alabama Power Company submits tariff filing per 35.15: O'Neal Solar (Solar + BESS) LGIA Termination Filing to be effective 7/30/2026.

Filed Date: 7/30/26.

Accession Number: 20260730–5104.

Comment Date: 5 p.m. ET 8/20/26.

Docket Numbers: ER26–3340–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii: Bogalusa West

Solar Project Affected System Upgrade Agreement Amendment Filing to be effective 7/1/2026.

Filed Date: 7/30/26.

Accession Number: 20260730–5105.

Comment Date: 5 p.m. ET 8/20/26.

Docket Numbers: ER26–3341–000.

Applicants: Public Service Company of Colorado.

Description: 205(d) Rate Filing: PSCo MBR—SPP WEIS Removal to be effective 9/28/2026.

Filed Date: 7/30/26.

Accession Number: 20260730–5127.

Comment Date: 5 p.m. ET 8/20/26.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern Time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov.*

Dated: July 30, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–15769 Filed 8–3–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD26–7–000]

PJM Governance and Stakeholder Reforms; Notice Requesting Post-Conference Comment

On July 23, 2026, the Federal Energy Regulatory Commission (Commission) convened a Chairman and Commissioner-led technical conference to discuss PJM Interconnection, L.L.C.'s (PJM) governance and stakeholder processes, with a particular focus on identifying and evaluating concrete, actionable reforms to improve PJM's ability to address operational and market needs in a timely and efficient manner.

All interested persons are invited to file post-conference comments to address issues raised during the conference that they believe would benefit from further discussion. Parties are also invited to provide comments on the questions presented in the conference agenda.[1]

Commenters may reference material previously filed in this docket but are encouraged to avoid repetition or replication of previous material. In addition, commenters are encouraged, when possible, to provide examples and evidence in support of their answers. In addition, commenters are to fill out the issues list found in the appendix. We also encourage commenters to avoid discussing the merits of any contested, pending proceeding before the Commission.[2] Comments must be submitted on or before Friday, August 21, 2026.

A future notice will issue in this proceeding establishing a forum for an Alternative Dispute Resolution (ADR) process that will commence on September 1, 2026. That notice will provide additional details regarding ADR registration, participation logistics, and scope of issues and discussion topics informed by the record developed at the PJM technical conference.

Comments may be filed electronically via the internet.[3] Instructions are available on the Commission's website *http://www.ferc.gov/docs-filing/efiling.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, submissions sent via the U.S. Postal Service must be addressed to: Federal Energy Regulatory Commission, Office of the Secretary, 888 First Street NE, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Federal Energy Regulatory Commission, Office of the Secretary, 12225 Wilkins Avenue, Rockville, MD 20852.

To stay apprised of issuances in this docket, there is an ''eSubscription'' link on the Commission's website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). Information about this technical conference is available on the conference web page.[4]

For further information about this Notice, please contact:

Alandro Valdez, Office of Technical Reporting and Economics, (202) 502–8986, *Alandro.Valdez@ferc.gov.*

Emmett Barnes, Office of the General Counsel, (202) 502–8413, *Emmett.Barnes@ferc.gov.*

ADR Helpline, *ferc.adr@ferc.gov.*

(Authority: 16 U.S.C. 825h.)

Dated: July 30, 2026.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2026–15781 Filed 8–3–26; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–13503–01–OAR]

Administration of Cross-State Air Pollution Rule Trading Program Assurance Provisions for 2025 Control Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of data availability.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is providing notice of the availability of data on the administration of the assurance provisions of the Cross-State Air Pollution Rule (CSAPR) trading program for the 2025 control period. Virginia units participating in the CSAPR NO_X Ozone Season Group 2E Trading Program during the 2025 control period reported total nitrogen oxides (NO_X) emissions that exceeded the State's assurance level under the program. The EPA has posted on the Agency's website a spreadsheet that presents data demonstrating the exceedance and the Agency's preliminary calculations of the additional allowances that owners and operators of certain Virginia units must surrender. The EPA will consider timely objections to the data and calculations before making final determinations of the additional allowances that owners and operators of certain Virginia units must surrender.

DATES: The EPA must receive any objections to the information referenced

[1] *See Third Supplemental Notice of Commissioner-Led Technical Conference,* Docket No. AD26–7–000 (July 16, 2026).

[2] *See* 18 CFR 385.2201(b) (2025); *see also Third Supplemental Notice of Commissioner-Led Technical Conference,* Docket No. AD26–7–000 (July 16, 2026) (listing pending proceedings).

[3] *See* 18 CFR 385.2001(a)(1)(iii).

[4] *https://www.ferc.gov/news-events/events/PJM-Governance-Stakeholder-Reforms.*

in this notice on or before September 3, 2026.

ADDRESSES: Submit your objections via email to *CSAPR@epa.gov.* Include ''2025 CSAPR Assurance Provisions'' in the email subject line and include your name, title, affiliation, address, phone number, and email address in the body of the email.

FOR FURTHER INFORMATION CONTACT: For information about this notice, contact Lisa Thompson at telephone number: (919) 541–5158 or email address: *thompson.lisa@epa.gov.*

SUPPLEMENTARY INFORMATION: *Preamble acronyms and abbreviations.* Throughout this document, the use of ''we,'' ''us,'' or ''our'' refers to the EPA. The EPA uses multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

CFR Code of Federal Regulations
CSAPR Cross-State Air Pollution Rule
EPA Environmental Protection Agency
FR Federal Register
NODA Notice of data availability
NOX Nitrogen oxides

The regulations for each CSAPR trading program contain ''assurance provisions'' designed to ensure that the emission reductions required from each State covered by the program occur within the State. If total emissions from a State's affected units exceed the State's assurance level, the State must surrender two allowances for each ton of emissions exceeding the assurance level (in addition to the ordinary obligation to surrender one allowance for each ton of emissions). In the emissions reports covering the 2025 control period, Virginia units participating in the CSAPR NO_X Ozone Season Group 2E Trading Program reported emissions exceeding the State's assurance level under the program by 70 tons, resulting in a requirement to surrender 140 additional allowances.

When a State exceeds its assurance level, the EPA apportions the responsibility for surrendering the required additional allowances among groups of units in the State represented by ''common designated representatives'' based on the extent to which each group's emissions exceeded the group's share of the State's assurance level.[1] Applying the procedures in the regulations for the 2025 control period, the EPA completed preliminary calculations that indicate that the responsibility for surrendering 140 additional allowances in Virginia should be apportioned primarily to the group of units operated by Hopewell Power Generation, LLC and Dominion Generation, with smaller shares apportioned to the groups of units operated by Wolf Hills Energy, LLC and Calpine Operating Services Company, Inc.

In this notice, the EPA is providing notice of the data on which the Agency relied to determine the amounts of the exceedance of the Virginia assurance level and the notice of the preliminary calculations of the amounts of additional allowances that owners and operators of certain Virginia units must surrender as a result of the exceedance.[2] By October 1, 2026, the EPA will provide notice of the final calculations of the amounts of additional allowances that must be surrendered, incorporating any adjustments made in response to objections received.[3] Each set of owners and operators identified pursuant to the notice of the final calculations must hold the required additional allowances in an assurance account by November 1, 2026.

The data and preliminary calculations are available in an Excel spreadsheet titled ''2025_CSAPR_assurance_provision_calculations_prelim.xlsx'' at *https://www.epa.gov/Cross-State-Air-Pollution/csapr-assurance-provision-nodas.* The spreadsheet contains data for the 2025 control period showing, for each Virginia unit identified as affected under the CSAPR NO_X Ozone Season Group 2E Trading Program, the unit's reported amount of NO_X emissions and the amount of CSAPR NO_X Ozone Season Group 2E allowances allocated to the unit, including any allowances allocated from new unit set-asides. The spreadsheet also provides 2025 control period calculations showing the total reported NO_X emissions from all such units in Virginia and the amounts by which those total reported NO_X emissions exceeded the State's assurance level under the program. Finally, the spreadsheet includes calculations for the 2025 control period showing, for each common designated representative for a group of such units, the common designated representative's share of the total reported NO_X emissions, the common designated representative's share of the State's assurance level, and the amount of additional CSAPR NO_X Ozone Season Group 2E allowances that the owners and operators of the units in the group must surrender.

Objections should strictly be limited to whether the EPA identified the data and performed the calculations in the spreadsheet correctly in accordance with the regulations. Objections must include: (1) precise identification of the specific data or calculations the commenter believes are inaccurate, (2) new proposed data or calculations upon which the commenter believes the EPA should rely instead, and (3) the reasons why the EPA should rely on the commenter's proposed data or calculations and not the data and calculations referenced in this notice.

Abigale Tardif,

Principal Deputy Assistant Administrator, Office of Air and Radiation, U.S. Environmental Protection Agency.

[FR Doc. 2026–15740 Filed 8–3–26; 8:45 am]

BILLING CODE 6560–50–P

[1] For the CSAPR NO_X Ozone Season Group 2E Trading Program, the procedures are set forth at 40 CFR 97.802 (definitions of ''common designated representative,'' ''common designated representative's assurance level,'' and ''common designated representative's share''), 97.806(c)(2) and (c)(4)(iv), and 97.825.

[2] 40 CFR 97.825(b)(1)(ii).

[3] 40 CFR 97.825(b)(2)(ii).

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1255; FR ID 360075]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it

displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before October 5, 2026. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1255.

Title: Rules and Policies Regarding Calling Number Identification Service—Caller ID, CC Docket No. 91–281.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 46,291 respondents; 1,705 responses.

Estimated Time per Response: .083 hours (5 minutes).

Frequency of Response: Monthly and on-going reporting requirements.

Obligation to Respond: Required to obtain or retain benefit. The statutory authority for the information collection requirements is found at section 201(b) of the Communications Act of 1934, as amended, 47 U.S.C. 201(b), and section 222, 47 U.S.C. 222. The Commission's implementing rules are codified at 47 CFR 64.1600–01.

Total Annual Burden: 142 hours.

Total Annual Cost: No cost.

Needs and Uses: The Commission amended rules requiring that carriers honor privacy requests to state that § 64.1601(b) of the Commission's rules shall not apply when calling party number (CPN) delivery is made in connection with a threatening call. Upon report of such a threatening call by law enforcement on behalf of the threatened party, the carrier will provide any CPN of the calling party to law enforcement and, as directed by law enforcement, to security personnel for the called party for the purpose of identifying the party responsible for the threatening call. Carriers now have a recordkeeping requirement in order to quickly provide law enforcement with information relating to threatening calls.

The Commission also amended rules to allow non-public emergency services to receive the CPN of all incoming calls from blocked numbers requesting assistance. The Commission believes amending its rules to allow non-public emergency services access to blocked Caller ID promotes the public interest by ensuring timely provision of emergency services without undermining any countervailing privacy interests. Carriers now have a recordkeeping requirement in order to provide emergency serve providers with the information they need to assist callers.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2026–15789 Filed 8–3–26; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0110; FR ID 360531]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before October 5, 2026. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0110.

Title: FCC Form 2100, Application for Renewal of Broadcast Station License, LMS Schedule 303–S.

Form Number: FCC Form 2100, LMS Schedule 303–S.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not for profit institutions; State, Local or Tribal Governments.

Number of Respondent and Responses: 4,738 respondents, 4,738 responses.

Estimated Time per Response: 0.075 hours—12 hours.

Frequency of Response: On occasion reporting requirement; Every eight-year reporting requirement; Third party disclosure requirement.

Total Annual Burden: 13,090 hours.

Total Annual Cost: $4,181,731.

Obligation of Respond: Required to obtain or retain benefits. The statutory authority for the collection is contained Sections 154(i), 303, 307 and 308 of the Communications Act of 1934, as amended, and Section 204 of the Telecommunications Act of 1996.

Needs and Uses: The Commission is requesting Office of Management and Budget (OMB) approval for an extension of an existing information collection.

The Licensing Management System (LMS) Schedule 303–S is used to apply for license renewals for commercial or noncommercial AM, FM, TV, FM translator, TV translator, Class A TV, or Low Power TV, and Low Power FM broadcast station licenses. Licensees of broadcast stations must apply for renewal of their licenses every eight years.

Schedule 303–S's On-Air and Online Notice (third party disclosure) Requirements: 47 CFR 73.3580, as amended in the Commission's *2020 Public Notice Second Report and Order,* requires local public notice of the filing of all applications to renew a broadcast

station license. Notice is given by an applicant for renewal of a full-service AM, FM, full-power TV, Class A TV, Low-Power FM (LPFM), or Low-Power TV (LPTV) station that locally originates programming, by making a total of six on-air announcements, at least one per week and no more than one per day or two per week, to be broadcast between 7:00 a.m. and 11:00 p.m. local time, Monday through Friday, beginning after the application is accepted for filing. Notice is given by an applicant for renewal of an FM or TV translator, an LPTV station that does not locally originate programming, or by a silent station, by posting notice online, either on the station website or a website affiliated with the station, its licensee, or its parent entity, or else by posting notice on a publicly accessible, locally targeted website, for 30 continuous days following acceptance of the application for filing.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2026–15744 Filed 8–3–26; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than September 3, 2026.

A. Federal Reserve Bank of Chicago (Christopher Koopmans, Senior Vice President), 230 South LaSalle Street, Chicago, Illinois 60690–1414. Comments can also be sent electronically to *Comments.applications@chi.frb.org:*

1. *Isabella Bank Corporation, Mount Pleasant, Michigan;* to merge with Grand River Commerce, Inc., and thereby indirectly acquire Grand River Bank, both of Grandville, Michigan.

Board of Governors of the Federal Reserve System.

Erin Cayce,

Assistant Secretary of the Board.

[FR Doc. 2026–15768 Filed 8–3–26; 8:45 am]

BILLING CODE;P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9172–N]

Healthcare Advisory Committee (HAC); Announcement of the HAC Meetings for Fiscal Year 2026–2027

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice of meetings.

SUMMARY: This meeting notice announces the virtual meeting public components of the Healthcare Advisory Committee (HAC or Committee) for the fiscal year 2026–2027. The purpose of the Committee is to advise the Secretary of HHS and the CMS Administrator on programs and policies that can improve the United States healthcare system consistent with the Executive Order Establishing the President's Make American Healthy Again Commission. The virtual meetings are open to the public.

DATES: The virtual meetings will take place on Monday, August 31, 2026; Monday, November 9, 2026; Monday, February 22, 2027; and Monday, May 10, 2027.

All meetings will take place from 8:00 a.m. to 5:00 p.m. Eastern Time (ET). The time listed in this notice is approximate. Consequently, the meeting may be longer or shorter than the times listed in this notice but will not begin before or end after the posted window of time. Please check the Committee's website for the most up-to-date information.

Deadline for comments: Comment letters must be received by 5:00 p.m. ET 2 weeks prior to the scheduled meeting date. Deadlines are therefore August 18, 2026 (for the August 31, 2026 meeting), October 26, 2026 (for the November 9, 2026 meeting), February 8, 2027 (for the February 22, 2027 meeting), and April 26, 2027 (for the May 10, 2027 meeting). Comment letters must be submitted via email as specified in the **ADDRESSES** section of this notice. Comment letters that are not received by the due date and time will be considered late or incomplete and may not be included in the agenda. Comment letters may not be revised once they are submitted. If a comment letter requires changes, a new submittal must be submitted by the scheduled due date.

Deadline for request for special accommodations: Requests for special accommodations must be received by 5:00 p.m. ET 2 weeks prior to the scheduled meeting dates. Deadlines are therefore August 17, 2026 (for the August 31, 2026 meeting), October 26, 2026 (for the November 9, 2026 meeting), February 8, 2027 (for the February 22, 2027 meeting), and April 26, 2027 (for the May 10, 2027 meeting).

ADDRESSES: *Virtual meetings location and webinar:* The meetings will be held virtually and participants do not have to register. Closed captioning will be available on the webinar. Webinar information will appear on the final meeting agendas, which will be posted on the Committee's website when available at *https://www.cms.gov/priorities/healthcare-advisory-committee/overview.*

Virtual meeting registration: There is no planned meeting registration required for participants who plan to view the Committee meetings via webinar or for those making a public comment during the meetings. If the webinar platform changes and registration is required information will be posted on the Committee's website, and registration will also be accessible through the Committee's website.

Requests for special accommodations: Requests for special accommodations

should be emailed to *HAC@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: For questions regarding the HAC meetings, please send an email to *HAC@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The first HAC meeting was held on May 18, 2026, and the meeting transcript and summary can be found on the Committee's website at *https://www.cms.gov/priorities/healthcare-advisory-committee/overview.* Items and topics to be discussed during the next four meetings that will take place during the fiscal year 2026–2027 will expand on furthering the charge and introductions of the established Committee working groups, discussion of preliminary working group proposals for Committee consideration, and voting on Committee recommendations. A final and detailed agenda will be available approximately 1 week prior to the meeting dates on the Committee's website.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Mehmet Oz, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2026–15786 Filed 7–31–26; 4:15 pm]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Partially Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Regents of the National Library of Medicine.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Regents of the National Library of Medicine.

Date: September 15–16, 2026.

Closed: September 15, 2026, 11:20 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Address: National Institutes of Health, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Open: September 15, 2026, 1:00 p.m. to 4:00 p.m.

Agenda: Call to Order, Introductions, NLM Director's Report and Discussion.

Address: National Institutes of Health, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Open: September 16, 2026, 12:00 p.m. to 2:15 p.m.

Agenda: Call to Order, Concept Clearance and Open Discussions.

Address: National Institutes of Health, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Closed: September 16, 2026, 2:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate breakout Closed—Strategic Plan Working Group.

Address: National Institutes of Health, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Stephen T. Sherry, Ph.D., Acting Director, National Library of Medicine, National Institutes of Health, U.S. Department of Health and Human Services, Bethesda, MD 20892, (301) 435–7799, *SHERRY@NIH.GOV.*

Registration is not required to attend the open portion of this meeting.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.nlm.nih.gov/od/bor/bor.html,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance; 93.LM2, National Library of Medicine—Other Research and Resources; 93.LM2, National Library of Medicine—Other Research and Resources, National Institutes of Health, HHS)

Dated: July 31, 2026.

Denise M. Santeufemio,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–15787 Filed 8–3–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[OMB Control Number 1651–0109]

Agency Information Collection Activities; Revision; Guam-CNMI Visa Waiver Information (Form I–736)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day Notice and request for comments.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection (CBP) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than September 3, 2026) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Please submit written comments and/or suggestions in English. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals

seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (89 FR 3299) on January 18, 2024, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Guam-CNMI Visa Waiver Information (Form I–736).
OMB Number: 1651–0109.
Form Number: I–736.
Current Actions: Revision.
Type of Review: Revision.
Affected Public: Individuals.
Abstract: Public Law 110–229 provides for certain aliens to be exempt from the nonimmigrant visa requirement if seeking entry into Guam or the Commonwealth of the Northern Mariana Islands (CNMI) as a visitor for a maximum stay of 45 days, provided that no potential threat exists to the welfare, safety, or security of the United States, or its territories, and other criteria are met. At the Secretary's discretion, passport holders of the People's Republic of China who are not in possession of a visitors' visa may be allowed to enter CNMI for up to 14 days under the discretionary parole authority. Upon arrival at the Guam or CNMI Ports-of-Entry, each applicant for admission presents a completed paper Form I–736 to CBP, which collects information about the applicant's identity and travel documents. CBP Form I–736 is provided for by 8 CFR 212.1(q).

Please note that certain items on the new version remains identical to those in the original version. However, updates are necessary to be able to transition to automating Form I–736, Guam-CNMI Visa Waiver Information that is used in compliance with the Guam-CNMI Visa Waiver Program. The automation will facilitate CBP to gather information on travelers from Guam-CNMI Visa Waiver Program countries to determine their admissibility to enter Guam or the CNMI. In addition, CBP intends to migrate from paper I–736 to a mandatory automated environment; therefore, the collection of a paper form will no longer be acceptable. However, after the regulation implementing mandatory automation is published, CBP will grant a transition period of three months to facilitate travelers adjusting to the new collection method. At the end of the transition period, the paper I–736 form will become obsolete and travelers must input and submit in advance their personal information and respond to the eligibility questions using the new electronic format. The travelers' information is pre-screened or vetted against law enforcement databases. Based on the results of the pre-screening, the application is approve or denied. The system generates a board or no board status message to the carrier indicating a denied or approved authorization to board before the flight. The applicant also receives a message with the application status: approved, denied, canceled or pending. All information will be saved in the newly created Guam-CNMI Visa Waiver Program database.

In a recent approval, several data elements were added to the Form I–736: the foreign passport type (mandatory), social media identifier (optional), valid email address (mandatory), and social media provider/platform (optional). Adding these data elements enhances the existing vetting process and provides CBP with additional information to determine travelers' admissibility to enter Guam or the CNMI under the Guam-CNMI Visa Waiver Program. CBP intends to migrate from the paper Form I–736 process to a mandatory automated process via rulemaking.

Proposed Changes

As part of the regulatory updates for the Interim Final Rule (IFR) which fully automates the collection of Form I–736 and requires that travelers under the G–CNMI VWP submit this information in advance of arrival. The rule also creates a new system, CNMI EVS–TAP, wherein travelers from the PRC to the CNMI can submit advance information to CBP so they may be vetted for a 14-day visa free admissibility period. These travelers will also need to complete an additional set of vetting questions.

Type of Information Collection: Form I–736.
Estimated Number of Respondents: 1,370,000.
Estimated Number of Annual Responses per Respondent: 1.
Estimated Number of Total Annual Responses: 1,370,000.
Estimated Time per Response: 21 minutes.
Estimated Total Annual Burden Hours: 479,500.
Type of Information Collection: CNMI EVS–TAP.
Estimated Number of Respondents: 230,000.
Estimated Number of Annual Responses per Respondent: 1.
Estimated Number of Total Annual Responses: 230,000.
Estimated Time per Response: 26 minutes.
Estimated Total Annual Burden Hours: 99,667.

Robert F. Altneu,
Director, Regulations and Disclosure Law Division, U.S. Customs and Border Protection.

[FR Doc. 2026–15773 Filed 8–3–26; 8:45 am]
BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2026–0430; OMB No. 1660–0083]

Agency Information Collection Activities: Proposed Collection; Comment Request; Application for Community Disaster Loan (CDL) Program

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 60-Day notice of revision and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on an extension, with change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the Community Disaster Loan (CDL) Program. This collection allows the Federal Government to make loans to local governments that have suffered economic problems due to disasters.

DATES: Comments must be submitted on or before October 5, 2026.

ADDRESSES: To avoid duplicate submissions to the docket, please submit comments at *www.regulations.gov* under Docket ID FEMA–2026–0430. Follow the instructions for submitting comments.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy and Security Notice that is available via a link on the homepage of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Martha Castro, Section Chief, Program Support and Monitoring Branch, Public Assistance Division, 202–701–4023, or *Martha.Castro@fema.dhs.gov.* You may contact the Information Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The information collection is required for Community Disaster Loan (CDL) Program eligibility determinations, CDL management, and compliance with other Federal laws and regulations. The CDL Program is authorized by Section 417 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Pub. L. 93–288, as amended, 88 Stat. 143 (42 U.S.C. 5184) and implementing regulations at 44 CFR part 206, subpart K. FEMA may make a CDL to any local government which has suffered a substantial loss of tax or other revenues as a result of a major disaster or emergency and which demonstrates a need for Federal financial assistance to perform its governmental functions.

The CDL must be justified on the basis of need and be based on the actual and projected expenses, as a result of the disaster, for the fiscal year in which the disaster occurred and the three succeeding fiscal years. FEMA has the authority to cancel repayment of all or part of these CDLs to the extent that a determination is made that revenues of the local government during the three fiscal years following the disaster are insufficient to meet the operating budget of that local government because of disaster related revenue losses and additional unreimbursed disaster-related municipal operating expenses.

The proposed information collection would revise FEMA Form–104–FY–22–224, Promissory Note to remove Part III—Schedule of Loan Increments to Be Disbursed to Borrower. FEMA has determined that the information was not sufficiently useful to reviewing the application and opted to eliminate the entire table titled ''Part III—Schedule of Loan Increments to Be Disbursed to Borrower'' from the form.

Collection of Information

Title: Application for Community Disaster Loan (CDL) Program.

Type of Information Collection: Extension, with minor change, of a currently approved information collection.

OMB Number: 1660–0083.

FEMA Forms: FEMA Form–104–FY–22–223 (formerly 090–0–1), Certification of Eligibility for Community Disaster Loans; FEMA Form–104–FY–22–224 (formerly 116–0–1), Promissory Note; FEMA Form-104–FY–22–225 (formerly 085–0–1), Local Government Resolution—Collateral Security; FEMA Form–104–FY–22–226 (formerly 112–0–3C), Certifications Regarding Lobbying, Debarment, Suspension and Other Responsibility Matters, and Drug-Free Workplace Requirements; FEMA Form–104–FY–22–227 (formerly 009–0–15), Application for Loan Cancellation.

Abstract: The loan package for the CDL Program provides local governments that have suffered substantial loss of tax or other revenues as a result of a major disaster, the opportunity to obtain financial assistance in order to perform their governmental functions. The loan must be justified on the basis of need and disaster-related expenses.

Affected Public: Local, U.S. Territory, or Tribal Government.

Estimated Number of Respondents: 260.

Estimated Number of Responses: 260.

Estimated Total Annual Burden Hours: 552.

Estimated Total Annual Respondent Cost: $29,990.

Estimated Respondents' Operation and Maintenance Costs: 0.

Estimated Respondents' Capital and Start-Up Costs: 0.

Estimated Total Annual Cost to the Federal Government: $80,961.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Nigel S. Allicock,

Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2026–15783 Filed 8–3–26; 8:45 am]

BILLING CODE 9111–24–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7107–N–18; OMB Control No.: 2577–0218]

30-Day Notice of Proposed Information Collection: Indian Housing Block Grants (IHBG) Formula and Competitive Programs

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* September 3, 2026.

ADDRESSES: Interested persons are invited to submit comments regarding

this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Anna Guido, PRA Compliance Officer, Paperwork Reduction Act Division, PRAD, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; email at *PaperworkReductionActOffice@hud.gov,* ATTN: Anna Guido, telephone (202) 402–5535. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A. The Federal Register notice that solicited public comment on the information collection for a period of 60 days was published on March 19, 2026 at 90 FR 13316.

A. Overview of Information Collection

Title of Information Collection: Indian Housing Block Grants (IHBG) Formula and Competitive Programs.

OMB Approval Number: 2577–0218.

Type of Request: Revision of a currently approved collection.

Form Number: HUD–4117, HUD–4117 A–D, HUD–4119, HUD–4119 A–D, HUD–4123, HUD–4125, HUD–52736–A, HUD–52736–B, HUD–52737 IHP–APR, HUD–52737 GEMS IHP/APR, HUD–53248 IHBG–COMP APR, HUD–426, HUD Form 2880, SF–424, SF–424B SF–424D, SF–425.

Description of the need for the information and proposed use: HUD's Office of Native American Programs (ONAP) will use the pre-award and post-award information collected to assess program feasibility and compliance, monitor program performance throughout the grant term, and to report annually to Congress. ONAP is responsible for managing the IHBG Formula and IHBG Competitive programs, as described below.

IHBG Formula Program: The Native American Housing Assistance and Self-Determination Reauthorization Act of 1996 (25 U.S.C. 4101 *et seq.*) (NAHASDA) authorizes the IHBG Formula program which supports the development, management, and operation of affordable homeownership and rental housing; infrastructure development; and other forms of housing assistance intended for low-income persons. Federally recognized Native American Tribes, Alaska Native Villages, tribally designated housing entities, and a limited number of State-recognized Tribes that were funded under the Indian Housing Program authorized by the U.S. Housing Act of 1937 are eligible to receive IHBG funds. Under the IHBG Formula Program, eligible recipients receive an equitable share of funds as appropriated by Congress based on housing stock and housing needs, and other funding criteria.

IHBG Competitive Program: Since 2018, Congress has appropriated additional funding under the IHBG Formula program for the IHBG Competitive Grant (IHBG–COMP). IHBG–COMP prioritizes projects that increase the availability of affordable housing in Tribal communities with consideration to the extent of need and administrative capacity. The regulations and requirements governing the IHBG Formula Program apply to the IHBG Competitive Program. The IHBG–COMP Notices of Funding Opportunities are published on *Grants.gov*, where applicants submit applications.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
SF–424: Application for Federal Assistance (2501–0044)	300	1	300	0	0	0	0
SF–424D: Assurances for Construction Programs (2501–0044)	300	1	300	0	0	0	0
SF–425 Federal Financial Report (4040–0014)	300	1	300	0	0	0	0
HUD Form–2880: Applicant/Recipient Disclosure/Update Report (2501–0044)	300	1	300	0	0	0	0
HUD Form–424B: HUD Applicant/Recipient Assurances and Certifications (2501–0044)	300	1	300	0	0	0	0
HUD Form–4117: Formula Response Form	500	1	500	2	1,000	$45.10	$45,100.00
HUD Form–4117: Appendix A	50	1	50	2	100	45.10	4,510.00
HUD Form–4117: Appendix B	50	1	50	2	100	45.10	4,510.00
HUD Form–4117: Appendix C	50	1	50	2	100	45.10	4,510.00
HUD Form–4117: Appendix D	50	1	50	2	100	45.10	4,510.00
HUD Form–4119: Challenging U.S. Census Data	15	1	15	150	2,250	45.10	101,475.00
HUD Form–4119: Appendix A	15	1	15	10	150	45.10	6,765.00
HUD Form–4119: Appendix B	15	1	15	10	150	45.10	6,765.00
HUD Form–4119: Appendix C	15	1	15	15	225	45.10	10,148.00
HUD Form–4119: Appendix D	15	1	15	10	150	45.10	6,765.00
HUD Form–4123: Cost Summary	300	1	300	40	12,000	45.10	541,200.00
HUD Form–4125: Implementation Schedule	300	1	300	40	12,000	45.10	541,200.00
HUD Form–52736–A: Depository Agreement (Bank Accounts)	15	1	15	1	15	45.10	677.00
HUD Form–52736–B: Depository Agreement (Broker/Dealer)	15	1	15	1	15	45.10	677.00

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
HUD Form–52737: IHP/APR	20	2	40	62	2,480	45.10	111,848.00
HUD Form–52737: GEMS IHP/APR	370	2	740	62	45,880	45.10	2,069,188.00
HUD Form–53248: IHBG–COMP APR	65	1	65	30	1,950	45.10	87,945.00
Record retention	30	1	30	1	30	45.10	1,353.00
Code of Conduct (as needed) Code of Conduct	300	1	300	0	0	0	0
HUD–426 Indirect Cost Information (2501–0044) (if applicable)	300	1	300	0	0	0	0
Annual *SAM.gov* registration (3090–0290)	300	1	300	0	0	0	0
Totals	4,290	28	4,680	442	78,695		3,549,145.00

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 2 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Anna Guido,

Department PRA Compliance Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2026–15751 Filed 8–3–26; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7106–N–37]

Privacy Act of 1974; Matching Program

AGENCY: Office of Policy Development and Research, Department of Housing and Urban Development (HUD).

ACTION: Notice of a Re-established Matching Program.

SUMMARY: Pursuant to the Privacy Act of 1974, as amended, HUD is providing notice of its intent to re-establish a matching program with Department of Health and Human Services (HHS) for a recurring matching program with HUD's Office of Public and Indian Housing (PIH) and Multifamily Housing (MFH), involving comparisons of information pertaining to participants in authorized HUD rental housing assistance program with the independent sources of income information available through the National Directory of New Hires (NDNH) maintained by HHS. After verifying the comparison outcomes, HUD will upload the information into the Enterprise Income Verification (EIV) system of records, maintained by HUD, and make it available to: (1) Program administrators such as public housing agencies (PHAs) and private owners and management agents (O/As) (collectively referred to as POAs) to enable them to verify the accuracy of income reported by the tenants (participants) of HUD rental assistance programs and (2) contract administrators (CAs) overseeing and monitoring O/A operations as well as independent public auditors (IPAs) that audit both PHAs and O/As. The most recent renewal of the current matching agreement expires on September 8, 2026.

DATES: *Comment Due Date:* September 3, 2026. The period of this matching program is estimated to cover the 18-month period from September 9, 2026 through March 8, 2028. However, the computer matching agreement (CMA) will become applicable on the latter of the following two dates: September 9, 2026 or 30 days after publication of this notice in the **Federal Register**, provided no public comments are received that require modification to the notice and republication for an additional 30-day comment period. The matching program will continue for 18 months after the applicable date and may be extended for an additional 12 months if the respective agency Data Integrity Boards (DIBs) determine that the conditions specified in 5 U.S.C. 552a(o)(2)(D) have been met.

ADDRESSES: Interested persons are invited to submit comments regarding this notice at *www.regulations.gov* or to the Rules Docket Clerk, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, Room 10276, SW, Washington, DC 20410. Communications should refer to the above docket number A copy of each communication submitted will be available for public inspection and copying between 8:00 a.m. and 5:00 p.m. on weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Contact the Recipient Agency Priscilla W. Clark, Senior Agency Official for Privacy, Department of Housing and Urban Development, 451 7th Street SW, Room 6204, Washington, DC 20410, telephone number (202) 340–2978. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit: *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION: Pursuant to the Privacy Act of 1974, as amended; OMB's guidance on this statute entitled, ''*Final Guidance Interpreting the Provisions of Public Law 100–503*''*;* OMB Circular No. A–108, ''*Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act;*'' and OMB Circular No. A–130, ''*Managing Information as a Strategic Resource;*'' HUD is providing the public with notice of a re-established computer matching agreement with the Department of Health and Human Services (HHS). The previous notice of this computer matching program between HUD and HHS was published at 89 FR 18776 (March 15, 2024). The first HUD–HHS computer matching program was

conducted in September 2005 with HUD's Office of Public and Indian Housing (PIH). The scope of the HUD–HHS computer matching program was expanded in December 2007 to include HUD's Office of Housing for certain Multifamily Housing (MFH) programs and was revised in January 2011 to include participants in HUD's Disaster Housing Assistance Program.

The matching program will be carried out only to the extent necessary to: (1) verify the employment and income of participants in certain rental assistance programs to correctly determine the amount of their rent and assistance, (2) identify, prevent, and recover improper payments made on behalf of tenants, and (3) after removal of personal identifiers, to conduct analyses of the employment and income reporting of individuals participating in any HUD authorized rental housing assistance program.

HUD will make the results of the computer matching program available to public housing agencies (PHAs), private housing owners and management agents (O/As) administering HUD rental assistance programs to enable them to verify employment and income and correctly determine the rent and assistance levels for individuals participating in those programs, and contract administrators (CAs) overseeing and monitoring O/A operations. This information also may be disclosed to the HUD Office of Inspector General (HUD/OIG) and the United States Attorney General in detecting and investigating potential cases of fraud, waste, and abuse within HUD rental assistance programs.

In addition to the above noted information disclosures, limited redisclosure of reports containing NDNH information may be redisclosed to the following persons and/or entities: (1) Independent auditors for the sole purpose of performing an audit of whether these HUD authorized entities verified tenants' employment and/or income and calculated the subsidy and rent correctly; and (2) entities and/or individuals associated with grievance procedures and judicial proceedings (*i.e.* lawyers, court personnel, agency personnel, grievance hearing officers, etc.) relating to independently verified unreported income identified through this matching program.

HUD will use this matching authority to provide and its third-party administrators (PHAs, O/As, and CAs) of eligible programs with information to identify, reduce or eliminate improper payments in HUD's rental housing assistance programs, while continuing to ensure that HUD rental housing assistance programs serve and are accessible by its intended program beneficiaries.

Participating Agencies

Department of Housing and Urban Development and the Department of Health and Human Services.

Authority for Conducting the Matching Program

This matching program is authorized by: Subsections 453(j)(7)(A), (C)(i), and (D)(i) of the Social Security Act (42 U.S.C. 653(j)(7)(A), (C)(i), and (D)(i)) provide the legal authority to conduct the matching program.

Section 453(j)(7) Information comparisons for housing assistance programs states:

(A) Furnishing of information by HUD. Subject to subparagraph (G), the Secretary of Housing and Urban Development shall furnish to the Secretary, on such periodic basis as determined by the Secretary of Housing and Urban Development in consultation with the Secretary, information in the custody of the Secretary of Housing and Urban Development for comparison with information in the National Directory of New Hires, in order to obtain information in such Directory with respect to individuals who are participating in any program under—

(i) the United States Housing Act of 1937 (42 U.S.C. 1437 *et seq.*);

(ii) section 202 of the Housing Act of 1959 (12 U.S.C. 1701q);

(iii) section 221(d)(3), 221(d)(5), or 236 of the National Housing Act (12 U.S.C. 1715l(d)(3), 1715l(d)(5) or 1715z–1);

(iv) section 811 of the Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 8013); or

(v) section 101 of the Housing and Urban Development Act of 1965 (12 U.S.C. 1701s).

* * * * *

(C) Duties of the Secretary

(i) Information disclosure—The Secretary, in cooperation with the Secretary of Housing and Urban Development, shall compare information in the National Directory of New Hires with information provided by the Secretary of Housing and Urban Development with respect to individuals described in subparagraph (A), and shall disclose information in such Directory regarding such individuals to the Secretary of Housing and Urban Development, in accordance with this paragraph, for the purposes specified in this paragraph.

* * * * *

(D) Use of information by HUD. The Secretary of Housing and Urban Development may use information resulting from a data match pursuant to this paragraph only—

(i) for the purpose of verifying the employment and income of individuals described in subparagraph (A); and (ii) after removal of personal identifiers, to conduct analyses of the employment and income reporting of individuals described in subparagraph (A).

42 U.S.C. 653(j)(7)(A), (C)(i), and (D). Subsection 453(j)(7)(D)(ii) of the Social Security Act provides legal authority to conduct analysis of employment and income reporting, ''after the removal of personal identifiers.''

42 U.S.C. 653(j)(7)(D)(ii). HUD does not currently use NDNH match information to conduct analysis of employment and income reporting; however, if HUD seeks to conduct such analyses in the future, HUD must first obtain OCSE approval by requesting authorization and providing OCSE with documentation of the proposed analyses. The documentation must include the specific purpose for the analyses, specific HUD users, procedures for the removal of personal identifiers, data storage location and safeguards, retention periods, and other information about the use of the results of the information comparison for analyses.

Purpose(s)

HUD's primary objective of the computer matching program is to verify the employment and income of participants in certain rental assistance programs to determine the appropriate level of rental assistance, and to detect, deter and correct fraud, waste, and abuse in rental housing assistance programs. In meeting these objectives, HUD also is carrying out a responsibility under 42 U.S.C. 1437f(K) to ensure that income data provided to PHAs, and O/As, by household members is complete and accurate. HUD's various rental housing assistance programs require that participants meet certain income and other criteria to be eligible for rental assistance. In addition, tenants generally are required to report and recertify the amounts and sources of their income at least annually. However, under the Quality Housing and Work Responsibility Act (QHWRA) of 1998, PHAs operating Public Housing programs may offer tenants the option to pay a flat rent, or an income-based rent. Those tenants who select a flat rent will be required to recertify income at least every three years. In addition, the changes to the Admissions and Occupancy final rule, published at 65 FR 16692 (March 29, 2000), specified that household composition must be

recertified annually for tenants who select a flat rent or income-based rent.

Categories of Individuals

Covered Programs

This notice of computer matching program applies to individuals receiving services from the following rental assistance programs:

A. Disaster Housing Assistance Program (DHAP)

B. Public Housing

C. Section 8 Housing Choice Vouchers (HCV)

D. Project-Based Vouchers

E. Section 8 Moderate Rehabilitation

F. Project-Based Section 8

1. New Construction

2. State Agency Financed

3. Substantial Rehabilitation

4. Sections 202/8

5. Rural Housing Services Section 515/8

6. Loan Management Set-Aside (LMSA)

7. Property Disposition Set-Aside (PDSA)

G. Section 101 Rent Supplement

H. Section 202/162 Project Assistance Contract (PAC)

I. Section 202 Project Rental Assistance Contract (PRAC)

J. Section 811 Project Rental Assistance Contract (PRAC)

K. Section 236 Rental Assistance Program

L. Section 221(d)(3) Below Market Interest Rate (BMIR)

Note: This notice does not apply to the Low-Income Housing Tax Credit (LIHTC) or the Rural Housing Services Section 515 without Section 8 programs.

Categories of Records

The following are the categories of record in this matching agreement:

HUD Input File

- First name
- Last name
- Date of birth
- Social Security number

HHS New Hire File

- New hire processed date
- Employee name
- Employee address
- Employee date of hire
- Employee state of hire
- Federal Employer Identification Number
- State Employer Identification Number
- Department of Defense status code
- Employer name
- Employer address
- Transmitter agency code
- Transmitter state code
- Transmitter state or agency name

HHS Quarterly Wage File

- Quarterly wage processed date
- Employee name
- Federal Employer Identification Number
- State Employer Identification Number
- Department of Defense code
- Employer name
- Employer address
- Employee wage amount
- Quarterly wage reporting period
- Transmitter agency code
- Transmitter state code
- Transmitter state or agency name

HHS Unemployment Insurance File

- Unemployment insurance processed date
- Claimant name
- Claimant address
- Claimant benefit amount
- Unemployment insurance reporting period
- Transmitter state code
- Transmitter state or agency name

System(s) of Records

The Office of Child Support Enforcement (OCSE) National Directory of New Hires (NDNH) contains new hire, quarterly wage, and unemployment insurance information furnished by state and federal agencies and is maintained by OCSE in the system of records ''OCSE National Directory of New Hires,'' System No. 09–80–0381, published at 89 FR 25625 (April 11, 2024). The disclosure of NDNH records by OCSE to HUD constitutes a routine use as defined by the Privacy Act, 5 U.S.C. 552a(b)(3). Routine Use (12) published in the NDNH SORN authorizes the disclosure of NDNH records to HUD.

The HUD records used in the information comparison are retrieved from, and the results of the information comparison are maintained within, the Enterprise Income Verification (EIV) System, HUD/PIH–05, as published in the applicable System of Records Notice. The applicable routine use in that SORN authorizes the disclosure of HUD records to OCSE for purposes of this matching program.

Kimberly Morton,

Acting Chief Privacy Officer, Office of Administration.

[FR Doc. 2026–15753 Filed 8–3–26; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7107–N–17; OMB Control No.: 2502–0178]

30-Day Notice of Proposed Information Collection: Management Review for Multifamily Housing Projects

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: Comments due September 3, 2026.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Anna Guido, PRA Compliance Officer, Paperwork Reduction Act Division, PRAD, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; email at *PaperworkReductionActOffice@hud.gov,* ATTN: Anna Guido, telephone (202) 402–5535. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on December 6, 2024 at 89 FR 97062.

A. Overview of Information Collection

Title of Information Collection: Management Review for Multifamily Housing Projects.

OMB Approval Number: 2502–0178.

Type of Request: Revision of a currently approved collection.

Form Number: HUD Form-9834, HUD Form-91067.

Description of the need for the information and proposed use: HUD Form-9834 Management Review for Multifamily Housing Projects is used by HUD staff, Mortgagees, and Contract Administrators (CAs) to evaluate project management; determine causes of project problems; devise corrective actions to stabilize projects and prevent defaults; and ensure that fraud, waste, and mismanagement are not occurring. The information collected also supports enforcement actions when corrective actions are not implemented.

HUD Form-91067 VAWA Lease Addendum for Multifamily Housing Programs informs tenants of statutory requirements under the Violence Against Women Act of 2013 (Pub. L. 113–4) and its 2022 reauthorization (Pub. L. 117–103). HUD developed HUD Form –91067 to incorporate VAWA protections into leases. 24 CFR 5.2005(a)(4). The lease addendum ensures tenants are informed of their rights under VAWA and owners/agents document compliance by retaining a signed lease addendum. Protections apply to all victims of domestic violence, dating violence, sexual assault, or stalking, regardless of sex, marital status, or age. The addendum is executed and retained in tenant files and may be reviewed by HUD during compliance monitoring or in response to tenant complaints.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hours per response	Annual burden hours	Hourly cost per response* * ***	Total annual cost
HUD–9834	*27,127	**1	****27,127	8.33	225,968	$39.77	$8,986,744.00
HUD–91067	413,929	***1	413,929	.13	55,811	39.77	2,140,54.00
Totals	441,056	.....	441,056	.....	281,021	.....	11,126,798.00

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 2 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Anna Guido,

Department PRA Compliance Officer Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2026–15796 Filed 8–3–26; 8:45 am]

BILLING CODE 4210–67–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1456]

Certain Mobile Cellular Communications Devices; Notice of a Commission Determination Not To Review an Initial Determination Terminating All Remaining Respondents From the Investigation; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review five initial determinations (''ID'') (Order Nos. 25–29) of the presiding administrative law judge (''ALJ'') terminating all remaining respondents from the investigation based on a consent order and settlement agreements and terminating the investigation in its entirety.

FOR FURTHER INFORMATION CONTACT: B. Rashmi Borah, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2518. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on August 7, 2025, based on a complaint filed by Pantech Corporation of the Republic of Korea (''Pantech''). 90 FR 38177 (Aug. 7, 2025). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain mobile cellular communications devices by reason of the infringement of U.S. Patent Nos. 9,548,839; 11,659,503; 11,051,344; and 12,267,876. *Id.* The complaint further alleges that a domestic industry exists. *Id.*

The notice of investigation names the following respondents: (1) OnePlus Technology (Shenzhen) Co., Ltd. of Shenzhen City, Guangdong Province, China; (2) OnePlus USA Corp. of Irving, Texas; (3) Lenovo Group Ltd. of Beijing, China; (4) Lenovo (United States) Inc. of Morrisville, North Carolina; (5) Motorola Mobility LLC of Libertyville, Illinois; (6) TCL Industries Holdings Co., Ltd. of Huizhou City, Guangdong Province, China; (7) TCL Electronics Holdings Ltd. of Hong Kong; (8) TCL Communication Ltd. of Hong Kong; (9) TCL Communication Technology Holdings Ltd. of Huizhou City, Guangdong Province, China; (10) TCL Mobile International Ltd. of Hong Kong; (11) Huizhou TCL Mobile Communication Co., Ltd. of Huizhou City, Guangdong Province, China; (12) TCL Mobile Communication (HK) Company Ltd. of Hong Kong; (13) Tinno

USA, Inc. of Plano, Texas; (14) Shenzhen Tinno Mobile Technology Corp. of Shenzhen City, Guangdong Province, China; (15) HMD Global of Espoo, Finland; (16) HMD Global Oy of Espoo, Finland; and (17) HMD America, Inc. of Miami, Florida. *Id.* at 38177–78. The Office of Unfair Import Investigations (''OUII'') is also named as a party to this investigation. *Id.* at 38178.

On September 30, 2025, the Commission terminated the investigation with respect to respondent HMD Global. Order No. 7 (Sept. 10, 2025), *unreviewed by* Comm'n Notice (Sept. 30, 2025).

On May 22, 2026, respondents HMD Global Oy and HMD America, Inc. (collectively, ''HMD'') moved to terminate the investigation as to HMD based on a consent order stipulation and proposed consent order. Pantech did not oppose the motion. On June 2, 2026, OUII filed a response in support of HMD's motion.

On May 26, 2026, Pantech and respondents OnePlus Technology (Shenzhen) Co., Ltd., and OnePlus USA Corp. (collectively, ''OnePlus'') filed a joint motion to terminate the investigation as to OnePlus based on a settlement agreement. On June 4, 2026, OUII filed a response in support of the motion as to OnePlus.

On June 4, 2026, Pantech and respondents Lenovo Group Limited, Lenovo (United States) Inc., and Motorola Mobility LLC (collectively, ''Lenovo'') filed a joint motion to termination the investigation as to Lenovo based on a settlement agreement. On June 15, 2026, OUII filed a motion in support of the motion as to Lenovo.

On June 15, 2026, Pantech and respondents Tinno USA, Inc. and Shenzhen Tinno Mobioe Technology Corp. (collectively, ''Tinno'') filed a joint motion to terminate the investigation as to Tinno based on a settlement agreement. On June 25, 2026, OUII filed a response in support of the motion as to Tinno.

On June 22, 2026, Pantech and respondents TCL Industries Holdings Co., Ltd., TCL Electronics Holdings Ltd., TCL Communication Ltd., TCL Communication Technology Holdings Ltd., TCL Mobile International Ltd., Huizhou TCL Mobile Communication Co., Ltd., and TCL Mobile Communication (HK) Company Ltd., (collectively, ''TCL'') filed a joint motion to terminate the investigation as to TCL based on a settlement agreement. On June 25, 2026, OUII filed a response in support of the motion as to TCL.

On June 30, 2026, the ALJ issued the five subject IDs, terminating HMD, OnePlus, Lenovo, Tinno, and TCL from the investigation. Order No. 25 (as to HMD); Order No. 26 (as to OnePlus); Order No. 27 (as to Lenovo); Order No. 28 (as to Tinno), and Order No. 29 (as to TCL). Order No. 25 confirms that HMD's consent order stipulation and proposed consent orders satisfy the requirements of Commission Rules 210.2(c)(3) and (c)(4) (19 CFR 210.21(c)(3), (c)(4)). Order No. 25 also finds that termination of HMD would not be contrary to the public interest. Order Nos. 26, 27, 28, and 29 each find that the respective motions comply with the requirements of Commission Rule 210.21(b)(1) (19 CFR 210.21(b)(1)), and that the proposed settlements do not adversely affect the public interest in accordance with Commission Rule 210.50(b)(2) (19 CFR 210.50(b)(2)). As the five subject IDs terminate all remaining respondents, Order No. 29 also terminates the investigation in its entirety. No petitions for review of the subject IDs were filed.

The Commission has determined not to review the subject IDs. The Commission has issued consent orders to HMD Global Oy and HMD America, Inc. HMD, OnePlus, Lenovo, Tinno, and TCL are terminated from the investigation, and the investigation is terminated in its entirety.

The Commission vote for this determination took place on July 30, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.
Issued: July 30, 2026.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2026–15730 Filed 8–3–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–802–804 and 731–TA–1799–1803 (Preliminary)]

Linear Hydraulic Cylinders From Canada, China, India, Mexico, and South Korea; Institution of Antidumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–802–804 and 731–TA–1799–1803 (Preliminary) pursuant to the Tariff Act of 1930 to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of linear hydraulic cylinders from Canada, China, India, Mexico, and South Korea, provided for in subheadings 8412.21.00 and 8412.90.90 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Governments of China, India, and Mexico. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by September 14, 2026. The Commission's views must be transmitted to Commerce within five business days thereafter, or by September 21, 2026.

DATES: July 29, 2026.

FOR FURTHER INFORMATION CONTACT: Stamen Borisson ((202) 205–3125), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to a petition filed on July 29, 2026, by the Hydraulic Cylinders Fair Trade Coalition and its individual members: Aggressive Hydraulics Inc., Cedar, Minnesota; Hol-Mac Corporation, Bay Springs, Mississippi; Ligon

Hydraulics, Tonawanda, New York; Prince Manufacturing Corporation, Lexington, South Carolina; PTC Alliance LLC, Wexford, Pennsylvania; Rosenboom Machine and Tool Inc., Sheldon, Iowa; Scot Industries Inc., Lone Star, Texas; Stillwell Inc., Burnsville, Minnesota; and Texas Hydraulics Inc., Temple, Texas.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Office of Investigations will hold a staff conference in connection with the preliminary phase of these investigations beginning at 9:30 a.m. on August 19, 2026. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before noon on August 17, 2026. Please provide an email address for each conference participant in the email. Information on conference procedures, format, and participation, including guidance for requests to appear as a witness via videoconference, will be available on the Commission's Public Calendar (Calendar (USITC) | United States International Trade Commission). A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before 5:15 p.m. on August 24, 2026, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than 4:00 p.m. on August 18, 2026. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.
Issued: July 30, 2026.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2026–15722 Filed 8–3–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–975 (Rescission)]

Certain Computer Cables, Chargers, Adapters, Peripheral Devices and Packaging Containing the Same; Notice of Commission Determination To Institute a Rescission Proceeding; Rescind a Limited Exclusion Order; and Terminate the Rescission Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined to institute a rescission proceeding and rescind the limited exclusion order (''LEO'') that was issued in the above-captioned investigation. The rescission proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Edward S. Jou, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3316. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the

Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On October 13, 2016, the Commission issued an LEO in the above-captioned investigation based on a complaint filed on behalf of Belkin International, Inc. of Playa Vista, California (''Complainant''), alleging violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain computer cables, chargers, adapters, peripheral devices and packaging containing the same by reason of infringement of U.S. Trademark Nos. 2,339,459; 2,339,460; 4,168,379; and 4,538,212 (collectively, the ''Asserted Trademarks''). 81 FR 71765 (Oct. 18, 2016). The LEO was directed to respondents Dongguan Pinte Electronic Co., Ltd. and Dongguan Shijie Fresh Electronic Products Factory of Dongguan City, China.

The LEO included a requirement that Complainant make annual filings with the Commission stating whether it continued to use the Asserted Trademarks in commerce, but the Complainant has not made any such filings since the LEO issued.

On March 24, 2026, the Commission issued a notice requesting written submissions from the public, the parties to the investigation, and other interested parties, on whether the LEO should be modified or rescinded under 19 U.S.C. 1337(k) and 19 CFR 210.76, in whole or in part. 91 FR 14879–80 (Mar. 27, 2026). The Commission did not receive any submissions in response to this notice.

Based on the foregoing and the lack of any response to the Commission's notice, the Commission has determined to institute a rescission proceeding pursuant to Commission Rule 210.76, 19 CFR 210.76. In view of Complainant's failure to comply with the LEO's annual filing requirement to show continued use of the Asserted Trademarks, the Commission has determined that changed conditions of fact warrant rescission of the LEO under 19 U.S.C. 1337(k). Accordingly, the Commission has determined to rescind the LEO. The rescission proceeding is hereby terminated.

The Commission vote for this determination took place on July 31, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: July 31, 2026.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2026–15794 Filed 8–3–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–563 (Modification)]

Certain Portable Power Stations and Packaging Therefor; Notice of Commission Determination To Institute a Modification Proceeding; Modify a Limited Exclusion Order; and Terminate the Modification Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined to institute a modification proceeding and modify the limited exclusion order (''LEO'') that was issued in the above-captioned investigation. The modification proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Edward S. Jou, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3316. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On November 9, 2006, the Commission issued an LEO in the above-captioned investigation based on a complaint filed by Roadmaster (USA) Corporation (''Complainant'') alleging violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain portable power stations and packaging therefor by reason of infringement of U.S. Design Patent No. D469,739 (''the D'739 patent''); U.S. Trademark Registration No. 2,594,538 (''the '538 mark''); and U.S. Copyright Registration No. VA–1–261–495 (' the '495 copyright''). 71 FR 66554 (Nov. 15, 2006). The LEO was directed to respondent Sinochem Ningbo, Ltd. of Ningbo, China. *Id.*

The LEO included a requirement that Complainant make annual filings with the Commission stating whether it continued to use the '538 mark in commerce, but the Complainant has not made any such filings since 2007. In addition, the D'739 patent has expired and the '538 mark has been canceled by the U.S. Patent and Trademark Office due to a failure to file a declaration of continued use. *See* U.S. Trademark Registration No. 2,594,538, Cancelled/Expired (USPTO Trademark Status & Document Retrieval, Feb. 22, 2013).

On March 24, 2026, the Commission issued a notice requesting written submissions from the public, the parties to the investigation, and other interested parties, on whether the LEO should be modified or rescinded under 19 U.S.C. 1337(k) and 19 CFR 210.76, in whole or in part. 91 FR 14879–80 (Mar. 27, 2026). The Commission did not receive any submissions in response to this notice.

Based on the foregoing and the lack of any response to the Commission's notice, the Commission has determined to institute a modification proceeding pursuant to Commission Rule 210.76, 19 CFR 210.76. In consideration of the expiration of the D'739 patent, the cancellation of the '538 mark, and Complainant's failure to comply with the LEO's annual filing requirement to show continued use of the '538 mark, the Commission has determined that changed conditions of fact warrant modification of the LEO under 19 U.S.C. 1337(k). Accordingly, the Commission has determined to modify the LEO to rescind the exclusions based on infringement of the D'739 patent and the '538 mark. The modification proceeding is hereby terminated.

The Commission vote for this determination took place on July 31, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: July 31, 2026.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2026–15792 Filed 8–3–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–977 (Modification)]

Certain Arrowheads With Deploying Blades and Components Thereof; Notice of Commission Determination To Institute a Modification Proceeding; Modify a General Exclusion Order; and Terminate the Modification Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined to institute a modification proceeding and modify the general exclusion order (''GEO'') that was issued in the above-captioned investigation. The modification proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Edward S. Jou, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3316. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On April 6, 2017, the Commission issued a GEO in the above-captioned investigation based on a complaint filed by FeraDyne Outdoors, LLC and Out RAGE, LLC of Cartersville, Georgia (collectively, ''Complainants'') alleging violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain arrowheads with deploying blades and components thereof and packaging therefor by reason of infringement of certain claims of U.S. Patent Nos. RE44,144; 6,517,454; 7,771,298; 8,758,176; 8,986,141; 9,068,806; D710,962; and D711,489; and U.S. Trademark Registration No. 4,812,058 (''the '058 mark''). 82 FR 17689–90 (Apr. 12, 2017).

The GEO included a requirement that Complainants make annual filings with the Commission stating whether they continued to use the '058 mark in commerce, but the Complainants have not made any such filings since the issuance of the GEO.

On March 24, 2026, the Commission issued a notice requesting written submissions from the public, the parties to the investigation, and other interested parties, on whether the GEO should be modified or rescinded under 19 U.S.C. 1337(k) and 19 CFR 210.76, in whole or in part. 91 FR 14879–80 (Mar. 27, 2026). The Commission did not receive any submissions in response to this notice.

Based on the foregoing and the lack of any response to the Commission's notice, the Commission has determined to institute a modification proceeding pursuant to Commission Rule 210.76, 19 CFR 210.76. In consideration of Complainants' failure to comply with the GEO's annual filing requirement to show continued use of the '058 mark, the Commission has determined that changed conditions of fact warrant modification of the GEO under 19 U.S.C. 1337(k). Accordingly, the Commission has determined to modify the GEO to rescind the exclusion based on the '058 mark. The modification proceeding is hereby terminated.

The Commission vote for this determination took place on July 31, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: July 31, 2026.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2026–15791 Filed 8–3–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1256 (Rescission)]

Certain Portable Battery Jump Starters and Components Thereof; Notice of Commission Determination to Institute a Rescission Proceeding; Rescind a Limited Exclusion Order; and Terminate the Rescission Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined to institute a rescission proceeding and rescind the limited exclusion order (''LEO'') that was issued in the above-captioned investigation. The rescission proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Edward S. Jou, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3316. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On August 29, 2022, the Commission issued an LEO in the above-captioned investigation based on a complaint filed on behalf of The NOCO Company of Glenwillow, Ohio (''Complainant''), alleging violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain portable battery jump starters and components thereof by reason of infringement of U.S. Trademark Nos. 4,811,656 and 4,811,749 (collectively, the ''Asserted Trademarks''). 87 FR 54260–61 (Sept. 2, 2022). The LEO was directed to respondents Zhejiang Quingyou Electronic Commerce Co., Ltd. of Hangzhou, China and Shenzhen Mediatek Tong Technology Co., Ltd. of Shenzhen, China.

The LEO included a requirement that Complainant make annual filings with

the Commission stating whether it continued to use the Asserted Trademarks in commerce, but the Complainant has not made any such filings since the LEO issued.

On March 24, 2026, the Commission issued a notice requesting written submissions from the public, the parties to the investigation, and other interested parties, on whether the LEO should be modified or rescinded under 19 U.S.C. 1337(k) and 19 CFR 210.76, in whole or in part. 91 FR 14879–80 (Mar. 27, 2026). The Commission did not receive any submissions in response to this notice.

Based on the foregoing and the lack of any response to the Commission's notice, the Commission has determined to institute a rescission proceeding pursuant to Commission Rule 210.76, 19 CFR 210.76. In view of Complainant's failure to comply with the LEO's annual filing requirement to show continued use of the Asserted Trademarks, the Commission has determined that changed conditions of fact warrant rescission of the LEO under 19 U.S.C. 1337(k). Accordingly, the Commission has determined to rescind the LEO. The rescission proceeding is hereby terminated.

The Commission vote for this determination took place on July 31, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: July 31, 2026.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2026–15790 Filed 8–3–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–763 (Modification)]

Certain Radio Control Transmitters and Receivers and Products Containing Same; Notice of Commission Determination To Institute a Modification Proceeding; Modify a Limited Exclusion Order; and Terminate the Modification Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined to institute a modification proceeding and modify the limited exclusion order (''LEO'') that was issued in the above-captioned investigation. The modification proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Edward S. Jou, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3316. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On September 27, 2011, the Commission issued an LEO in the above-captioned investigation based on a complaint filed by Horizon Hobby, Inc. of Champaign, Illinois (''Complainant'') alleging violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain radio control hobby transmitters and receivers and products containing same by reason of infringement of certain claims of U.S. Patent No. 7,391,320; U.S. Copyright Reg. No. TX–7–226–001; and U.S. Trademark Registration No. 3,080,770 (''the '770 mark''). 76 FR 60872–73 (Sept. 30, 2011).

The LEO included a requirement that Complainant make annual filings with the Commission stating whether it continued to use the '770 mark in commerce, but the Complainant has not made any such filings since 2017.

On March 24, 2026, the Commission issued a notice requesting written submissions from the public, the parties to the investigation, and other interested parties, on whether the LEO should be modified or rescinded under 19 U.S.C. 1337(k) and 19 CFR 210.76, in whole or in part. 91 FR 14879–80 (Mar. 27, 2026). The Commission did not receive any submissions in response to this notice.

Based on the foregoing and the lack of any response to the Commission's notice, the Commission has determined to institute a modification proceeding pursuant to Commission Rule 210.76, 19 CFR 210.76. In consideration of Complainant's failure to comply with the LEO's annual filing requirement to show continued use of the '770 mark, the Commission has determined that changed conditions of fact warrant modification of the LEO under 19 U.S.C. 1337(k). Accordingly, the Commission has determined to modify the LEO to rescind the exclusion based on the '770 mark. The modification proceeding is hereby terminated.

The Commission vote for this determination took place on July 31, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: July 31, 2026.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2026–15793 Filed 8–3–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–778 and 731–TA–1764 (Final)]

Fresh Mushrooms From Canada; Scheduling of the Final Phase of Countervailing Duty and Antidumping Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping and countervailing duty investigation Nos. 701–TA–778 and 731–TA–1764 (Final) pursuant to the Tariff Act of 1930 to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of fresh mushrooms from Canada, provided for in subheading 0709.51.01 of the Harmonized Tariff Schedule of the United States, preliminarily determined by the Department of Commerce (''Commerce'') to be subsidized and sold at less-than-fair-value.

DATES: July 17, 2026.

FOR FURTHER INFORMATION CONTACT: Jordan Harriman ((202) 205–2610),

Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Scope.— For purposes of these investigations, Commerce has defined the subject merchandise as ''. . . fresh mushrooms of the genus *Agaricus* (fresh mushrooms). This includes, but is not limited to, fresh mushrooms of the species *Agaricus bisporus,* which are commonly referred to as button mushrooms, chestnut mushrooms, cremini or crimini mushrooms, baby bellas, portabella or portobello mushrooms, table mushrooms, or as white or browns. Fresh mushrooms include whole mushrooms, as well as mushrooms that have been sliced, diced, or separated into stems and pieces prior to importation. Fresh mushrooms may also be imported in bulk or loose form, or may be imported in individual containers packaged for retail sale. The scope of this investigation includes all fresh mushrooms of the genus *Agaricus,* whether or not organic, and irrespective of age, cut, color, size, species, or packaging. Subject merchandise may be cleaned, washed, inspected, subjected to metal detection, sliced, diced, or de-stemmed, and/or vacuum cooled prior to importation, but otherwise undergoes minimal further processing. The scope of this investigation covers fresh mushrooms of the genus *Agaricus* regardless of end use, including both mushrooms destined for the fresh market and mushrooms intended for food processing.'' Fresh mushrooms of the genus *Agaricus* are currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheading 0709.51.01. Although the HTSUS number is provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Background.—The final phase of these investigations is being scheduled pursuant to sections 705(b) and 731(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 1673d(b)), as a result of affirmative preliminary determinations by Commerce that certain benefits which constitute subsidies within the meaning of § 703 of the Act (19 U.S.C. 1671b) are being provided to manufacturers, producers, or exporters in Canada of fresh mushrooms, and that such products are being sold in the United States at less than fair value within the meaning of § 733 of the Act (19 U.S.C. 1673b). The investigations were requested in petitions filed on September 16, 2025, by the Fresh Mushrooms Fair Trade Coalition and its individual members.[1]

For further information concerning the conduct of this phase of the investigations, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Participation in the investigations and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record on November 5, 2026, and a public version will be issued thereafter, pursuant to § 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on Tuesday, November 17, 2026. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before Friday, November 13, 2026. Any requests to appear as a witness via videoconference must be included with your request to appear. Requests to appear via videoconference must include a statement explaining why the witness cannot appear in person; the Chairman, or other person designated to conduct the investigation, may in their discretion for good cause shown, grant such a request. Requests to appear as remote witness due to illness or a positive COVID–19 test result may be submitted by 3:00 p.m. the business day prior to the hearing. Further information about participation in the hearing will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.*

A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference, if deemed necessary, to be held at 9:30 a.m. on Monday, November 16, 2026. Parties shall file and serve written testimony and presentation slides in connection with their presentation at the hearing by no later than noon on November 16, 2026. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later

[1] The individual members of the Fresh Mushrooms Fair Trade Coalition are: Giorgio Fresh Co. (including Donna Bella Farms LLC and Giorgi Mushroom Co.); J–M Farms LLC; Kennett Square Mushroom Operation LLC; Modern Mushroom Farms, Inc.; Needham's Mushroom Farms, Inc.; and Sher-Rockee Mushroom Farms.

than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of § 207.23 of the Commission's rules; the deadline for filing is November 12, 2026. Parties shall also file written testimony in connection with their presentation at the hearing, and posthearing briefs, which must conform with the provisions of § 207.25 of the Commission's rules. The deadline for filing posthearing briefs is November 24, 2026. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petition, on or before November 24, 2026. On December 14, 2026, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before December 16, 2026, but such final comments must not contain new factual information and must otherwise comply with § 207.30 of the Commission's rules. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to § 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

By order of the Commission.

Issued: July 30, 2026.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2026–15745 Filed 8–3–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1472 (Review)]

Difluoromethane (R–32) From China; Determination

On the basis of the record [1] developed in the subject five-year review, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty order on difluoromethane (R–32) from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[2]

Background

The Commission instituted this review on February 2, 2026 (91 FR 4620, February 2, 2026) and determined on May 8, 2026 that it would conduct an expedited review (91 FR 30726, May 26, 2026).

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on July 31, 2026. The views of the Commission are contained in USITC Publication 5767 (July 2026), entitled *Difluoromethane (R–32) from China: Investigation No. 731–TA–1472 (Review).*

By order of the Commission.

Issued: July 31, 2026.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2026–15797 Filed 8–3–26; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Chairman Doyle not participating.

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–638 and 731–TA–1473 (Review)]

Corrosion Inhibitors From China; Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping and countervailing duty orders on corrosion inhibitors from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on February 2, 2026 (91 FR 4617), and determined on May 8, 2026, that it would conduct expedited reviews (91 FR 35267, June 10, 2026).

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on July 30, 2026. The views of the Commission are contained in USITC Publication 5769 (July 2026), entitled *Corrosion Inhibitors From China: Investigation Nos. 701–TA–638 and 731–TA–1473 (Review).*

By order of the Commission.

Issued: July 30, 2026.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2026–15723 Filed 8–3–26; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

DEPARTMENT OF JUSTICE

[OMB Number 1105–0112]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Revision of a Previously Approved Collection; Title: Crime Victim's Rights Act Complain Form

AGENCY: Executive Office for United States Attorney, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Executive Office for United States Attorney (EOUSA), Department of Justice (DOJ), will be submitting the following information

collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until October 5, 2026.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Ellen M. FitzGerald, Victim's Rights Ombudsman, EOUSA, 950 Pennsylvania Avenue NW, Washington, DC 20530,*ellen.fitzgerald@usdoj.gov,* 202–252–1015.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the (component), including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether, and, if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

1. *Type of Information Collection:* Revision of a previously approved collection.

2. *The Title of the Form/Collection:* Crime Victim's Rights Act Complaint Form

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* not applicable

4. *Abstract:* The Crime Victims' Rights Act of 2004, 18 U.S.C. 3771(CVRA), sets forth the rights of a federal crime victim to file a complaint against any Department of Justice employee who violated or failed to provide rights established under the CVRA. The Department of Justice has created the Office of the Victims' Rights Ombudsman to receive and investigate complaints filed by Federal crime victims against its employees and has implemented ''Procedures to Promote Compliance with Crime Victims' Rights Obligations,'' 28 CFR 45.10. The complaint process is not designed for the correction of specific victims' rights violations but is instead used to request corrective or disciplinary action against Department of Justice employees who may have failed to provide rights to crime victims. The Department of Justice will investigate the allegations in the complaint to determine whether the employee used his or her ''best efforts'' to provide crime victim rights. The Office of the Crime Victims' Rights Ombudsman does not administer crime victim funds or provide services.

5. *Obligation to Respond:* The affected public are individuals. The obligation to respond is voluntary.

6. *Total Estimated Number of Respondents:* 100

7. *Estimated Time per Respondent:* 45 mins

8. *Frequency:* Once

9. *Total Estimated Annual Time Burden:* 75

10. *Total Estimated Annual Other Costs Burden:*

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Enterprise Portfolio Management, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2026–15721 Filed 8–3–26; 8:45 am]

BILLING CODE 4410–BE–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that a proposed Consent Decree in *United States and State of Alaska* v. *Duran Construction Co. LLC, Marciano Duran, and Josette Duran,* No. 1:22–cv–00091–ACP, was lodged with the United States District Court for the District of Alaska on July 30, 2026.

This proposed Consent Decree concerns a complaint filed by the United States against Duran Construction Co. LLC, Marciano Duran, and Josette Duran, pursuant to 33 U.S.C. 1319, to obtain injunctive relief from and impose civil penalties against the Defendants for violating the Clean Water Act by discharging pollutants without a permit into waters of the United States. The proposed Consent Decree resolves these allegations by requiring the Defendants to restore the impacted areas and/or perform mitigation and to pay a civil penalty.

The Department of Justice will accept written comments relating to this proposed Consent Decree for thirty (30) days from the date of publication of this Notice. Please address comments to Daniel Martin, United States Department of Justice, Environmental Defense Section, P.O. Box 7611, Washington, DC 20044–7611, or *pubcomment_eds.enrd@usdoj.gov* and refer to *United States, et al.* v. *Duran Construction Co. LLC, et al.,* DJ # 90–5–1–1–21970.

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the District of Alaska, James M. Fitzgerald U.S. Courthouse and Federal Building, 222 W 7th Avenue, Anchorage, AK 99513. In addition, the proposed Consent Decree may be examined electronically at *http://www.justice.gov/enrd/consent-decrees.*

Charles Spear,

Assistant Chief, Environmental Defense Section, Environment and Natural Resources Division.

[FR Doc. 2026–15762 Filed 8–3–26; 8:45 am]

BILLING CODE P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (25–045)]

Privacy Act of 1974; System of Records

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of a Modified System of Records, Correction

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, the National Aeronautics and Space Administration is providing public notice of a modification to an existing system of records entitled NASA Core Financial Management Records (CFMR). Records in this system are used to process reimbursement payments to employees for travel, purchase of books or other miscellaneous items; and to process payments and collections in which an individual is reimbursing the Agency. The system of records is more

fully described in the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: Submit comments within 30 calendar days from the date of this publication. The proposed modification to this system will take effect at the end of that period if no significant adverse comments are received.

ADDRESSES: Submit comments to Stayce Hoult, Privacy Act Officer, Office of the Chief Information Officer, Mary W. Jackson, NASA Headquarters, Washington, DC 20546–0001, 757–864–3292, or *NASA-PAOfficer@nasa.gov.*

FOR FURTHER INFORMATION CONTACT: NASA Privacy Act Officer, Stayce Hoult, 256–544–7705, or *NASA-PAOfficer@nasa.gov.*

SUPPLEMENTARY INFORMATION: This system of records notice (SORN) is a correction to the Notice of a modified system of records; correction of February 3, 2026 FR Doc. 2026–02105, pages 4969–4970, the Routine Use section for additional coverage and extra clarity to the December 5, 2025, publication (90 FR 56183). It also updates the Privacy Act Officer and contact information. Finally, it also modifies the notice to make editorial changes.

In the **Federal Register** of December 5, 2025, in FR Doc. 2025–21971, on page 56184, in the second column, correct paragraph 2 in the ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES section to read:

To external entities (*e.g.,* organizers of symposiums, conferences and workshops), which have provided funds to NASA employees, to process payments and/or collections for activities undertaken in the performance of their duties (*e.g.,* attending conferences, travel, training, or other assignment for NASA).

Correct the citations in the HISTORY section to read:

- (91 FR 4969, pp. 4969–4970) Published: 2/3/2026.
- (90 FR 56183, pp. 56183–56185) Published: 12/05/2025.
- (88 FR 30171, pp. 30171–30173) Published: 05/10/2023.

Stayce Harris Hoult,

NASA Chief Privacy Officer.

SYSTEM NAME AND NUMBER

Core Financial Management Records, NASA 10CFMR.

SECURITY CLASSIFICATION

Unclassified.

SYSTEM LOCATION

George C. Marshall Space Flight Center, National Aeronautics and Space Administration, Marshall Space Flight Center, AL 35812

SYSTEM MANAGER(S)

- Director, Agency Financial Systems Office, Mary W. Jackson NASA Headquarters, National Aeronautics and Space Administration, Washington, DC 20546–0001
- IS90/Associate Chief Information Officer, Applications Division, George C. Marshall Space Flight Center, National Aeronautics and Space Administration, Marshall Space Flight Center, AL 35812

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES

Any disclosures of information will be compatible with the purpose for which the Agency collected the information. The following are routine uses:

1. To the U.S. Department of the Treasury for financial reimbursement of individual expenses, such as travel, books, and other miscellaneous items.

2. To external entities (*e.g.,* organizers of symposiums, conferences and workshops), which have provided funds to NASA employees, to process payments and/or collections for activities undertaken in the performance of their duties (*e.g.,* attending conferences, travel, training, or other assignment for NASA).

3. To the U.S. Department of the Treasury when disclosure of the information is relevant to review payment and award eligibility through the Do Not Pay Working System for the purposes of identifying, preventing, or recouping improper payments to an applicant for, or recipient of, Federal funds, including funds disbursed by a state (meaning a state of the United States, the District of Columbia, a territory or possession of the United States, or a federally recognized Indian tribe) in a state-administered, federally funded program.

In addition, information may be disclosed under the following NASA Standard Routine Uses:

1. *Law Enforcement*—When a record on its face, or in conjunction with other information, indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order, disclosure may be made to the appropriate agency, whether Federal, foreign, State, local, or tribal, or other public authority responsible for enforcing, investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order, if NASA determines by careful review that the records or information are both relevant and necessary to any enforcement, regulatory, investigative or prosecutive responsibility of the receiving entity.

2. *Certain Disclosures to Other Agencies*—A record from this system of records (SOR) may be disclosed to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary, to obtain information relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

3. *Certain Disclosures to Other Federal Agencies*—A record from this SOR may be disclosed to a Federal agency, in response to its request, for a matter concerning the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

4. *Department of Justice*—A record from this SOR may be disclosed to the Department of Justice when a) NASA, or any component thereof; or b) any employee of NASA in his or her official capacity; or c) any employee of NASA in his or her individual capacity where the Department of Justice has agreed to represent the employee; or d) the United States, where NASA determines that litigation is likely to affect NASA or any of its components, is a party to litigation or has an interest in such litigation, and by careful review, the use of such records by the Department of Justice is deemed by NASA to be relevant and necessary to the litigation.

5. *Courts*—A record from this SOR may be disclosed in an appropriate proceeding before a court, grand jury, or administrative or adjudicative body, when NASA determines that the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant and necessary to the proceeding.

6. *Response to an Actual or Suspected Compromise or Breach of Personally Identifiable Information*—A record from

this SOR may be disclosed to appropriate agencies, entities, and persons when (1) NASA suspects or has confirmed that there has been a breach of the system of records; (2) NASA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, NASA (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with NASA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

7. *Contractors*—A record from this SOR may be disclosed to contractors (as defined in 5 U.S.C. 552a(m)), grantees, experts, consultants, students, volunteers, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for NASA, when necessary to accomplish a NASA function related to this SOR.

Contractors provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to NASA employees.

8. *Members of Congress*—A record from this SOR may be disclosed to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

9. *Disclosures to Other Federal Agencies in Response to an Actual or Suspected Compromise or Breach of Personally Identifiable Information*—A record from this SOR may be disclosed to another Federal agency or Federal entity, when NASA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

10. *National Archives and Records Administration*—A record from this SOR may be disclosed as a routine use to the officers and employees of the National Archives and Records Administration (NARA) pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

11. *Audit*—NASA may release records to the NASA OIG or GAO during an audit or investigation, as authorized by law, where the release of such information to the entity is necessary to perform the audit or its oversight function.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system are maintained on paper and electronic media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved from the system by name or SSN (Tax ID).

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are stored in the NASA Applications & Platform Services (APS) database and managed, retained and dispositioned in accordance with NASA Records Retention Schedules, Schedule 9, Items 11 and 16.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Electronic records are maintained on secure NASA servers and protected in accordance with all Federal standards and those established in NASA regulations at 14 CFR 1212.605. Additionally, server and data management environments employ infrastructure encryption technologies both in data transmission and at rest on servers. Electronic messages sent within and outside of the Agency that convey sensitive data are encrypted and transmitted by staff via pre-approved electronic encryption systems as required by NASA policy. Approved security plans are in place for information systems containing the records in accordance with the Federal Information Security Modernization Act of 2014 (FISMA) and OMB Circular No. A–130, Managing Information as a Strategic Resource. Only authorized personnel requiring information in the official discharge of their duties are authorized access to records through approved access or authentication methods. Access to electronic records is achieved only from workstations within the NASA Intranet or via a secure Virtual Private Network (VPN) connection that requires two-factor hardware token authentication or via employee Personal Identity Verification (PIV) badge authentication from NASA-issued computers. Non-electronic records are secured in locked rooms or locked file cabinets.

RECORD ACCESS PROCEDURES:

In accordance with 14 CFR part 1212, Privacy Act—NASA Regulations, information may be obtained by contacting in person or in writing the system or subsystem manager listed above at the location where the records are created and/or maintained. Requests must contain the identifying data concerning the requester, *e.g.,* first, middle and last name; date of birth; description and time periods of the records desired. NASA Regulations also address contesting contents and appealing initial determinations regarding records access.

CONTESTING RECORD PROCEDURES:

In accordance with 14 CFR part 1212, Privacy Act—NASA Regulations, information may be obtained by contacting in person or in writing the system or subsystem manager listed above at the location where the records are created and/or maintained. Requests must contain the identifying data concerning the requester, *e.g.,* first, middle and last name; date of birth; description and time periods of the records desired. NASA Regulations also address contesting contents and appealing initial determinations regarding records access.

NOTIFICATION PROCEDURES:

In accordance with 14 CFR part 1212, Privacy Act—NASA Regulations, information may be obtained by contacting in person or in writing the system or subsystem manager listed above at the location where the records are created and/or maintained. Requests must contain the identifying data concerning the requester, *e.g.,* first, middle and last name; date of birth; description and time periods of the records desired. NASA Regulations also address contesting contents and appealing initial determinations regarding records access.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

- (91 FR 4969, pp. 4969–4970) Published: 2/3/2026.
- (90 FR 56183, pp. 56183–56185) Published: 12/05/2025.
- (88 FR 30171, pp. 30171–30173) Published: 05/10/2023.

[FR Doc. 2026–15738 Filed 8–3–26; 8:45 am]

BILLING CODE 7510–13–P

NUCLEAR REGULATORY COMMISSION

[NRC–2026–0001]

Sunshine Act Meetings

TIME AND DATE: Week of August 3, 2026. The schedule for Commission meetings

is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

PLACE: Via Teleconference.

STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Betty.Thweatt@nrc.gov* or *Samantha.Miklaszewski@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of August 3, 2026

Friday, August 7, 2026

2:00 p.m. Affirmation Session (Public Meeting) (Tentative)

Direct Final Rule [DFR–5]: NRC Modernization: Federal Advisory Committee Act Alignment, Access, and Security (RIN 3150–AL46) (Tentative)

(Contact: Wesley Held: 301–287–3591)

Additional Information: The public is invited to attend the Commission's meeting live; via teleconference. Details for joining the teleconference in listen only mode at *https://www.nrc.gov/pmns/mtg.*

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: July 31, 2026.

For the Nuclear Regulatory Commission.

Monika G. Coflin,

Technical Coordinator, Office of the Secretary.

[FR Doc. 2026–15821 Filed 7–31–26; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2026–3697]

Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Biweekly notice.

SUMMARY: Pursuant to section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration (NSHC), notwithstanding the pendency before the Commission of a request for a hearing from any person.

DATES: Comments must be filed by September 3, 2026. A request for a hearing or petitions for leave to intervene must be filed by October 5, 2026. This biweekly notice includes all amendments issued, or proposed to be issued, from July 7, 2026, to July 20, 2026. The last biweekly notice was published on July 21, 2026.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website.

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2026–3697. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301–415–1003; email: *Bridget.Curran@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Nuclear Material Safety and Safeguards, Mail Stop: TWFN–5–A85, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Paula Blechman, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2242; email: *Paula.Blechman@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2026–3697, facility name, unit number(s), docket number(s), application date, and subject when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2026–3697.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin ADAMS Public Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2026–3697, facility name, unit number(s), docket number(s), application date, and subject, in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

For the facility-specific amendment requests shown in this notice, the Commission finds that the licensees' analyses provided, consistent with section 50.91 of title 10 of *the Code of Federal Regulations* (10 CFR) ''Notice for public comment; State consultation,'' are sufficient to support the proposed determinations that these amendment requests involve NSHC. Under the Commission's regulations in 10 CFR 50.92, operation of the facilities in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The Commission is seeking public comments on these proposed determinations. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determinations.

Normally, the Commission will not issue the amendments until the expiration of 60 days after the date of publication of this notice. The Commission may issue any of these license amendments before expiration of the 60-day period provided that its final determination is that the amendment involves NSHC. In addition, the Commission may issue any of these amendments prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. If the Commission takes action on any of these amendments prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final NSHC determination for any of these amendments, any hearing will take place after issuance. The Commission expects that the need to take action on any amendment before 60 days have elapsed will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by any of these actions may file a request for a hearing and petition for leave to intervene (petition) with respect to that action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult 10 CFR 2.309. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 60 days from the date of publication of this notice in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration, which will serve to establish when the hearing is held. If the final determination is that the license amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the license amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h) no later than 60 days from the date of publication of this notice. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may participate as a non-party under 10 CFR 2.315(c).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315, see ADAMS Accession No. ML20340A053 (*https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML2034 0A053*) and the NRC's public website (*https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate*).

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the ''Guidance for Electronic Submissions to the NRC'' (ADAMS Accession No. ML13031A056), and on the NRC's public website (*https://www.nrc.gov/site-help/e-submittals.html*).

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *Hearing.Docket@nrc.gov,* or by telephone at 301–415–1677, to: (1) request a digital identification (ID) certificate which allows the participant (or their counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or their counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website (*https://www.nrc.gov/site-help/e-submittals/getting-started.html*). After a digital ID certificate is obtained and a docket is created, the participant must submit adjudicatory documents in the Portable Document Format. Guidance on submissions is available on the NRC's public website (*https://www.nrc.gov/site-help/electronic-sub-ref-mat.html*). A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59

p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed in order to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website (*https://www.nrc.gov/site-help/e-submittals.html*), by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)–(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available on the NRC's public website (*https://ehd.nrc.gov*), unless otherwise excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing docket where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

The following table provides the plant name, docket number, date of application, ADAMS accession number, and location in the application of the licensees' proposed NSHC determinations. For further details with respect to these license amendment applications, see the applications for amendment, which are available for public inspection in ADAMS. For additional direction on accessing information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

LICENSE AMENDMENT REQUESTS

Dominion Energy South Carolina, Inc.; Virgil C. Summer Nuclear Station, Unit 1, Fairfield County, SC	
Docket No	50–395.
Application date	June 4, 2026.
ADAMS Accession No	ML26155A152.
Location in Application of NSHC	Page 28–30 of Attachment 1.
Brief Description of Amendment	The proposed amendment would address non-conservatisms in the Heat Flux Hot Channel Factor (F_Q) identified by Westinghouse Nuclear Safety Advisory Letter (NSAL) 09–5, Revision 1, and incorporate the NRC-approved Improved F_Q Methodology in WCAP–17661–P–A, as well as implement other improvements to V.C. Summer Technical Specifications as described in the submittal.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	W.S. Blair, Senior Counsel, Dominion Energy Services, Inc., 120 Tredegar St., RS–2, Richmond, VA 23219.
NRC Project Manager, Telephone Number	G. Ed Miller, 301–415–2481.

Energy Northwest; Columbia Generating Station; Benton County, WA	
Docket No	50–397.
Application date	June 24, 2026.
ADAMS Accession No	ML26175A269.
Location in Application of NSHC	Pages 1–3 of the Enclosure.
Brief Description of Amendment	The proposed amendment would revise the technical specifications (TSs) for Columbia Generating Station for adoption of Technical Specifications Task Force (TSTF) Traveler TSTF–591, ''Revise Risk Informed Completion Time (RICT) Program,'' which is an approved change to the Standard Technical Specifications. Traveler TSTF–591 revises TS Section 5.5.16, ''Risk Informed Completion Time Program,'' to reference Regulatory Guide 1.200, Revision 3, instead of Revision 2, and to make other changes. A new report will be added to TS Section 5.6, ''Reporting Requirements,'' to inform the NRC of newly developed methods used to calculate a RICT.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Ryan Lukson, Assistant General Counsel, Energy Northwest, MD 1020, P.O. Box 968, Richland, WA 99352.

LICENSE AMENDMENT REQUESTS—Continued

NRC Project Manager, Telephone Number	Mahesh Chawla, 301–415–8371.

Indiana Michigan Power Company; Donald C. Cook Nuclear Plant, Units 1 and 2; Berrien County, MI

Docket Nos	50–315, 50–316.
Application date	June 2, 2026.
ADAMS Accession No	ML26153A216.
Location in Application of NSHC	Pages 45–47 of Enclosure 2.
Brief Description of Amendments	The proposed amendments would revise the Emergency Plan to reflect the updates contained in NUREG–0654/FEMA–REP–1, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,'' Revision 2, dated December 2019.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Robert G. Garpenter, Assistant General Counsel, American Electric Power, 1 Riverside Plaza, 29, Columbus, OH 43215.
NRC Project Manager, Telephone Number	Scott Wall, 301–415–2855.

Northern States Power Company; Prairie Island Nuclear Generating Plant, Units 1 and 2; Goodhue County, MN

Docket Nos	50–282, 50–306.
Application date	June 4, 2026.
ADAMS Accession No	ML26155A281.
Location in Application of NSHC	Pages 5–7 of the Enclosure.
Brief Description of Amendments	The proposed amendments would adopt Technical Specifications (TS) Task Force (TSTF) Traveler TSTF–596, ''Expand the Applicability of the Surveillance Frequency Control Program (SFCP).'' TSTF–596 expands the applicability of the SFCP to include other periodic testing frequencies in TS. The proposed change would also revise the SFCP to reference additional regulatory mechanisms that may be used to control Surveillance Frequencies, such as 10 CFR 50.55a and 10 CFR 50.69. The proposed change revises Surveillance Requirements that reference the Inservice Testing Program to instead reference the SFCP.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Andrew Van Duzer, Assistant General Counsel, Xcel Energy, 701 Pennsylvania Ave. NW, Suite 250, Washington, DC 20004.
NRC Project Manager, Telephone Number	Ramon Gascot Lozada , 301–415–2004.

Susquehanna Nuclear, LLC and Allegheny Electric Cooperative, Inc.; Susquehanna Steam Electric Station, Units 1 and 2; Luzerne County, PA

Docket Nos	50–387, 50–388.
Application date	June 17, 2026.
ADAMS Accession No	ML26168A346.
Location in Application of NSHC	Pages 4–5 of the Enclosure.
Brief Description of Amendments	The proposed amendments would revise the Technical Specifications (TSs) at each facility based on Technical Specifications Task Force (TSTF) Traveler TSTF–596, ''Expand the Applicability of the Surveillance Frequency Control Program (SFCP),'' which is an approved change to the standard technical specifications. TSTF–596 expands the applicability of the SFCP to include other periodic testing frequencies in the TS. The licensee requested that the amendment be reviewed under the consolidated line item improvement process (CLIIP).
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Jason Usher, 600 Hamilton Street, Suite 600, Allentown, PA 18101.
NRC Project Manager, Telephone Number	Richard Guzman, 301–415–1030.

Tennessee Valley Authority; Browns Ferry Nuclear Plant, Units 1, 2, and 3; Limestone County, AL

Docket Nos	50–259, 50–260, 50–296.
Application date	June 15, 2026.
ADAMS Accession No	ML26166A227.
Location in Application of NSHC	Pages E10–E11 of the Enclosure.
Brief Description of Amendments	The proposed amendments would revise Browns Ferry Nuclear Plant, Units 1, 2, and 3, Technical Specification 3.3.8.2, ''Reactor Protection System (RPS) Electric Power Monitoring,'' to modify the limiting condition for operation to remove specificity of the power supply and Surveillance Requirement 3.3.8.2.2 to add a new calibration for over-frequency.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Edward C. Meade (Interim), Executive VP and General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, WT 6A, Knoxville, TN 37902.

LICENSE AMENDMENT REQUESTS—Continued

NRC Project Manager, Telephone Number	Kimberly Green, 301–415–1627.

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed NSHC determination, and opportunity for a hearing in connection with these actions, were published in the **Federal Register** as indicated in the safety evaluation for each amendment.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated in the safety evaluation for the amendment.

For further details with respect to each action, see the amendment and associated documents such as the Commission's letter and safety evaluation, which may be obtained using the ADAMS accession numbers indicated in the following table. The safety evaluation will provide the ADAMS accession numbers for the application for amendment and the **Federal Register** citation for any environmental assessment. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

LICENSE AMENDMENT ISSUANCES

Constellation Energy Generation, LLC; Christopher M. Crane Clean Energy Center; Dauphin County, PA

Docket No	50–289.
Amendment Date	July 1, 2026.
ADAMS Accession No	ML26135A004.
Amendment No	307.
Brief Description of Amendment	The amendment revised the facility license to allow receipt and possession of new reactor fuel and new sealed neutron sources at the Christopher M. Crane Clean Energy Center.
Public Comments Received as to Proposed NSHC (Yes/No)	No.

NextEra Energy Duane Arnold, LLC; Duane Arnold Energy Center; Linn County, IA

Docket No	50–331.
Amendment Date	July 15, 2026.
ADAMS Accession No	ML26175A137 (Package).
Amendment No	319.
Brief Description of Amendment	The amendment revised the facility license to reflect completion of the direct transfer of Renewed Facility License No DPR–49 for the Duane Arnold Energy Center (DAEC) and the associated general license for the DAEC independent spent fuel storage installation (collectively, the facility), which consolidates Central Iowa Power Cooperative's 20-percent ownership interest and Corn Belt Power Cooperative's 10-percent ownership interest in the facility in NextEra Energy Duane Arnold, LLC.
Public Comments Received as to Proposed NSHC (Yes/No)	No.

PSEG Nuclear LLC; Hope Creek Generating Station; Salem County, NJ; PSEG Nuclear LLC; Salem Nuclear Generating Station, Unit Nos 1 and 2; Salem County, NJ

Docket Nos	50–272, 50–311, 50–354.
Amendment Date	July 16, 2026.
ADAMS Accession No	ML26188A116.
Amendment Nos	355, 337, 240.
Brief Description of Amendments	The amendments adopted Technical Specifications Task Force (TSTF) Traveler –585 (TSTF–585), ''Revise LCO [limiting condition for operation] 3.0.3 to Require Managing Risk.'' TSTF–585 revised LCO 3.0.3 to require assessing and managing plant risk whenever LCO 3.0.3 is entered. If the risk assessment determines that continuing plant operation is acceptable and other conditions are satisfied, 24-hours from entry into LCO 3.0.3 is permitted to initiate a shutdown. Otherwise, initiation of the shutdown is required immediately. The proposed amendments also revised or added Technical Specification Required Actions to direct other actions instead of entry into LCO 3.0.3.

LICENSE AMENDMENT ISSUANCES—Continued

Public Comments Received as to Proposed NSHC (Yes/No)	No.

Southern Nuclear Operating Company, Inc.; Edwin I. Hatch Nuclear Plant, Units 1 and 2; Appling County, GA

Docket Nos	50–321, 50–366.
Amendment Date	July 14, 2026.
ADAMS Accession No	ML26174A354.
Amendment Nos	332 (Unit 1), 277 (Unit 2).
Brief Description of Amendments	The amendments adopted Technical Specifications Task Force (TSTF) Traveler TSTF–585, ''Revise LCO [Limiting Condition for Operation] 3.0.3 to Require Managing Risk,'' and TSTF–597, ''Eliminate LCO 3.0.3 Mode 2 Requirements.''
Public Comments Received as to Proposed NSHC (Yes/No)	No.

Tennessee Valley Authority; Browns Ferry Nuclear Plant, Units 1, 2, and 3; Limestone County, AL; Tennessee Valley Authority; Sequoyah Nuclear Plant, Units 1 and 2; Hamilton County, TN; Tennessee Valley Authority; Watts Bar Nuclear Plant, Units 1 and 2; Rhea County, TN

Docket Nos	50–259, 50–260, 50–296, 50–327, 50–328, 50–390, 50–391.
Amendment Date	July 16, 2026.
ADAMS Accession No	ML26188A014.
Amendment Nos	342 (Browns Ferry, Unit 1), 365 (Browns Ferry, Unit 2), 325 (Browns Ferry, Unit 3), 376 (Sequoyah, Unit 1), 371 (Sequoyah, Unit 2), 182 (Watts Bar, Unit 1), and 87 (Watts Bar, Unit 2).
Brief Description of Amendments	The amendments revised the technical specifications (TSs) for Browns Ferry Nuclear Plant, Units 1, 2, and 3; Sequoyah Nuclear Plant, Units 1 and 2; and Watts Bar Nuclear Plant, Units 1 and 2, to adopt Technical Specifications Task Force (TSTF) Traveler TSTF–585, Revision 5, ''Revise LCO [Limiting Condition for Operation] 3.0.3 to Require Managing Risk.''
Public Comments Received as to Proposed NSHC (Yes/No)	No.

Vistra Operations Company LLC; Beaver Valley Power Station, Units 1 and 2; Beaver County, PA

Docket Nos	50–334, 50–412.
Amendment Date	July 14, 2026.
ADAMS Accession No	ML26155A388.
Amendment Nos	329 (Unit 1), 219 (Unit 2).
Brief Description of Amendments	The amendments adopted Technical Specifications Task Force (TSTF) Traveler TSTF–585, ''Revise LCO [Limiting Condition for Operation] 3.0.3 to Require Managing Risk.''
Public Comments Received as to Proposed NSHC (Yes/No)	No.

Vistra Operations Company LLC; Comanche Peak Nuclear Power Plant, Unit Nos 1 and 2; Somervell County, TX

Docket Nos	50–445, 50–446.
Amendment Date	July 6, 2026.
ADAMS Accession No	ML26155A181.
Amendment Nos	195 (Unit 1) and 195 (Unit 2).
Brief Description of Amendments	The amendments modified technical specification requirements to incorporate risk-informed requirements for selected Required Action end states. Specifically, the changes permit a Required Action end state of Mode 4 rather than an end state of Mode 5. These changes are consistent with NRC-approved Technical Specifications Task Force (TSTF) Traveler TSTF–432, ''Change in Technical Specifications End States (WCAP–16294).''
Public Comments Received as to Proposed NSHC (Yes/No)	No.

Vistra Operations Company LLC; Comanche Peak Nuclear Power Plant, Unit Nos 1 and 2; Somervell County, TX

Docket Nos	50–445, 50–446.
Amendment Date	July 14, 2026.
ADAMS Accession No	ML26148A199.
Amendment Nos	196 (Unit 1) and 196 (Unit 2).
Brief Description of Amendments	The amendments adopted Technical Specifications Task Force (TSTF) Traveler TSTF–585, ''Revise LCO [Limiting Condition for Operation] 3.0.3 to Require Managing Risk.''
Public Comments Received as to Proposed NSHC (Yes/No)	No.

Vistra Operations Company LLC; Perry Nuclear Power Plant, Unit 1; Lake County, OH

Docket No	50–440.
Amendment Date	July 14, 2026.
ADAMS Accession No	ML26181A169.
Amendment No	209.

LICENSE AMENDMENT ISSUANCES—Continued

Brief Description of Amendment	The amendment adopted Technical Specifications Task Force (TSTF) Traveler TSTF–585, ''Revise LCO [Limiting Condition for Operation] 3.0.3 to Require Managing Risk.''
Public Comments Received as to Proposed NSHC (Yes/No)	No.

(Authority: 42 U.S.C. 2011 *et seq.*)

Dated: July 27, 2026.

For the Nuclear Regulatory Commission.

Hipólito González,

Chief, Operating Reactor Licensing Branch 4, Division of Licensing Projects I, Office of Nuclear Reactor Regulation.

[FR Doc. 2026–15750 Filed 8–3–26; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Renewal of an Existing Information Collection, Optional Form 306, Declaration for Federal Employment

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Office of Personnel Management (OPM), Suitability Executive Agent Programs, is notifying the general public and Federal agencies that OPM proposes to request the Office of Management and Budget (OMB) renew a previously approved information collection, Optional Form 306 (OF 306), Declaration for Federal Employment, without change.

DATES: Comments must be received on or before September 3, 2026.

ADDRESSES: You may submit comments on the Federal Rulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Joe Knouff, Director, Suitability Executive Agent Programs, U.S. Office of Personnel Management, P.O. Box 699, Slippery Rock, PA 16057, or by email at *SuitEA@opm.gov.*

SUPPLEMENTARY INFORMATION: The OF 306 is completed by applicants who are under consideration for Federal or Federal contract employment. The information collected on this form is mainly used to determine a person's acceptability for Federal and Federal contract employment, and that person's retirement status and life insurance enrollment. The information on this form may be used in conducting an investigation to determine a person's suitability or ability to hold a security clearance, and it may be disclosed to authorized officials making similar, subsequent determinations. The form asks for personal identifying data and information about violations of the law, past convictions, imprisonments, probations, parole, military court martial, delinquency on a Federal debt, Selective Service Registration, United States military service, Federal civilian or military retirement benefits received or applied for, and life insurance enrollment. The information collected can be obtained at the pre-appointment stage and may support preliminary eligibility and suitability screening; additional investigative forms may be required where appropriate.

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(a)(1)(D)), OPM has submitted to OMB for review a request for renewal of a currently approved information collection. OPM published a 60-day **Federal Register** notice for this information collection on May 14, 2026, at 91 FR 27379. OPM received two comments that resulted in no changes to the form.

One commenter recommended changing the estimated completion-time range from 5–30 minutes to 15–30 minutes. The commenter did not provide data, testing results, or other information demonstrating that respondents cannot complete the form in fewer than 15 minutes. Based on OPM's experience administering the collection and the differing circumstances of respondents, OPM is retaining the existing estimated range.

The same commenter recommended ''modernizing and revising'' the form to make it electronic. It is important to note that this form is primarily collected via USA Staffing. USA Staffing is the primary government-wide hiring and onboarding system used by more than 100 Federal agencies. A limited number of agencies may collect the information through other systems or through paper forms, and OPM will continue to provide agencies flexibility in how the form is collected.

One additional commenter suggested adding a field for ''email address[,]'' however, because this form is mainly collected via USAStaffing, which is an electronic system that requires the individual provide their email address for other communication purposes, it is not necessary to duplicate the collection of email address on this form.

OPM invites comments on:

1. Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. The accuracy of the agency's estimate of the burden of the proposed collection of information;

3. Ways to enhance the quality, utility, and clarity of the information to be collected; and

4. Ways to minimize the burden of the collection of information on respondents, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Analysis

Agency: Suitability Executive Agent Program, Office of Personnel Management.

Title: Optional Form 306 (OF 306), Declaration for Federal Employment.

OMB Control Number: 3206–0182.

Frequency: On occasion.

Affected Public: Individuals or households.

Number of Respondents: 217,102.

Estimated Time per Respondent: 15 minutes.

Total Burden Hours: 54,276.

Obligation To Respond: Required to obtain or retain a benefit.

Authority: 44 U.S.C. 3507(a)(1)(D).

Office of Personnel Management.

Jerson Matias,

Federal Register Liaison.

[FR Doc. 2026–15741 Filed 8–3–26; 8:45 am]

BILLING CODE 6325–66–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2026–330 and K2026–325]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *https://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Public Proceeding(s)
III. Summary Proceeding(s)

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any individual person, entity or particular point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

None. *See* Section III for summary proceedings.

III. Summary Proceeding(s)

1. *Docket No(s).:* MC2026–330 and K2026–325; *Filing Title:* USPS Request to Add New Fulfillment Standardized Distinct Product, PM–GA Contract 1057, and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 30, 2026; *Filing Authority:* 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

This Notice will be published in the **Federal Register**.

Danielle LeFlore,

Legal Assistant.

[FR Doc. 2026–15765 Filed 8–3–26; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0268]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Rule 2a–7

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. § 3501 *et seq.*), the Securities and Exchange Commission (SEC or ''Commission'') is soliciting comments on the proposed collection of information described below.

Money market funds are open-end management investment companies that differ from other open-end management investment companies in that they seek to maintain a stable price per share, usually $1.00, or seek to minimize fluctuations in their price per share. Rule 2a–7 [17 CFR 270.2a–7] under the Investment Company Act of 1940 [15 U.S.C. 80a–1 *et seq.*] (the ''Act'') exempts certain money market funds from the valuation requirements of the Act, and, subject to certain risk-limiting conditions, permits these money market funds to use the ''amortized cost method'' of asset valuation or the ''penny-rounding method'' of share pricing.

Rule 2a–7 imposes certain recordkeeping obligations on money market funds, some of which vary based on the type of money market fund. For example, the board of directors of a government or retail money market fund, in supervising the fund's operations, must establish written procedures designed to stabilize the fund's net asset value (''NAV''). An institutional prime or institutional tax-exempt money market fund must have written guidelines established and reviewed by the board related to mandatory liquidity fees, while non-government money market funds similarly must have written guidelines related to discretionary liquidity fees. In addition, money market fund boards must adopt written procedures that provide for periodic stress testing (and reporting to the board) of the fund's ability to minimize principal volatility and maintain sufficient minimum liquidity under certain hypothetical events and to maintain policies and procedures that specifically address ongoing minimal credit risk monitoring. A money market fund's board must also adopt guidelines and procedures

relating to certain responsibilities it delegates to the fund's investment adviser. These procedures and guidelines typically address various aspects of the fund's operations. The fund must maintain and preserve for six years a written copy of both these procedures and guidelines. The fund also must maintain and preserve for six years a written record of the board's considerations and actions taken in connection with the discharge of its responsibilities, to be included in the board's minutes. In addition, the fund must maintain and preserve for three years written records of certain credit risk analyses, evaluations with respect to securities subject to demand features or guarantees, and determinations with respect to adjustable rate securities and asset backed securities.

Funds must also post monthly portfolio information and certain other information on their websites and maintain records of creditworthiness evaluations on counterparties to repurchase agreements that the fund intends to ''look through'' for purposes of rule 2a–7's diversification limitations. If a retail or government money market fund determines to use a share cancellation method to maintain a stable net asset value in a period with negative interest rates, it must provide certain disclosures to investors in advance of using share cancellation and when share cancellation is used. Compliance with rule 2a–7's information collection requirements is required to obtain or retain benefits.

We estimate that approximately 284 money market funds are subject to rule 2a–7. We estimate that each money market fund incurs an average of 700 hours per year to comply with the recordkeeping requirements of rule 2a–7 (relating to the establishment and maintenance of policies and procedures, records of credit risk analyses, certain notices or reports to the fund's board of directors, determinations made by the fund's board of directors, and other information collection requirements that do not involve third-party disclosures) and an average of 75 hours per year to comply with the third-party disclosure requirements of rule 2a–7 (including requirements to provide certain information on money market fund websites and requirements for certain funds to provide disclosures to investors related to share cancellation). We estimate the total annual burden of the collection of information requirements of rule 2a–7 to be 220,100 hours, with an aggregate external cost burden of $51,120,000.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will have practical utility; (b) the accuracy of the SEC's estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to *PaperworkReductionAct@sec.gov* by October 5, 2026.

Dated: July 30, 2026.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–15729 Filed 8–3–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106014; File No. SR–MSRB–2026–04]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing of a Proposed Rule Change To Amend MSRB Rule G–27 To Exclude Certain Public Finance Activities From Term ''Structuring of Public Offerings or Private Placements,'' Extend the Length of the Exclusion for Non-Primary Residences From Municipal Branch Office Designation, and Make a Technical Update to the Rule's Title

July 30, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 27, 2026 the Municipal Securities Rulemaking Board (''MSRB'' or ''Board'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the MSRB. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The MSRB filed with the Commission a proposed rule change to (i) exclude certain public finance activities from the term ''structuring of public offerings or private placements'' as used within MSRB Rule G–27, (ii) extend the length of the exclusion for non-primary residences from municipal branch office designation, and (iii) make a technical update to the title of MSRB Rule G–27, as described herein (the ''proposed rule change'').

If the Commission approves the proposed rule change, the MSRB will announce the operative date of the proposed rule change in a regulatory notice to be published on the MSRB website no later than 30 days following Commission approval. The compliance date would be no earlier than 90 days and no later than 180 days following Commission approval.

The text of the proposed rule change is available on the MSRB's website at *https://msrb.org/2026-SEC-Filings* and at the MSRB's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the MSRB included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The MSRB has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

As part of the MSRB's broad retrospective rule review,[3] the MSRB continues to evaluate ways to modernize its rules to reflect how brokers, dealers, and municipal securities dealers (collectively,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The MSRB regularly engages in retrospective reviews of its rules and associated interpretive guidance with the goal of ensuring that they achieve their intended purposes and take into account the current state of the municipal securities market. *See* MSRB Rulebook Modernization web page, available at *https://www.msrb.org/Rulebook-Modernization.*

''dealers'') operate today and will continue to evolve their businesses to operate in the future. Additionally, the MSRB recognizes that advancements in technology and compliance tools have enhanced dealers' ability to more effectively supervise the conduct of the municipal securities activities of the dealer and that of its associated persons in a decentralized environment due to hybrid work arrangements. The MSRB understands that certain surveillance and monitoring technology can provide a more real-time supervision of associated persons regardless of their physical location Thus, dealers have made strides in modernizing their workplace while also undertaking the necessity of putting proper safeguards in place to ensure compliance with MSRB rules and the applicable provisions of the Exchange Act and rules thereunder.

The proposed rule change is intended to provide greater flexibility to dealers and their associated persons with respect to hybrid work arrangements without modifying the office of municipal supervisory jurisdiction (''OMSJ'') and municipal branch office definitions within MSRB Rule G–27(g)(i) and MSRB Rule G–27(g)(ii), respectively. These provisions were originally adopted to harmonize with the supervisory requirements for broker-dealer members of FINRA (formerly NASD) under applicable supervisory rules (then NASD Rules 3010 and 3012, now FINRA Rules 3110 and 3120).[4] In the context of harmonizing the prior version of MSRB Rule G–27 to parallel the overall supervisory obligations established by FINRA for its member firms, the MSRB stated that it intends generally that the provisions of Rule G–27 be read consistently with the analogous NASD provisions, unless the MSRB specifically indicates otherwise. Thus, relevant NASD interpretations would be presumed to apply to the comparable MSRB provision, subject to the MSRB's right to make distinctions when necessary and appropriate.[5] The MSRB highlights that this presumption with respect to MSRB Rule G–27 and interpretations of analogous FINRA provisions only applies where there are no material differences between such comparable provisions and that any material differences in MSRB Rule G–27 from the provisions of otherwise comparable FINRA supervisory requirements cannot be ignored.

The proposed rule change would extend an exemption from municipal branch office designation under MSRB Rule G–27(g)(ii)(A)(3) for non-primary residences from less than 30 business days per year to up to 90 business days per year providing broader latitude to dealers designing their remote or hybrid work policies. The proposed rule change would also provide clarity to dealers attempting to interpret and comply with MSRB Rule G–27(g)(i) by providing guidance on the meaning of the term ''structuring of public offerings or private placements'', also commonly referred to as public finance banking activities. More specifically, the proposed rule change describes the types of activities that would be included or excluded from the meaning of ''structuring of public offerings or private placements'' under MSRB Rule G–27. The MSRB notes it has never publicly defined the scope of the term ''structuring of public offerings or private placements,''[6] which the MSRB understands has led to dealers designating some locations as an OMSJ out of an abundance of caution.[7] Thus, the MSRB believes defining the term would permit dealers to better evaluate such designations. Resultingly, a better understanding for the municipal securities market regarding how the term is interpreted would aid understanding of the required supervisory framework under MSRB Rule G–27. The proposed rule change would also make clarifying edits to the title of MSRB Rule G–27 to plainly state that the rule is applicable to brokers, dealers, and municipal securities dealers.

Background

MSRB Rule G–27(a), on obligation to supervise, requires each dealer to supervise the conduct of the municipal securities activities of the dealer and its associated persons to ensure compliance with MSRB rules, and the applicable provisions of the Exchange Act and rules thereunder. As such, MSRB Rule G–27(b)(iii) requires dealers to designate as an OMSJ any office at which any one or more of the enumerated activities under MSRB Rule G–27(g)(i) occurs at such office with respect to municipal securities. Locations that are not required to be designated as an OMSJ constitute either a municipal branch office or a non-branch location.[8]

Definition of Municipal Branch Office

Rule G–27(g)(ii)(A) defines a municipal branch office as any location where one or more associated persons of a dealer regularly conducts the business of effecting any transactions in, or inducing or attempting to induce the purchase or sale of any municipal security, or is held out as such, with certain exceptions.[9] The MSRB has not defined the phrase ''regularly conducts'' for purposes of MSRB Rule G–27(g)(ii)(A), on municipal branch office, but instead, has provided a measure of flexibility for dealers to define and interpret how the phrase ''regularly conducts'' fits within their respective business models, and what frequency would constitute regularly working from a particular location for purposes of MSRB Rule G–27(g)(ii)(A)'s definition of municipal branch office.[10] The exceptions from municipal branch office designation pursuant to MSRB Rule G–27(g)(ii) are applicable to locations that would not otherwise trigger designation as an OMSJ under the conditions outlined in MSRB Rule G–27(g)(i),[11] as an OMSJ designation for a particular office would trump the exceptions under the rule. One such exception from the municipal branch office definition, listed in Rule G–27(g)(ii)(A)(3), is for any location, other than a primary residence, that is used for municipal

[4] *See* Exchange Act Release No. 55792 (May 22, 2007), 72 FR 29564 (May 29, 2007) (File No. SR–MSRB–2006–10) (the ''2007 Supervisory Amendments'').

[5] *Id.,* 72 FR at 29564. Currently, FINRA publishes guidance with respect to its supervisory requirements on its website at *https://www.finra.org/rules-guidance/key-topics/supervision#guidance.*

[6] The MSRB notes that FINRA also has never defined the term ''structuring of public offerings or private placements.''

[7] The MSRB reviewed some data derived from the Uniform Branch Office Registration Form (Form BR), which is a form that firms use to register branch offices and offices of supervisory jurisdiction (''OSJs'') with FINRA and as required by the relevant state jurisdiction or other SROs. Form BR's Section 2 (Registration/Notice Filing/Type of Office/Activities) requires a firm to indicate whether a branch office is an OSJ. The MSRB notes that the designation of a branch office as an OMSJ, as defined under MSRB Rule G–27, is optional on Form BR, so while incomplete, the MSRB took note of the significant number of single-person OMSJ's, which was useful in the MSRB's analysis of current designation practices.

[8] FINRA similarly distinguishes among offices of supervisory jurisdiction and branch offices, which must be registered, and unregistered offices or non-branch locations in FINRA Rule 3110. *See also* Exchange Act Release No. 48897 (December 9, 2003), 68 FR 70059, 70061 (December 16, 2003) (File No. SR–NASD–2003–104) (Notice of Filing of Proposed Rule Change and Amendment Nos. 1 and 2 Related to Proposed New Uniform Definition of ''Branch Office'' Under NASD Rule 3010(g)(2)) (the ''2003 FINRA Notice of Filing'').

[9] *See* MSRB Rule G–27(g)(ii)(A)(1)–(7).

[10] FINRA has also publicly stated ''[t]he term ''regularly conducts'' in Rule 3110(f)(2)(A) historically has not been a defined term under the uniform branch office definition. As such, there is no defined threshold level of ''regular'' that would make a location a ''branch office'' under Rule 3110(f)(2)(A).'' *See* FINRA's Residential Supervisory Locations (RSLs) Frequently Asked Questions, Q.18 on meaning of ''regularly conducts'' under FINRA Rule 3110(f)(2), available at *https://www.finra.org/rules-guidance/key-topics/residential-supervisory-locations#faqs.*

[11] *See* MSRB Rule G–27(g)(i).

securities activities for less than 30 business days in any one calendar year, provided the dealer complies with the provisions of MSRB Rule G–27(g)(ii)(A)(2)(a) through (h).[12] The MSRB also points out that conduct that rises to the level of constituting regularly conducting the business of effecting transactions in municipal securities is conduct that could cause a primary residence to be designated as a municipal branch office.

Definition of Office of Municipal Supervisory Jurisdiction

Rule G–27(g)(i) defines the term OMSJ as any office of a dealer where one or more of the following functions take place:

(A) order execution and/or market making;

(B) structuring of public offerings or private placements;

(C) maintaining custody of customers' funds and/or municipal securities;

(D) final acceptance (approval) of new accounts on behalf of the dealer;

(E) review and endorsement of customer orders, pursuant to MSRB Rule G–27(c)(i)(G)(2);

(F) final approval of advertising for use by persons associated with the dealer, pursuant to MSRB Rule G–21(f); or

(G) responsibility for supervising the municipal securities activities of persons associated with the dealer at one or more other municipal branch offices of the dealer.

As aforementioned, the MSRB has never defined the phrase ''structuring of public offerings or private placements'' under MSRB Rule G–27(g)(i)(B). As such, it has been up to dealers to determine which public finance banking activities would fall under the umbrella of ''structuring of public offerings or private placements,'' and would therefore be required to be conducted at an OMSJ, and which activities would not fall under the umbrella and could potentially be conducted at other location types.

There are additional compliance and regulatory obligations for locations classified as an OMSJ or a municipal branch office. MSRB Rule G–27(d)(i)(A) requires dealers to inspect every OMSJ and supervisory municipal branch office at least annually.[13] MSRB Rule G–27(d)(i)(B) requires every non-supervisory municipal branch office to be inspected at least every three years.[14] MSRB Rule G–27(d)(i)(C) requires every non-branch location to be inspected on a regular periodic schedule.[15] Furthermore, an office that is designated as an OMSJ or a supervisory municipal branch office must have one or more appropriately registered principals on-site.[16] All municipal branch offices must have at least one or more appropriately registered representatives or principal.[17] The OMSJ and municipal branch office supervisory framework is currently harmonized with FINRA Rule 3110's definitions of an OSJ and branch office, respectively.[18] The proposed rule change is discussed in greater detail below.

Description of Proposed Rule Change

Extend the 30-Business Day Exclusion for Non-Primary Residences from Municipal Branch Office Designation

MSRB Rule G–27(g)(ii)(A)(3) currently allows for a non-primary residence where municipal securities business is conducted for less than 30 business days per calendar year to be excluded from municipal branch office designation, if the location meets the provisions of MSRB Rule G–27(g)(ii)(A)(2)(a) through (h), as described above.[19] The proposed rule change would increase this limit in MSRB Rule G–27(g)(ii)(A)(3) to up to 90 business days per calendar year without amending the conditions outlined in the rule.

The increase from less than 30 business days per calendar year to up to 90 business days per calendar year for an associated person to work from a non-primary residence without triggering municipal branch office designation would provide dealers greater latitude in permitting their associated persons to work at non-primary residential locations, such as a vacation home or the home of a partner or family member, or at another location. The MSRB believes that the proposed rule change would also provide dealers additional and reasonable flexibility in implementing hybrid work arrangements that acknowledge and account for advances in technology that could allow for effective remote supervision capabilities, while also appropriately limiting the municipal securities related work that could be done away from a municipal branch office. In addition to changing the annual business day limit from 30 to 90, the proposed rule change would also make minor technical edits to MSRB Rule G–27(g)(ii)(A)(3) to improve clarity of the rule by removing the term ''less than'' and adding the term ''or fewer'' into the text of the rule.

The MSRB notes that the current less than 30-business days per calendar year exclusion from municipal branch office designation for work performed at a non-primary residence, and the potential extension to up to 90 business days per calendar year under the proposed rule change, is an exclusion that would be allowed under MSRB Rule G–27. However, dealers would need to conduct their own risk analysis to determine if this type of remote work, and the 90-business day limit allowed under the proposed rule change, is appropriate for their business model,

[12] MSRB Rule G–27(g)(ii)(A)(2)(a) through (h) requires, as conditions for meeting the exception from municipal branch office designation, that: (a) only one associated person, or multiple associated persons who reside at that location and are members of the same immediate family, conduct business at the location; (b) the location is not held out to the public as an office and the associated person does not meet with customers at the location; (c) neither customer funds nor securities are handled at that location; (d) the associated person is assigned to a designated municipal branch office, and such designated municipal branch office is reflected on all business cards, stationery, advertisements and other communications to the public by such associated person; (e) the associated person's correspondence and communications with the public are subject to the dealer's supervision in accordance with MSRB Rule G–27; (f) electronic communications (*e.g.,* email) are made through the dealer's electronic system; (g) all orders are entered through the designated municipal branch office or an electronic system established by the dealer that is reviewable at the municipal branch office; and (h) written supervisory procedures pertaining to supervision of sales activities conducted at the residence are maintained by the dealer.

[13] Pursuant to MSRB Rule G–27(g)(ii)(B), notwithstanding the exclusions in MSRB Rule G–27(g)(ii)(A), any location that is responsible for supervising the municipal securities activities of persons associated with the dealer at one or more non-branch locations of the dealer is considered to be a municipal branch office. Moreover, this type of municipal branch office is known as a ''supervisory municipal branch office.'' *See, e.g.,* MSRB Rule G–27(d)(i)(B). *See also* FINRA Rule 3110 Describes Four Office Classifications available at: *https://www.finra.org/rules-guidance/key-topics/residential-supervisory-locations/office-clasifications* (the ''FINRA Office Classification Guidance'').

[14] A non-supervisory municipal branch office would generally be deemed a location that is not charged with supervising the municipal securities activities of persons associated with the dealer. *See generally* FINRA Office Classification Guidance (distinguishing supervisory branch office and non-supervisory branch office locations).

[15] While MSRB rules do not explicitly establish a specific timeframe for such regular periodic inspections, currently FINRA Rule 3110.13 sets out a general presumption that a non-branch location will be inspected at least every three years, even in the absence of any red flags, and if a FINRA-member dealer establishes a longer periodic inspection schedule, such member must document in its written supervisory and inspection procedures the factors used in determining that a longer periodic inspection cycle is appropriate. *See* FINRA Rule 3110.13.

[16] *See* MSRB Rule G–27(b)(iv).

[17] *Id.*

[18] *See* FINRA Rule 3110(f)(1), defining office of supervisory jurisdiction, and FINRA Rule 3110(f)(2), defining branch office.

[19] *See supra* note 12.

supervisory structure and overarching supervisory system.

Structuring of Public Offering or Private Placements

The proposed rule change would add proposed new Supplementary Material .06, on Exemption of Excluded Public Finance Activities from Office of Municipal Supervisory Jurisdiction and Municipal Branch Office Designation, and .07, on Definition of Excluded Public Finance Activities to MSRB Rule G–27. Proposed new Supplementary Material .06 of MSRB Rule G–27 would state that a location would not meet the definition of an OMSJ under MSRB Rule G–27(g)(i) if associated persons at such location engage in excluded public finance activities, so long as that location does not engage in any other activities that would require designation as an OMSJ. The proposed supplementary material would also expressly state that these excluded public finance activities would not be deemed to constitute ''structuring of public offerings or private placements'' within the meaning of OMSJ under MSRB Rule G–27(g)(i)(B). Furthermore, under proposed new Supplementary Material .06 of MSRB Rule G–27, a primary residence that otherwise meets the exception from municipal branch office designation under MSRB Rule G–27(g)(ii)(A)(2), and from which an associated person engages in excluded public finance activities, would be deemed a non-branch location, as long as the associated person does not engage in any other activities that would require designation of such location as an OMSJ, under MSRB Rule G–27(g)(i). Dealers would need to look carefully at the activities of their non-branch locations to ensure that they are not considered by MSRB Rule G–27 to be a municipal branch office. In addition, the proposed rule change would add a reference to new Supplementary Materials .06 and .07.

Proposed new Supplementary Material .07 of MSRB Rule G–27 would define the term excluded public finance activities as activities that are associated with the structuring of public offerings or private placements, including but not limited to, debt modeling, financial analysis, number running and the solicitation of issuers or obligated persons for the dealer's investment banking services in connection with municipal securities (*e.g.* public finance banking services). However, this does not include final approval of a public offering or private placement transaction (*i.e.,* structuring) conducted by the dealer. Proposed new Supplementary Material .07 of MSRB Rule G–27 would also make clear that the activities described within the definition of excluded public finance activities are not an exhaustive list of excluded public finance activities, and other activities could fall within the definition if a dealer can demonstrate that such other activities do not include the final approval of a public offering or private placement transaction. The MSRB believes that activities such as preliminary data analysis and modeling, as well as running standard debt capacity or sensitivity analyses using established firm models controlled by senior personnel, which are much more specific than the broader enumerated list of excluded public finance activities, would be examples of activities that would be categorized as excluded public finance activities under proposed new Supplementary Material .07 of MSRB Rule G–27. The MSRB is intentionally leaving the definition of excluded public finance activities under proposed new Supplementary Material .07 as business model neutral, without listing an exhaustive list of activities that would qualify as excluded public finance activities, to account for the diversity in business models among dealers.

Proposed new Supplementary Material .07 of MSRB Rule G–27 would also expressly state that the final approval of a public offering or private placement transaction would be explicitly outside of the scope and definition of excluded public finance activities, since such final approval of a public offering or private placement transaction is deemed structuring for purposes of the OMSJ definition, pursuant to MSRB Rule G–27(g)(i). The MSRB recognizes that there are many individual supportive decisions made in the overall work to be done on a municipal securities public offering or private placement and, as a result, the MSRB is clarifying that it deems the final approval of a public offering or private placement transaction as constituting ''structuring of public offerings or private placements.'' The MSRB notes that such final approval of a public offering or private placement transaction should be conducted by a person in a principal-level capacity.[20]

The MSRB believes that proposed new Supplementary Material .06 and .07 of MSRB Rule G–27 would not alter the definition of OMSJ, but rather, would clarify that certain activities performed by municipal securities professionals in furtherance of the ''structuring of a public offering or private placements'' do not constitute structuring and therefore do not rise to the level of activities that need to take place at an OMSJ. Furthermore, by clarifying that the MSRB deems structuring as the final approval of a public offering or private placement transaction, dealers are better equipped, given varying business models, to evaluate their specific business model and make determinations as to where ultimate decision making and supervisory authority rest for purposes of designating such locations as an OMSJ.

The MSRB notes that the phrase ''final approval of a public offering or private placement transaction'' in proposed new Supplementary Material .07 would reference actions internal to the dealer relating to the decision to approve such transaction, the timing of which may vary depending on the specific transaction or the processes undertaken by a specific dealer. It is not the MSRB's intention for final approval to entail the act itself of executing a bond purchase agreement (which may occur at an issuer's location or at some other location away from the offices of the dealer) or submitting a bid in response to a notice of sale. Rather, this provision of the proposed rule change turns on dealers' actions that ultimately leads to the formality of executing the bond purchase agreement or submitting a bid. The MSRB notes that, while the proposed rule change takes a principles-based approach to the determination of what constitutes final approval of a public offering or private placement transaction, proposed new Supplementary Material .07 would require dealers to adopt compliance policies and procedures reasonably designed to make clear what action taken constitutes such final approval by the dealer. Proposed new Supplementary Material .07 would also require dealers to take into consideration all relevant factors in determining what action taken constitutes final approval of a public offering or private placement transaction to ensure dealers'

[20] Pursuant to MSRB Rule G–2, on standards of professional qualification, no dealer shall effect any transaction in, or induce or attempt to induce the purchase or sale of, any municipal security, unless such dealer and every natural person associated with such dealer is qualified in accordance with the rules of the MSRB. MSRB Rule G–3(b)(i) defines a municipal securities principal as a person, associated with a dealer, who is directly engaged in the management, direction or supervision of, among other things, underwriting, trading or sales of municipal securities, and MSRB Rule G–3(b)(ii) requires such individuals that meet the definition of a municipal securities principal to be appropriately qualified by taking and passing the Municipal Securities Principal Qualification Examination.

supervisory systems are reasonably designed to achieve compliance with applicable securities laws and regulations, and with applicable MSRB rules. The proposed rule change also prescribes that such compliance policies and procedures should support evidencing compliance to the appropriate examining authority.

Regulatory Need

The MSRB acknowledges that extending the exclusion for municipal securities work performed at a non-primary residence from municipal branch office designation from less than 30 business days per calendar year to up to 90 business days per calendar year under MSRB Rule G–27(g)(ii)(A)(3) would result in a move away from harmonization with FINRA Rule 3110, which contains a similar exclusion from branch office registration for work performed at a non-primary residence for less than 30 business days per year.[21] The MSRB also recognizes that defining ''structuring of public offerings or private placements,'' and resultingly potential changes in designations of office or locations may cause regulatory inconsistencies. Although harmonization allows dealers who are also FINRA members to more easily comply with the requirements under both rule sets regarding office classification and designation, it has been the MSRB's longstanding position that it would weigh rule harmonization in the context of the uniqueness of the municipal securities market.

The MSRB highlights that there are an estimated 50,000 issuers (and other issuing authorities) that rely on municipal bonds to fund local projects, which provide essential services to local communities.[22] In the last five years, the MSRB estimates that 22,000 issuers engaged in a public offering or private placement transaction. In addition, there are approximately one million unique municipal bonds outstanding, whereas by comparison the corporate bond market has about 6,600 different issuers and 60,000 unique bonds outstanding.[23] Given the broad geographical dispersion of municipal issuers across the entirety of the country in all 50 states, the District of Columbia, and U.S. territories in which offerings of municipal securities are conducted according to state and local laws and regional practices that vary considerably, it can be uniquely challenging for dealers in this market, as compared to other securities markets, to effectively engage with prospective issuer clients and service existing issuer clients.[24] It is the MSRB's understanding that many dealers may choose a business model that segments their issuer coverage by region to offer more tailored and more easily accessible service to such issuer clients. In addition, the MSRB estimates that a large segment of the issuer community is not geographically positioned in close proximity to larger metropolitan areas where financial services firms have historically operated the bulk of their activities. Resultingly, many dealers choose to have public finance bankers operate in a much more geographically dispersed manner as compared to other segments of their securities activities so as to meet the needs of their issuer clients in a more effective manner in light of the realities of the municipal securities market. Often, these geographically dispersed public finance bankers must operate under current MSRB Rule G–27 as a single-person OMSJ, meeting all of the requirements under MSRB Rule G–27 arising from being an OMSJ. The MSRB believes that the proposed rule change would support the competitiveness of the municipal securities market and would provide greater workplace flexibility while maintaining appropriate supervisory requirements for the activities conducted in the manner described above.

Rule Title Clarification

The proposed rule change would change the title of MSRB Rule G–27 from ''Supervision'' to ''Supervisory and Compliance Obligations of Brokers, Dealers and Municipal Securities Dealers.'' This non-substantive, technical change would clarify that MSRB Rule G–27 is applicable to dealers only, as well as standardize the title with MSRB Rule G–44, on Supervisory and Compliance Obligations of Municipal Advisors.

2. Statutory Basis

The MSRB believes that the proposed rule change is consistent with Section 15B(b)(2) of the Exchange Act,[25] which provides that the MSRB shall propose and adopt rules to effect the purposes of the Exchange Act with respect to, among other matters, transactions in municipal securities effected by dealers. Section 15B(b)(2)(C) of the Exchange Act[26] provides that the MSRB's rules shall be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in municipal securities and municipal financial products, to remove impediments to and perfect the mechanism of a free and open market in municipal securities and municipal financial products, and, in general, to protect investors, municipal entities, obligated persons, and the public interest.

The MSRB believes the proposed rule change is consistent with Section 15B(b)(2)(C) of the Exchange Act[27] because the proposed rule change would promote just and equitable principles of trade by interpreting and clarifying the meaning behind the term structuring of public offerings or private placements by way of excluding certain activities from the definition. The MSRB believes that clear guidance as to what work functions are included within the meaning of the term ''structuring'' for the municipal securities market would facilitate dealers' understanding and implementation of sound compliance policies and procedures when applying the principles of MSRB Rule G–27 to each dealer's business model. Furthermore, while differing from FINRA, the proposed rule change's definition of excluded public finance activities would remove impediments from a free and open market in municipal securities and municipal financial products. By clarifying the phrase, ''structuring of public offerings or private placements,'' that has not been defined by the MSRB and has been interpreted inconsistently by the dealer community, dealers are able to lessen resources spent on such compliance matters and focus on the functional work that facilitate a free and open market in municipal securities and municipal financial products.

In addition, the proposed rule change would remove an impediment to a free and open market by providing flexibility to firms implementing their hybrid work models. The MSRB believes that

[21] FINRA Rule 3110(f)(2)(A)(iii) contains an exception from branch office registration for any location, other than a primary residence, that is used for securities business for less than 30 business days in any one calendar year, provided certain conditions proscribed by FINRA Rule 3110 are met.

[22] *See* MSRB's 2026 Municipal Market Factsheet, January 2026, available at: *https://www.msrb.org/sites/default/files/2022-09/MSRB-Muni-Facts.pdf*.

[23] The MSRB used the Bloomberg Terminal to analyze and aggregate the data on the size of the corporate bond market and unique outstanding bonds.

[24] The MSRB notes that, based on Form A–12 filings, only 177 of the 926 MSRB-registered dealers identify municipal debt underwriting as a business activity.

[25] 15.U.S.C. 78*o*–4(b)(2).

[26] 15 U.S.C. 78*o*–4(b)(2)(C).

[27] *Id.*

allowing the additional flexibility of working remote from a non-primary residence for up to 90 business days per calendar year, and clarifying that excluded public finance activities can generally be conducted at a primary residence if the applicable conditions are met, in both cases without triggering municipal branch office designation would remove an impediment to dealers and their municipal securities professionals by allowing dealers more flexibility to craft their hybrid work models that reflect their own individual risk factors and technological capabilities. Furthermore, the MSRB does not believe that any changes to MSRB Rule G–27 under the proposed rule change would cause harm to investors, issuers, obligated persons or the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

Section 15B(b)(2)(C) of the Exchange Act [28] requires that MSRB rules not be designed to impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. The MSRB has considered the economic impact of the proposed rule change and believes that it would not impose any burden on competition, as the proposed rule change to MSRB Rule G–27 on dealer supervision would clarify the meaning of ''structuring of public offerings or private placements'' and increase the 30-business day per calendar year exclusion from the municipal branch office designation for locations that are not a primary residence to 90-business days per calendar year. The MSRB believes that the proposed rule change would provide reasonable flexibility for public finance activities without compromising the need for investor and issuer protection. In addition, the proposed rule change would be applicable to all dealers. Therefore, the MSRB believes the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.[29]

In determining whether the proposed rule change is necessary and appropriate, the MSRB was guided by the MSRB's Policy on the Use of Economic Analysis in MSRB Rulemaking.[30] In accordance with this policy, the MSRB evaluated the potential impacts of the proposed rule change relative to the baseline, which is the current MSRB Rule G–27. The proposed rule change to MSRB Rule G–27 is intended to foster greater flexibility for municipal market professionals in two separate ways. First, the proposed rule change seeks to outline, in proposed new Supplementary Material .07, a non-exhaustive list of excluded activities from the ''structuring of public offerings or private placements'' by drawing a distinction between the function of final approval of a public offering or private placement transaction from the functional work that supports the structuring of such a transaction and exclude these supporting activities from the definition of ''structuring of public offerings or private placements.'' Under the proposed rule change, these excluded public finance activities would not be required to be conducted at an OMSJ or, if conducted at a primary residence and the applicable conditions are met, at a municipal branch office. Second, the proposed rule change is intended to create flexibility for municipal market professionals by extending the exclusion for locations, other than a primary residence, that are used for municipal securities activities from less than 30 business days per calendar year to up to 90 business days per calendar year from municipal branch office designation.

Benefits

The MSRB believes that dealers would benefit from proposed new Supplementary Material .06 and .07 of MSRB Rule G–27 regarding public finance activities that are excluded from the definition of OMSJ. At present, any location with one or more persons engaging in activities that consist of structuring of public offerings or private placements should be classified by the dealer under MSRB Rule G–27(g)(i) as an OMSJ, and as a result, these locations must comply with MSRB Rule G–27's accompanying regulatory and compliance requirements for OMSJs. These requirements include the presence of an on-site supervisor qualified as a municipal securities principal and the annual inspection of the location.[31] The proposed rule change identifies a non-exhaustive list of excluded public finance activities that support the overall structuring process but would not necessarily need to be conducted from a location designated as an OMSJ. More specifically, performing these activities at a given location would not, by itself, qualify the office or location as an OMSJ if no other activities occurring at such location would necessitate OMSJ designation. Further, the proposed rule change would provide that performing such excluded public finance activities at an associated person's primary residence, if all other applicable conditions are met, would not necessitate municipal branch office designation. The MSRB expects that dealers would benefit from the proposed rule change with a reduction in expenses related to inspecting, licensing and supervising at OMSJs without harming issuer and investor protection.

In addition, the proposed rule change's extended 90-business day per calendar year exclusion from municipal branch office designation for locations, other than a primary residence, that are used for municipal securities activities would provide dealers' associated persons additional and reasonable flexibility to work from locations that are not their primary residence, such as a vacation or second home, without triggering a municipal branch office designation. The MSRB believes the extension would lessen the compliance burden for firms tracking the location of their employees by extending the number of days they are allowed to work at these locations each calendar year, without materially reducing the protections for investors and issuers given the widespread adoption of a culture of hybrid work environments, which the MSRB believes would help in recruiting and maintaining valuable personnel.

Costs [32]

The MSRB acknowledges that dealers would likely incur some higher compliance costs due to the proposed rule change, relative to the baseline state (current state). Dealers would be expected to incur one-time, upfront costs related to assessing the functions of OMSJs for purposes of re-designation, as applicable, and revising policies and procedures along with ongoing compliance costs with the proposed rule change. Table 1 shows that firms would incur one-time upfront costs of approximately $3,446. This includes the costs associated with compliance

[28] *Id.*

[29] *Id.*

[30] *See* The MSRB's Policy on the Use of Economic Analysis in MSRB Rulemaking, available at *https://www.msrb.org/Policy-Use-Economic-Analysis-MSRB-Rulemaking.* In evaluating whether there was any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act, the MSRB was guided by its principles that required the MSRB to consider costs and benefits of a rule change, its impact on efficiency, capital formation and competition, and the main reasonable alternative regulatory approaches.

[31] *See* MSRB Rule G–27(b)(iv) and MSRB Rule G–27(d)(i)(A).

[32] Due to rounding, numbers presented throughout this document may not add up precisely to the totals provided.

personnel evaluating all current OMSJs and making a determination on whether certain locations should be re-designated based on functional work ($393 × 2 hours = $786) updating existing written supervisory procedures (WSPs) along with a review by an inhouse compliance counsel ($463 × 1 hour = $463) and outside legal counsel ($630 × 1 hour = $630) and the approvals conducted by the director of compliance ($610 × 1 hour = $610) and the chief compliance officer ($693 × 0.5 hours = $347).[33] The MSRB also estimates one hour of training and education conducted by the director of compliance ($610 × 1 hour = $610). In addition to the upfront costs, the MSRB also identified one area of incremental ongoing costs for a total of approximately $2,440 for the purpose of ensuring compliance, especially in light of different requirements between FINRA's Rule 3110 and MSRB's Rule G–27, which includes dealers undertaking a review of the policies on an annual basis to be conducted by the director of compliance ($610 × 4 hours = $2,440). On aggregate, the MSRB believes the upfront and ongoing costs are minor. The MSRB notes, while dealers would have initial upfront costs and may face higher ongoing compliance costs, brought on by having diverging regulatory requirements, the MSRB notes that the proposed rule change does not remove any of the current designations that are available under the baseline. Thus, the MSRB expects that dealers will assess and re-designate locations, as applicable, only if doing so is beneficial to their operations—recognizing that the cost of complying with the proposed rule change would presumably be a factor in dealers' decision-making process.[34]

TABLE 1—UPFRONT AND PARTIAL ONGOING COSTS FOR DEALERS[35]

Cost components	Hourly rate	Number of hours	Cost per firm
Upfront Costs.			
(a) Revision of Policies and Procedures:			
Compliance Manager	$393	2	$786
In-House Compliance Counsel	463	1	463
Outside Legal Counsel	630	1	630
Director of Compliance	610	1	610
Chief Compliance Officer (CCO)	693	0.5	347
			2,836
(b) Training and Education:			
Director of Compliance	610	1	610
			610
Total Upfront Costs			3,446
Ongoing Costs			
(a) Compliance Review.			
Director of Compliance	610	4	2,440
Total Ongoing Costs			2,440

It is the MSRB's belief that investors and issuers would not realize any material reduction in protections from the proposed rule change as the proposed 90-business days per calendar year exclusion would account for approximately one-third (35%) of the total business days in a year and the majority of municipal securities activities would be conducted at a municipal branch office location.[36] In addition, the final approval of a public offering or private placement transaction would continue to take place at OMSJs and all activities in the structuring process would continue to be subject to the same fair practice and supervisory obligations established under MSRB rules. In summary, the MSRB anticipates that the benefits, as described above, would outweigh the costs over time.

Effect on Competition, Efficiency, and Capital Formation

The MSRB believes that the proposed rule change would not impose a burden on competition nor hinder capital formation, as the changes are applicable to all dealers. The proposed rule change could improve the municipal securities market's operational efficiency and promote regulatory certainty by providing dealers with greater flexibility in achieving the regulatory obligations outlined in MSRB Rule G–27. At present, the MSRB is unable to quantitatively evaluate the magnitude of the efficiency gains or losses but believes the benefits of greater flexibility and a reduction in certain compliance burdens, including expenses related to annual office inspection requirements and the on-site principal requirement for OMSJs, if dealers choose to re-designate locations, are accumulated over time for all dealers and would outweigh the one-time upfront costs of revising policies and procedures as well as the incremental ongoing compliance and recordkeeping costs by dealers.

[33] The total cost to update policies and procedures is estimated as $2,836 ($786 + $463 + $630 + $610 + $347 = $2,836).

[34] The MSRB believes that dealers may find that some existing OMSJs become unnecessary in light of the proposed rule change, and thereby, are able to reduce their expenses attendant to those locations, including FINRA branch office registration fees.

[35] The hourly rates data is gathered from a previous Commission filing. *See* Exchange Act Release No. 94062 (January 26, 2022), 87 FR 15496, 15624 (March 18, 2022) (File No. S7–02–22). The Commission's economic analysis utilizes the Securities Industry and Financial Markets Association, Management & Professional Earnings in the Securities Industry—2013 Report for the hourly rates of various financial industry market professionals. To compensate for inflation, the data reflects the fourth quarter of 2025 hourly rate level after adjusting for the annual cumulative wage inflation rate of 47% between 2013 and 2025. *See* The Federal Reserve Bank of St. Louis Employment Cost Index: Wages and Salaries: Private Industry Workers, available at *https://fred.stlouisfed.org/series/ECIWAG.* The MSRB estimates the number of hours for each task based on the MSRB's consultation with regulated entities' compliance officers for a median-sized firm.

[36] The number of business days, as percentages, as used in this alternative assumes 250 business days per year.

Reasonable Regulatory Alternatives

The MSRB has identified several reasonable alternatives for the proposed rule change that were first presented in the request for comment.[37]

One alternative contemplated was to remove the activity of ''structuring of public offerings or private placements'' from MSRB Rule G–27(g)(i)'s definition of OMSJ. This alternative would reduce instances of designating a location as an OMSJ, as well as the burden associated with such designation because ''structuring of public offerings or private placements'' would no longer prompt a designation. This would further decrease compliance burdens associated with assigning an on-site supervisor qualified as a municipal securities principal, as well as remove the need to conduct an annual inspection of that location by the dealer. While this alternative calls for the removal of ''structuring of public offerings or private placements'' from MSRB Rule G–27(g)(i)'s definition of OMSJ, dealers may still be required to designate such locations as an OSJ under FINRA Rule 3110, which does not contain a similar provision excluding certain public finance activities from the definition of OSJ, and could lead to an increase in burdens and challenges due to inconsistencies in regulatory approach in complying with MSRB and FINRA rules. Additionally, there are interdependencies upon which the current office and location framework rests, for example, state security regulators utilize data collected by FINRA on OSJ and voluntary OMSJ designations. The result would be a patchwork of supervisory regulation that may introduce additional compliance burdens for dealers. For this reason, the MSRB believes the proposed rule change is superior to this alternative, although the MSRB believes that this alternative could be reconsidered in the future if, for example, other regulators were to revisit, in a holistic manner, the office designation requirements in their respective regulatory frameworks.

Another alternative the MSRB considered was to explicitly provide for a fully principle-based approach to defining the term ''structuring of public offerings or private placements.'' MSRB Rule G–27 does not currently differentiate between the various public finance activities that may be performed as part of the ''structuring of public offerings or private placements.'' A fully principles-based approach would allow dealers to make their own determination, with significantly less regulatory guidance, of what structuring means to each individual dealer, and subsequently which locations would require OMSJ designation. However, this alternative approach may introduce additional regulatory uncertainty into dealer supervision. A dealer may require all public finance activities to occur at an OMSJ out of an abundance of caution, which would not reduce any compliance burden. By comparison, the approach taken by the proposed rule change would provide a framework that would allow greater certainty for dealers regarding those activities that may constitute structuring and those that may be excluded. The proposed rule change would also maintain some degree of flexibility in determining whether any activities not explicitly outlined in the proposed rule change are best treated in one category or another, depending on a dealer's specific business model, practices and processes. It is for this reason that the MSRB determined this alternative is inferior to the proposed rule change.

Finally, an alternative to extending the 30-business day per calendar year exclusion from municipal branch office designation to 90-business days per calendar year for non-primary residences, would be to extend the 30-business day per calendar year exclusion to 120 business days per calendar year, or approximately 48% of the total business days in a year.[38] As noted above, the 90-business days per calendar year exclusion in the proposed rule change would account for approximately 35% of the total business days in a year. This alternative of 120 business days per calendar year would provide even more flexibility for associated persons and further reduce the burdens associated with designation of municipal branch offices, and accompanying office inspection requirements. However, the MSRB believes that approaching the threshold of one half of all business days of remote work from such locations without triggering municipal branch office designation for such locations could, under the current supervisory rule paradigm, incrementally raise risks to investor and issuer protection and could be inconsistent with the rule's intended use for such locations on a temporary basis, since these remote working locations are subject to a less stringent dealer inspection requirement than municipal branch offices. Therefore, the MSRB believes the proposed rule change offers a superior approach to this alternative.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The MSRB sought comment on the proposed rule change in a request for comment that was published on January 14, 2026 (the ''Request for Comment'').[39] The MSRB received 4 letters in response to the Request for Comment.[40] In addition to the proposed rule change, the Request for Comment sought comment on additional areas of MSRB Rule G–27 that the MSRB should consider amending through future rulemaking efforts. The four comment letters are summarized below as they pertain to the proposed rule change, with MSRB responses provided.[41]

Extend the 30-Business Day Exclusion for Non-Primary Residences From Municipal Branch Office Designation

The Request for Comment solicited comments on draft rule text that would extend MSRB Rule G–27(g)(ii)(A)(3)'s exclusion from municipal branch office designation for non-primary residences from less than 30 business days per calendar year to up to 60 business days per calendar year. Comment letters were generally in favor of the Request for Comment's proposed extension from 30 to 60 business days per calendar year. ASA stated that the proposed extension would better align with hybrid work patterns and ease administrative tracking of occasional remote work.[42] SIFMA encouraged the MSRB to adopt the increase to the 30-business day exclusion from municipal branch office designation for locations other than a

[37] *See* MSRB Notice 2026–01, Request for Comment on MSRB Rule G–27 on Dealer Supervision (January 14, 2026), at 12–13, available at *https://www.msrb.org/sites/default/files/2026-01/2026-01.pdf.*

[38] *See supra* note 36.

[39] *See* MSRB Notice 2026–01, Request for Comment on MSRB Rule G–27 on Dealer Supervision (January 14, 2026), available at *https://www.msrb.org/sites/default/files/2026-01/2026-01.pdf.*

[40] Comment letters were received from: American Securities Association (''ASA''): Letter from Jessica R. Giroux, Chief Legal Officer, dated March 16, 2026 (the ''ASA Letter''); Bond Dealers of America (''BDA''): Letter from Michael Decker, Senior Vice President, Research and Public Policy, dated March 16, 2026 (the ''BDA Letter''); Peg Henry LLC: Letter from Margaret C. (Peg) Henry, Sole Member, dated March 6, 2026 (the ''Henry Letter''); and Securities Industry and Financial Markets Association (''SIFMA''): Letter from Leslie M. Norwood, Managing Director and Associate General Counsel, Head of Municipal Securities, dated March 16, 2026 (the ''SIFMA Letter''). Comment letters are available at: *https://www.msrb.org/sites/default/files/2026-03/All-Comments-to-Notice-2026-01.pdf.*

[41] The MSRB will continue to consider separately the comments received on additional areas of MSRB Rule G–27 that the MSRB should potentially amend through future rulemaking efforts.

[42] *See* ASA Letter at 2.

primary residence to 60-business days per year.[43]

However, certain comment letters advocated for the MSRB to further extend MSRB Rule G–27(g)(ii)(A)(3)'s exclusion past the proposed 60 business days per calendar year limit in the proposed rule change. SIFMA suggested that the MSRB consider a 120 business day per year exclusion.[44] ASA encouraged the MSRB to consider additional flexibility tied to supervisory risk rather than fixed day counts, and to explicitly recognize that firms may rely on centralized electronic surveillance to manage remote work.[45] BDA suggested that the MSRB remove the distinction between primary residences or other locations and that the MSRB specify that employees subject to supervision can work and be supervised remotely for up to 60 business days per year regardless whether those days are spent at a primary residence or other location.[46]

The MSRB appreciates the views expressed in the comment letters requesting additional flexibility than provided for in the Request for Comment's proposal to extend the 30-business days per calendar exclusion from municipal branch office designation for non-primary residences to 60 business days per calendar year. The MSRB recognizes that providing 90 business days per calendar year would remain consistent with the objectives of the proposed rule change without reducing investor and issuer protections, as the proposed 90-business days per calendar year exclusion would only account for approximately one-third (35%) of the total 250 business days typically in a year—thus the majority of municipal securities activities would still be conducted at a municipal branch office location. As such, the proposed rule change would extend the exclusion from municipal branch office designation for non-primary residences to 90 business days per calendar year. The MSRB believes that an extension up to 90 business days per calendar year will provide the industry with additional and reasoned flexibility, while also maintaining an appropriate limit for registered persons to work from a non-primary residence location without triggering municipal branch office designation. The MSRB believes that an extension to the municipal branch office designation exclusion past 90 business days per calendar year at a particular location would no longer qualify such location as a temporary location (*i.e.,* as occasional work from a non-primary residence location) and instead could be considered regularly engaged in conduct under MSRB Rule G–27(g)(ii)(A)'s definition of municipal branch office. In addition, the MSRB will consider the suggestions to remove the distinctions among various types of offices and locations (including with respect to the treatment of primary residences), or the reliance on a centralized supervision model, at a later date.

Structuring of Public Offering or Private Placements

The Request for Comment solicited comments on potentially excluding certain public finance activities from MSRB Rule G–27(g)(i)'s definition of OMSJ by way of adding new supplementary material explaining the scope of excluded public finance activities that would not qualify as ''structuring of public offerings or private placements'' and would therefore not trigger OMSJ designation.

The comment letters were generally in favor of this draft amended rule text. ASA stated that they support the clarification of ''structuring of public offerings or private placements'' in the definition of an OMSJ and that clarification would reduce uncertainty about which public finance activities trigger OMSJ designation.[47] SIFMA stated that the proposed rule change is a significant and positive development which creates necessary added clarity and recognizes that some public finance activities commonly occur at a client site, while traveling, or otherwise away from an OMSJ.[48]

BDA pointed out that its member firms have interpreted the meaning of ''structuring of public offerings or private placements'' differently, and the confusion has led to a lack of consistency in how dealers are complying with the rule.[49] As a result, BDA welcomed the MSRB's proposed rule change to provide clarity and consistency and urged the MSRB to provide as much flexibility as possible around the specifics each firm might identify as their own process for final approval within the proposed rule change.[50]

Comment letters in support of the proposed rule change also provided suggestions as to how to amend the draft language of the definition of excluded public finance activities. SIFMA proposed removing references to bespoke recommendations, commitment of dealer capital or other formal action with respect to a public offering or private placement conducted by the dealer from proposed language in the Request for Comment's definition of excluded public finance activities.[51] SIFMA further stated that its members believe that the final approval of a transaction by the broker-dealer is what should be considered structuring.[52] BDA stated that it is important that the proposed rule change allow firms to define a single, clear moment or event that meets the criteria for structuring and not lead to a misinterpretation that multiple events within a transaction would trigger OMSJ registration.[53] The MSRB removed language referencing bespoke recommendations from the definition of excluded public finance activities in the Request for Comments in response to the comments received. As a result, the MSRB believes that the proposed rule change is business model neutral and acknowledges that dealers may have different business practices pertaining to the ''structuring of public offerings or private placements.''

One comment letter questioned whether the proposed rule change would allow a municipal securities principal to supervise excluded public finance activities from a private residence but may not engage in structuring from that residence.[54] The comment letter went on to question whether the municipal securities principal would therefore need to go to a dealer's office to sign a bond purchase agreement, and argued that there is no supervisory benefit to be gained by requiring a bond purchase agreement to be signed in the office of a dealer as opposed to a primary residence.[55]

As aforementioned, the final approval of a public offering or private placement transaction, as used in proposed new Supplementary Material .07, would reference actions internal to the dealer relating to the decision to approve such transaction. The timing of such decisive action may vary depending on the specific transaction or the processes undertaken by a specific dealer and may, for example, coincide with pricing and re-pricing, as necessary, in an effort to get to verbal award. As the MSRB previously noted, the physical act of signing a bond purchase agreement (*i.e.,* formal award) is distinct from the meaning of ''final approval'' as used

[43] *See* SIFMA Letter at 4.

[44] *Id.*

[45] *See* ASA Letter at 2.

[46] *See* BDA Letter at 3.

[47] *See* ASA Letter at 1.

[48] *See* SIFMA Letter at 4.

[49] *See* BDA Letter at 2.

[50] *Id.*

[51] *See* SIFMA Letter at 4–5.

[52] *See* SIFMA Letter at 6.

[53] *See* BDA Letter at 2–3.

[54] *See* Henry Letter at 1.

[55] *See* Henry Letter at 1–2.

within the proposed rule change and for purposes of this rule. Therefore, final approval would not include the mere formality of executing a bond purchase agreement. Proposed new Supplementary Material .07 would require dealers to adopt compliance policies and procedures reasonably designed to make clear what action taken would constitute final approval of a public offering or private placement transaction conducted by the dealer. Proposed new Supplementary Material .07, would also require dealers to take into consideration all relevant factors in determining what action taken constitutes final approval of a public offering or private placement transaction to ensure dealers' supervisory systems are reasonably designed to achieve compliance with applicable securities laws and regulations, and with applicable Board rules.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period of up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–MSRB–2026–04 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–MSRB–2026–04. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the MSRB. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Number SR–MSRB–2026–04 and should be submitted on or before August 25, 2026.

For the Commission, pursuant to delegated authority.[56]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–15736 Filed 8–3–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106017; File No. SR–NYSEAMER–2026–34]

Self-Regulatory Organizations; NYSE American LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Change To Amend Its Rules To Extend Trading Hours for Certain Eligible Equity Options

July 30, 2026.

On June 5, 2026, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission''), pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] a proposal to amend its rules to extend trading hours for certain eligible equity options and make related conforming changes. The proposed rule change was published for comment in the **Federal Register** on June 22, 2026.[4]

Section 19(b)(2) of the Act[5] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is August 6, 2026. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised therein. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates September 20, 2026, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEAmer–2026–34).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–15735 Filed 8–3–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106013; File No. SR–CBOE–2026–008]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Adopt Rule 8.23

July 30, 2026.

On January 20, 2026, Cboe Exchange, Inc. (''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt Exchange Rule (''Rule'') 8.23 to codify certain order and quote entry and trading activity that is prohibited on the Exchange. The proposed rule change was immediately effective upon filing with the Commission pursuant to Section

[56] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 105704 (June 16, 2026), 91 FR 37201.

[5] 15 U.S.C. 78s(b)(2).

[6] 15 U.S.C. 78s(b)(2).

[7] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

19(b)(3)(A) of the Act.[3] The proposed rule change was published for comment in the **Federal Register** on February 2, 2026.[4] On March 20, 2026, the Commission temporarily suspended the proposed rule change and instituted proceedings to determine whether to approve or disapprove the proposed rule change.[5]

Section 19(b)(2) of the Act[6] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes reasons for such determination. The proposed rule change was published for notice and comment in the **Federal Register** on February 2, 2026.[7] The 180th day after publication of the proposed rule change is August 1, 2026. The Commission is extending the time period for approving or disapproving the proposed rule change for an additional 60 days.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change and submitted comments, and the issues raised therein. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Exchange Act,[8] designates September 30, 2026, as the date by which the Commission shall either approve or disapprove the proposed rule change (File No. SR–CBOE–2026–008).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–15734 Filed 8–3–26; 8:45 am]

BILLING CODE 8011–01–P

[3] 15 U.S.C. 78s(b)(3)(A).

[4] *See* Securities Exchange Act Release No. 104721 (January 28, 2026), 91 FR 4645 (February 2, 2026). Comments received on the proposed rule change are available on the Commission's website at: *https://www.sec.gov/rules-regulations/public-comments/sr-cboe-2026-008*.

[5] *See* Securities Exchange Act Release No. 105061 (March 20, 2026), 91 FR 14613.

[6] 15 U.S.C. 78s(b)(2).

[7] *See supra* note 4 and accompanying text.

[8] 15 U.S.C. 78s(b)(2).

[9] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106015; File No. SR–ISE–2026–44]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend FLEX Options Listing Rules

July 30, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 29, 2026, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its FLEX Options Trading Rules at Options 3A, Section 3, FLEX Option Listings.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/ise/rulefilings,* and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

ISE proposes to amend Options 3A, Section 3, FLEX Option Listings as it relates to FLEX Equity Options where the underlying security is an ETF that is eligible for cash settlement. Specifically, the proposed amendments would: (1) permit newly FLEX-eligible ETFs that satisfy heightened eligibility thresholds of $600 million average daily notional value and 5,616,000 shares ADV, based on the previous one-month period of trading statistics to be eligible for cash settlement as a contract term; (2) establish tiered criteria governing the treatment of cash-settled FLEX ETF Options where the underlying ETF ceases to satisfy the requirements of Options 3A, Section 3(c)(5)(A)(ii) at the time of the Exchange's bi-annual review; and (3) eliminate the existing provision limiting cash settlement as a contract term to no more than 50 underlying ETFs. This filing is identical to a rule proposal by Cboe.[3]

Background

Prior to the adoption of the rules described herein, FLEX Equity Options were generally required to be settled by physical delivery of the underlying security upon exercise. FLEX Index Options, by contrast, have long been settled by delivery in cash. Cash settlement was also available for customized equity options transacted in the over-the-counter (''OTC'') market, where settlement restrictions do not apply. The absence of a cash-settled exchange-traded alternative for equity-based FLEX Options created a gap between the exchange-traded and OTC markets that exchange-traded participants sought to bridge.

The Exchange previously submitted a filing with the Commission adopting cash settlement as an optional contract term for certain FLEX Equity Options where the underlying security is an ETF.[4] Specifically, Options 3A, Section 3(c)(5)(A)(ii) permits cash settlement for FLEX Equity Options where the underlying ETF has, measured over the prior six-month period, an average daily notional value of $500 million or more and a national average daily volume (''ADV'') of at least 4,680,000 shares.

The Exchange adopted these specific thresholds to limit cash-settled FLEX ETF Options to the most highly liquid and actively-traded ETFs, thereby mitigating concerns about susceptibility

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 105929 (July 16, 2026), 91 FR 45856 (July 21, 2026) (SR–Cboe–2026–035) (Notice of Filing of Amendment No. 1 and Order Approving a Proposed Rule Change, as Modified and Superseded by Amendment No. 1, To Amend Rule 4.21 (Series of FLEX Options).

[4] *See* Securities Exchange Act Release No. 101720 (November 22, 2024), 89 FR 94986 (November 29, 2024) (SR–ISE–2024–12) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Adopt Rules To List and Trade FLEX Options).

to manipulation at settlement. With respect to the notional value threshold, the Exchange determined that average daily notional value is an appropriate proxy for manipulation resistance because, as a general matter, the more expensive an underlying ETF's price, the less cost-effective manipulation becomes, and the more volume traded in an ETF, the more difficult manipulation of its price becomes. With respect to the ADV threshold, the Exchange determined that a requirement of 4,680,000 shares per day is appropriate because it represents average trading in the underlying ETF of approximately 200 shares per second, a level of continuous trading activity that the Exchange believes meaningfully limits the ability to influence the ETF's price for purposes of establishing a settlement value. The Exchange acknowledged that no security is immune from all manipulation, but determined that the combination of these two requirements would appropriately limit cash settlement of FLEX ETF Options to underlying securities that are less susceptible to manipulation.

Under this framework, the Exchange conducts a bi-annual review on January 1 and July 1 of each year to identify qualifying ETFs, with newly eligible ETFs permitted to list cash-settled FLEX options beginning on February 1 and August 1, respectively. The rule caps the number of eligible underlying ETFs at 50; if more than 50 ETFs satisfy the criteria, the Exchange selects the top 50 by highest ADV. This cap was designed to prevent the scope of cash-settled FLEX ETF Options from expanding considerably without a corresponding evaluation of whether the level of the requirements remains reasonable, while still providing flexibility to add ETFs given that the initial list of eligible ETFs numbered well below 50 at the time of adoption. In the event a previously eligible ETF fails to satisfy the criteria at the time of a bi-annual review, any new positions overlying that ETF must be physically settled and any existing open cash-settled positions may be traded only to close. This provision was designed to address how to wind down outstanding cash-settled positions in an ETF that no longer qualifies under the liquidity and volume criteria, thereby addressing manipulation concerns while still permitting market participants to exit existing positions.

In connection with the adoption of this framework, the Exchange committed to conducting a five-year review of cash-settled FLEX ETF Option trading activity and furnishing the Commission with five annual reports. Pursuant to this commitment, the Exchange has submitted one annual monitoring report to the Commission covering the first year of trading. The report assessed trading volume and open interest in cash-settled FLEX ETF options relative to physically settled options on the same underlying ETFs, market maker participation, position limit activity, and manipulation concerns. The Exchange had no recommendations for enhancements to the listing standards based on its review. The Exchange had no open investigation, inquiry, or enforcement matter relating to the manipulation of cash-settled FLEX ETF options or their underlying ETFs.

Cboe noted in SR–Cboe–2026–035 that it submitted two annual monitoring reports to the Commission covering the periods of August 1, 2023 through July 31, 2024 and August 1, 2024 through July 31, 2025, respectively.[5] The reports assessed trading volume and open interest in cash-settled FLEX ETF options relative to physically settled options on the same underlying ETFs, market maker participation, position limit activity, and manipulation concerns.[6] Cboe had no recommendations for enhancements to the listing standards based on either review.[7] Also, Cboe noted that in both review periods, neither Cboe nor any affiliated Cboe securities exchange had an open investigation, inquiry, or enforcement matter relating to the manipulation of cash-settled FLEX ETF options or their underlying ETFs.[8] Financial Industry Regulatory Authority (''FINRA''), acting as Cboe's regulatory services provider for position limit surveillance, confirmed the same finding for both periods.[9] While both of Cboe's reports note that certain regulatory matters arose during each period involving the applicable ETFs or related physically-settled options, Cboe's surveillance and investigatory staff confirmed in each instance that the activity did not appear to relate to manipulation of an ETF for the purpose of benefiting a cash-settled FLEX ETF option position.[10]

The review period reflects broad and stable market maker participation across the eligible underlying ETFs. Cboe, which has been trading FLEX for a longer period than ISE, stated in SR–Cboe–2026–035 that the highest levels of FLEX market maker participation were observed in SPY (9 to 12 per month), QQQ (6 to 10 per month), and IWM (3 to 15 per month).[11] Cboe noted that participation in less actively traded eligible ETFs was more limited but consistent across both periods, reflecting a well-supported and liquid product across the eligible universe.[12]

Proposal

The Exchange proposes to amend Options 3A, Section 3(c)(5)(A)(ii) to refine two aspects of the framework governing cash-settled FLEX ETF Options and to eliminate the 50–ETF cap. First, the Exchange proposes to permit newly FLEX-eligible ETFs to qualify for cash settlement as a contract term based on one month of trading statistics outside of the Exchange's regular bi-annual review cycle. Second, the Exchange proposes to replace the existing provision governing ETFs that cease to satisfy the eligibility criteria with a tiered framework that more precisely calibrates treatment to the actual state of open interest in cash-settled FLEX ETF Options overlying the affected ETF. Third, the Exchange proposes to eliminate the existing cap limiting cash settlement as a contract term to no more than 50 underlying ETFs.

One-Month Lookback for Newly Eligible ETFs

Under the current rule, the Exchange determines eligible underlying ETFs bi-annually, on January 1 and July 1 of each year, using six months of prior trading statistics, with newly eligible ETFs permitted to list cash-settled FLEX options beginning on February 1 and August 1, respectively. No mechanism currently exists to add newly FLEX-eligible ETFs to the eligible list between bi-annual reviews. As a result, an ETF that becomes FLEX-eligible after a bi-annual review has been conducted may not be considered for cash-settled FLEX ETF Option eligibility for up to six months, even if it otherwise satisfies the notional value and ADV requirements of Options 3A, Section 3(c)(5)(A)(ii). The Exchange proposes to address this gap by permitting, outside of the regular bi-annual review, the Exchange to determine that a newly FLEX-eligible ETF satisfies heightened notional value and trading volume requirements of $600 million average daily notional value and 5,616,000 shares ADV based on the previous one-month period of trading statistics. Any ETF satisfying such requirements on that basis shall be

[5] *See supra* note 3.
[6] *See id.*
[7] *See id.*
[8] *See id.*
[9] *See id.*
[10] *See id.*
[11] *See id.*
[12] *See id.*

eligible for cash settlement as a contract term.

The Exchange believes a one-month lookback is appropriate in this context because an ETF that has newly become FLEX-eligible and simultaneously satisfies both the $600 million average daily notional value threshold and the 5,616,000-share ADV requirement over the prior month has already demonstrated the degree of liquidity and trading activity that the eligibility criteria are designed to capture. These thresholds represent a 20% increase over the standard $500 million and 4,680,000-share thresholds that apply to the bi-annual review, reflecting the Exchange's determination that heightened criteria are appropriate for ETFs seeking to qualify based on a shorter lookback period. The Exchange believes Cboe's and its annual monitoring reports demonstrate that the existing criteria are an effective proxy for identifying ETFs that are not readily susceptible to manipulation. Requiring newly eligible ETFs to await the next bi-annual review before becoming eligible for cash settlement would delay investor access to the product.

Cboe's back-testing analysis of newly listed FLEX ETFs supports the appropriateness of the heightened thresholds.[13] Under the standard eligibility criteria ($500 million average daily notional value and 4,680,000 shares ADV), ten ETFs would have qualified based on one month of trading data. Under the 20% increased thresholds ($600 million average daily notional value and 5,616,000 shares ADV), only eight ETFs qualified. Cboe noted that the two ETFs excluded by the heightened thresholds did not qualify at their next six-month bi-annual review, demonstrating that the heightened thresholds effectively filter out ETFs whose initial trading activity may not be sustained.

The Exchange believes the heightened thresholds for the one-month lookback appropriately address the concern that a newly listed ETF may experience elevated trading activity in its initial period that is not representative of sustained liquidity. By requiring newly eligible ETFs to satisfy thresholds that are 20% above the standard bi-annual review criteria, the Exchange ensures that only those ETFs demonstrating a meaningfully higher level of liquidity and trading activity—beyond what may reflect initial market interest—are eligible for cash settlement based on the shorter lookback period.

Further, the Exchange represents that it will continue to monitor the one-month lookback criteria on an ongoing basis to assess the appropriateness of the threshold. As part of this ongoing monitoring, the Exchange will evaluate whether the heightened criteria continue to effectively identify ETFs with sustained liquidity and trading activity, and will propose adjustments to the threshold if warranted by the Exchange's review.

Tiered Criteria for ETFs Ceasing To Satisfy Eligibility Requirements

Under the current rule, if the Exchange determines at the time of a bi-annual review that an underlying ETF ceases to satisfy the eligibility criteria, any new position overlying that ETF must be physically settled and any existing open cash-settled positions may be traded only to close. While this provision addresses the wind-down of cash-settled activity in a straightforward manner, it does not distinguish between ETFs with active open interest and those with no meaningful cash-settled activity, nor does it account for the possibility that an ETF may temporarily fall below the eligibility thresholds and subsequently recover.

The Exchange proposes to replace this provision with a tiered framework that more precisely calibrates the treatment of an ineligible ETF to the actual state of the market for cash-settled FLEX ETF Options overlying that ETF. Under the proposed framework, if no open interest in cash-settled FLEX Equity Options overlying the ETF exists during the previous six-month period at the time of the bi-annual review determination, the existing treatment will apply: any new position must be physically settled and any open cash-settled positions may be traded only to close. Where open interest in cash-settled FLEX Equity Options overlying the ETF does exist during the previous six-month period, the Exchange will permit the opening of new cash-settled positions in that ETF for a period of one year from the date of the bi-annual review, after which any new position must be physically settled and any remaining open cash-settled positions may be traded only to close. This one-year continuation period is intended to provide market participants holding or seeking to manage existing cash-settled positions with a reasonable and predictable runway to do so, rather than abruptly restricting new position activity at the time of the bi-annual review determination.

The proposed framework also includes a recovery provision: if the underlying ETF satisfies the eligibility criteria at the time of either bi-annual review conducted during the one-year continuation period, that period will terminate and the ETF will resume full eligibility for cash settlement as a contract term. The Exchange believes this provision appropriately accounts for the possibility that an ETF's trading statistics may fluctuate around the eligibility thresholds and prevents an unnecessarily disruptive wind-down in cases where the ETF promptly returns to eligibility.

Elimination of the 50–ETF Cap

The Exchange also proposes to eliminate the existing provision limiting cash settlement as a contract term to no more than 50 underlying ETFs. The cap was adopted at the outset of the program to prevent the scope of cash-settled FLEX ETF Options from expanding considerably without a corresponding evaluation of whether the level of the eligibility requirements remained reasonable. While the number of ETFs satisfying the eligibility criteria remained well below 50 during the initial period of the program's operation, over the two-year period that Cboe monitored the market, the number of qualifying ETFs has grown to exceed that threshold (as of February 1, 2026, 60 ETFs were eligible), such that the cap now operates as an active constraint on the availability of cash-settled FLEX ETF Options on ETFs that otherwise satisfy the established eligibility criteria. The Exchange does not believe this result is consistent with the purpose of the cap, which was intended as a programmatic guardrail rather than a permanent numerical ceiling. As noted above, neither the Exchange nor Cboe identified manipulation concerns in their reviews. Given the same eligibility criteria and position and exercise limits would apply to any cash-settled FLEX ETF option, as would the Exchange's surveillance program, the Exchange believes the 50–ETF cap is no longer necessary. The Exchange believes these protections and the eligibility criteria themselves sufficiently mitigate any manipulation concerns associated with cash-settled FLEX ETF Options.

The Exchange also notes that, consistent with its commitment in the original proposal, it will continue to furnish the Commission with annual reports for the remainder of the five-year review period. The Exchange believes that the continued reporting commitment, together with the proposed amendments, appropriately positions the cash-settled FLEX ETF Option framework to address the operational gaps identified through the Exchange's review to date while preserving the monitoring mechanisms

[13] For purposes of the back-testing analysis, Cboe reviewed all newly listed FLEX-eligible ETFs from January 1, 2025 through April 6, 2026.

that allow the Exchange and the Commission to evaluate the ongoing impact of the program.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[14] in general, and furthers the objectives of Section 6(b)(5) of the Act,[15] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes the proposed rule change is consistent with Section 6(b)(5) of the Act because each of the proposed amendments is designed to refine an existing, Commission-approved framework in a manner that is reasonably calibrated to address identified operational gaps while preserving and reinforcing the manipulation-mitigating features of that framework.

One-Month Lookback for Newly Eligible ETFs

The Exchange believes the proposed one-month lookback for newly FLEX-eligible ETFs is consistent with the Act because it removes an impediment to the offering of cash-settled FLEX ETF Options on ETFs that have already demonstrated the liquidity and trading activity that the eligibility criteria are designed to capture, without compromising the manipulation-resistant features of those criteria. Under the current rule, an ETF that becomes FLEX-eligible after a bi-annual review has been conducted must wait up to six months before it may be considered for cash-settled FLEX ETF Option eligibility, even if it satisfies both the $600 million average daily notional value threshold and the 5,616,000-share ADV requirement at the time it becomes FLEX-eligible. The Exchange believes this gap is not necessary to protect against manipulation.

An ETF that satisfies both heightened thresholds over the prior one-month period has demonstrated a degree of liquidity and breadth of trading activity exceeding that which the six-month bi-annual review is designed to identify as indicative of reduced susceptibility to manipulation. The heightened thresholds, which represent a 20% increase over the standard $500 million and 4,680,000-share thresholds applicable to the bi-annual review, are designed to account for the possibility that a newly listed ETF may experience elevated trading activity in its initial period that is not representative of sustained liquidity. As noted above, Cboe's and the Exchange's annual monitoring reports have demonstrated the existing eligibility criteria are an effective and reliable proxy for identifying ETFs that are not readily susceptible to manipulation, and neither Cboe nor the Exchange has identified any manipulation concerns in connection with cash-settled FLEX ETF Options or their underlying ETFs during that period. The Exchange therefore believes that permitting a one-month lookback for newly FLEX-eligible ETFs between bi-annual reviews, subject to the heightened thresholds, removes an impediment to and perfects the mechanism of a free and open market and protects investors and the public interest by providing timely investor access to a cash-settlement alternative on ETFs that satisfy the established eligibility criteria, while maintaining the protections afforded by those criteria.

Cboe's back-testing analysis further supports the consistency of the heightened thresholds with the Act's anti-manipulation objectives. Under the standard criteria, ten newly listed FLEX ETFs would have qualified based on one month of trading data, but under the 20% increased thresholds only 8 qualified. The two names excluded (AMDL and SIVR) did not qualify at their next six-month bi-annual review, confirming that the heightened thresholds effectively identify and exclude ETFs whose initial trading statistics do not reflect sustained market activity. The Exchange believes this empirical evidence demonstrates that the heightened thresholds are reasonably designed to prevent ETFs with potentially transient liquidity from qualifying for cash settlement based on the shorter lookback period.

Tiered Criteria for ETFs Ceasing To Satisfy Eligibility Requirements

The Exchange believes the proposed tiered framework for ETFs that cease to satisfy the eligibility criteria at the time of a bi-annual review is consistent with the Act because it is reasonably designed to prevent fraudulent and manipulative acts and practices while also promoting just and equitable principles of trade and protecting investors. The current rule applies a single, uniform wind-down treatment to any ETF that falls below the eligibility thresholds at bi-annual review, regardless of whether active open interest in cash-settled FLEX ETF Options overlying that ETF exists. The Exchange believes this one-size-fits-all approach does not adequately account for the legitimate interests of market participants that hold existing cash-settled positions or that need the ability to open new positions to manage existing risk exposure in an ETF that has temporarily fallen below the thresholds.

The proposed tiered framework addresses this concern in a manner consistent with the Act's investor protection and anti-manipulation objectives. Where no open interest in cash-settled FLEX ETF Options overlying the affected ETF has existed during the previous six-month period, the current treatment would continue to apply, because the Exchange believes an immediate restriction on new cash-settled positions would not disrupt market participants' activity. Where open interest does exist at the time of the bi-annual review, the proposed one-year continuation period provides market participants with a reasonable and predictable runway to manage existing positions, which the Exchange believes promotes just and equitable principles of trade. The Exchange further believes that the recovery provision, under which the continuation period terminates and full eligibility is restored if the ETF satisfies the criteria at either bi-annual review during the one-year period, is consistent with the Act because it prevents an unnecessarily disruptive wind-down where an ETF's trading statistics temporarily dip below the eligibility thresholds and then recover, and it reinforces the principle that the eligibility criteria, rather than arbitrary timing, are the appropriate determinant of cash-settlement eligibility. Taken together, the Exchange believes the tiered framework is a reasonable means to address manipulation concerns while not unduly burdening market participants with existing cash-settled positions, as it eliminates the current immediate disruption to their investment strategies.

Elimination of the 50–ETF Cap

The Exchange believes the elimination of the 50–ETF cap is consistent with the Act because the cap is no longer necessary to protect against the concerns it was designed to address and, as currently operative, functions as an impediment to the offering of cash-settled FLEX ETF Options on ETFs that otherwise satisfy the established eligibility criteria. The cap was adopted at the outset of the program to prevent the scope of cash-settled FLEX ETF Options from expanding considerably without a corresponding evaluation of

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

whether the level of the eligibility requirements remained reasonable. While the number of qualifying ETFs remained well below 50 during the initial period of the program's operation, that number has more recently grown to exceed the cap, such that the cap now actively restricts the availability of cash-settled FLEX ETF Options on ETFs that fully satisfy the notional value and ADV requirements of Options 3A, Section 3(c)(5)(A)(ii). The Exchange believes that retaining this arbitrary restriction is inconsistent with the Act's objectives because Cboe's two-year monitoring record demonstrates that the eligibility criteria themselves limit the availability of cash settlement to FLEX ETF Options. The liquidity and trading activity requirements mitigate manipulation concerns for any ETF that satisfies those requirements, not just the top 50.

During the first two years that cash-settled FLEX ETF Options were available on Cboe, it identified (and its annual monitoring reports demonstrated) no manipulation concerns in connection with cash-settled FLEX ETF Options or their underlying ETFs. The Exchange did not identify any manipulation in its one year of monitoring. The Exchange believes the eligibility criteria, position and exercise limits, and surveillance program applicable to the 50 ETFs eligible for FLEX options with cash-settlement provide adequate protections against manipulation and market disruption to all ETFs that satisfy the criteria, regardless of the number of qualifying ETFs. The Exchange therefore believes that eliminating the cap removes an impediment to and perfects the mechanism of a free and open market, protects investors and the public interest, and is otherwise consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange does not believe the proposed rule change will impose any burden on intramarket competition. The proposed amendments apply uniformly to all market participants that trade cash-settled FLEX ETF Options on the Exchange. All newly FLEX-eligible ETFs would be eligible for the one-month lookback, subject to the same heightened eligibility thresholds ($600 million average daily notional volume and 5,616,000 shares ADV) and any ETF that satisfies those heightened criteria within that one-month lookback would be eligible for cash-settlement, and cash-settled FLEX options on such ETFs would be available to all market participants. The tiered framework for ETFs ceasing to satisfy the eligibility criteria applies in the same manner to all market participants holding or seeking to open positions in cash-settled FLEX ETF Options overlying the affected ETF, and the one-year continuation period and recovery provision provide all such participants with the same predictable and equitable treatment. The elimination of the 50–ETF cap permits any ETF that satisfies the eligibility criteria to be eligible for FLEX cash-settlement rather than arbitrarily restricting that product availability to 50 ETFs. The Exchange believes the proposed rule promotes competition, as it would treat all ETFs that satisfy the eligibility criteria for cash-settled FLEX Options in the same manner.

The Exchange does not believe the proposed rule change will impose any burden on intermarket competition. Cash-settled FLEX ETF Options with the same underlying ETF may be listed on multiple exchanges, and the proposed amendments do not restrict the ability of other exchanges to adopt similar or competing frameworks. This rule proposal is a competitive response to Cboe's proposal [16] and it would enhance competition among the options exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [17] and subparagraph (f)(6) of Rule 19b–4 thereunder.[18]

A proposed rule change filed under Rule 19b–4(f)(6) [19] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[20] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that waiver of the operative delay would permit the Exchange to amend its FLEX rules consistent with Cboe [21] and competitively offer the same products on a cash-settled basis. For this reason, and because the proposed rule change raises no new or novel legal or regulatory issues, the Commission finds that waiver of the operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change to be operative upon filing.[22]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–ISE–2026–44 on the subject line.

[16] *See supra* note 3.

[17] 15 U.S.C. 78s(b)(3)(A)(iii).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[19] 17 CFR 240.19b–4(f)(6).

[20] 17 CFR 240.19b–4(f)(6)(iii).

[21] *See supra* note 3.

[22] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–ISE–2026–44. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–ISE–2026–44 and should be submitted on or before August 25, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–15737 Filed 8–3–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0133]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Rule 17a–19 and Form X–17A–19

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17a–19 (17 CFR 240.17a–19) and Form X–17A–19 under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17a–19 requires every national securities exchange and registered national securities association to file a Form X–17A–19 with the Commission and the Securities Investor Protection Corporation (''SIPC'') within 5 business days of the initiation, suspension, or termination of any member and, when terminating the membership interest of any member, to notify that member of its obligation to file financial reports as required by Exchange Act Rule 17a–5(b) (17 CFR 240.17a–5(b)). There are currently a total of 30 national securities exchanges and registered national securities associations that are potential respondents under the rule.

Commission staff anticipates that the national securities exchanges and registered national securities associations collectively will make 206 total filings annually pursuant to Rule 17a–19 and that each filing will take approximately 15 minutes. The total reporting burden is estimated to be approximately 52 total annual hours.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will have practical utility; (b) the accuracy of the SEC's estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to *PaperworkReductionAct@sec.gov* by October 5, 2026.

Dated: July 31, 2026.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–15772 Filed 8–3–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0705]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Rule 30b1–8 and Form N–CR

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. § 3501 *et seq.*), the Securities and Exchange Commission (''SEC'' or ''Commission'') is soliciting comments on the proposed collection of information discussed below.

A money market fund is required to file Form N–CR if a portfolio security defaults, an affiliate provides financial support to the fund, or the fund experiences a significant decline in its shadow price.[1] In most cases, a money market fund is required to submit a brief summary filing on Form N–CR within one business day of the occurrence of the event, and a follow up filing within four business days that includes a more complete description and information. Compliance with rule 30b1–8 is mandatory for any fund that holds itself out as a money market fund in reliance on rule 2a 7. Responses to the disclosure requirements will not be kept confidential.

The Commission estimates that it will receive, in the aggregate, an average of 1 report per year filed on Form N–CR.[2] Taking into account a blend of legal and financial in-house professionals, as well as the additional burdens associated with the amendments,[3] we estimate that

[23] 17 CFR 200.30–3(a)(12).

[1] 17 CFR 270.30b1–8.

[2] The number of reports per year filed on Form N–CR, based on initial and follow-up amendment filings with the Commission in 2023–2025, was 0, 0, and 2 respectively.

[3] We have estimated the time costs for a financial manager to be $731 per hour, costs for lawyers to be $744 per hour, and costs for a computer programmer to be $416 per hour; to calculate the occupational hourly rates the Commission uses occupational mean hourly wage data from the Occupational Employment and Wage Statistics (OEWS) program of the Bureau of Labor Statistics (BLS) for [''Securities, Commodity Contracts, and Other Financial Investments and Related Activities'' (NAICS 523)][the private sector]; *see Occupational Employment and Wage Statistics,* U.S. Bureau of Labor Statistics, *https://www.bls.gov/oes/; see also Standard Occupational Classification,* U.S. Bureau of Labor Statistics, *https://www.bls.gov/soc/* (describing occupational classification system used by BLS); Exec. Off. of the President, Off. of Mgmt. & Budget, North American Industry Classification System (2022), *available at https://www.census.gov/naics/reference_files_tools/*

Continued

a fund will spend, on average, 10.5 burden hours [4] and time costs of approximately $7,104 [5] for one report. The Commission therefore estimates that the total annual burden for Form N–CR reporting will be 10.5 burden hours and the total annual time cost will be $7,104.[6]

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will have practical utility; (b) the accuracy of the SEC's estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to *PaperworkReductionAct@sec.gov* by October 5, 2026.

Dated: July 30, 2026.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–15727 Filed 8–3–26; 8:45 am]

BILLING CODE 8011–01–P

2022_NAICS_Manual.pdf (describing the industry classification system used by BLS and other agencies); the mean hourly wage for each occupation is adjusted for changes in the seasonally adjusted employment cost index for private wages and salaries between the data reference period and when the data are released by BLS; *see Employment Cost Index,* U.S. Bureau of Labor Statistics, *https://www.bls.gov/eci/;* the adjusted mean hourly wage is then multiplied by a factor that accounts for nonwage costs borne by employers, such as bonuses, benefits, and overhead; this factor is calculated as an average over the 10 most recently available years of data of the ratio of the Bureau of Economic Analysis's annual gross output data for [NAICS 523][the private sector] to total annual wages across all occupations for [NAICS 523][the private sector] in the OEWS data; *see Gross Output by Industry,* U.S. Bureau of Economic Analysis, *https://www.bea.gov/data/industries/gross-output-by-industry; Occupational Employment and Wage Statistics,* U.S. Bureau of Labor Statistics, *https://www.bls.gov/oes/;* the final product is the occupational hourly rate. *See generally* Updated Methodology for Calculating Occupational Hourly Rates (Dec. 19, 2025), *available at https://www.sec.gov/files/method-occupational-hourly-rates.pdf.*

[4] When filing a report, the Commission estimates that a fund will spend on average approximately 4.5 hours of lawyer time, 4 hours of financial manager time, and 2 hours of computer programmer time to prepare, review and submit a filing.

[5] This estimate is based on the following calculations: (4.5 hours × $744 per hour for a lawyer = $ 3,348) + (4 hours × $731 per hour for a financial manager = $2,924) + (2 hours × $416 per hour for a computer programmer) = $7,104.

[6] This estimate is based on the following calculation: 1 reports per year × 10.5 burden hours per report = 10.5 burden hours; 1 reports per year × $ 7,104 time cost per report = $7,104 in time costs.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106016; File No. SR–Phlx–2026–49]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend FLEX Electronic Options Listing Rules

July 30, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 29, 2026, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its FLEX Options Trading Rules at Options 3A, Section 3, FLEX Option Listings.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rulefilings,* and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Phlx proposes to amend Options 3A, Section 3, FLEX Option Listings as it relates to FLEX Equity Options where the underlying security is an ETF that is eligible for cash settlement. Specifically, the proposed amendments would: (1) permit newly FLEX-eligible ETFs that satisfy heightened eligibility thresholds of $600 million average daily notional value and 5,616,000 shares ADV, based on the previous one-month period of trading statistics to be eligible for cash settlement as a contract term; (2) establish tiered criteria governing the treatment of cash-settled FLEX ETF Options where the underlying ETF ceases to satisfy the requirements of Options 3A, Section 3(c)(5)(A)(ii) at the time of the Exchange's bi-annual review; and (3) eliminate the existing provision limiting cash settlement as a contract term to no more than 50 underlying ETFs. This filing is identical to a rule proposal by Cboe.[3]

Background

Prior to the adoption of the rules described herein, FLEX Equity Options were generally required to be settled by physical delivery of the underlying security upon exercise. FLEX Index Options, by contrast, have long been settled by delivery in cash. Cash settlement was also available for customized equity options transacted in the over-the-counter (''OTC'') market, where settlement restrictions do not apply. The absence of a cash-settled exchange-traded alternative for equity-based FLEX Options created a gap between the exchange-traded and OTC markets that exchange-traded participants sought to bridge.

The Exchange previously submitted a filing with the Commission adopting cash settlement as an optional contract term for certain FLEX Equity Options where the underlying security is an ETF.[4] Specifically, Options 3A, Section 3(c)(5)(A)(ii) permits cash settlement for FLEX Equity Options where the underlying ETF has, measured over the

[3] *See* Securities Exchange Act Release No. 105929 (July 16, 2026), 91 FR 45856 (July 21, 2026) (SR–Cboe–2026–035) (Notice of Filing of Amendment No. 1 and Order Approving a Proposed Rule Change, as Modified and Superseded by Amendment No. 1, To Amend Rule 4.21 (Series of FLEX Options).

[4] *See* Securities Exchange Act Release No. 103759 (August 21, 2025), 90 FR 41636 (August 26, 2025) (SR–Phlx–2025–38) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt Electronic FLEX Options Rules).

prior six-month period, an average daily notional value of $500 million or more and a national average daily volume (''ADV'') of at least 4,680,000 shares.

The Exchange adopted these specific thresholds to limit cash-settled FLEX ETF Options to the most highly liquid and actively-traded ETFs, thereby mitigating concerns about susceptibility to manipulation at settlement. With respect to the notional value threshold, the Exchange determined that average daily notional value is an appropriate proxy for manipulation resistance because, as a general matter, the more expensive an underlying ETF's price, the less cost-effective manipulation becomes, and the more volume traded in an ETF, the more difficult manipulation of its price becomes. With respect to the ADV threshold, the Exchange determined that a requirement of 4,680,000 shares per day is appropriate because it represents average trading in the underlying ETF of approximately 200 shares per second, a level of continuous trading activity that the Exchange believes meaningfully limits the ability to influence the ETF's price for purposes of establishing a settlement value. The Exchange acknowledged that no security is immune from all manipulation, but determined that the combination of these two requirements would appropriately limit cash settlement of FLEX ETF Options to underlying securities that are less susceptible to manipulation.

Under this framework, the Exchange conducts a bi-annual review on January 1 and July 1 of each year to identify qualifying ETFs, with newly eligible ETFs permitted to list cash-settled FLEX options beginning on February 1 and August 1, respectively. The rule caps the number of eligible underlying ETFs at 50; if more than 50 ETFs satisfy the criteria, the Exchange selects the top 50 by highest ADV. This cap was designed to prevent the scope of cash-settled FLEX ETF Options from expanding considerably without a corresponding evaluation of whether the level of the requirements remains reasonable, while still providing flexibility to add ETFs given that the initial list of eligible ETFs numbered well below 50 at the time of adoption. In the event a previously eligible ETF fails to satisfy the criteria at the time of a bi-annual review, any new positions overlying that ETF must be physically settled and any existing open cash-settled positions may be traded only to close. This provision was designed to address how to wind down outstanding cash-settled positions in an ETF that no longer qualifies under the liquidity and volume criteria, thereby addressing manipulation concerns while still permitting market participants to exit existing positions.

In connection with the adoption of this framework, the Exchange committed to conducting a five-year review of cash-settled FLEX ETF Option trading activity and furnishing the Commission with five annual reports. Pursuant to this commitment, the Exchange has not submitted an annual monitoring report to the Commission covering the first year of trading as one year has not yet passed. The report will assess trading volume and open interest in cash-settled FLEX ETF options relative to physically settled options on the same underlying ETFs, market maker participation, position limit activity, and manipulation concerns when it is submitted after the first year of trading.

Cboe noted in SR–Cboe–2026–035 that it submitted two annual monitoring reports to the Commission covering the periods of August 1, 2023 through July 31, 2024 and August 1, 2024 through July 31, 2025, respectively.[5] The reports assessed trading volume and open interest in cash-settled FLEX ETF options relative to physically settled options on the same underlying ETFs, market maker participation, position limit activity, and manipulation concerns.[6] Cboe had no recommendations for enhancements to the listing standards based on either review.[7] Also, Cboe noted that in both review periods, neither Cboe nor any affiliated Cboe securities exchange had an open investigation, inquiry, or enforcement matter relating to the manipulation of cash-settled FLEX ETF options or their underlying ETFs.[8] Financial Industry Regulatory Authority (''FINRA''), acting as Cboe's regulatory services provider for position limit surveillance, confirmed the same finding for both periods.[9] While both of Cboe's reports noted that certain regulatory matters arose during each period involving the applicable ETFs or related physically-settled options, Cboe's surveillance and investigatory staff confirmed in each instance that the activity did not appear to relate to manipulation of an ETF for the purpose of benefiting a cash-settled FLEX ETF option position.[10]

Cboe's review period reflected broad and stable market maker participation across the eligible underlying ETFs. Cboe, which has been trading FLEX for a longer period than Phlx, stated in SR–Cboe–2026–035 that the highest levels of FLEX market maker participation were observed in SPY (9 to 12 per month), QQQ (6 to 10 per month), and IWM (3 to 15 per month).[11] Cboe noted that participation in less actively traded eligible ETFs was more limited but consistent across both periods, reflecting a well-supported and liquid product across the eligible universe.[12]

Proposal

The Exchange proposes to amend Options 3A, Section 3(c)(5)(A)(ii) to refine two aspects of the framework governing cash-settled FLEX ETF Options and to eliminate the 50–ETF cap. First, the Exchange proposes to permit newly FLEX-eligible ETFs to qualify for cash settlement as a contract term based on one month of trading statistics outside of the Exchange's regular bi-annual review cycle. Second, the Exchange proposes to replace the existing provision governing ETFs that cease to satisfy the eligibility criteria with a tiered framework that more precisely calibrates treatment to the actual state of open interest in cash-settled FLEX ETF Options overlying the affected ETF. Third, the Exchange proposes to eliminate the existing cap limiting cash settlement as a contract term to no more than 50 underlying ETFs.

One-Month Lookback for Newly Eligible ETFs

Under the current rule, the Exchange determines eligible underlying ETFs bi-annually, on January 1 and July 1 of each year, using six months of prior trading statistics, with newly eligible ETFs permitted to list cash-settled FLEX options beginning on February 1 and August 1, respectively. No mechanism currently exists to add newly FLEX-eligible ETFs to the eligible list between bi-annual reviews. As a result, an ETF that becomes FLEX-eligible after a bi-annual review has been conducted may not be considered for cash-settled FLEX ETF Option eligibility for up to six months, even if it otherwise satisfies the notional value and ADV requirements of Options 3A, Section 3(c)(5)(A)(ii). The Exchange proposes to address this gap by permitting, outside of the regular bi-annual review, the Exchange to determine that a newly FLEX-eligible ETF satisfies heightened notional value and trading volume requirements of $600 million average daily notional value and 5,616,000 shares ADV based

[5] *See supra* note 3.
[6] *See id.*
[7] *See id.*
[8] *See id.*
[9] *See id.*
[10] *See id.*
[11] *See id.*
[12] *See id.*

on the previous one-month period of trading statistics. Any ETF satisfying such requirements on that basis shall be eligible for cash settlement as a contract term.

The Exchange believes a one-month lookback is appropriate in this context because an ETF that has newly become FLEX-eligible and simultaneously satisfies both the $600 million average daily notional value threshold and the 5,616,000-share ADV requirement over the prior month has already demonstrated the degree of liquidity and trading activity that the eligibility criteria are designed to capture. These thresholds represent a 20% increase over the standard $500 million and 4,680,000-share thresholds that apply to the bi-annual review, reflecting the Exchange's determination that heightened criteria are appropriate for ETFs seeking to qualify based on a shorter lookback period. The Exchange believes that Cboe's annual monitoring reports demonstrate that the existing criteria are an effective proxy for identifying ETFs that are not readily susceptible to manipulation. Requiring newly eligible ETFs to await the next bi-annual review before becoming eligible for cash settlement would delay investor access to the product.

Cboe's back-testing analysis of newly listed FLEX ETFs supports the appropriateness of the heightened thresholds.[13] Under the standard eligibility criteria ($500 million average daily notional value and 4,680,000 shares ADV), ten ETFs would have qualified based on one month of trading data. Under the 20% increased thresholds ($600 million average daily notional value and 5,616,000 shares ADV), only eight ETFs qualified. Cboe noted that the two ETFs excluded by the heightened thresholds did not qualify at their next six-month bi-annual review, demonstrating that the heightened thresholds effectively filter out ETFs whose initial trading activity may not be sustained.

The Exchange believes the heightened thresholds for the one-month lookback appropriately address the concern that a newly listed ETF may experience elevated trading activity in its initial period that is not representative of sustained liquidity. By requiring newly eligible ETFs to satisfy thresholds that are 20% above the standard bi-annual review criteria, the Exchange ensures that only those ETFs demonstrating a meaningfully higher level of liquidity and trading activity—beyond what may reflect initial market interest—are eligible for cash settlement based on the shorter lookback period.

Further, the Exchange represents that it will continue to monitor the one-month lookback criteria on an ongoing basis to assess the appropriateness of the threshold. As part of this ongoing monitoring, the Exchange will evaluate whether the heightened criteria continue to effectively identify ETFs with sustained liquidity and trading activity, and will propose adjustments to the threshold if warranted by the Exchange's review.

Tiered Criteria for ETFs Ceasing To Satisfy Eligibility Requirements

Under the current rule, if the Exchange determines at the time of a bi-annual review that an underlying ETF ceases to satisfy the eligibility criteria, any new position overlying that ETF must be physically settled and any existing open cash-settled positions may be traded only to close. While this provision addresses the wind-down of cash-settled activity in a straightforward manner, it does not distinguish between ETFs with active open interest and those with no meaningful cash-settled activity, nor does it account for the possibility that an ETF may temporarily fall below the eligibility thresholds and subsequently recover.

The Exchange proposes to replace this provision with a tiered framework that more precisely calibrates the treatment of an ineligible ETF to the actual state of the market for cash-settled FLEX ETF Options overlying that ETF. Under the proposed framework, if no open interest in cash-settled FLEX Equity Options overlying the ETF exists during the previous six-month period at the time of the bi-annual review determination, the existing treatment will apply: any new position must be physically settled and any open cash-settled positions may be traded only to close. Where open interest in cash-settled FLEX Equity Options overlying the ETF does exist during the previous six-month period, the Exchange will permit the opening of new cash-settled positions in that ETF for a period of one year from the date of the bi-annual review, after which any new position must be physically settled and any remaining open cash-settled positions may be traded only to close. This one-year continuation period is intended to provide market participants holding or seeking to manage existing cash-settled positions with a reasonable and predictable runway to do so, rather than abruptly restricting new position activity at the time of the bi-annual review determination.

The proposed framework also includes a recovery provision: if the underlying ETF satisfies the eligibility criteria at the time of either bi-annual review conducted during the one-year continuation period, that period will terminate and the ETF will resume full eligibility for cash settlement as a contract term. The Exchange believes this provision appropriately accounts for the possibility that an ETF's trading statistics may fluctuate around the eligibility thresholds and prevents an unnecessarily disruptive wind-down in cases where the ETF promptly returns to eligibility.

Elimination of the 50–ETF Cap

The Exchange also proposes to eliminate the existing provision limiting cash settlement as a contract term to no more than 50 underlying ETFs. The cap was adopted at the outset of the program to prevent the scope of cash-settled FLEX ETF Options from expanding considerably without a corresponding evaluation of whether the level of the eligibility requirements remained reasonable. While the number of ETFs satisfying the eligibility criteria remained well below 50 during the initial period of the program's operation, over the two-year period that Cboe monitored the market, the number of qualifying ETFs has grown to exceed that threshold (as of February 1, 2026, 60 ETFs were eligible), such that the cap now operates as an active constraint on the availability of cash-settled FLEX ETF Options on ETFs that otherwise satisfy the established eligibility criteria. The Exchange does not believe this result is consistent with the purpose of the cap, which was intended as a programmatic guardrail rather than a permanent numerical ceiling. As noted above, Cboe did not identify manipulation concerns in its reviews. Given the same eligibility criteria and position and exercise limits would apply to any cash-settled FLEX ETF option, as would the Exchange's surveillance program, the Exchange believes the 50–ETF cap is no longer necessary. The Exchange believes these protections and the eligibility criteria themselves sufficiently mitigate any manipulation concerns associated with cash-settled FLEX ETF Options.

The Exchange also notes that, consistent with its commitment in the original proposal, it will continue to furnish the Commission with annual reports for the remainder of the five-year review period. The Exchange believes that the continued reporting commitment, together with the proposed amendments, appropriately positions the cash-settled FLEX ETF

[13] For purposes of the back-testing analysis, Cboe reviewed all newly listed FLEX-eligible ETFs from January 1, 2025 through April 6, 2026.

Option framework to address the operational gaps identified through the Exchange's review to date while preserving the monitoring mechanisms that allow the Exchange and the Commission to evaluate the ongoing impact of the program.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[14] in general, and furthers the objectives of Section 6(b)(5) of the Act,[15] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes the proposed rule change is consistent with Section 6(b)(5) of the Act because each of the proposed amendments is designed to refine an existing, Commission-approved framework in a manner that is reasonably calibrated to address identified operational gaps while preserving and reinforcing the manipulation-mitigating features of that framework.

One-Month Lookback for Newly Eligible ETFs

The Exchange believes the proposed one-month lookback for newly FLEX-eligible ETFs is consistent with the Act because it removes an impediment to the offering of cash-settled FLEX ETF Options on ETFs that have already demonstrated the liquidity and trading activity that the eligibility criteria are designed to capture, without compromising the manipulation-resistant features of those criteria. Under the current rule, an ETF that becomes FLEX-eligible after a bi-annual review has been conducted must wait up to six months before it may be considered for cash-settled FLEX ETF Option eligibility, even if it satisfies both the $600 million average daily notional value threshold and the 5,616,000-share ADV requirement at the time it becomes FLEX-eligible. The Exchange believes this gap is not necessary to protect against manipulation.

An ETF that satisfies both heightened thresholds over the prior one-month period has demonstrated a degree of liquidity and breadth of trading activity exceeding that which the six-month bi-annual review is designed to identify as indicative of reduced susceptibility to manipulation. The heightened thresholds, which represent a 20% increase over the standard $500 million and 4,680,000-share thresholds applicable to the bi-annual review, are designed to account for the possibility that a newly listed ETF may experience elevated trading activity in its initial period that is not representative of sustained liquidity. As noted above, Cboe's annual monitoring reports demonstrated the existing eligibility criteria are an effective and reliable proxy for identifying ETFs that are not readily susceptible to manipulation, and did not identify any manipulation concerns in connection with cash-settled FLEX ETF Options or their underlying ETFs during that period. The Exchange therefore believes that permitting a one-month lookback for newly FLEX-eligible ETFs between bi-annual reviews, subject to the heightened thresholds, removes an impediment to and perfects the mechanism of a free and open market and protects investors and the public interest by providing timely investor access to a cash-settlement alternative on ETFs that satisfy the established eligibility criteria, while maintaining the protections afforded by those criteria.

Cboe's back-testing analysis further supports the consistency of the heightened thresholds with the Act's anti-manipulation objectives. Under the standard criteria, ten newly listed FLEX ETFs would have qualified based on one month of trading data, but under the 20% increased thresholds only 8 qualified. The two names excluded (AMDL and SIVR) did not qualify at their next six-month bi-annual review, confirming that the heightened thresholds effectively identify and exclude ETFs whose initial trading statistics do not reflect sustained market activity. The Exchange believes this empirical evidence demonstrates that the heightened thresholds are reasonably designed to prevent ETFs with potentially transient liquidity from qualifying for cash settlement based on the shorter lookback period.

Tiered Criteria for ETFs Ceasing To Satisfy Eligibility Requirements

The Exchange believes the proposed tiered framework for ETFs that cease to satisfy the eligibility criteria at the time of a bi-annual review is consistent with the Act because it is reasonably designed to prevent fraudulent and manipulative acts and practices while also promoting just and equitable principles of trade and protecting investors. The current rule applies a single, uniform wind-down treatment to any ETF that falls below the eligibility thresholds at bi-annual review, regardless of whether active open interest in cash-settled FLEX ETF Options overlying that ETF exists. The Exchange believes this one-size-fits-all approach does not adequately account for the legitimate interests of market participants that hold existing cash-settled positions or that need the ability to open new positions to manage existing risk exposure in an ETF that has temporarily fallen below the thresholds.

The proposed tiered framework addresses this concern in a manner consistent with the Act's investor protection and anti-manipulation objectives. Where no open interest in cash-settled FLEX ETF Options overlying the affected ETF has existed during the previous six-month period, the current treatment would continue to apply, because the Exchange believes an immediate restriction on new cash-settled positions would not disrupt market participants' activity. Where open interest does exist at the time of the bi-annual review, the proposed one-year continuation period provides market participants with a reasonable and predictable runway to manage existing positions, which the Exchange believes promotes just and equitable principles of trade. The Exchange further believes that the recovery provision, under which the continuation period terminates and full eligibility is restored if the ETF satisfies the criteria at either bi-annual review during the one-year period, is consistent with the Act because it prevents an unnecessarily disruptive wind-down where an ETF's trading statistics temporarily dip below the eligibility thresholds and then recover, and it reinforces the principle that the eligibility criteria, rather than arbitrary timing, are the appropriate determinant of cash-settlement eligibility. Taken together, the Exchange believes the tiered framework is a reasonable means to address manipulation concerns while not unduly burdening market participants with existing cash-settled positions, as it eliminates the current immediate disruption to their investment strategies.

Elimination of the 50–ETF Cap

The Exchange believes the elimination of the 50–ETF cap is consistent with the Act because the cap is no longer necessary to protect against the concerns it was designed to address and, as currently operative, functions as an impediment to the offering of cash-settled FLEX ETF Options on ETFs that otherwise satisfy the established eligibility criteria. The cap was adopted at the outset of the program to prevent

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

the scope of cash-settled FLEX ETF Options from expanding considerably without a corresponding evaluation of whether the level of the eligibility requirements remained reasonable. While the number of qualifying ETFs remained well below 50 during the initial period of the program's operation, that number has more recently grown to exceed the cap, such that the cap now actively restricts the availability of cash-settled FLEX ETF Options on ETFs that fully satisfy the notional value and ADV requirements of Options 3A, Section 3(c)(5)(A)(ii). The Exchange believes that retaining this arbitrary restriction is inconsistent with the Act's objectives because Cboe's two-year monitoring record demonstrates that the eligibility criteria themselves limit the availability of cash settlement to FLEX ETF Options. The liquidity and trading activity requirements mitigate manipulation concerns for any ETF that satisfies those requirements, not just the top 50.

During the first two years that cash-settled FLEX ETF Options were available on Cboe, it identified (and its annual monitoring reports demonstrated) no manipulation concerns in connection with cash-settled FLEX ETF Options or their underlying ETFs. The Exchange believes the eligibility criteria, position and exercise limits, and surveillance program applicable to the 50 ETFs eligible for FLEX options with cash-settlement provide adequate protections against manipulation and market disruption to all ETFs that satisfy the criteria, regardless of the number of qualifying ETFs. The Exchange therefore believes that eliminating the cap removes an impediment to and perfects the mechanism of a free and open market, protects investors and the public interest, and is otherwise consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange does not believe the proposed rule change will impose any burden on intramarket competition. The proposed amendments apply uniformly to all market participants that trade cash-settled FLEX ETF Options on the Exchange. All newly FLEX-eligible ETFs would be eligible for the one-month lookback, subject to the same heightened eligibility thresholds ($600 million average daily notional volume and 5,616,000 shares ADV) and any ETF that satisfies those heightened criteria within that one-month lookback would be eligible for cash-settlement, and cash-settled FLEX options on such ETFs would be available to all market participants. The tiered framework for ETFs ceasing to satisfy the eligibility criteria applies in the same manner to all market participants holding or seeking to open positions in cash-settled FLEX ETF Options overlying the affected ETF, and the one-year continuation period and recovery provision provide all such participants with the same predictable and equitable treatment. The elimination of the 50–ETF cap permits any ETF that satisfies the eligibility criteria to be eligible for FLEX cash-settlement rather than arbitrarily restricting that product availability to 50 ETFs. The Exchange believes the proposed rule promotes competition, as it would treat all ETFs that satisfy the eligibility criteria for cash-settled FLEX Options in the same manner.

The Exchange does not believe the proposed rule change will impose any burden on intermarket competition. Cash-settled FLEX ETF Options with the same underlying ETF may be listed on multiple exchanges, and the proposed amendments do not restrict the ability of other exchanges to adopt similar or competing frameworks. This rule proposal is a competitive response to Cboe's proposal [16] and it would enhance competition among the options exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [17] and subparagraph (f)(6) of Rule 19b–4 thereunder.[18]

A proposed rule change filed under Rule 19b–4(f)(6) [19] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[20] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that waiver of the operative delay would permit the Exchange to amend its FLEX rules consistent with Cboe [21] and competitively offer the same products on a cash-settled basis. For this reason, and because the proposed rule change raises no new or novel legal or regulatory issues, the Commission finds that waiver of the operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change to be operative upon filing.[22]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–Phlx–2026–49 on the subject line.

[16] See supra

[17] 15 U.S.C. 78s(b)(3)(A)(iii).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[19] 17 CFR 240.19b–4(f)(6).

[20] 17 CFR 240.19b–4(f)(6)(iii).

[21] *See supra* note 3.

[22] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–Phlx–2026–49. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml.* Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–Phlx–2026–49 and should be submitted on or before August 25, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–15732 Filed 8–3–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 36276; 812–15935]

Yorkville America Investment Trust and Yorkville America Equities, LLC

July 30, 2026.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from section 15(a) of the Act, as well as from certain disclosure requirements in rule 20a–1 under the Act, Item 19(a)(3) of Form N–1A, Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A under the Securities Exchange Act of 1934, and sections 6–07(2)(a), (b), and (c) of Regulation S–X (''Disclosure Requirements'').

SUMMARY OF APPLICATION: The requested exemption would permit Applicants to enter into and materially amend subadvisory agreements with subadvisors without shareholder approval and would grant relief from the Disclosure Requirements as they relate to fees paid to the subadvisors.

APPLICANTS: Yorkville America Investment Trust and Yorkville America Equities, LLC.

FILING DATES: The application was filed on November 6, 2025, and amended on July 14, 2026.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. The email should include the file number referenced above. Hearing requests should be received by the Commission by 5:30 p.m., Eastern time, on August 25, 2026, and should be accompanied by proof of service on the Applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Steve Neamtz, President, Yorkville America Equities, LLC, 1012 Springfield Avenue, Mountainside, New Jersey 07092; John H. Lively, Practus, LLP, 11300 Tomahawk Creek Parkway, Suite 310, Leawood, KS, 66211.

FOR FURTHER INFORMATION CONTACT: Asaf Barouk, Senior Counsel, or Matthew Cook, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' amended and restated application, dated July 14, 2026, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *https://www.sec.gov/search-filings.* You may also call the SEC's Office of Investor Education and Assistance at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–15731 Filed 8–3–26; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice: 13090]

Imposition of Nonproliferation Measures Against Foreign Persons, Including a Ban on U.S. Government Procurement

ACTION: Notice.

SUMMARY: A determination has been made that a number of foreign persons have engaged in activities that warrant the imposition of measures pursuant to the Iran, North Korea, and Syria Nonproliferation Act (INKSNA).

DATES: These measures went into effect July 24, 2026.

FOR FURTHER INFORMATION CONTACT: On general issues: Pam Durham, Office of WMD and Missile Controls, Bureau of Arms Control and Nonproliferation, Department of State, Telephone (202) 647–4930. Email: *acn-wmc-sanctions@state.gov.* For U.S. Government procurement ban issues: Eric Moore, Office of the Procurement Executive, Department of State, Telephone: (703) 875–4079. Email: *mooreen@state.gov.*

SUPPLEMENTARY INFORMATION: The INKSNA provides for sanctions on foreign entities and individuals for the transfer to or acquisition from Iran since January 1, 1999; the transfer to or acquisition from Syria since January 1, 2005; or the transfer to or acquisition from the DPRK since January 1, 2006, of goods, services, or technology controlled under multilateral control lists (Australia Group, Chemical Weapons Convention, Missile Technology Control Regime, Nuclear Suppliers Group, and Wassenaar Arrangement) or otherwise having the potential to make a material contribution to the development of weapons of mass destruction (WMD) or cruise or ballistic missile systems.

On July 24, 2026, the U.S. Government applied the measures authorized in section 3 of the Iran, North Korea, and Syria Nonproliferation Act (Pub. L. 106–178) against the following foreign persons identified in the report submitted pursuant to section 2(a) of the Act:

1061st Material-Technical Support Center (MTSC) (Russia); and any

[23] 17 CFR 200.30–3(a)(12).

successor, sub-unit, or subsidiary thereof;

Abdullah Hammam bin Mustafar (Malaysia-national)

Aleksandr Ivanovich Prikhodko (Russian national)

Andrei Gusev (Russian national)

Andrey Vladimirovich Kosolapov (Russian national)

Ellengo Lori (Malaysia national)

Gedion Alpha Company LLC (Russia); and any successor, sub-unit, or subsidiary thereof;

Huang Chin Hsin (aka Huang Jinxing) (Taiwan national)

International Invest Company (IIC) (Russia); and any successor, sub-unit, or subsidiary thereof;

Kala Gozar Pars Shipping and Logistics Company (Iran); and any successor, sub-unit, or subsidiary thereof;

Kang T'ae-so'ng (aka Kang Thae Song) (DPRK national)

Mehdi Ghasemi (Malaysia national)

Mohammad Ejen (Malaysia national)

Morozik Vladislav Antonovich (Russian national)

NS Global Logistics (Malaysia); and any successor, sub-unit, or subsidiary thereof;

Rabi' Madkhanah (Syrian national)

Ruhollah Katebi (Iranian national)

Russian Ground Forces (RGF) (Russia); and any successor, sub-unit, or subsidiary thereof;

Russian Main Missile and Artillery Directorate (Russia); and any successor, sub-unit, or subsidiary thereof;

Russian Ministry of Defense Directorate for Advanced Inter-Service Research and Special Projects (UPMLiSP) (Russia); and any successor, sub-unit, or subsidiary thereof;

Sergey Nikolayevich Tsibarev (Russia)

Yixing Ruibang High Performance Carbon Fiber Products Co. Ltd (aka Yixing Ruibang) (China); and any successor, sub-unit, or subsidiary thereof;

Accordingly, pursuant to section 3 of the Act, the following measures are imposed on these persons:

1. No department or agency of the U.S. government may procure or enter into any contract for the procurement of any goods, technology, or services from these foreign persons, except to the extent that the Secretary of State otherwise may determine;

2. No department or agency of the U.S. government may provide any assistance to these foreign persons, and these persons shall not be eligible to participate in any assistance program of the U.S. government, except to the extent that the Secretary of State otherwise may determine;

3. No U.S. government sales to these foreign persons of any item on the United States Munitions List are permitted, and all sales to these persons of any defense articles, defense services, or design and construction services under the Arms Export Control Act are terminated; and

4. No new individual licenses shall be granted for the transfer to these foreign persons of items the export of which is controlled under the Export Control Reform Act of 2018 or the Export Administration Regulations, and any existing such licenses are suspended.

These measures shall be implemented by the responsible departments and agencies of the U.S. government and will remain in place for two years from the effective date, except to the extent that the Secretary of State may subsequently determine otherwise. These measures are independent of and in addition to any other sanctions imposed on such entities and/or individuals by other federal agencies under separate legal authorities.

Christopher T. Yeaw,

Assistant Secretary for Bureau of Arms Control and Nonproliferation, Department of State.

[FR Doc. 2026–15759 Filed 8–3–26; 8:45 am]

BILLING CODE 4710–27–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2026–9076]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: National Air Tours Safety Standards

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves requirements in FAA regulations that set safety and oversight rules for a broad variety of sightseeing and commercial air tour flights to improve the overall safety of commercial air tours by requiring all air tours to submit information.

DATES: Written comments should be submitted by October 5, 2026.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Sandra Ray, Federal Aviation Administration, AFS–260, 1187 Thorn Run Road, Suite 200, Coraopolis, PA 15108.

By fax: 412–239–3063.

FOR FURTHER INFORMATION CONTACT: *Sandra.ray@faa.gov;* phone: 412–546–7344.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0717.

Title: National Air Tours Safety Standards.

Form Numbers: None.

Type of Review: Renewal of an information collection.

Background: FAA regulations set safety and oversight rules for a broad variety of sightseeing and commercial air tour flights to improve the overall safety of commercial air tours by requiring all air tour operators to submit information. The FAA uses the information it collects and reviews to ensure compliance and adherence to regulations and, if necessary, take enforcement action on violators of the regulations.

Respondents: Commercial Air Tour Operators.

Frequency: Most Requirements are annual, One requirement is one time only.

Estimated Average Burden per Response: Burden varies per individual requirement. Average burden is 5 hours per response.

Estimated Total Annual Burden: 2,560 Hours.

Issued in Washington, DC on July 31, 2026.

Sandra L. Ray,

Aviation Safety Inspector, AFS–260.

[FR Doc. 2026–15771 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2026–3339]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Fueling Aviation's Sustainable Transition Grant (FAST) Program

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on April 23, 2026. The collection consists of reports from grant recipients documenting technical progress, schedule, risks, and costs for each already awarded FAST grant. The information to be collected will be used to monitor performance of these projects.

DATES: Written comments should be submitted by September 3, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Chris Dorbian by email at: *christopher.dorbian@faa.gov;* phone: 202–267–8156.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0817.

Title: Fueling Aviation's Sustainable Transition Grant Program.

Form Numbers: N/A.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on April 23, 2026 (91 FR 21860). The FAA will use this renewed collection to continue to monitor and evaluate the performance of awarded FAST grants. FAA is collecting information on technical progress, schedule, risks, and costs for each project. This information is collected via required performance reporting deliverables, including quarterly and publicly releasable annual reports and semi-annual review presentations. A team of subject matter experts in aircraft technology development and aviation fuels from the FAA and other government agencies review these deliverables. This collection is necessary to ensure proper oversight of the use of taxpayer funding and to provide transparency to the public in the form of public reports. The FAST Grant Program was established under Public Law 117–169.

Respondents: FAST grant recipients.

Frequency: Quarterly.

Estimated Average Burden per Response: 134 hours per grant recipient per year.

Estimated Total Annual Burden: 1876 hours.

Issued in Washington, DC on July 30, 2026.

Julie Marks,

Executive Director, Federal Aviation Administration—Office of Environment and Energy.

[FR Doc. 2026–15728 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2026–0727]

Agency Information Collection Activities; Renewal of an Approved Information Collection Request: Commercial Driver's License Drug and Alcohol Clearinghouse

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for review and approval and invites public comment. The Agency's final rule titled ''Commercial Driver's License Drug and Alcohol Clearinghouse'' (Clearinghouse), published in the **Federal Register** on December 5, 2016, established the regulatory requirements for the Clearinghouse. The compliance date for the final rule was January 6, 2020. FMCSA began collecting data as authorized users began registering in the Clearinghouse in September 2019. This ICR revision is needed to support the continuation of the querying and reporting requirements to address the problem of commercial driver's license (CDL) and commercial learner's permit (CLP) holders who test positive for the use of controlled substances or the misuse of alcohol and then continue to perform safety sensitive functions, including driving a commercial motor vehicle (CMV), without completing the required return-to-duty (RTD) process.

DATES: Comments on this notice must be received on or before September 3, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be submitted within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Derrick Carrington, Drug and Alcohol Programs Division, DOT, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 366–9394; *derrick.carrington@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Commercial Driver's License Drug and Alcohol Clearinghouse.

OMB Control Number: 2126–0057.

Type of Request: Renewal of an approved ICR.

Respondents: Motor carriers (employers), drivers, MROs, SAPs, consortia/third-party administrators (C/TPAs), and SDLAs.

Estimated Number of Respondents: 9,834,949.

Estimated Time per Response: Varies; 10 to 20 minutes.

Expiration Date: August 31, 2026.

Frequency of Response: On occasion.

A user's role will determine the frequency of the response in the Clearinghouse.

- *Employers, or C/TPAs acting on behalf of an employer:* At a minimum, employers are required to query the Clearinghouse for each driver they currently employ at least once a year. Employers must query the Clearinghouse for all prospective employees, as needed. In addition, employers report to the Clearinghouse

alcohol confirmation tests with a concentration of 0.04 or higher, refusal to test (alcohol), refusal to test (drug) that is not determined by an MRO, and actual knowledge of violations, negative RTD testing, and completion of the follow-up testing plan. Employer reporting must be completed by the close of the third business day following the date they obtained the information on the driver.

- *MROs:* Verified positive, adulterated, or substituted drug test result and refusals to tests (drug) must be entered to the Clearinghouse on occasion, but no later than 2 business days after making a determination or verification.
- *SAPs:* Must enter the initial assessment date and the date the driver successfully complied with RTD requirements. SAPs are required to enter this information on occasion by the close of business day following the date of the initial assessment or completion of the RTD process.
- *SDLAs:* May query the Clearinghouse prior to specified licensing transactions to determine whether drivers are listed in the ''prohibited status.''
- *Drivers:* Provide general consent to employer queries outside of the Clearinghouse.
- *Drivers:* Must provide their specific consent to pre-employment queries electronically through the Clearinghouse.

Estimated Total Annual Burden: 1,653,032 hours.

Background

Agency regulations at 49 Code of Federal Regulations (CFR) part 382 apply to persons and employers of such persons who operate CMVs in commerce in the United States and who are subject to the CDL requirements in 49 CFR part 383 or the equivalent CDL requirements for Canadian and Mexican drivers operating in the United States (49 CFR 382.103(a)). Part 382 requires that employers conduct pre-employment drug testing; random, post-accident, and reasonable suspicion drug and alcohol testing; and RTD testing and follow-up testing for those drivers who test positive or otherwise violate DOT drug and alcohol program requirements. Motor carrier employers are prohibited from allowing an employee to perform safety-sensitive functions, which include operating a CMV, if the employee tests positive on a DOT drug or alcohol test, refuses to take the required test, or otherwise violates FMCSA's drug and alcohol testing regulations.

Section 32402 of the Moving Ahead for Progress in the 21st Century Act (Pub. L. 112–141, 126 Stat. 405 (2012)) required that the Secretary of Transportation (the Secretary) establish, operate, and maintain a national clearinghouse for records relating to alcohol and controlled substances testing of CMV operators to improve compliance with the DOT's alcohol and controlled substances testing program and to enhance the safety of our roadways by reducing crashes and injuries involving the misuse of alcohol or use of controlled substances by operators of CMVs. FMCSA published a final rule on December 5, 2016, with an effective date of January 4, 2017, and a compliance date of January 6, 2020, to implement the requirements of the Clearinghouse (81 FR 87686). In September 2019 FMCSA first began collecting data relating to authorized users' registration in the Clearinghouse. On January 6, 2020, FMCSA began collecting data related to drivers' drug and alcohol program violations and associated return to duty process, as well as allowing queries conducted by employers on CDL or CLP holders.

The Clearinghouse functions as a repository for records relating to the positive test results and test refusals of CMV operators and violations by such operators of prohibitions set forth in 49 CFR, part 382, subpart B. An employer utilizes the Clearinghouse to determine whether current and prospective employees have incurred a drug or alcohol program violation that would prohibit them from performing safety-sensitive functions, including operating a CMV.

The Clearinghouse provides FMCSA and employers with the necessary tools to identify drivers who are prohibited from operating a CMV and ensure that such drivers receive the required evaluation and treatment before resuming safety-sensitive functions. Specifically, information maintained in the Clearinghouse will ensure that drivers who commit a drug or alcohol program violation while working for one employer and attempt to find work with another employer can no longer conceal their drug and alcohol violations merely by moving on to the next job or the next State. Drug and alcohol violation records maintained in the Clearinghouse follow the driver regardless of how many times he or she changes employers, seeks employment, or applies for a CDL in a different State.

The information in the Clearinghouse is used by FMCSA and its State partners for enforcement purposes to:

- Ensure employers are meeting their pre-employment investigation and reporting requirements.
- Place drivers out of service if drivers are found to be operating a CMV without completing the RTD process; and
- Ensure medical review officers (MROs) and substance abuse professionals (SAPs) meet their reporting requirements.

Only authorized users, including employers and their service agents, Federal and State enforcement personnel, and State Driver Licensing Agencies (SDLAs) may register and access the Clearinghouse for designated purposes. State enforcement personnel may also receive the driver's eligibility status to operate a CMV, based on Clearinghouse information, when they check Query Central, the Commercial Driver's License Information System, or the National Law Enforcement Telecommunications System for driver information. FMCSA will share a driver's drug and alcohol violation information with the National Transportation Safety Board when it is investigating a crash involving that driver.

Drivers may access their own information, but not the information of other drivers. The Clearinghouse meets all relevant Federal security standards and FMCSA continuously monitors compliance with applicable security regulations.

Public Comments Received: A total of 88 comments were received with 71 by June 1, 2026, deadline. Information collection comments received suggested changes to the current regulation. Comments provided recommended changes to the underlying drug and alcohol regulations but did not directly address the published costs or burdens hours associated with the information collection. For example, it was widely suggested that SAPs have access to complete driver information and violation history. Associated comments included that SAPs should also be required to upload a copy of a driver's follow-up testing plan to the Clearinghouse. Additionally, recommendations of Clearinghouse SAP credentialing verification were received. In this renewal of the approval of information collection, FMCSA sought comments on burden and costs associated with the current rule. Suggested changes to the current rule would be facilitated through a notice of proposed rulemaking per 49 CFR 389.31.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1)

whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued under the authority of 49 CFR 1.87.

Nicole S. Michel,

Acting Associate Administrator, Office of Research and Registration.

[FR Doc. 2026–15760 Filed 8–3–26; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the name of one person whose property and interests in property have been unblocked and who has been removed from the Specially Designated Nationals and Blocked Persons List (SDN List). OFAC is also publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: This action was issued on July 30, 2026. See **SUPPLEMENTARY INFORMATION** for relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, 202–622–2420; Assistant Director for Licensing, 202–622–2480; Assistant Director for Sanctions Compliance, 202–622–2490; or *https://ofac.treasury.gov/contact-ofac.*

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website: *https://ofac.treasury.gov.*

Notice of OFAC Actions

On July 30, 2026, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following person are unblocked under the relevant sanctions authority listed below.

Individual

1. DURANSOY, Cagri; DOB 04 Aug 1985; POB Kadikoy, Turkey; Passport TR–T 577847 (Turkey); alt. Passport 31/2857612/2007 (Turkey) (individual) [NPWMD] [IFSR].

Removed pursuant to Executive Order 13382 of June 28, 2005, ''Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters,'' 70 FR 38567, 3 CFR, 2005 Comp., p. 170 (E.O. 13382).

On July 30, 2026, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

Individuals

1. TANG, Xin (a.k.a. ''TANG, Mike''), China; DOB 16 Dec 1969; nationality China; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 110105196912164113 (China) (individual) [SDGT] [IFSR] (Linked To: MAHAN AIR).

Designated pursuant to section 1(a)(iii)(C) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism,'' (E.O. 13224), 66 FR 49079, as amended by Executive Order 13886 of September 9, 2019, ''Modernizing Sanctions To Combat Terrorism,'' 84 FR 48041, 3 CFR, 2019 Comp., p. 356 (E.O. 13224, as amended), for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MAHAN AIR, a person whose property and interests in property are blocked pursuant to E.O. 13224.

2. DURANSOY, Cagri, Turkey; DOB 04 Aug 1985; POB Kadikoy, Turkey; nationality Turkey; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; Passport TR–T 577847 (Turkey); alt. Passport 31/2857612/2007 (Turkey) (individual) [NPWMD] [IFSR] (Linked To: JAFARI, Milad).

Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, JAFARI, Milad, a person whose property and interests in property are blocked pursuant to E.O. 13382.

Entities

1. AIR CARGO PRO LIMITED (a.k.a. AIRCARGOPRO LTD; a.k.a. LIMITED LIABILITY COMPANY AIRCARGOPRO), Moscow, Russia; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 26 May 2010; Tax ID No. 5047116112 (Russia) [SDGT] [IFSR] (Linked To: MAHAN AIR).

   Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MAHAN AIR, a person whose property and interests in property are blocked pursuant to E.O. 13224.

2. DADENEGAR STARTUP STUDIO, Fereydounkhani Street, South Dibaji, Tehran, Iran; Heravi Hossein Abad, Tehran, Iran; 6743 W 75th St, Al Fallujah, Al Anbar Governate 31002, Iraq; Scharmbarg 109, Assen 9407 EA, Netherlands; Website https://dadenegarco.com; Email Address dadenegarcompany@gmail.com; alt. Email Address dadenegarhr@gmail.com; alt. Email Address dn.bi.api@gmail.com; Organization Established Date 2021; Organization Type: Computer programming activities [SDGT].

   Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, ISLAMIC REVOLUTIONARY GUARD CORPS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

3. SHANGHAI ELITE INTERNATIONAL TRAVEL CO LTD (Chinese Simplified: 上海马汉国际旅行社有限公司) (a.k.a. SHANGHAI

MAHAN INTERNATIONAL TRAVEL SERVICE COMPANY LTD), Shanghai 200020, China; Website www.iranmahanair.com; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 24 Feb 2014; Tax ID No. 310104087826111 (China); Registration Number 310104000567670 (China); Unified Social Credit Code (USCC) 913101040878261110 (China) [SDGT] [IFSR] (Linked To: TANG, Xin).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, TANG, Xin, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

4. SHANGHAI WINGS INTERNATIONAL LOGISTICS CO (Chinese Simplified: 上海翼上国际货运有限公司) (a.k.a. SHANGHAI WINGS INTERNATIONAL FREIGHT CO LTD; a.k.a. SHANGHAI YISHANG INTERNATIONAL FREIGHT CO LTD), Shenzhen, Guangdong, China; Room 172, Building A, No. 888, Huanhu West, 2nd Road, Lingang New Area, Pilot Free Trade Zone, Shanghai 200120, China; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 15 Jan 2021; Trade License No. 310142000159721 (China); Unified Social Credit Code (USCC) 91310000MA1H3GWY6C (China) [SDGT] [IFSR] (Linked To: MAHAN AIR).

   Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MAHAN AIR, a person whose property and interests in property are blocked pursuant to E.O. 13224.

5. SKIEZ TRAVELS AND LOGISTICS PRIVATE LIMITED (a.k.a. SKIEZ TRAVELS AND LOGISTICS PVT LTD; a.k.a. "SKIEZ TRAVEL"), Srinagar, Jammu and Kashmir 190001, India; A-287, Second Floor, Defence Colony, New Delhi, Delhi, India; Website https://skiez.in; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 27 Nov 2020; Tax ID No. ABECS9772K (India); Identification Number U60210JK2020PTC011906 (India) [SDGT] [IFSR] (Linked To: MAHAN AIR).

   Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MAHAN AIR, a person whose property and interests in property are blocked pursuant to E.O. 13224.

(Authority: E.O. 13224, as amended; E.O. 13902; E.O. 13382.)

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2026–15785 Filed 8–3–26; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activities: Comment Request on the Burden Related to the Withholding and Information Reporting for Transfers of Partnership Interests

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of information collection and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

DATES: Written comments should be received on or before October 5, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments and recommendations to Andrés Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email at *pra.comments@irs.gov.* Please include, ''OMB Number: 1545–2292—Public Comment Request Notice'' in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to Ronald J. Durbala, (202)–317–5746 or via email at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION: The IRS, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the IRS assess its impact and minimize the burden of its information collection requirements. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record and be viewable on relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Title: Withholding and Information Reporting for Transfers of Partnership Interests.

OMB Number: 1545–2292.

Project Number(s): TD 9926.

Abstract: This collection of information relates to regulations under Internal Revenue Code section 1446(f) governing withholding and information reporting for certain transfers of partnership interests. The regulations require certifications, notifications, partnership statements, and related recordkeeping by transferors, transferees, partnerships, brokers, and other affected parties. The information is used to administer the statutory withholding and reporting requirements, determine whether exceptions or adjustments to withholding apply, and ensure that the proper amount of tax is reported and collected.

Current Actions: There are no changes being made to the burden at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, and individuals.

Estimated Number of Respondents: 76,000.

Estimated Time per Respondent: 40 min.

Estimated Total Annual Burden Hours: 50,920.

Dated: July 31, 2026.

Ronald J. Durbala,

Tax Analyst.

[FR Doc. 2026–15767 Filed 8–3–26; 8:45 am]

BILLING CODE 4831–GV–P



FEDERAL REGISTER

Vol. 91 Tuesday,
No. 148 August 4, 2026

Part II

Federal Reserve System

12 Parts 217 and 239
Regulatory Modernization and Relief for Mutual Holding Companies; Proposed Rule

FEDERAL RESERVE SYSTEM

12 CFR Parts 217 and 239

[Regulations Q and MM; Docket No. R–1895]

RIN 7100–AH26

Regulatory Modernization and Relief for Mutual Holding Companies

AGENCY: Board of Governors of the Federal Reserve System (Board).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Board invites comment on a notice of proposed rulemaking (proposal) to modernize the regulatory framework applicable to mutual holding companies (MHCs), primarily through proposed revisions to Regulation MM (12 CFR part 239), which governs the formation, operations, activities, and conversion of savings and loan holding companies in mutual form. The proposal would amend Regulation MM by, among other things, eliminating certain dividend waiver requirements, reducing burden associated with conversions from mutual-to-stock form, revising certain post-conversion restrictions, eliminating the requirement that subsidiary holding companies of MHCs obtain federal charters, and revising and clarifying other provisions of the regulation. The proposal also would amend the capital rule (12 CFR part 217) to clarify that certain mutual capital instruments may qualify as regulatory capital and to codify model term sheets for mutual capital certificates as appendices to the regulation.

DATES: Comments must be submitted by October 5, 2026.

ADDRESSES: You may submit comments, identified by Docket No. R–1895 and RIN 7100–AH26, by using any of the following methods:

- *Agency Website: https://www.federalreserve.gov/apps/proosals/.* Follow the instructions for submitting comments, including attachments. *Preferred Method.*
- *Mail:* Benjamin W. McDonough, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.
- *Hand Delivery/Courier:* Same as mailing address.
- *Other Means: publiccomments@frb.gov.* You must include the docket number in the subject line of the message.

Comments received are subject to public disclosure. In general, comments received will be made available on the Board's website at *https://www.federalreserve.gov/apps/proposals/* without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure. Public comments may also be viewed electronically or in person in Room M—4365A, 2001 C St. NW, Washington, DC 20551, between 9 a.m. and 5 p.m. during Federal business weekdays.

FOR FURTHER INFORMATION CONTACT: Lucy Chang, Assistant General Counsel, (202) 475–6331; Mark Buresh, Senior Special Counsel, (202) 452–5270; Victoria Szybillo, Senior Counsel, (202) 475–6325; Trevor Feigleson, Senior Counsel, (202) 452–3274; Jonah Kind, Senior Counsel, (202) 452–2045; Tara Hofbauer, Senior Attorney, (202) 680–2503; Sean KimKwon, Attorney, (240) 374–7747; Timothy Kelly, Attorney, (771) 210–6989, Legal Division; Anna Lee Hewko, Associate Director, (202) 250–1577, Jonathan Rono, Manager, (202) 603–9780, Missaka Nuwan Warusawitharana, Manager, (202) 452–3461, Helen Xu, Manager, (202) 603–1924, Division of Supervision and Regulation; Board of Governors of the Federal Reserve System, 20th and C Street NW, Washington, DC 20551. For the hearing impaired only, Telecommunication Device for the Deaf (TDD), (202) 263–4869.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
A. Comments Received
B. Board Experience as Primary Federal Regulator of MHCs
II. The Proposal
A. Changes To Support Capital Raising
1. Dividend Waivers
2. Special Deposits and Mutual Capital Certificates
3. Appendices to the Capital Rule
4. Model Charter Amendments
B. Other Changes to Regulation MM
1. Subpart B
2. Subpart C
3. Subpart E
C. Other Technical Amendments
D. Bank MHC Commitments
III. Economic Analysis
A. Baseline
B. Affected Parties
C. Broad Economic Considerations
D. Costs and Benefits of the Proposal
1. Better Access to Capital
2. Reduced Compliance Costs
3. Potential for Conflicts of Interest and Reduced Accountability
4. Adjustment Costs
E. Conclusion
IV. Administrative Law Matters
A. Paperwork Reduction Act Analysis
B. Regulatory Flexibility Act Analysis
C. Solicitation of Comments on the Use of Plain Language
D. Riegle Community Development and Regulatory Improvement Act of 1994
E. Providing Accountability Through Transparency Act of 2023

I. Background

On July 21, 2011, pursuant to section 312 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), the Board assumed responsibility for the supervision and regulation of savings and loan holding companies (SLHCs) from the former Office of Thrift Supervision (OTS).[1] This responsibility extended to SLHCs in mutual form (thrift MHCs) and involved all functions of the OTS and the Director of the OTS related to SLHCs, including rulemaking authority and authority to issue orders.[2]

Mutual banking organizations are a type of banking organization owned directly by those with deposit and lending relationships with the institution (members), rather than by shareholders. These institutions are arranged in mutual, rather than stock form, and their charters typically set forth how individuals can qualify for membership. Typically, customers gain membership in such an institution through deposits or through a lending relationship with the mutual organization (similar to credit unions). Depending on the institution's charter and relevant state law, as applicable, members may have the right to vote on matters affecting the mutual banking organization, as well as other rights and privileges.[3]

Because of their ownership by members (sometimes referred to as mutuality), mutual banking organizations focus uniquely on their members and their local communities and can prioritize long-term stability over near-term profits. Additionally, mutuality can support the safety and soundness of these banking organizations, as members (generally depositors and borrowers) have an additional incentive based on their ownership of the organization to support the organization's long-term health. Mutual banking organizations also support the safety and stability of the U.S. banking system by contributing to the diversity of institutions in the U.S. banking system. However,

[1] 12 U.S.C. 5412.

[2] *See id.*

[3] For example, members may have an interest in the proceeds of the institution in the event the institution liquidated (known as a liquidation interest).

mutuality also can result in mutual banking organizations facing issues that are not faced by stock-form banking organizations. For example, as discussed in section I.B., mutual banking organizations face additional challenges in raising capital due to their general inability to sell equity securities.

Mutual banking organizations can be arranged in three main structures. First, a mutual bank or mutual savings association can be a stand-alone entity that is owned directly by its members. Second, a mutual bank or mutual savings association may undergo a ''reorganization'', whereby a company is formed (the mutual holding company, or MHC) to control the subsidiary bank or savings association, which itself would become a stock-form entity that is wholly owned by the MHC.[4] This structure is primarily utilized by institutions that seek to retain 100 percent mutuality but seek the corporate flexibility provided by the holding company format. Finally, a mutual banking organization can be organized in a three-tier format with (i) a top-tier MHC, (ii) a stock-form holding company formed as a majority-owned subsidiary to the top-tier MHC (mid-tier holding company or subsidiary holding company);[5] and (iii) a stock-form bank or savings association that is wholly owned by the mid-tier holding company. In this structure, the top-tier MHC must own at least a majority of the mid-tier holding company in order to preserve mutuality for the top-tier MHC. This three-tier structure allows institutions to blend mutuality with stock ownership, as the mid-tier holding company has the ability to issue stock to outside shareholders, as long as a majority of its stock continues to be held by the top-tier MHC. MHCs and mid-tier holding companies within the two- or three-tier structure can be either an SLHC or a BHC, depending on the charter of the subsidiary depository institution.

In addition to having varying structures, the entities that make up mutual banking organizations—like stock-form institutions—also can have varying charter types. As mentioned, the Board is responsible for supervising and regulating thrift MHCs. In 2011, the Board adopted an interim final rule (IFR) that provided for the transfer of the OTS's regulations necessary for the Board to administer the statutes applicable to SLHCs, including the Home Owners' Loan Act (HOLA) and the Change in Bank Control Act of 1978, and to supervise SLHCs, including thrift MHCs.[6] The IFR established Regulation LL, which applies to all SLHCs, and Regulation MM, which applies to thrift MHCs and their subsidiary holding companies, and made certain technical amendments to existing Board regulations necessary to accommodate the transfer of supervisory authority for SLHCs from the OTS to the Board.[7] Regulation MM adopted, with minimal changes, the predecessor regulations of the OTS, which first finalized in 1993.[8] Regulation MM has not been amended since its adoption in 2011.

Bank MHCs are not subject to HOLA or Regulation MM by their terms, but are instead subject to the Board's supervision and regulation pursuant to the Bank Holding Company Act of 1956 (BHC Act).[9] As discussed in section II.D, bank MHCs are governed by relevant state law and generally have entered into commitments with the Federal Reserve to comply with certain provisions of Regulation MM. Banks and savings associations in mutual form that are not state member banks are not directly supervised or regulated by the Board. The Board has not issued regulations specifically relating to the mutuality of state member banks in mutual form.

A. Comments Received

In connection with this proposed rulemaking, the Board has taken into consideration comments received in response to its earlier IFR[10] and through outreach conducted pursuant to the Economic Growth and Regulatory Paperwork Reduction Act (EGRPRA),[11] as well as feedback received from regulated entities. These comments were taken into consideration in developing this proposed rulemaking (proposal).

Multiple comments focused on section 239.8(d) of Regulation MM, which sets forth provisions governing the waiver of dividends by a thrift MHC. These comments are discussed in more detail in section II.A.1. of this proposal, which addresses those provisions.

The Board received comments on other aspects of Regulation MM as well. For example, one commenter suggested that the Board's source of strength doctrine (as it applies to SLHCs) renders the proposed share repurchase provisions set forth at sections 239.8(c) and 239.63(c) and (d) of Regulation MM unnecessary.

The same commenter also suggested that the Board delete the 5 percent limit on repurchasing shares in the first year following conversion in section 239.63(c)(1)(i) and apply only a valid business purpose standard to such repurchases. This comment will be discussed in more detail in section II.A.3.iv. of the proposal, which addresses that provision.

Another commenter argued that the Board is not the primary federal regulator of MHCs, has no authority to issue MHC charters, and has usurped any authority it has from other Federal regulatory institutions or state regulators. This comment will be addressed in section II.A.2.i. of the proposal, which discusses the Board's authority and Regulation MM's provisions concerning thrift MHCs and their subsidiary holding companies. Meanwhile, a different commenter noted that certain provisions of Regulation MM relating to business activities and investments of mutual holding companies are unclear, including references throughout the regulation to ''non-controlling investments'' by thrift MHCs. The Board does not propose to make any changes to the specific Regulation MM provisions regarding ''non-controlling'' investments by thrift MHCs. However, the proposal in general strives to improve the general clarity of the regulation and to provide additional transparency for mutual banking organizations.

B. Board Experience as Primary Federal Regulator of MHCs

Mutual banking organizations tend to be uniquely community-oriented with straightforward business models. Their structure as member-owned institutions makes them durable, preserves their ability to remain independent, and allows them to be closely tied to the communities in which they operate.

[4] Under this structure, mutuality ''shifts up,'' such that the members of the bank or savings association instead become members of the MHC (since the bank or savings association becomes a stock-form entity wholly owned by the MHC) and any new customer of the bank or savings association would become members of the MHC upon establishing a deposit or loan account at the bank or savings association.

[5] Regulation MM uses the term ''subsidiary holding company,'' but such entities are often also referred to, both in practice and in this proposal, as mid-tier holding companies.

[6] 76 FR 56508 (September 13, 2011) (hereafter, the 2011 IFR).

[7] *See id.*

[8] 58 FR 44104 (August 19, 1993).

[9] 12 U.S.C. 1841 *et seq.*

[10] In 2011, the Board sought comment on all aspects of the IFR and received 49 comments in total referencing Regulation MM. The Board did not make any changes to the regulation in response to the comments received to the IFR.

[11] Public Law 104–208, Div. A, Title II, section 2222, 110 Stat. 3009–414, (1996) (codified at 12 U.S.C. 3311). *See also* Regulatory Publication and Review Under the Economic Growth and Regulatory Paperwork Reduction Act of 1996, 89 FR 8084 (February 6, 2024); Regulatory Publication and Review Under the Economic Growth and Regulatory Paperwork Reduction Act of 1996, 90 FR 35241 (July 25, 2025).

Mutual banking organizations confront many of the same issues facing other community banks, including high compliance and technology costs relative to asset size, challenges with succession planning, an older depositor base, and competition from credit unions. Rising compliance and technology costs have contributed to consolidation across the banking industry, especially as many smaller institutions, including mutual banking organizations, have pursued mergers and acquisitions to achieve economies of scale, improve operational efficiency, and support technology and compliance infrastructure. These institutions are challenged with maintaining relationship-based community banking models while needing to invest in advances in financial technologies to meet evolving consumer expectations.

In addition, mutual banking organizations face issues specific to their mutuality. First, mutual banking organizations face constraints with respect to their ability to raise capital because of their unique ownership structure. Since mutual banking organizations are owned by their members, they have limited available options for raising capital. Stock-form banking organizations, on the other hand, generally are permitted to issue a range of capital instruments under their charters and applicable law. As a result, mutual banking organizations tend to rely heavily on retained earnings to meet capital requirements. While thrift MHCs can raise capital by having a subsidiary stock holding company conduct a minority stock issuance, mutual banking organizations historically have struggled to raise capital quickly without diminishing or ceding their mutuality.

In addition, since the Board assumed the regulation and supervision of thrift MHCs, it has found the regulatory framework applicable to such institutions to be overly complicated and burdensome. In the Board's view, thrift MHCs would benefit greatly from updates, clarifications, and modernizations to Regulation MM that would appropriately reduce burden, consistent with those organizations' safe and sound operations. The Board believes that the changes outlined in section II would achieve this goal through a simplified regulatory framework applicable to thrift MHCs that would make them more competitive in the modern banking environment.

II. The Proposal

The Board proposes to make changes to Regulation MM based on the Board's supervisory experience and consideration of feedback received from regulated entities. The Board is also proposing targeted changes to its capital rule to clarify the treatment of capital instruments issued by mutual banking organizations. The Board invites comments generally on any of the proposed changes to the capital rule and Regulation MM, or with respect to any other revisions to the regulatory framework applicable to MHCs that commenters believe may be appropriate. In addition, the Board invites comment in response to the specific questions included throughout this notice.

A. Changes To Support Capital Raising

As noted in section I.B., due to their mutuality, mutual banking organizations may be constrained in their ability to raise capital, especially common equity tier 1 [12] and additional tier 1 capital.[13] MHCs cannot issue traditional equity instruments and often rely on retained earnings to meet capital requirements. A subsidiary holding company in stock form can raise capital through a minority stock issuance; however, the amount that can be raised is limited, as the top-tier MHC must remain the majority shareholder. These constraints on the ability of mutual banking organizations to raise capital limit their ability to grow and to increase the amount of products and services they provide to their communities. In addition, the reliance on retained earnings as a source of capital for mutual banking organizations makes it difficult to establish a de novo mutual banking organization, which, by definition, will not have retained any earnings.

The Board is proposing modifications to both Regulation MM and to its capital rule that are meant to clarify and support mutual banking organizations' ability to raise capital.

1. Dividend Waivers

Dividend waivers can be an important tool for thrift MHCs to raise capital while still retaining their mutual form of ownership. When a thrift MHC waives its right to receive a dividend declared by its subsidiary holding company, the dividend that would otherwise be allocated to the thrift MHC is instead distributed to the other shareholders of the thrift MHC's subsidiary holding company. This reallocation helps increase the value of the public stock of the mid-tier holding company, improving its ability to attract investors for future capital raises. In doing so, dividend waivers also enable thrift MHCs to continue to compete with other similar institutions effectively without losing their mutuality by converting fully to stock form.

As mentioned in section I.A., many of the comments that the Board received on the IFR concerned dividend waivers. Some of the comments related to the procedural requirements associated with dividend waivers, including the specific items that must be provided to the Board in connection with a thrift MHC's notice of its intent to waive dividends. Regulation MM currently includes overly prescriptive procedural requirements. These requirements were designed to mitigate potential conflicts of interest concerns. When a thrift MHC's directors approve a waiver of dividends, they may directly benefit from the MHC's waiver of dividends.[14] Some commenters suggested that no conflict of interest exists or that the conflict is perceived or potential in nature. Other commenters acknowledged the conflict of interest but suggested that, because thrift MHC directors often also serve as directors of the mid-tier holding company and savings association, it is difficult or impossible to segregate the fiduciary duties the directors owe to each organization.

HOLA guarantees the ability of certain thrift MHCs to waive dividends, even if waiving dividends may benefit insiders of the organization, as long as such institutions comply with the Board's procedural requirements.[15] Specifically, thrift MHCs that waived dividends prior to December 1, 2009 (legacy waiver MHCs), may continue to do so if a 30-day notice has been submitted to the Board pursuant to Regulation MM in advance of the institution waiving its right to receive dividends.[16] As part of the notice, the board of directors of the thrift MHC must determine expressly that the dividend waiver is consistent with their fiduciary duties to the members of the thrift MHC.[17] Additionally, the notice must affirm that

[12] Common equity tier 1 capital is the most loss-absorbing form of capital. It includes, among other things, retained earnings and common stock (plus any related surplus), net of treasury stock, that meet certain criteria. *See* 12 CFR 217.20(b).

[13] Additional tier 1 capital instruments are intended to be available to absorb losses on a going-concern basis and can have a broader range of terms than common equity tier 1 instruments. *See* 12 CFR 217.20(c).

[14] *See* 2011 IFR at 56508, 56512; Letter from William W. Wiles, Secretary of the Board, to Kevin M. Houlihan, Greater Delaware Valley Holding, MHC (May 28, 1997).

[15] 12 U.S.C. 1467a(o)(11)(D)(iii).

[16] 12 CFR 239.8(d)(1)(ii).

[17] 12 CFR 239.8(d)(3)(ii). The resolution containing this determination from the board of directors must include a description of the conflict of interest that exists because of an MHC director's ownership of stock in the mid-tier holding company that is declaring dividends.

a majority of members eligible to vote have approved the waiver within the last 12 months.[18] Many of the comments on the IFR concerned the member vote requirement.[19]

HOLA does not guarantee expressly the ability of thrift MHCs that did not waive dividends prior to December 1, 2009 (non-legacy waiver MHCs), to do so. Therefore, in addition to the requirements applicable to legacy waiver MHCs, the Board by regulation has restricted non-legacy waiver MHCs from waiving dividends and they may only waive dividends if either (i) a majority of the entire thrift MHC board of directors approves the waiver, with any directors who would benefit directly or indirectly from the waiver, abstaining from the vote; [20] or (ii) any thrift MHC insider who would benefit from the waiver waives the right to receive any dividend.[21]

Since Regulation MM's promulgation in 2011, the Board has received input from many legacy waiver MHCs—both via comments on the IFR and the EGRPRA process—regarding the burdens and costs associated with the procedural requirements for waiving dividends. Most of the burdens and costs arise as a result of the requirement to seek the approval of a majority of members on an annual basis. The Board understands that members typically do not have any concerns with the potential conflicts of interest associated with dividend waivers; therefore, this annual vote requirement often represents an unnecessary expenditure of resources on the part of the legacy waiver MHC. Likewise, the Board understands from non-legacy waiver MHCs that, given the fact that many of their other shareholders are insiders or related parties, they are effectively prevented from issuing dividend waivers due to the additional requirement that either (i) a majority of the entire thrift MHC board of directors approve the waiver, with any directors who would benefit directly or indirectly from the waiver, abstaining from the vote; or (ii) any thrift MHC insider who would benefit from the waiver waives the right to receive any dividend. As a result, non-legacy waiver MHCs effectively are prevented from using dividend waivers to increase the value of the shares of their mid-tier holding companies. These restrictions thereby constrain the ability of these MHCs to raise capital and retain their mutuality.

Based on the comments received that the annual member vote requirement is overly burdensome, costly, and unnecessary, the Board is proposing to eliminate the requirement that legacy waiver MHCs affirm that a majority of members eligible to vote have approved the waiver within the last 12 months. As indicated in the comments, most members of the legacy waiver MHCs do not appear concerned with dividend waivers, have consistently voted to approve such waivers, and institutions and their management must spend significant time and money to encourage members to participate in the necessary vote under the present regulation.

Notwithstanding some of the assertions by commenters, the Board observes that dividend waivers may still present potential for conflicts of interest concerns. However, in connection with a dividend waiver notice, HOLA requires that a thrift MHC's board of directors must already determine that the dividend waiver is consistent with their fiduciary duties to members.[22] The Board believes that this determination is sufficient to mitigate any potential conflicts of interest concerns. Additionally, to ensure members are aware of these potential conflicts of interest concerns, the Board would require legacy waiver MHCs to make appropriate disclosures regarding dividend waivers to new members at time of opening of a deposit account or loan relationship.

Additionally, to create a more level playing field across thrift MHCs and in response to the comments received, the Board is proposing to allow non-legacy waiver MHCs also to waive dividends without requiring that either (i) a majority of the entire thrift MHC board of directors approve the waiver, with any directors who would benefit directly or indirectly from the waiver, abstaining from the vote, or that (ii) any thrift MHC insider who would benefit from the waiver waive their right to receive any dividend. Instead, consistent with the statutory distinction between legacy waiver MHCs and non-legacy waiver MHCs,[23] the proposal would require that non-legacy waiver MHCs affirm to the Board that, in a vote held within the past ten years, members have approved the dividend waiver. However, to reduce the burden associated with proxy solicitation outlined in the comments to the IFR, non-legacy waiver MHCs would not be required to obtain the approval of a majority of members eligible to vote, instead just a majority of votes cast.

Finally, all dividend waivers would remain subject to safety and soundness and applicable limitations.[24]

The Board seeks comment on all aspects of its proposed changes to the dividend waiver framework, particularly:

Question 1: Is the determination by the thrift MHC board of directors that dividend waivers are consistent with their fiduciary duties to the institution's members sufficient to mitigate any potential conflict of interest concerns with dividend waivers? Should the Board consider any alternative requirements? If so, what would be the advantages and disadvantages of those alternatives?

Question 2: Should the Board continue to maintain a distinction between its treatment of legacy waiver MHCs and non-legacy waiver MHCs? If so, is the balance struck by the proposal appropriate? If not, why not, and what would be the advantages and disadvantages of an alternative balancing?

Question 3: Is the requirement that non-legacy waiver MHCs obtain the approval of members on a decennial basis appropriate? Should non-legacy waiver MHCs be required to obtain the approval of members on a more or less frequent basis (such as every three years or every five years)? If so, why?

Question 4: Should the Board consider any additional changes to the procedural requirements associated with dividend waivers to reduce burden? If so, what would be the advantages and disadvantages of such additional changes?

[18] 12 CFR 239.8(d)(2)(iv).

[19] Some commenters noted that most members did not understand dividend waivers, requiring costly outreach and education, or do not care about dividend waivers. Those commenters asserted that, as a result, the member vote requirement was unnecessary and overly burdensome. Commenters also stated that members are not harmed by dividend waivers. Certain commenters further argued that members' interests in the thrift MHC do not rise to the level of shareholders' interests, and, therefore, members are not entitled to a vote on corporate governance matters in the same way as shareholders in a stock-form company. In addition to these substantive issues, commenters also raised concerns about the burden associated with the member vote requirement. Commenters noted that the cost and burden on management of obtaining the approval of a majority of the members eligible to vote is substantially greater than gaining the approval of members by a majority of votes cast at a meeting. Commenters pointed out that large numbers of members typically do not vote without significant efforts by management and significant expenditures by the thrift MHCs. Some of the commenters further stated that the cost and burden of obtaining member approval is magnified because section 239.8(d) of Regulation MM permits consideration of only one year's worth of dividend waivers at a time.

[20] 12 CFR 239.8(d)(4)(v)(A).

[21] 12 CFR 239.8(d)(4)(v)(B).

[22] 12 U.S.C. 1467a(o)(11)(D)(ii).

[23] 12 U.S.C. 1467a(o)(11).

[24] 12 U.S.C. 1467a(o)(11)(D)(i); 12 CFR part 238, subpart K.

2. Special Deposits and Mutual Capital Certificates

To further support mutual banking organizations' capital raising efforts, the Board proposes to amend sections 217.20(b)(1), (c)(1), and (d)(1) of its capital rule to clarify that special deposits and mutual capital certificates issued by a mutual banking organization can qualify as common equity tier 1, additional tier 1, or tier 2 capital,[25] respectively, if all of the qualifying criteria are satisfied. Special deposits are capital instruments issued by mutual banking organizations that may be especially useful as a means for newly formed organizations to raise capital. It is possible that the exact features and terms of special deposits may vary. However, a special deposit may be sold for a higher price; similar to equity stock, it could entitle holders to modest earnings based on bank profits, and may not be insured by the Federal Deposit Insurance Corporation. Mutual capital certificates are a form of instrument that mutual banking organizations can issue, to the extent authorized by their organizing documents and governing law, that can serve similar loss-absorbing functions as qualifying regulatory capital instruments. Mutual banking organizations may be able to issue additional forms of capital instruments beyond special deposits and mutual capital certificates. The goal of the proposal is to clarify that forms of capital instruments that the Board understands have been issued by mutual banking organization may qualify as regulatory capital and not to preclude any other form of instrument issued by mutual banking organizations from qualifying as regulatory capital.

There can be substantial variation in the form and terms of mutual capital certificates and special deposits. In order to qualify as common equity tier 1, additional tier 1, or tier 2 capital under the Board's capital rule, mutual capital certificates and special deposits must meet the qualifying criteria listed in section 217.20(b)(1)(i)–(xiii), section 217.20(c)(1)(i)–(xiv), or section 217.20(d)(1)(i)–(xi), respectively, of the rule. The proposed amendment would clarify that mutual capital certificates and special deposits are eligible for this treatment, as long as the qualifying criteria are met, giving increased certainty to issuing organizations.

The Board seeks comment on all aspects of its proposed changes to clarify the capital treatment of special deposits. In particular:

Question 5: What are the advantages and disadvantages of the Board's proposed changes to make clear that instruments that meet the definition of regulatory capital qualify as regulatory capital? Do the amendments to section 217.20(b)(1), 217.20(c)(1), and 217.20(d)(1) provide additional clarity regarding the treatment of special deposits in particular?

Question 6: What other steps, if any, should the Board take to enhance the ability of mutual banking organizations to raise qualifying capital? Are there any other changes that the Board could make to meaningfully broaden the market for these capital instruments, improving the ability for mutual banking organizations to raise qualifying capital?

3. Appendices to the Capital Rule

The second proposed modification to the capital rule concerns the treatment of mutual capital certificates, which are capital instruments issued by mutual banking organizations that may be eligible for treatment as common equity tier 1, additional tier 1, or tier 2 capital under the Board's capital rule, depending on their features. In October 2025, Board staff published on the Board's public website a set of frequently asked questions and two model term sheets to help clarify how mutual banking organizations may issue mutual capital certificates that qualify as regulatory capital, while maintaining mutuality.[26] One term sheet set out key terms for mutual capital certificates to be eligible to qualify as common equity tier 1 capital, while the other set out terms for qualification as additional tier 1 capital. Board staff requested public comment on the model term sheets by June 30, 2026.[27]

The Board has received some feedback on the model term sheets. A commenter recommended revisions to language in the term sheets that would clarify the permissibility of a disclosed target distribution rate and confirm that certificate holders are not considered members of the mutual banking organization solely by virtue of holding such certificates. In addition, the commenter recommended edits that would modify the provisions governing the seniority and subordination of mutual capital certificates relative to other capital instruments and liquidation claims, and that would prescribe the treatment of mutual capital certificates following corporate reorganizations or liquidation scenarios. Finally, the commenter suggested new sections to the term sheets: one addressing charter amendments and another discussing the permissibility and conditions under which depository institutions and their affiliates may invest in mutual capital certificates.

The Board now proposes to include these mutual capital certificate term sheets as appendices to the Board's capital rule, amended to reflect certain feedback received on the model term sheets published in October 2025. By adding these term sheets as appendices to the capital rule, the Board hopes to assist mutual banking organizations in developing capital instruments eligible for consideration under the rule. The term sheets are intended to serve as templates for mutual banking organizations to use as references when issuing capital instruments intended to qualify as common equity tier 1 or additional tier 1 capital.

In publishing these model term sheets as appendices to the Board's capital rule, the Board is incorporating certain changes recommended in the feedback received on the model term sheets. More specifically, the term sheets proposed as appendices to the capital rule in this proposal include revisions to clarify the permissibility of a disclosed nonbinding target distribution rate and to confirm that certificate holders are not considered members of the mutual banking organization solely by virtue of holding certificates. The Board believes these changes provide additional transparency to mutual banking organizations seeking to use the model term sheets.

The Board seeks comment on all aspects of the proposed appendices to the capital rule. In particular:

Question 7: What are the advantages and disadvantages of including the mutual capital certificate term sheets as appendices to the capital rule? Does incorporating the term sheets in the appendices to the capital rule limit in any way the flexibility mutual banking organizations have to craft their own instrument? Should the Board consider any changes to how it publishes or codifies the term sheets?

Question 8: Should the Board consider any additional changes to the provisions of the term sheets?

[25] Tier 2 capital instruments are the least loss-absorbing instruments permitted to be counted as regulatory capital. *See* 12 CFR 217.20(d).

[26] *See* ''Frequently Asked Questions about Regulation MM'' available at *www.federalreserve.gov/supervisionreg/legalinterpretations/reg-mm-frequently-asked-questions.htm.*

[27] Members of the public that seek to comment on the proposed model term sheets should review the proposed appendices included in this proposal and must submit comments in line with the procedures under this proposal.

4. Model Charter Amendments

In one of the frequently asked questions posted to the Board's public website, Board staff noted that a mutual banking organization must be legally authorized to issue mutual capital certificates and therefore should consult its charter and applicable law to determine whether it has the authority to issue such certificates. The frequently asked question noted that a Board-chartered mutual banking organization whose charter conforms to the Mutual Holding Company Model Charter provided at Appendix A to Regulation MM (Model Charter) would need to adopt a charter amendment in order to issue mutual capital certificates because the existing Model Charter states, ''The Mutual Holding Company shall have no capital stock.'' [28]

As outlined in section II.B.1.vi., the Board is proposing changes as part of this notice of proposed rulemaking that would eliminate the requirement that thrift MHCs' charters conform to the Model Charter. However, and as explained more fully in section II.B.1.vi., the Board intends to retain the Model Charter as an appendix to Regulation MM as an example document. To ensure the Model Charter remains a useful and up-to-date example, the Board is proposing to codify the staff guidance on mutual capital certificates, discussed in section II.A.4., by updating the Model Charter. Specifically, the Model Charter would be revised to include optional language authorizing the issuance of mutual capital certificates. Institutions need not amend their charters to incorporate this language if they do not wish to issue mutual capital certificates. However, if an institution seeks to issue mutual capital certificates, it should ensure that its charter allows such issuance and may wish to adopt the language in the revised Model Charter. Any mutual institution desiring to amend its charter must follow the procedures in section 239.14 of Regulation MM. Charter amendments consistent with the proposed amendment to the Model Charter generally would require only 30 days' prior notice, pursuant to section 239.14(a)(2)(ii) of Regulation MM, and not an application pursuant to section 239.14(a)(2)(i).

The Board seeks comment on all aspects of its proposed updates to the Model Charter, particularly:

Question 9: Should the Board consider any additional changes to the language included in the Model Charter to make clear that institutions may issue mutual capital certificates? What would be the advantages and disadvantages of any such changes?

B. Other Changes to Regulation MM

As discussed in section I.B., supervisory experience indicates that Regulation MM is overly complicated and burdensome for regulated entities. Because of the regulation's complexity, thrift MHCs are often required to obtain sophisticated and expensive legal counsel in order to ensure compliance with the rule. Such resources could be better utilized through re-investment in the mutual banking organization or in its local community. The Board believes the proposed changes would reduce the regulatory burden borne by these institutions.

1. Subpart B

Subpart B of Regulation MM governs the operations of thrift MHCs. It contains requirements regarding reorganization from a stand-alone mutual savings association structure into a thrift MHC structure. It also includes, among other things, requirements related to member rights, communications with members, and thrift MHC charters and bylaws. In addition, Subpart B outlines restrictions and requirements around acquisitions of other mutual savings associations, general operations and governance (including with respect to dividend waivers), and voluntary and involuntary liquidations of MHCs. The following section outlines the Board's proposed changes to Subpart B of Regulation MM.[29]

i. Reorganization Into the Multi-Tier Structure

Sections 239.3 and 239.4 of Regulation MM outline the procedural requirements associated with reorganization from a single-tier mutual savings association structure into a multi-tier MHC structure. Stand-alone mutual savings associations may seek to convert to a multi-tier structure for increased corporate flexibility and to be able to raise capital through a minority stock issuance. Such institutions must first develop a Reorganization Plan (Plan),[30] that contains all of the provisions outlined in section 239.6 of Regulation MM [31] and is approved by a majority of the savings association's board of directors.[32] The Plan also must be voted upon by the savings association's members and receive the approval of a majority of the total votes eligible to be cast at a meeting.[33] Additionally, the mutual savings association must submit a Reorganization Notice to the Board [34] and receive all necessary regulatory approvals.[35] Section 239.4 then outlines the grounds under which the Board may disapprove a proposed MHC reorganization.[36]

At this time, the Board does not propose to amend the requirements associated with a mutual savings association's reorganization into a multi-tier structure. However, the Board invites comment on whether it should amend the procedural requirements or disapproval standard in any way, including to reduce burden for reorganizing mutual savings associations.

Question 10: What changes, if any, should the Board consider making to the procedural requirements associated with MHC reorganizations under section 239.3 of Regulation MM? What would be the advantages and disadvantages of any such changes?

Question 11: What value, if any, is served by the member vote requirement, provided at section 239.3(a)(3), for reorganization into the MHC structure? Is the vote standard of approval by a majority of the total votes eligible to be cast appropriate and why? If not, what alternatives should the Board consider, and what would be the advantages and disadvantages of such alternatives?

Question 12: What changes, if any, should the Board consider making to the approval standard for reorganizations, provided at section 239.4 of Regulation MM? What would be the advantages and disadvantages of any such changes?

Question 13: What changes, if any, should the Board consider making to the contents and provisions that must be included in a Plan submitted under section 239.6 of Regulation MM? What would be the advantages and disadvantages of any such changes?

ii. Membership Rights

Section 239.5(a) of Regulation MM currently addresses membership rights of depositors and borrowers of resulting associations and target mutual savings associations. It provides that when a mutual savings association reorganizes into the thrift MHC structure, the members of the savings association must receive the same membership rights in the new thrift MHC as they had held in

[28] 12 CFR part 239, app. A.

[29] For proposed changes with respect to dividend waivers, *see* section II.A.1. above.

[30] 12 CFR 239.2(o); 12 CFR 239.3(a).

[31] 12 CFR 239.6.

[32] 12 CFR 239.3(a)(1).

[33] 12 CFR 239.3(a)(3).

[34] 12 CFR 239.2(n); 12 CFR 239.3(a)(2).

[35] 12 CFR 239.3(a)(4).

[36] 12 CFR 239.4.

the mutual savings association.[37] It also provides that, when a thrift MHC acquires a mutual savings association, the members of the target mutual savings association must receive membership rights in the acquiring thrift MHC.[38] However, section 239.5 of Regulation MM does not currently contemplate a thrift MHC's acquisition of another MHC, likely because that such transactions were rare when the OTS first issued the regulation.

The Board proposes to modify section 239.5(a) to add that the members of a target thrift MHC will receive the same membership rights in the acquiring MHC as those conferred upon the members of the acquiring thrift MHC. This change would help guarantee that the rights of the members of a target MHC remain equivalent to those of the acquiring MHC's members. It also would align section 239.5(a) of Regulation MM with existing practice, as thrift MHCs typically have granted membership rights to the members of target thrift MHCs upon consummation of the acquisition. Similarly, section 239.5(b) of Regulation MM would be amended to ensure that membership rights would be conferred upon target MHC members regardless of whether the thrift subsidiaries are merged into a single institution by the acquiring MHC or continue operations as stand-alone institutions.

Question 14: Are there additional advantages or disadvantages of the proposed change to the membership rights provisions that the Board should consider? If so, what?

Question 15: What additional changes, if any, should the Board consider in order to clarify the membership rights afforded to the members of a target thrift MHC? What would be the advantages and disadvantages of any such changes?

Question 16: What additional burden, if any, is imposed by the proposed change to the membership rights provisions? Are the Board's proposed amendments the most appropriate way to guarantee the membership rights of a target thrift MHC, or should the Board consider other changes? If so, what would be the advantages and disadvantages of any such changes?

iii. Acquisitions

Section 239.7 of Regulation MM outlines requirements and restrictions associated with the acquisition by a thrift MHC of a savings association, SLHC, or other corporation.[39] In particular, section 239.7(a)(3) provides that, with respect to a thrift MHC's acquisition of another thrift MHC, ''[t]he approval of the members of the mutual holding companies shall also be obtained if the Board advises the mutual holding companies in writing that such approval will be required.'' This language applies broadly to both an approval by the members of the acquiring institution and to an approval by the members of the institution to be acquired. Currently, Regulation MM does not include any information regarding the factors that the Board may consider in determining whether to require the approval of either institution's members. This lack of transparency can cause confusion for institutions and contribute to delays in the processing of applications.

The Board proposes to amend section 239.7(a) to codify factors that the Board or Reserve Bank would evaluate in considering whether to require approval by an institution's members. The proposed factors reflect facts that the Federal Reserve historically has considered when evaluating whether a member vote may be warranted. Specifically, the proposal would update section 239.7(a) to include four factors that the Board or Reserve Bank shall consider in determining whether approval by members will be required. These factors would include: (i) the corporate governance structure of the thrift MHC; (ii) the ability of members to vote on any future mutual-to-stock conversion of the resulting thrift MHC; (iii) the supervisory condition of the institution that would be acquired; and (iv) the burden and cost associated with obtaining the members' approval.

In considering the corporate governance factor, the Board would take into consideration members' opportunities for direct participation in corporate governance matters following consummation of the transaction. If, as a result of the transaction, the members of either institution would have fewer opportunities to participate in corporate governance, this proposed factor may suggest a member vote by the affected institution may be warranted. Likewise, if, as a result of the transaction, members of either institution would not have the ability to vote on any future mutual-to-stock conversion of the resulting institution, the second proposed factor may indicate a member vote by the affected institution may be warranted. Next, under the third proposed factor, the Board would weigh the supervisory condition of the target institution and whether potential delays associated with obtaining members' approval could exacerbate the institution's existing condition or delay its resolution. Under the fourth proposed factor, the Board would consider the cost and burden upon either institution associated with obtaining its members' approval. In situations where the cost of obtaining members' approval represents a significant expenditure, especially with respect to the institution's annual earnings, a member vote may not appear reasonable.

The Board invites comment on all aspects of its proposed changes to codify the factors it would consider in determining whether to require members' approval of an MHC's acquisition of another mutual banking organization, particularly with respect to the following:

Question 17: What are the advantages and disadvantages of the Board requiring thrift MHCs to obtain members' approval of an acquisition by or of another thrift MHC? Should the Board consider requiring this only in specific circumstances and, if so, what would be the appropriate circumstances?

Question 18: What are the advantages and disadvantages of the proposed factors for determining whether to require members' approval? Should the Board consider any other factors in determining whether to require thrift MHCs to obtain members' approval of an acquisition by or of another thrift MHC? If so, what other factors should the Board consider, and what would be the advantages and disadvantages of including those factors?

Question 19: Should the Board consider making any other changes to the requirements and restrictions associated with a thrift MHC's acquisition of a savings association, SLHC, or other corporation?

iv. Running Proxies

In the Board's experience, many thrift MHCs rely on ''running'' proxies as a corporate governance tool. Section 239.10(a)(4) provides that an MHC ''may make use of any proxy conferring general authority to vote on any and all matters at any meeting of members,'' although so-called ''running'' proxies ''may not be used to vote for a [thrift MHC] reorganization, mutual-to-stock conversion undertaken by a [thrift MHC], dividend waiver, or any other material transaction.'' [40] The Board does not propose to change its approach to running proxies. However, the Board invites comment on all aspects of its

[37] 12 CFR 239.5(a)(1); 12 CFR 239.5(a)(3).

[38] 12 CFR 239.5(a)(2); 12 CFR 239.5(a)(4).

[39] 12 CFR 239.7(a)(6).

[40] 12 CFR 239.10(a)(4).

rules related to running proxies, particularly:

Question 20: What are the advantages and disadvantages of the Board's existing limitations around the use of running proxies—specifically, that they cannot be used to vote for a thrift MHC reorganization, mutual-to-stock conversion, dividend waiver, or any other material transaction? Should the Board consider incorporating any additional limitations around the use of running proxies? Why or why not? What would be the advantages and disadvantages of any such additional limitations? Alternatively, should the Board consider allowing running proxies to be used to vote for a thrift MHC reorganization, mutual-to-stock conversion, dividend waiver, or any other material transaction? If so, why?

v. Postal Mail Requirements

As noted in section I., Regulation MM adopted with minimal changes the predecessor regulations of the OTS, which had first been finalized in 1993. At the time the OTS first implemented these predecessor regulations, email was not widely accessible and postal mail was the primary form of communication. As a result, Regulation MM contains numerous references to postal mail, requiring thrift MHCs to communicate with members almost exclusively via physical mail. For instance, section 239.12 of Regulation MM sets out the right of members to communicate with other members of the thrift MHC but provides solely for physical mail communication. Additionally, provisions regarding stock issuances by a mid-tier holding company and those with respect to conversion offerings exclusively refer to communications with members being ''mailed.''

The varying physical mail requirements throughout Regulation MM are out-of-date, costly, and unduly burdensome for institutions. Therefore, the proposal updates various provisions in subparts B, C, and E of Regulation MM, as well as in the Appendices to the regulation, to change references to ''mailing'' certain information or communications to ''sending'' certain information or communications. The Board intends through this change to allow institutions to use electronic mail or other available technology to notify its members instead of relying on physical, postal mail, consistent with all other federal and state law. The Board believes these changes will modernize Regulation MM, reduce expenses for thrift MHCs, and provide increased flexibility for both institutions and their members.

The Board seeks comment on all aspects of its proposed changes to allow institutions greater flexibility in its communications with members, particularly:

Question 21: Are there any communications that the Board should specifically require to be physically mailed to members? Are there any for which confirmation of receipt or some other notice of receipt should be required?

Question 22: What are the advantages and disadvantages of the Board's proposed changes to improve the flexibility of thrift MHCs options for communicating with members? Should the Board consider additional or alternative changes? If so, what would be the advantages and disadvantages of such changes?

Question 23: Given the continued advancement of communication technologies, is the term ''send'' sufficiently flexible enough to give thrift MHCs optionality in how they communicate with their members? Should the Board consider using a different term than ''send,'' such as ''provide,'' in order to ensure thrift MHCs have sufficient flexibility to adapt to new communication technologies? What would be the advantages and disadvantages of using a term other than ''send'' for describing how thrift MHCs must communicate with members?

vi. Charter and Bylaws

Regulation MM provides model charters and bylaws for thrift MHCs and their mid-tier holding companies in Appendices A through D.[41] Subparts B and C of Regulation MM contain numerous references to thrift MHCs and their subsidiary holding companies needing to comply with the provisions of the model charter and bylaws. For instance, section 239.6(a) of Regulation MM requires that the charter and bylaws of a mutual savings association reorganizing into a multi-tier structure ''read in the form of the charter and bylaws of a mutual holding company, and attach and incorporate such charter and bylaws.'' [42] Likewise, section 239.11(c) mandates that the charter and bylaws of a subsidiary holding company of a thrift MHC ''be in the form set forth in Appendices B and D, respectively.'' [43] The Board does not believe such prescriptions are necessary. Therefore, in order to promote corporate flexibility, the Board proposes to abolish the requirements that thrift MHCs and their subsidiary holding companies adopt the model charters and bylaws, although the Board would retain the authority to review proposed charters and bylaws as part of its review of the formation of thrift MHCs and their subsidiary holding companies.[44] Additionally, a thrift MHC seeking to make any changes to its charter would continue to be required to follow the procedures outlined in section 239.14 of Regulation MM.[45]

Although the Board proposes to remove the requirements that a thrift MHC and its subsidiary holding company adopt the model charters and bylaws, the Board would retain the model charters and bylaws as appendices to Regulation MM as examples and would retain provisions contained in subparts B and C of Regulation MM identifying terms that thrift MHCs and their subsidiary holding companies may include in their charters and bylaws. The Board believes that it may be helpful to thrift MHCs and their subsidiary holding companies to retain these as example documents, even though these institutions will no longer be required to adhere to them. Small institutions and institutions without sophisticated counsel may particularly benefit from the provision of example documents. Additionally, as described in section II.A.4., the Board is implementing changes to the Model Charter that institutions may implement should they wish to be able to issue mutual capital certificates.

The Board seeks comment on all aspects of its proposed changes to the model charters and bylaws provided in the appendices to Regulation MM, particularly:

Question 24: What are the advantages and disadvantages of the Board removing the requirements contained throughout Regulation MM that an MHC and its subsidiary holding company adhere to the model charters and bylaws provided in the appendices to Regulation MM? How could removal of these requirements improve corporate flexibility?

Question 25: Are the model charters and bylaws provided in the appendices to Regulation MM useful? What are the advantages and disadvantages of retaining these model charters and bylaws but not requiring adherence to them? Should the Board remove the

[41] *See* 12 CFR part 239, app. A, ''Mutual Holding Company Model Charter''; 12 CFR part 239, app. B, ''Subsidiary Holding Company of a Mutual Holding Company Model Charter''; 12 CFR part 239, app. C, ''Mutual Holding Company Model Bylaws''; 12 CFR part 239, app. D, ''Subsidiary Holding Company of a Mutual Holding Company Model Bylaws.''

[42] 12 CFR 239.6(a).

[43] 12 CFR 239.11(c).

[44] 12 CFR 239.3; 12 CFR 239.4.

[45] 12 CFR 239.14.

model charters and bylaws from the appendices to Regulation MM?

Question 26: What are the advantages and disadvantages of retaining the provisions throughout subparts B and C of Regulation MM identifying the terms that MHCs and their subsidiary holding companies may include in their charters and bylaws? Would retaining these provisions contribute to the unnecessary complexity of the overall regulation? Should the Board instead remove these provisions?

vii. Voluntary Dissolution

Regulation MM permits a thrift MHC to propose a plan of voluntary dissolution.[46] In addressing voluntary dissolutions, section 239.16(b) of Regulation MM currently provides that the Board will approve a proposed dissolution plan if the plan is ''advisable'' and ''best for all concerned.'' Similarly, section 239.16(a)(2) provides that a thrift MHC's directors, when proposing a plan for dissolution, may propose a plan that provides for dissolution in a manner that the directors consider ''best for all concerned.'' [47] In the Board's experience, these standards are confusing for thrift MHCs seeking to dissolve back into the single-tier mutual savings association structure and contribute to unnecessary delays in applications processing. The Board proposes to amend section 239.16(b) to (i) remove the terms ''advisable'' and ''best for all concerned'' from its standard of review, (ii) clarify that the Board will consider impact of the dissolution on the thrift MHC's members and other relevant parties (such as, creditors), and (iii) state that the Board may approve the plan if dissolution is appropriate under the circumstances. This proposed amendment is consistent with the Federal Reserve's current approach to considering whether to approve a dissolution plan and provides clarity on the focus and scope of review. The Board believes that this change would reduce ambiguity for thrift MHCs seeking to dissolve into a single-tier mutual savings association structure and facilitate expeditious processing of applications for voluntary dissolution. Similarly, the Board proposes to amend section 239.16(a)(2) of Regulation MM to provide that directors may propose a plan of dissolution that provides for dissolution in a manner that appropriately takes into account the impact of the proposed dissolution on the thrift MHC's members and other relevant parties like creditors. A requirement that the plan be ''appropriate'' rather than ''consider[ed] best'' by the directors would better align with the Board's standard of review for assessing the plan, and the Board would have a better ability to assess compliance with the revised requirement.

The Board seeks feedback on all aspects of its proposed changes to the voluntary dissolution standard, particularly:

Question 27: What are the advantages and disadvantages of replacing the current ''advisable'' and ''best for all concerned'' standard for the Board's review of plans of voluntary dissolution with the proposed standard? Is the proposed standard sufficiently clear? What modifications to the proposed standard should the Board make in order to make it clearer or more appropriate for assessing plans of voluntary dissolution?

Question 28: Is the proposed standard for plans of dissolution proposed by directors sufficiently clear? Should the Board consider alternative approaches? If so, what would be the advantages or disadvantages of such alternatives?

2. Subpart C

Subpart C of Regulation MM governs the operations of mid-tier holding companies of MHCs. It contains requirements relating to the general governance of subsidiary holding companies of thrift MHCs, including with respect to their charter and bylaws. It also contains detailed provisions regarding issuances of stock by subsidiary holding companies of thrift MHCs. The following section outlines the Board's proposed changes to Subpart C of Regulation MM.

i. Chartering of Subsidiary Holding Companies of Thrift MHCs

Prior to the transfer of supervision of SLHCs to the Board in 2011, the OTS was the chartering authority for thrift MHCs and their subsidiary holding companies. When the Board took over supervision of SLHCs from the OTS in 2011, it became the chartering authority for thrift MHCs and their subsidiary holding companies.[48]

HOLA specifically requires the Board to charter thrift MHCs.[49] Regulation MM also requires subsidiary holding companies of thrift MHCs to be chartered by the Board.[50] However, although HOLA explicitly requires a thrift MHC to be chartered by the Board, it does not explicitly require a subsidiary holding company of a thrift MHC to be chartered by the Board. To allow for greater flexibility, including with respect to choice of corporate structure,[51] the Board proposes to eliminate the requirement that subsidiary holding companies of thrift MHCs have federal charters. This proposed change would allow subsidiary holding companies of thrift MHCs to obtain a validly issued charter from any state, as defined by section 238.2(nn) of Regulation LL.[52] A subsidiary holding company of a thrift MHC would not be required to obtain a charter from the state in which its main office is located or in which its MHC parent or subsidiary depository institution operates.[53] As a result of this change, subsidiary holding companies of MHCs would have increased flexibility to select the appropriate chartering entity while remaining subject to applicable provisions of Regulation MM (in particular sections 239.24 and 239.25 of Regulation MM, which govern issuances of stock by subsidiary holding companies).

The Board invites comment on its proposal to eliminate the requirement that subsidiary holding companies of MHCs be chartered by the Board, particularly:

Question 29: What are the advantages and disadvantages of allowing subsidiary holding companies of thrift MHCs to organize under state law rather than requiring they be chartered by the Board?

Question 30: What are the advantages and disadvantages of the proposal to allow a subsidiary holding company of a thrift MHC to organize in a state of its choosing? Should the Board instead require a subsidiary holding company of a thrift MHC to organize in the state in which its subsidiary depository institution operates or maintains its main office, or based on some other qualification or criteria? What would be

[46] 12 CFR 239.16(b).

[47] Alternatively, the plan may provide for ''[t]ransfer of all the mutual holding company's assets to another mutual holding company or home-financing institutions under Federal charter either for cash sufficient to pay all obligations of the mutual holding company and retire all outstanding accounts or in exchange for that mutual holding company's payment of all the mutual holding company's outstanding obligations and issuance of share accounts or other evidence of interest to the mutual holding company's members on a pro rata basis.'' 12 CFR 239.16(a)(1).

[48] 12 CFR 239.11(c) and 239.21.

[49] 12 U.S.C. 1467a(o)(7).

[50] 12 CFR 239.11(c).

[51] For example, organizing under state law may allow a subsidiary holding company of a thrift MHC to be organized as a corporation, LLC, or some other corporate form. Currently, subsidiary holding companies may organize only as Federal corporations.

[52] 12 CFR 238.2(nn).

[53] This is consistent with the flexibility available generally to bank holding companies concerning corporate form.

the advantages or disadvantages of those alternate criteria or requirements?

ii. Issuances of Stock by Subsidiary Holding Companies of MHCs

The Board is proposing a series of amendments to sections 239.24 and 239.25 of Regulation MM that concern stock issuances by mid-tier holding companies of thrift MHCs. These provisions are unnecessarily complex, creating an undue burden for the subject institutions. The Board's proposed changes are intended to simplify and streamline the applicable provisions and to reduce cross-references to other provisions within the regulation as much as possible so that the requirements are clearer. The proposed updates are intended to make the regulation easier to understand, reducing burden on institutions and allowing for expeditious processing of applications.

First, the Board proposes amendments to sections 239.24 and 239.25 of Regulation MM to clarify the provisions that apply to stock issuances solely to a stock benefit plan, employee stock ownership plan, stock option plan, or management recognition plan (collectively, a stock plan for employees). Currently, sections 239.24 and 239.25 of Regulation MM do not distinguish between stock issuances involving the public offering and sale of shares in the MHC's subsidiary holding company and stock issuances solely to a stock plan for employees. As a result, institutions can face uncertainty regarding the exact provisions of Regulation MM that apply to a particular proposed issuance. Some of the changes to sections 239.24 and 239.25 of Regulation MM are intended to address this unnecessary source of confusion by clarifying the provisions that do not apply to stock issuances solely to a stock plan for employees.

The Board proposes further to streamline the requirements related to stock issuances to a stock plan for employees under sections 239.24 and 239.25. Currently, section 239.25 includes many provisions regarding the size of a proposed issuance to a stock plan for employees. These requirements can be confusing and require the retention of sophisticated legal counsel. The Board proposes to streamline these requirements to make them both easier to understand and to simplify compliance. Rather than include many varied requirements regarding the size of each stock plan for employees, the Board proposes instead to require only (i) that all stock plans for employees not, at any given time, hold in the aggregate more than either 4.9 percent of the outstanding shares of the subsidiary holding company's common stock or 4.9 percent of the subsidiary holding company's stockholders' equity; and (ii) that at the close of the proposed issuance, the amount of stock authorized to be issued or acquired by all stock plans for employees may not exceed, in the aggregate, 25 percent of the outstanding shares of the subsidiary holding company's common stock or 25 percent of the subsidiary holding company's stockholders' equity. These requirements are intended to ensure that a stock plan for employees does not become an SLHC. The Board believes that these proposed changes are easier to understand and, therefore, less burdensome for regulated institutions.

In addition to changes intended to clarify the requirements applicable for stock issuances to stock plans for employees, the Board also proposes changes to sections 239.24 and 239.25 to clarify the applicability of certain requirements contained in subpart E of Regulation MM. Currently, sections 239.24 and 239.25 of Regulation MM include many confusing cross-references to subpart E of Regulation MM, which can be difficult for regulated entities to understand and require the retention of sophisticated counsel. The Board proposes changes to sections 239.24 and 239.25 to make clearer the interaction between these parts of the regulation. Specifically, the Board proposes changes to section 239.24(a) of Regulation MM to clarify the applicability of the convenience and needs standard to a proposed minority stock issuance. Additionally, the Board proposes changes to section 239.25(c) to indicate expressly the applicability of provisions of section 239.63(a)(1) of Regulation MM to minority stock issuances.

The Board invites comment on all aspects of its proposed changes to the rules regarding issuances of public stock by MHCs' subsidiary holding companies, particularly:

Question 31: Are the proposed changes sufficient to make clear which provisions of sections 239.24 and 239.25 apply to proposed stock issuances solely to a stock plan for employees? How could the Board better delineate the requirements applicable to stock issuances solely to a stock plan for employees?

Question 32: What are the advantages and disadvantages of the proposed changes regarding the size of a stock plan for employees? Do the proposed changes adequately simplify the size thresholds applicable to stock issuances to a stock plan for employees? What, if any, alternatives should the Board consider and why?

Question 33: Do the proposed changes to sections 239.24 and 239.25 of Regulation MM make clear which provisions of subpart E of Regulation MM are applicable to a stock issuance by a subsidiary holding company of a thrift MHC? What other clarifying changes should the Board consider making to sections 239.24 and 239.25 of Regulation MM to better indicate what provisions of subpart E are applicable to stock issuances by a subsidiary holding company of a thrift MHC?

Question 34: What other changes should the Board consider making to the requirements applicable to stock issuances by a subsidiary holding company of a thrift MHC? What would be the advantages and disadvantages of any such change?

3. Subpart E

Subpart E of Regulation MM governs how a thrift MHC may convert from the mutual-to-stock form of ownership. It includes numerous requirements related to the process of conversion and also contains limitations on certain actions of a converted stock holding company within the first few years of completion of the conversion. The Board is proposing several changes to subpart E of Regulation MM. These changes are intended to reduce the regulatory burden associated with mutual-to-stock conversions and to implement corrections to known drafting errors in the regulation.

i. Definition of Qualifying Deposits

Section 239.52 of Regulation MM sets forth definitions applicable to subpart E and the forms prescribed by it.[54] In particular, section 239.52(j) currently defines ''qualifying deposit'' to include ''the total balance in an account holder's savings accounts.'' [55] ''Savings account,'' in turn, is currently defined by section 239.2(r) of Regulation MM to mean ''any withdrawable account, except a demand account, a tax and loan account, a note account, a United States Treasury general account, or a United States Treasury time deposit-open account.'' [56] Because demand accounts are excluded from the definition of savings accounts, they also are excluded from the definition of ''qualifying deposits'', and as a result, demand deposit holders are currently not entitled to liquidation rights under Regulation MM. However, many thrift MHCs grant membership rights,

[54] 12 CFR 239.52.

[55] 12 CFR 239.52(j).

[56] 12 CFR 239.2(r).

including liquidation rights, to holders of demand accounts. Therefore, in order to be able to grant such individuals their promised membership rights, such institutions presently must request a waiver from the definition of qualifying deposits to ensure that demand deposit holders receive the liquidation rights associated with their membership. These waivers are unnecessarily burdensome on institutions seeking only to comply with the membership rights granted under the thrift MHC's organizational documents.

Therefore, the Board is proposing to amend the definition of ''savings account'' in section 239.2(r) of Regulation MM to include demand accounts. Because the definition of qualifying deposits provided at section 239.52(j) of Regulation MM uses the term ''savings account,'' this proposed change would have the effect of incorporating demand deposits into the definition of qualifying deposits for purposes of subpart E of Regulation MM. Additionally, to ensure that thrift MHCs are not required to grant liquidation rights to demand deposit holders, the definition of ''qualifying deposit'' in section 239.52(j) of Regulation MM would be amended to mean ''the total balance in an account holder's eligible savings account at the close of business on the eligibility or supplemental eligibility record date.'' As a result of this proposal, thrift MHCs that grant membership rights to demand deposit holders would no longer have to request a waiver of the definition of ''qualifying deposits'' in connection with their mutual-to-stock conversion, reducing burden for both the institutions and the Federal Reserve System. However, thrift MHCs would not be required to grant liquidation rights to such demand deposit holders.

Question 35: What are the advantages and disadvantages of the Board's proposed amendment to the definition of ''savings account,'' provided at section 239.2(r) of Regulation MM? Does the Board's proposed amendment to the definition of ''savings account'' ensure that demand deposit holders receive the liquidation rights associated with their membership? Should the Board consider alternative provisions and if so, what would be the advantages and disadvantages of such alternatives?

ii. Forms

Regulation MM includes requirements to file information in connection with certain proposals involving thrift MHCs, including the reorganization of a savings association into the MHC structure, stock issuances of subsidiary holding companies of thrift MHCs, and conversions of thrift MHCs to stock form. Among other reporting forms, applicants may be required to file a Proxy Statement (FR MM–PS or Form PS), Offering Circular (FR MM–OC or Form OC), or Order Form (FR MM–OF or Form OF). The Federal Reserve uses information submitted by an applicant or notificant on these forms to evaluate the aforementioned transactions with respect to the relevant statutory and regulatory factors.

a. FR MM–PS

The Form PS, otherwise known as the proxy statement, is used to provide members of the applicant mutual savings association or thrift MHC with information necessary to vote on a reorganization of the applicant to the thrift MHC structure, a conversion of the applicant from mutual-to-stock form, or other transactions. Information required by Regulation MM and Form PS includes, among other things, the notice of the members' meeting; description of the voting rights of the mutual members; the vote threshold required for approval of each matter presented for a vote; and presentation of business, financial, and managerial information of the organization. A proxy statement must be disclosed to all members prior to a member vote,[57] and must be submitted to the appropriate Reserve Bank in connection with a notice to reorganize into the MHC structure or an application to convert from mutual to stock form.[58] Subpart E of Regulation MM also contains certain additional procedural and informational requirements for proxy statements. Proxies requesting accountholder approval of an MHC reorganization or non-conforming minority stock issuance also must comply with the informational requirements of sections 239.10(a)(2) and 239.10(a)(3) of Regulation MM, respectively, as well as any other applicable federal and state laws and regulations.

b. FR MM–OC

A thrift MHC that files an application in connection with a stock issuance conducted as part of any transaction or proposal pursuant to HOLA and Regulation MM must file Form OC with the appropriate Reserve Bank.[59] An offering circular must accompany Form OC and such offering circular must be prepared in accordance with applicable state law and rules and regulations promulgated by the U.S. Securities and Exchange Commission (SEC).

c. FR MM–OF

A thrift MHC that applies for Board approval of its conversion from mutual-to-stock form must submit Form OF along with order forms to the Federal Reserve and distribute such order forms to all eligible account holders, supplemental eligible account holders, and other voting members to enable them to subscribe for the shares they are permitted under the proposed transaction. If applicable, order forms provided to the Board should comply with state law and be in the same format as any order forms that the applicant has provided to the SEC.

d. Elimination of Form OC and Form OF

In general, submission of these forms in connection with certain applications can create burden for thrift MHCs, especially given that much of the information contained in these forms is, in some manner, duplicative of information provided to the SEC. Therefore, in order to reduce burden, the Board proposes to eliminate the requirements in section 239.50 to submit the Form OC and Form OF to the Federal Reserve in connection with transactions involving thrift MHCs. Additionally, while the Board intends to retain the requirement that institutions submit Form PS, it proposes to streamline the form itself by removing many of the requirements contained within the General Instructions to the form.

With respect to Form OC and Form OF, the Board proposes to eliminate both the forms themselves and the references to them in sections 239.58 and 239.59, respectively, as well as their respective General Instructions. The General Instructions to Form OC state that offering circulars must be prepared in accordance with applicable state law and rules and regulations promulgated by the SEC. These instructions do not provide any specific guidance related to content necessary for Board review of Form OC. Likewise, Form OF's General Instructions state that order forms provided to the Board should comply with state law, as applicable, and be in the same format as any order forms that the applicant has provided to the SEC. Such instructions again do not provide any Board-specific guidance or request Board-specific information. Therefore, the Board may eliminate these unnecessary forms and reduce burden for thrift MHCs.

Question 36: What are the advantages and disadvantages of the Board retaining Form OC or Form OF and their

[57] 12 CFR 239.56(c).

[58] 12 CFR 239.10(a)(1) (notice to reorganize into mutual form); 12 CFR 239.55(b)(1)(iii) (application to convert from mutual-to-stock form).

[59] *See* 12 CFR 239.58.

respective General Instructions? Are there instances in which SEC rules and regulations regarding offering circulars and order forms would not apply to a given stock issuance (for instance, in situations where an institution does not meet Nasdaq or regional listing requirements)? If so, in the alternative, should the Board instead retain and update Form OC or Form OF?

e. Streamlining Form PS

With respect to Form PS, the Board intends to retain the form itself, but reduce many of the requirements contained in the form's General Instructions. While the SEC sets out rules and regulations regarding proxy soliciting materials, its requirements relate to securities issuances generally, without any specific requirements that may be appropriate for transactions applicable to mutual banking organizations and their members, such as conversions from mutual-to-stock form. The SEC's rules and regulations do not appear to specifically contemplate either the unique circumstances of a conversion or the appropriate disclosures to members in such instance. The Board's Form PS, though, contains disclosure requirements targeted to inform members of matters on which they will be asked to vote, including conversion transactions. These disclosures include the planned use of conversion proceeds and members' rights following consummation of the conversion. Therefore, the Board believes certain elements of the General Instructions to Form PS remain important to ensuring compliance by an MHC with its obligations to its members.

However, the Board believes many of the requirements contained in the General Instructions to Form PS are unnecessary and duplicative of the requirements of the SEC's Schedule 14A and applicable rules and regulations (SEC proxy regulations).[60] Accordingly, the proposal would eliminate the following items. First, the proposal would eliminate the requirements under Item 1 from the General Instructions to Form PS. The information contained in Item 1 regarding the member vote, its date, location, and the matters to be considered, is already required to be included in a proxy statement by the SEC proxy regulations. Therefore, the proposal would remove all of the requirements under the existing Item 1 from the General Instructions to Form PS.

The proposal would eliminate Item 3 regarding persons soliciting proxies from the General Instructions to Form PS as it is also duplicative of information required to be included in a proxy statement by the SEC proxy regulations. Additionally, existing Item 3(2) from the General Instructions to Form PS requires institutions to describe the method it will use to solicit proxies, unless it solicits by mail. This instruction has the effect of encouraging institutions to solicit proxies by mail. However, as discussed in section II.B.1.v., physical mail requirements are out-of-date, costly and unduly burdensome for institutions. Therefore, the proposal would remove Item 3 of the General Instructions to Form PS.

Next, the proposal would eliminate the existing Item 4(2) and (3) from the General Instructions to Form PS. These items require institutions to disclose the record date for individuals entitled to vote at the meeting and the vote required for approval of each matter to be considered at the meeting. This information must already be disclosed in connection with SEC proxy regulations. Therefore, the proposal would eliminate Item 4(2) and Item 4(3) from the General Instructions to Form PS.

The proposal would also eliminate Items 5 and 6 from the General Instructions to Form PS. Item 5 covers directors and executive officers of the institution, while Item 6 concerns management compensation. Both of these items include cross-references to requirements and forms promulgated by the SEC, and such information appears unnecessary to either the Board's review of the proxy statement and any associated filing or members' determination as to whether to furnish such proxy. The Board, therefore, proposes to remove the existing Items 5 and 6 from the General Instructions to Form PS.

Next, Item 7 of the General Instructions to Form PS requires institutions to furnish specific information concerning their business. Such information includes requirements concerning a description of the business, certain financial data, and management's views and analysis regarding the institution's operations. Most of the informational requirements outlined in Item 7 can be streamlined. The proposal would update Items 7(1), 7(2), and 7(3) to eliminate excessive detail. The proposal would also remove the existing Item 7(4) as duplicative of information already encompassed in Item 7. Finally, the proposal would eliminate Item 7(13), as it only includes cross-references to SEC requirements.

Finally, Items 8 through 13 of Form PS outline requirements applicable only in the case of a mutual-to-stock conversion. Generally, such requirements are unique to the context of thrift MHCs and would not be otherwise covered by the SEC's proxy regulations. Retaining such requirements is important to ensure members are sufficiently informed regarding the proposed conversion. The proposal would keep all of these items except for elements of Item 9. In general, Item 9 requires a description of the entity's stock. Items 9(1) and 9(2) are duplicative of requirements imposed by the SEC. Therefore, the proposal would eliminate Items 9(1) and 9(2), but otherwise retain Items 8 through 13 of Form PS. Following these revisions, Form PS would be markedly shorter and streamlined only to include necessary disclosures for members thrift MHCs.

The Board believes these proposed changes would reduce the regulatory burden borne by thrift MHCs. The Board invites comment on all aspects of its proposal, including:

Question 37: What are the advantages and disadvantages of the Board retaining Form PS and its General Instructions? What information from the General Instructions to Form PS should the Board retain? Is there any additional information (other than what is being proposed) that the General Instructions of Form PS currently require institutions to include in their proxy statements that the Board should remove or retain? For example, are there other Items (such as Item 2) in the General Instructions to Form PS that are duplicative of SEC proxy regulations and should be removed? What would be the advantages and disadvantages in removing or retaining additional requirements?

iii. Mathematical Error in Calculation of Liquidation Accounts

Section 239.62(b) sets forth how a thrift MHC should determine the initial balances of liquidation sub-accounts. Section 239.62(b)(1)(i) states a resulting stock holding company determines the initial sub-account balance for a savings account held by an eligible account holder by multiplying the initial balance of the liquidation account by a fraction that has as its numerator the qualifying deposits in the particular savings account expressed in dollars as of the eligibility record date and as its denominator the total qualifying deposits expressed in dollars of all eligible account holders on the eligibility record date. Section

[60] 12 CFR 240.14a–101. Schedule 14A sets out the information required to be in a proxy statement when a shareholder vote is being solicited.

239.62(b)(1)(ii) provides the same calculation for a savings account held by a supplemental eligible account holder, except that the eligibility record date is replaced with the supplemental eligible record date. Currently, the denominator used for the calculation of the initial sub-account balances for both eligible account holders and supplemental eligible account holders contains an error that results in both groups of account holders having a claim to 100 percent of all liquidation account funds rather than their appropriate portions of the liquidation account. The proposed amendments would correct this error, aligning the calculation with a similar OCC regulation, and make clear that the eligible account holders and supplemental eligible account holders would be allocated their proportionate shares of the liquidation account as defined in section 239.62(a). The proposed amendments also would clarify that, for savings accounts held on both the eligibility record date and the supplemental eligibility record date, the amount of the qualifying deposit for calculating a liquidation sub-account would be the higher account balance of the savings account on either the eligibility record date or the supplemental eligibility record date.

iv. Stock Repurchases

Regulation MM currently includes limitations that prevent recently converted institutions from repurchasing shares of stock within the first year of issuance. This limitation applies both to stock issuances by subsidiary holding companies of thrift MHCs, as well as to a stock issuance by resulting stock holding companies in connection with a mutual-to-stock conversion. With respect to stock issuances by a subsidiary holding company of a thrift MHC, section 239.8(c)(1) prohibits the subsidiary holding company from repurchasing shares of its stock within one year of issuance, except in certain narrow circumstances, some of which require providing prior notice to the Board. Additionally, section 239.8(c)(2) prohibits a thrift MHC from repurchasing shares of its subsidiary holding company within a year of the subsidiary holding company's issuance of stock. Meanwhile, with respect to mutual-to-stock conversions, section 239.53(b)(2) of Regulation MM prohibits a thrift MHC seeking to convert to stock form from including planned stock repurchases in the first year of its post-conversion business plan. Further, section 239.63(c) of Regulation MM prohibits resulting stock holding companies from repurchasing shares within the first year after the mutual-to-stock conversion, except in certain circumstances, some of which require written prior notice to the Board.

The purpose of these limitations is to support the ability of mutual banking organizations or former mutual banking organizations to raise capital without facing immediate pressure from investors to make capital distributions, as well as to reduce the likelihood of the issuing organization explicitly or implicitly promising to repurchase the stock soon after issuance, thereby reducing the quality of the capital. However, resulting stock holding companies or subsidiary holding companies of thrift MHCs may have valid reasons for repurchasing stock within the first year of issuance that do not fall within the existing exceptions to the general prohibition on repurchases in that period. For example, it may be in the interests of these companies to repurchase stock in order to provide price support for the company's share price, or the company may seek to distribute capital following a period of unexpectedly high profits.

The Board proposes to amend these provisions to allow repurchases of stock in the first year after the minority stock issuance or conversion issuance, if the stock issuance plan or business plan submitted in connection with the issuance or conversion contemplates such repurchases. In its review of a proposed minority stock issuance or conversion issuance, the Board would assess whether the contemplated stock repurchase is consistent with approval. With respect to minority stock issuances by a subsidiary holding company of a thrift MHC, repurchases of stock within the first year of the issuance would be permissible if the stock issuance plan issued in connection with the share issuance described the circumstances under which such repurchases would occur and the circumstances of the repurchase are consistent with those described in the plan. Share repurchases in the first year after issuance that were not contemplated in the stock issuance plan or which would be made outside of the circumstances discussed in the stock issuance plan, and which do not fall within an existing exception in the rule, would continue to require prior notice to the Board.

Likewise, with respect to conversion issuances, repurchases of stock within the first year after conversion would be permissible where such repurchases would be consistent with the company's strategy for deploying conversion proceeds under the business plan filed with the application to convert to stock form and where the business plan included projections to repurchase stock. The proposal also would amend section 239.53(b)(2) of Regulation MM to permit a conversion applicant to include such projections in its business plan and to plan for stock repurchases in the first year after conversion.[61]

These proposed amendments would give mutual banking organizations and former mutual banking organizations increased flexibility to deploy capital in the manner most appropriate to the organization's circumstances, while ensuring that the stock repurchase was appropriately planned by the institution and evaluated by the Board in connection with its review of the stock issuance proposal. These companies also would have increased certainty regarding the permissibility of their planned capital actions and would encounter less regulatory burden with respect to repurchases that are contemplated ahead of time. The proposed amendments also address concerns raised by commenters with respect to the limitations on repurchases of stock within the first year of issuance. Firms would be permitted to engage in stock repurchases that have a valid business purpose, without a particular regulatory limit, as long as the possibility of making repurchases was contemplated in the relevant filing reviewed by the Board and the circumstances of the repurchase are consistent with the discussion in the filing.

The Board invites comment on all aspects of its proposal to allow subsidiary holding companies and resulting stock holding companies to repurchase shares within the first year of a stock issuance or conversion issuance, particularly:

Question 38: Should the Board retain the limitations on repurchases but decrease the limitation period from one year to six months, or to some another amount of time? What would be the advantages and disadvantages of basing the restriction on an amount of time other than one year?

Question 39: As an alternative to the proposal, what would be the advantages and disadvantages of eliminating all restrictions on repurchases (i.e., including the requirement that the stock issuance plan or business plan contemplate the repurchase)?

Question 40: Should the Board consider retaining the existing limitations without amendment? What

[61] Conversion applicants would continue to be required to include in their business plans financial projections that do not include returns of capital or special dividends.

would be the advantages and disadvantages of doing so?

Question 41: Rather than the changes proposed, should the Board instead consider amending the current standard in section 239.63(c)(1)(i) of Regulation MM that allows for repurchasing shares in the first year after conversion in extraordinary circumstances? Should the Board consider providing further guidance as to what could constitute an extraordinary circumstance? If so, what definitions or factors should the Board consider and why? Should the Board consider providing further guidance as to what could constitute a compelling and valid business purpose for repurchasing (under section 239.63(d)(3)(iii) of Regulation MM)? If so, what definitions or factors should the Board consider and why?

Question 42: What are the advantages and disadvantages of continuing to require conversion applicants to include in their business plans financial projections that do not include returns of capital or special dividends? Should such a restriction apply for a more limited time period in the business plan (e.g., the first year)? If so, what would be the appropriate period and the advantages and disadvantages of adopting that period?

v. Pricing of Conversion Shares

Section 239.59(c) of Regulation MM sets forth certain requirements regarding the pricing of conversion shares.[62] Among other requirements, the maximum price of conversion shares must be between $5 and $50 per share, the maximum price must be no more than 15 percent above the midpoint of the estimated price range in the offering circular, and the minimum price must be no more than 15 percent below that midpoint. However, the Board may permit the maximum price of conversion shares sold to be increased to an amount no more than the otherwise applicable maximum price.

The Board is proposing to remove from Regulation MM the restrictions on conversion share pricing discussed in the previous paragraph. The regulation's requirements regarding the maximum price and the permissible pricing range of conversion shares impose unwarranted limitations on thrift MHCs' ability to convert to stock form, create additional burden for thrift MHCs and the Federal Reserve, and could lead to distortions in the functioning of the market for converting firms' stock. Although the Board recognizes the importance of appropriately pricing conversion shares, the restrictions that the Board proposes to eliminate are not necessary to further this goal. Regulation MM requires that an application for conversion include an appraisal by an independent appraiser, which the Board reviews in determining whether to approve the application.[63] Through its review of this independent appraisal, the Board can assess whether the conversion shares would be appropriately priced.

The Board proposes to retain the requirements that conversion shares be sold at a uniform price per share at a total price that equals the estimated pro forma market value of the shares after conversion and that the estimated price of conversion shares be included in any preliminary offering circular. The first of these requirements ensures that conversion shares are sold fairly and at an appropriate price, while the latter requirement ensures that prospective buyers are well-informed about the anticipated share price.

The restrictions on the maximum and minimum prices of conversion shares also apply, by cross-reference in Regulation MM, to minority issuances of stock by subsidiary holding companies of thrift MHCs.[64] Consistent with the removal of these requirements with regard to the pricing of conversion shares, and for the same reasons, the Board proposes to remove such restrictions as they apply to minority issuances of stock.

Question 43: What are the advantages and disadvantages of the Board's proposed changes to the pricing of conversion shares? Are the proposed changes likely to have an impact on the pricing of conversion shares, given that most converting thrift MHCs set the price of conversion shares at $10 per share?

vi. Offers and Sales of Stock

Section 239.59 of Regulation MM requires converting MHCs to give subscription rights to purchase conversion shares to all eligible account holders, supplemental eligible account holders, and other voting members who do not qualify as either an eligible account holder or supplemental eligible account holder.[65] In order to be able to offer its conversion shares to individuals, the MHC must either (i) list its shares on a national or regional securities exchange, such as the Nasdaq; or (ii) register its shares in each state in which an eligible account holder, supplemental eligible account holder, or other voting member is located.

The Board recognizes that converting MHCs that do not meet the standards to list their shares on a national or regional securities exchange face burdensome, costly, and varied state securities law requirements to register shares in each state where such individuals reside. These registration fees vary by state, and many states require an initial and annual fee. Additionally, MHCs are subject to a variety of filing and other miscellaneous costs that also vary by state. As a result of these varying requirements, converting MHCs often must retain sophisticated counsel to manage compliance with these burdensome provisions.

Therefore, the Board proposes to amend section 239.59 of Regulation MM to state that, notwithstanding the requirement to offer its shares to all eligible account holders, supplemental eligible account holders, and other voting members, MHCs that do not meet the standards to list their shares on a national or regional exchange need only register their conversion shares in states in which 5 percent or more depositors reside. The Board recognizes that the ability to participate in a conversion offering is an important benefit of membership, and notes that this change merely represents a regulatory floor, not a ceiling. MHCs that do not meet the standards to list their shares on a national or regional exchange may decide to register their conversion shares in states where fewer than 5 percent of depositors reside—for example, because they wish to ensure such depositors can participate in the offering, because they wish to ensure a broad distribution of the offering, because they wish to maximize the offering size, or for some other reason. However, such institutions would only be required under Regulation MM to register their shares in states where 5 percent or more of depositors reside. Additionally, this relief would not be available to institutions that qualify to list their shares on a national or regional securities exchange, as such listing does not impose the same burden as registration in individual states.

The Board invites comment on all aspects of its proposal to limit the burden of state securities registration requirements, particularly:

Question 44: Are the Board's proposed amendments the most appropriate way to balance a member's ability to participate in the offering with the burden associated with broad-based registration? Are there any other factors or alternative approaches the Board should consider? What would be the

[62] 12 CFR 239.59(c).

[63] 12 CFR 239.55(b)(1)(ii); 239.55(g)(2).

[64] 12 CFR 239.24(a)(9).

[65] 12 CFR 239.59(h); 12 CFR 239.59(j).

advantages or disadvantages of such other factors or alternative approaches?

Question 45: Under the proposal, MHCs that do not meet the standards for registering their shares on a national or regional exchange would only be required to offer their shares in states where 5 percent or more eligible account holders, supplemental eligible account holders, or other voting members reside. Should the Board consider a threshold other than 5 percent to ensure that most eligible account holders, supplemental eligible account holders, and other voting members would have the right to participate in conversion offerings where the converting MHC does not meet the listing standards for a national or regional exchange? What would be the advantages and disadvantages of adopting a different threshold or a fixed number of depositors?

vii. Loans to a Tax-Qualified Employee Stock Ownership Plan

Section 239.59(f)(2) of Regulation MM prohibits thrift MHCs from extending credit for the purchase of conversion shares. The Board did not change the loan restriction that the OTS originally imposed upon converting thrift MHCs when it adopted section 239.59(f)(2) in 2011. However, the OTS routinely permitted converting thrift MHCs to extend credit to a tax-qualified employee stock ownership plan (ESOP) established for the benefit of employees of the thrift MHC, resulting stock holding company, or subsidiary savings association. The Board similarly has permitted a resulting stock holding company and its subsidiary bank or thrift to make loans to tax-qualified ESOPs established for the benefit of employees of the thrift MHC, resulting stock holding company, or subsidiary savings association. Thus, the Board proposes to amend this section to permit thrift MHCs to extend credit to a tax-qualified ESOP established for the benefit of employees of the thrift MHC, resulting stock holding company, or subsidiary savings association, thereby bringing the regulation into conformation with current practice. This change also would be incorporated by reference into section 239.24(c)(6)(i) of Regulation MM to apply to extensions of credit made in connection with the issuance of stock by a subsidiary holding company.[66]

The Board invites comment on its proposal to amend section 239.59(f)(2) of Regulation MM, particularly:

Question 46: Should the Board impose any limits on the extension of credit to tax-qualified ESOPs for the purchase of conversion shares under Regulation MM for the protection of thrift MHCs? What would be the advantages or disadvantages of any such limits?

Question 47: What concerns might arise from exempting extensions of credit to tax-qualified ESOPs from the prohibition in section 239.59(f)(2)? Should the Board consider any alternative approaches that would allow such tax-qualified ESOPs to participate in such offerings? What would be the advantages and disadvantages of those alternative approaches?

viii. Benefit Plans

Section 239.63(a) of Regulation MM provides numerous requirements limiting the ability of an MHC to offer a stock plan for employees post-conversion. As mentioned in section II.B.2.ii. with respect to issuances by a subsidiary holding company, the provisions relating to implementation of a stock plan for resulting stock holding company employees can be confusing and may require the retention of sophisticated legal counsel. The complexity of these requirements is unnecessary. Therefore, the Board proposes to simplify and streamline them. Specifically, the proposal would remove the many, varied, and overlapping size limitations for stock plans for employees. Instead, section 239.63(a) would be amended to provide that, in the 12 months after the conversion, stock plans for employees cannot, in the aggregate, exceed 15 percent of the number of shares of the resulting stock holding company issued in the conversion. Additionally, to provide converting institutions added flexibility in the 12 months after the conversion, the proposal would allow such institutions to establish a stock option plan or management recognition plan in connection with the mutual-to-stock conversion.

The Board invites comment on its proposal to amend section 239.63(a) of Regulation MM, particularly:

Question 48: What are the advantages and disadvantages of the proposed changes regarding the size of a stock plan for employees? Do the proposed changes adequately simplify the size thresholds applicable to stock plans for employees? What are the advantages and disadvantages of the proposed 15 percent aggregate limit on stock held by stock plans for employees? Should it be increased or decreased and, if so, why? Additionally, should the Board retain the 12-month time limit for this ownership percentage limitation, or should the Board consider some other time frame (and if so, why)?

Question 49: Because the resulting stock holding company's disclosure of ownership interests by stock plans for employees is calculated and presented to the public on a pro forma basis in the proxy statement and offering circular, should the resulting stock holding company be required to notify its shareholders of the final ownership percentage held by stock plans for employees post-conversion? What would be the advantages and disadvantages of such a requirement?

Question 50: Is there any other language in section 239.63(a) that should be clarified or revised to help conversion applicants better understand the Board's expectations of stock plans for employees post-conversion? What would be the advantages and disadvantages of any such clarifications or revisions?

ix. Judicial Review

Section 239.55(h) of Regulation MM sets forth the availability of judicial review of a decision by the Board regarding an application for a conversion from mutual to stock form. Section 239.55(h) provides that any person aggrieved by the Board's final action on the application for conversion has the right to judicial review and outlines the procedures for such action. The Board is proposing to remove from Regulation MM the judicial review provision. The judicial review set forth by the regulation restates the availability of the judicial review set forth under 12 U.S.C. 1467a(j) that would apply to applications for conversion and therefore is duplicative and unnecessary.

C. Other Technical Amendments

In addition to the substantive changes outlined above, the Board also proposes to implement a number of technical amendments to Regulation MM to fix known typographical errors and to make

[66] Under section 11 of HOLA, savings associations generally must comply with sections 23A and 23B of the Federal Reserve Act in the same manner and to the same extent as if the savings association were a member bank. *See* 12 U.S.C. 1468(a); *see also* 12 CFR part 223 (the Board's regulation implementing sections 23A and 23B of the Federal Reserve Act). Both a thrift MHC parent and a tax-qualified ESOP established for the benefit of the employees of the thrift MHC, resulting stock holding company, or subsidiary savings association are affiliates of the subsidiary savings association for purposes of sections 23A and 23B; therefore, even with the proposed change to Regulation MM, any extension of credit by the savings association to an affiliate (including to the thrift MHC to permit it to lend to the ESOP) must comply with sections 23A and 23B. Section 23B also applies to discretionary contributions by the savings association to an affiliate (such as a tax-qualified ESOP).

other non-substantive changes. For example, the proposal would replace references to ''Savings and Loan Holding Company Act'' and ''Holding Company Act'' with ''Home Owners' Loan Act.'' The Home Owners' Loan Act or HOLA is the proper name for the statute that Regulation MM implements, not Savings and Loan Holding Company Act or Holding Company Act. In addition, in order to resolve a conflict between the model bylaws and the requirements of HOLA, the proposal would remove the requirement from the subsidiary holding company model bylaws that directors of the subsidiary holding company own at least 100 shares of the entity's stock. Finally, the proposal would remove other minor typographical errors.

Question 51: Are there any additional changes to Regulation MM that the Board should consider? What would be the advantages or disadvantages of any such changes?

D. Bank MHC Commitments

As discussed in Section I, Regulation MM applies to SLHCs in the mutual form and to their SLHC subsidiaries. It does not apply directly to bank holding companies organized in the mutual form or to their bank holding company subsidiaries. However, the Board generally has asked these institutions to provide the Board with commitments to comply with certain provisions of Regulation MM, including provisions regarding member rights, dividend waivers, conversion rules, and post-conversion operations (Regulation MM commitments).

Unlike thrift MHCs, bank MHCs are not chartered by the Board; instead, they are chartered under state law. Further, bank MHCs are not subject to HOLA, which is the source of authority for Regulation MM, but instead are subject to the BHC Act and to applicable state law, including with respect to their mutuality.

In order to reduce regulatory burden on bank MHCs, the Board proposes to change its general practice with respect to seeking Regulation MM commitments from bank MHCs. Going forward, the Board would not intend to obtain Regulation MM commitments from mutual BHCs in the ordinary course. Given the Board's authority to supervise bank MHCs pursuant to the BHC Act and chartering states' authority to govern the practices of bank MHCs, Regulation MM commitments generally would not be necessary to protect the rights of members or to assure the safe and sound operation of bank MHCs. The Board expects that it would continue to seek targeted commitments from bank MHCs on a case-by-case basis, where appropriate.

With respect to bank MHCs that have previously provided Regulation MM commitments to the Federal Reserve, these companies would be invited to contact the Board or the appropriate Federal Reserve Bank, following the issuance of a final rule, to seek relief from these commitments. Absent unusual circumstances, the Board expects to be receptive to such requests for relief. By not requiring bank MHCs to enter into the Regulation MM commitments or by releasing such institutions from previously entered into commitments, the Board would reduce regulatory burden for bank MHCs and return governance over these institutions to the states.

III. Economic Analysis

The proposal would modernize the regulatory framework applicable to MHCs. It would amend Regulation MM by, among other things, eliminating certain procedural requirements associated with dividend waivers, amending and reducing the burden associated with conversions from mutual to stock form, eliminating the requirement that subsidiary holding companies of MHCs obtain federal charters, and revising and clarifying other provisions of the regulation. The proposal also would amend the capital rule to clarify that certain mutual capital instruments may qualify as regulatory capital if applicable criteria are met and would provide model term sheets for mutual capital certificates.

The discussion below addresses the economic effects of the proposal, including likely costs and benefits.

A. Baseline

Mutual banking organizations are financial institutions owned by those with deposit and lending relationships with the banking organization rather than by shareholders. Their earnings may be retained as capital or returned to members in the form of higher interest rates on deposits, lower loan fees, and enhanced local services. They typically focus on traditional finance services: residential mortgages, personal loans, and small business lending.

Mutual banking organizations occupy a distinct corner of the U.S. banking system. They focus on specific local communities where they can build deep relationships with customers and build market share. According to recent data from the Federal Deposit Insurance Corporation (FDIC) as of March 31, 2026,[67] there are 4,287 FDIC-insured depository institutions active in the United States. Out of this total, there are 143 depository institutions that are subsidiaries of MHCs,[68] which corresponds to 3.3 percent of all depository institutions.

In terms of assets, depository institution subsidiaries of MHCs collectively hold around $244 billion in assets, which represents about 0.9 percent of those assets held by all depository institutions.

Turning to capital ratios, data from the Federal Financial Institutions Examination Council (FFIEC) for mutual banking organizations show that as of March 31, 2026, the average leverage ratio for depository institution subsidiaries of MHCs was 12.1 percent.[69] In comparison, the average leverage ratio for all FDIC-insured banks was 9.15 percent.[70] In terms of common equity tier 1 ratios, the average for depository institution subsidiaries of MHCs reporting common equity tier 1 [71] on March 31, 2026, was 11 percent, compared to an industry average of 13.86 percent.

Mutual banking organizations occupy a unique position in the financial services landscape. In their mission and structure, they closely resemble credit unions: both are member-owned institutions that prioritize their account holders over outside investors, and both focus on serving local communities. Nonetheless, credit unions operate under a not-for-profit cooperative charter and pay no federal income taxes.[72] Mutual banking organizations, on the other hand, are for-profit corporations that pay standard federal and state corporate taxes. Mutual banking organizations are also subject to more stringent regulatory requirements. This creates a competitive disadvantage when mutuals compete with credit unions for deposits and lending opportunities.

B. Affected Parties

Parties affected by the proposal include:

---

[67] *See https://banks.data.fdic.gov/bankfind-suite/financialreporting/report.*

[68] *See* FFIEC Consolidated Reports of Condition and Income Regulatory Reporting.

[69] The median leverage ratio for depository institution subsidiaries of MHCs was 10.94 percent. *See id.*

[70] *See https://www.fdic.gov/quarterly-banking-profile/quarterly-banking-profile-q1-2026.*

[71] Note that 137 mutual banks opt in to the Community Bank Leverage Ratio (CBLR) framework and thus do not report risk-based capital ratios.

[72] *See https://ncua.gov/regulation-supervision/legal-opinions/2001/not-profit-and-tax-exempt-status-federal-credit-unions.*

• *Mutual Savings and Loan Holding Companies (Thrift MHCs):* Holding companies organized in mutual form that own thrifts. As discussed in Section I, they are governed by HOLA and Regulation MM. Additionally, as discussed in section II.A.1., some thrift MHCs, known as legacy waiver MHCs, are allowed to waive dividends, subject to certain procedural requirements, including an annual member vote,[73] while others, known as non-legacy waiver MHCs, are effectively prevented from waiving dividends that benefit insiders.

• *Mutual Bank Holding Companies (Bank MHCs):* Holding companies organized in mutual form that own commercial banks. As discussed in section II.D., by their terms, they are not governed by HOLA or Regulation MM, but by the BHC Act and Regulation Y. They currently provide commitments to the Board to comply with Regulation MM.

• *De novo mutual banking organizations:* These are newly formed banks or thrifts (and, as applicable, their holding companies) in mutual form.

• *Public shareholders:* Owners of shares in mid-tier stock holding companies of MHCs.

• *Credit unions and community banking organizations:* Credit unions and community banking organizations are direct competitors of mutual banking organizations.

C. Broad Economic Considerations

The proposal would modernize Regulation MM, which hasn't been revised since it was introduced in 2011. The proposal would also make amendments to the Board's capital rule. The overall changes would address two problems: mutual banking organizations have fewer opportunities to raise equity compared to other banking organizations, and certain rules applicable to MHCs are unclear and thus burdensome to comply with.

As discussed in section II.A. above, due to their mutuality, mutual banking organizations may be constrained in their ability to raise capital. MHCs cannot issue traditional stock instruments and often primarily rely on retained earnings to meet capital requirements. These constraints can affect these institutions' ability to grow and increase the products and services they provide to their communities.

Additionally, the requirements set forth in Regulation MM are burdensome and complex to apply for small institutions. This creates two problems. First, it is costly to determine the actual regulatory requirement. When rules are vague or difficult to understand, institutions need to obtain costly expertise to understand the applicable rule or standard. These costs are particularly burdensome for smaller institutions, who lack economies of scale. Second, this complexity creates an incentive for consolidation, as larger institutions are better placed to absorb such costs. Such consolidation reduces competition and results in fewer locally owned mutual banking organizations that focus on serving their communities.

D. Costs and Benefits of the Proposal

1. Better Access to Capital

Currently, as discussed above, mutual banking organizations face limitations in their ability to raise capital compared to other banking organizations. The proposal addresses this in several ways. First, the proposal clarifies the circumstances under which certain instruments (like mutual capital certificates and special deposits)[74] qualify as regulatory capital. This change could increase investor confidence in these instruments, potentially increasing demand.

Additionally, the proposed changes would reduce the procedural requirements around dividend waivers. By waiving its right to a portion of the dividends declared by its mid-tier holding company and allowing that dividend to be redistributed to the other shareholders of the mid-tier holding company, an MHC can help make the public share of the mid-tier holding company more attractive to outside investors. Dividend waivers can be an important tool, as mutual banking organizations have fewer ways to raise capital than traditional banks. Finally, by clarifying rules around special deposits, the proposal could ease the formation of new mutual banking organizations, subsequently increasing competition in local banking markets. Altogether, enhancing the ability of mutual banking organizations to obtain capital facilitates their growth and enables them to better serve their communities.

2. Reduced Compliance Costs

The proposal would reduce the compliance burden of Regulation MM. In addition, it codifies certain current supervisory practices, which gives mutual banking organizations regulatory clarity and facilitates compliance. Likewise, the proposal would eliminate requirements to submit two forms to the Board in connection with certain transactions,[75] while streamlining another form.[76] These changes would reduce compliance costs.

In addition, the current process for converting from mutual to stock form involves navigating complex state and federal requirements. The proposal would clarify certain requirements, reducing the costs and regulatory burden associated with such conversions. Moreover, the proposal would list specific factors the Board considers when evaluating certain applications from mutual holding companies, reducing regulatory uncertainty. Lastly, Regulation MM currently prohibits institutions from extending credit for the purchase of conversion shares; however, the Board has routinely granted waivers from this provision for the extension of credit to tax-qualified ESOPs for the benefit of employees so that the ESOP can participate in conversion offerings. The proposal would clarify that loans to ESOPs are permissible, subject to existing regulatory requirements.

3. Potential for Conflicts of Interest and Reduced Accountability

The proposed changes to dividend waivers could create situations where management personally benefits from their choice to waive dividends. When an MHC waives its dividend rights, more money goes to stockholders, which often includes the same executives and directors making the waiver decision.

Furthermore, for the four legacy waiver MHCs that currently require annual member votes, the proposal would eliminate this requirement entirely and instead rely on a simple self-certification from the institution's board that it is acting in accordance with applicable law and its fiduciary duties. Finally, for non-legacy waiver MHCs,[77] the proposal would allow waivers that benefit insiders, for the first time since the Board assumed responsibility for supervision of thrift MHCs. For such institutions, member approval would only be required once every ten years. Since dividend waivers

[73] The four existing Legacy Waiver MHCs are First Federal MHC, Greene County Bancorp MHC, Greenville Federal MHC, Third Federal S&LA of Cleveland MHC.

[74] As explained in section II.A.2. (Special Deposits and Mutual Capital Certificates), special deposits are capital instruments issued by mutual banking organizations that may be especially useful as a means for newly formed organizations to raise capital.

[75] *See* section II.B.3.ii.d.

[76] *See* section II.B.3.ii.e.

[77] The different treatments afforded in the proposal to legacy and non-legacy waiver MHCs, with respect to dividend waivers, could also perpetuate a competitive imbalance between these two categories of thrift MHCs.

tend to persist over time, this change could result in a transfer of wealth to insiders who hold stock in a mid-tier holding company over time. These proposed changes would also reduce existing accountability mechanisms set forth under Regulation MM, as institutions would not be required to explain dividend waivers to their members on an annual basis.

Nevertheless, market forces and existing transparency requirements limit such conflicts of interest. The proposal maintains decennial member voting on dividend waivers by non-legacy waiver MHCs.

In addition, directors and officers of thrift MHCs also owe fiduciary duties of care and loyalty to the institutions they serve. These are legally enforceable obligations backed by potential personal liability. When directors vote to waive dividends or take other actions that involve potential conflicts of interest, they must reasonably believe such actions serve the institution's interests. HOLA requires that a thrift MHC's board of directors must determine that a dividend waiver is consistent with its fiduciary duty to members prior to approving a dividend waiver.[78] Furthermore, HOLA allows the Board to object to dividend waivers if the waiver would be detrimental to the safe and sound operation of the thrift, and any dividend from the thrift would be subject to the statutory limitations on dividends for all depository institutions.[79]

Finally, to mitigate the potential conflicts of interest stemming from the reduced requirements, the Board would require legacy waiver MHCs to make appropriate disclosures regarding dividend waivers to new members at time of opening of a deposit account or loan relationship. These disclosures should ensure that members, including new members, have clear information about potential conflicts and can make informed decisions about establishing and maintaining their membership.

Separate from the proposed changes to dividend waivers, the proposal would also make changes to other requirements around thrift MHC's required disclosures to and notification of members. For instance, the proposal would amend the requirements contained in Form PS to reduce the specific information that must be contained in a proxy solicitation to members. Proxy solicitations provide important disclosures to members and provide accountability to members, including regarding issues where management and directors have direct personal financial interests.

4. Adjustment Costs

While the proposal would reduce compliance costs over the long-term, institutions subject to Regulation MM would face short-term expenses as they learn and adapt to the new regulations. These institutions will need to review the updated rules, train staff, update internal policies and procedures, and potentially modify their compliance systems.

These costs will vary by institution, based on the size and experience of compliance staff; however, these are primarily one-time costs; once these institutions understand and implement the new framework, they would benefit from the overall reduction in compliance burdens.

E. Conclusion

The proposed amendments to Regulation MM and the capital rule modernize and clarify regulatory requirements for mutual banking organizations, reducing compliance burdens. They also would facilitate raising external equity by these entities, supporting their growth and enabling them to better serve their customers. The costs of the proposed changes are small. Overall, the analysis indicates that the benefits of the proposal justify the costs.

IV. Administrative Law Matters

A. Paperwork Reduction Act Analysis

Certain provisions of the proposal contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) (PRA). In accordance with the requirements of the PRA, the Board may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The information collection affected by this rulemaking is the Reporting and Disclosure Requirements Associated with Regulation MM (FR MM; OMB No. 7100–0340). This Board proposes to extend this information collection for three years, with revision. The Board reviewed the proposal under the authority delegated to the Board by OMB.

Comments are invited on:

(a) Whether the collections of information are necessary for the proper performance of the Board's functions, including whether the information has practical utility;

(b) The accuracy of the Board's estimate of the burden of the information collections, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

All comments will become a matter of public record. Comments on aspects of this notice that may affect reporting, recordkeeping, or disclosure requirements and burden estimates should be sent to the addresses listed in the **ADDRESSES** section of this document. A copy of the comments may also be submitted to the OMB desk officer for the Board by mail to U.S. Office of Management and Budget, 725 17th Street NW, #10235, Washington, DC 20503; facsimile to (202) 395–6974; or email to *oira_submission@omb.eop.gov,* Attention, Federal Banking Agency Desk Officer.

Current Actions: The proposal would modify certain reporting and disclosure requirements currently included in Regulation MM and in related reporting forms. First, the proposal would eliminate two formal Board reporting forms and their associated instructions: the Offering Circulars (FR MM–OC) and the Order Forms (FR MM–OF). Currently, these documents must include information prescribed by their respective instructions, and must be submitted to the Federal Reserve and distributed to a thrift MHC's members in connection with certain transactions or events. The proposal would eliminate the FR MM–OC and FR MM–OF as individual reporting forms Firms would still be required to submit to the Federal Reserve and disclose to members copies of an offering circular or ordering form in the situations described in Regulation MM.[80]

[78] 12 U.S.C. 1467a(o)(11)(D)(ii); 12 CFR part 238, subpart K.

[79] 12 U.S.C. 1467a(o)(11)(D)(i).

[80] With regard to the offering circular, *see* 12 CFR 239.58 (submission to Federal Reserve in connection with a stock issuance conducted as part of any transaction or proposal pursuant to HOLA and Regulation MM); 12 CFR 239.58(b) (disclosure to members at the same time as or after mailing of proxy statement); and 12 CFR 239.58(c) and 239.60 (submission to Federal Reserve and disclosure to members of post-effective amendments in certain circumstances). With regard to the order form, *see* 12 CFR 239.59(d)(1) (disclosure to members in connection with certain transactions or proposals pursuant to HOLA and Regulation MM).

Second, the Board proposes to revise the Proxy Statement (FR MM–PS), as discussed in further detail in section II.B.3.ii of this Supplementary Information, to streamline the form by removing many of the requirements contained within the General Instructions to the form.

In addition to the proposed revisions to FR MM related to this rulemaking, the Board proposes to revise the FR MM information collection to account for certain reporting provisions in the current Regulation MM, in sections 239.8(d), 239.14(a), 239.16(b), 239.22(a), 239.50(c), and 239.63(d), that have not previously been cleared by the Board under the PRA. The proposal to recognize sections 239.14(a), 239.22(a), 239.50(c), and 239.63(d) as part of the FR MM information collection is meant to ensure compliance with the PRA, but would not substantively change the regulatory requirements to which thrift MHCs and their subsidiary holding companies are subject. Similarly, recognition of sections 239.8(d) and 239.16(b), which would be revised under the proposal to be clearer and less burdensome on thrift MHCs, would ensure that the provisions comply with the PRA.

Currently, under section 239.8(d) of Regulation MM, a thrift MHC that wishes to waive the right to receive a dividend declared by a subsidiary holding company must provide written notice to the Board of the intent of the thrift MHC to waive the right to receive dividends not later than 30 days before the date of the proposed date of payment of the dividend. The notice must include a copy of the resolution of the board of directors of the thrift MHC together with any supporting materials relied upon by the board of directors of the thrift MHC, concluding that the proposed dividend waiver is consistent with the fiduciary duties of the board of directors to the mutual members of the thrift MHC. The resolution must include certain information described in section 239.8(d)(2) of Regulation MM, including a description of (1) the conflict of interest that exists because of a thrift MHC director's ownership of stock in the subsidiary declaring dividends; (2) representations related to the fiduciary duties of the board of directors of the thrift MHC; and an affirmation that a majority of the mutual members of the thrift MHC eligible to vote have, within the 12 months preceding the declaration date of the dividend, approved a waiver of dividends by the thrift MHC. As discussed in section II.A.1. of this Supplementary Information, the proposal would modify the required contents of the written notice required under section 239.8(d).

Separately, under sections 239.14(a) and 239.22(a) of Regulation MM, in order to adopt a charter amendment, a thrift MHC or subsidiary holding company of a thrift MHC, respectively, must adopt a resolution of the board of directors proposing the charter amendment that states the text of such amendment, and either apply to the Board in order to adopt the charter amendment, or submit notice of the proposed charter amendment. If the proposed charter amendment would render more difficult or discourage a merger, proxy contest, the assumption of control by a mutual account holder of the MHC, or the removal of incumbent management, or involve a significant issue of law or policy, then the thrift MHC or subsidiary holding company of the thrift MHC must apply to the appropriate Reserve Bank for approval of the charter amendment. In all other cases, the entity must submit notice and a copy of the proposed amendment to the appropriate Reserve Bank at least 30 days prior to the effective date of the proposed charter amendment.

Under section 239.16(b) of Regulation MM, a thrift MHC or subsidiary holding company of a thrift MHC that proposes a voluntary dissolution must submit to the appropriate Reserve Bank its plan for dissolution (plan), as well as a statement of reasons for proposing dissolution and for proposing the plan. The required contents of the plan are set forth in section 239.16(a) of Regulation MM, which would be modified as discussed in section II.B.1.vii. of this Supplementary Information. When the plan is approved by the board of directors of the thrift MHC or its subsidiary holding company and by the Board, it must be submitted to the thrift MHC's members at a duly called meeting and, approved by a majority of votes cast at that meeting. After dissolution in accordance with the plan, a certificate evidencing dissolution, supported by such evidence as the Board may require, shall immediately be filed with the Board.

Next, section 239.50(c) of Regulation MM provides that the Board may waive any requirement under subpart E of Regulation MM or a provision in any prescribed form. To obtain a waiver, a thrift MHC must file a written request with the Board that specifies the requirement or provision that the thrift MHC wants the Board to waive; demonstrates that the waiver is equitable, is not detrimental to the thrift MHC, mutual members, or other MHCs or savings associations, and is not contrary to the public interest; and includes an opinion of counsel demonstrating that applicable law does not conflict with the waiver of the requirement or provision.

Finally, under 239.63(d), a resulting stock holding company that has converted from mutual form must file a written notice with the appropriate Reserve Bank in order to repurchase its own stock in the first year following conversion, in certain circumstances. The notice must include the proposed repurchase plan, information regarding the effect of the repurchases on the regulatory capital and other capital levels, a description of the purpose of the repurchases and, if applicable, an explanation of the extraordinary circumstances necessitating the repurchases. The notice must be filed at least thirty days before the repurchases commence. This prior notice requirement also applies in certain circumstances when a subsidiary holding company of a thrift MHC seeks to repurchase shares of its stock within one year of the issuance of such shares.[81]

Proposed Extension for Three Years, with Revision, of the Following Information Collection

Collection title: Reporting and Disclosure Requirements Associated with Regulation MM.

Collection identifier: FR MM.

OMB control number: 7100–0340.

General description of collection: The FR MM includes collections of information in the Board's Regulation MM—Mutual Holding Companies (12 CFR part 239) as well as six reporting forms:

- Notice of Mutual Holding Company Reorganization (FR MM–10(o)–1),
- Application for Approval of a Stock Issuance by a Subsidiary Holding Company of a Mutual Holding Company (FR MM–10(o)–2),
- Application for Conversion of a Mutual Holding Company to Stock Form (FR MM–AC),
- Proxy Statement (FR MM–PS),
- Offering Circular (FR MM–OC), and
- Order Forms (FR MM–OF).

The FR MM consists of information that must be filed in connection with certain proposals involving SLHCs that are organized in MHC form, including the reorganization of a savings association into MHC form, stock issuances of holding company subsidiaries of MHCs, and conversions of MHCs to stock form, as well as certain disclosures related to these filings. The Board requires the submission of these filings to allow the

[81] 12 CFR 239.8(c)(2).

Board to fulfill its obligations to review such transactions under section 10(o) of the HOLA, as amended and the Board's Regulation MM. The Board uses the information submitted by an applicant or notificant to evaluate these transactions with respect to the relevant statutory and regulatory factors.

Frequency: Event-generated.

Respondents: Mutual savings associations and SLHCs that are organized in mutual form.

Total estimated number of respondents: 13.

Estimated average hours per response:

Reporting
- FR MM–10(o)–1—66.59.
- FR MM–10(o)–2—33.56.
- FR MM–AC—66.56.
- FR MM–PS—25.
- Section 239.4(d)(4) Notice of reorganization—1.
- Section 239.8(d) Restrictions on waiver of dividends—20.
- Section 239.14(a) Charter amendments (mutual holding company)—22.
- Section 239.16(b) Voluntary dissolution—20.
- Section 239.22 Charter amendments (subsidiary holding company)—22.
- Section 239.50© Request for waivers—16.5.
- Section 239.58 Offering circular—0.56.
- Section 239.60 Completion of the offering—0.56.
- Section 239.60(b) Offering period extension—1.
- Section 239.63(d) Post conversion—20.
- Section 239.65(g) Voluntary supervisory conversion—1.

Disclosure
- FR MM–10(o)–1—1.
- FR MM–AC—1.
- FR MM–PS—1.
- Sections 239.3(a)(2) and 239.54(c)(1) Newspaper publication—1.
- Section 239.16(b) Voluntary dissolution—1.
- Section 239.58(b) Distribution of the offering circular—1.
- Section 239.59(d)(1) Selling conversion shares—1.

Total estimated annual burden hours: 1,407.

B. Regulatory Flexibility Act Analysis

The Board is providing an initial regulatory flexibility analysis with respect to this proposal. The Regulatory Flexibility Act (RFA)[82] requires an agency to consider whether the rule it proposes will have a significant economic impact on a substantial number of small entities.[83] In connection with a proposal, the RFA requires an agency to prepare and invite public comment on an initial regulatory flexibility analysis describing the impact of the rulemaking on small entities, unless the agency certifies that the proposed rule, if promulgated, would not have a significant economic impact on a substantial number of small entities. An initial regulatory flexibility analysis must contain (1) a description of the reasons why action by the agency is being considered; (2) a succinct statement of the objectives of, and legal basis for, the proposed rule; (3) a description of, and, where feasible, an estimate of the number of small entities to which the proposed rule will apply; (4) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; (5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap with, or conflict with the proposed rule; and (6) a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and minimize any significant economic impact of the proposed rule on small entities.[84]

The Board has considered the potential impact of the proposal on small entities in accordance with the RFA. Based on its analysis and for the reasons stated here, the Board believes that this proposal will not have a significant economic impact on a substantial number of small entities. Nevertheless, the Board is publishing and inviting comment on this initial regulatory flexibility analysis.

As discussed in section II.B. of this Supplementary Information, the Board is proposing changes to Regulation MM that are intended to reduce the regulatory burden borne by thrift MHCs and their subsidiary holding companies. The proposal would, among other things, eliminate certain dividend waiver requirements, reduce burden associated with conversions from mutual-to-stock form, revise certain post-conversion restrictions, eliminate the requirement that subsidiary holding companies of MHCs obtain federal charters, and revise and clarify other provisions of the regulation. Pursuant to section 312 of the Dodd-Frank Act, the Board's responsibility for the supervision and regulation of SLHCs, including thrift MHCs and their subsidiary holding companies, involves all the former functions of OTS and its Director related to SLHCs, including rulemaking authority and the authority to issue orders.[85]

As discussed in section II.A. of this Supplementary Information, the Board is also proposing targeted changes to the capital rule to clarify the treatment of capital instruments issued by mutual banking organizations. First, the Board proposes to amend sections 217.20(b)(1), (c)(1), and (d)(1) of the capital rule to clarify that special deposits and mutual capital certificates issued by a mutual banking organization can qualify as common equity tier 1, additional tier 1, or tier 2 capital, respectively, if all of the qualifying criteria are satisfied. Second, the Board proposes to add two mutual capital certificate term sheets as appendices to the capital rule. The term sheets are intended to serve as templates for mutual banking organizations to use as a reference when issuing capital instruments intended to qualify as common equity tier 1 or additional tier 1 capital. Various statutory authorities provide the Board with broad authority to set capital requirements and standards for the institutions it regulates.[86]

The proposal would apply to mutual banking organizations supervised by the Board.[87] Based on regulatory report

[82] 5 U.S.C. 601 *et seq.*

[83] Under regulations issued by the U.S. Small Business Administration (SBA), a small entity includes a depository institution, bank holding company, or savings and loan holding company with total assets of $850 million or less. *See* 13 CFR 121.201. Consistent with the SBA's General Principles of Affiliation, the Board includes the assets of all domestic and foreign affiliates toward the size threshold when determining whether to classify a particular entity as a small entity. *See* 13 CFR 121.103. As of the fourth quarter of 2025, there were approximately 2,267 small BHCs and approximately 84 small SLHCs, and approximately 438 small state member banks.

[84] 5 U.S.C. 603(b)–(c).

[85] 12 U.S.C. 5412.

[86] *See, e.g.,* 12 U.S.C. 248(a), 321–338a, 481–486, 1462a, 1467a, 1818, 1828, 1831n, 1831o, 1831p–1, 1831w, 1835, 1844(b), 1851, 3904, 3906–3909, 4808, 5365, 5368, 5371, and 5371 note, and 15 U.S.C. 9050.

[87] As discussed in section I of this Supplementary Information, mutual banking organizations can have varying structures and charter types. HOLA and Regulation MM apply to thrift MHCs and their subsidiary holding companies. Although bank MHCs are not subject to HOLA or Regulation MM, they are subject to the Board's supervision and regulation pursuant to the BHC Act. Banks and savings associations in mutual form are not directly supervised or regulated by the Board, except for state member banks in mutual form. The Board generally uses the industry-specific size standards adopted by the SBA for purposes of estimating the number of small entities to which a proposal would apply. The SBA has adopted size standards that provide that mutual banking organizations with average assets of $850 million or less over the preceding year (based on the institution's four quarterly financial statements) are considered small

Continued

data, there are approximately 73 mutual banking organizations that have total domestic assets of $850 million or less and thus are considered small entities for purposes of the RFA.[88] The proposed amendments to Regulation MM would apply to thrift MHCs and their subsidiary holding companies. Although Regulation MM does not apply directly to bank MHCs, such institutions generally have provided the Federal Reserve with commitments to comply with certain provisions of Regulation MM. Therefore, these entities could be affected by the proposal to the extent the proposed changes would alter provisions of Regulation MM that are covered by the commitments. Additionally, small mutual banking organizations that are bank MHCs or thrift MHCs are generally subject to the Small Bank Holding Company and Saving and Loan Holding Company Policy Statement.[89]

As discussed in section III of this Supplementary Information, the proposal would modernize the regulatory framework applicable to MHCs, thereby reducing the compliance burdens borne by MHCs and supporting their ability to raise capital, grow, and better serve their communities. MHCs would face short-term expenses in adapting to the updated regulatory framework, such as expenses incurred by reviewing the updated rules, training staff, updating internal policies and procedures, and potentially modifying their compliance systems. However, these would primarily be one-time costs, the overall costs of the proposed changes are expected to be small, and MHCs would ultimately benefit from an overall reduction in compliance burdens. Further, as noted in section IV.A. of this Supplementary Information, the proposal would modify certain reporting and disclosure requirements currently included in Regulation MM and in related reporting forms, including by eliminating the FR MM–OC and FR MM–OF as individual reporting forms and streamlining the FR MM–PS. The proposal would not affect reporting, recordkeeping, and other compliance requirements under the capital rule. Therefore, there would be no reporting, recordkeeping, or other compliance requirements from this proposal that would impose a significant cost on small entities.

The Board is aware of no other federal rules that duplicate, overlap, or conflict with the proposal. The Board has not identified any significant alternatives to the proposal that would accomplish the stated objectives and minimize the economic impact of the proposal on small entities.

Therefore, the Board believes that the proposal will not have a significant economic impact on a substantial number of small entities supervised by the Board.

The Board welcomes comment on all aspects of its analysis. In particular, the Board requests that commenters describe the nature of any impact on small entities and provide empirical data to illustrate and support the extent of the impact.

C. Solicitation of Comments on the Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act (Pub. L. 106–102, 113 Stat.1338, 1471, 12 U.S.C. 4809) requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The Board has sought to present the proposed amendments in a simple and straightforward manner and invites comment on the use of plain language.

D. Riegle Community Development and Regulatory Improvement Act of 1994

Pursuant to section 302(a) of the Riegle Community Development and Regulatory Improvement Act (RCDRIA),[90] in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions (IDIs), the Board must consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations. In addition, section 302(b) of RCDRIA requires new regulations and amendments to regulations that impose additional reporting, disclosures, or other new requirements on IDIs generally to take effect on the first day of a calendar quarter that begins on or after the date on which the regulations are published in final form, with certain exceptions.[91]

The Board notes that comment on these matters has been requested in other sections of this Supplementary Information, and that the requirements of RCDRIA will be considered as part of the overall rulemaking. The Board has determined that the proposed rule (1) would not impose any additional reporting, disclosures, or other new requirements on IDIs, and (2) places no new administrative burdens on depository institutions, including small depository institutions, and customers of depository institutions. Therefore, the requirements of RCDRIA do not apply. However, the Board invites comments that will further inform its consideration of RCDRIA.

E. Providing Accountability Through Transparency Act of 2023

The Providing Accountability Through Transparency Act of 2023 [92] requires that a notice of proposed rulemaking include the internet address of a summary of not more than 100 words in length of a proposed rule, in plain language, that shall be posted on the internet website under section 206(d) of the E-Government Act of 2002.[93]

In summary, the Board proposes to modernize the regulatory framework applicable to mutual holding companies (MHCs). The proposal would amend Regulation MM (12 CFR part 239), including by eliminating certain dividend waiver requirements, reducing burden associated with conversions from mutual-to-stock form, revising certain post-conversion restrictions, eliminating federal charter requirements for subsidiary holding companies of MHCs, and revising and clarifying other provisions. The proposal also would amend the capital rule (12 CFR part 217) to clarify that certain mutual capital instruments may qualify as regulatory capital and to codify model term sheets for mutual capital certificates as appendices to the regulation.

The proposal and summary can be found at *https://www.regulations.gov* and *https://www.federalreserve.gov/supervisionreg/reglisting.htm.*

List of Subjects

12 CFR Part 217

Administrative practice and procedure, Banks, Banking, Capital, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Risk, Securities.

entities. *See* 13 CFR 121.201 (sectors 522110–522180).

[88] The Board's estimate is based on total consolidated assets reported on Forms FR Y–9C (Consolidated Financial Statements for Holding Companies), FR Y–9SP (Parent Company Only Financial Statements for Small Holding Companies), and FFIEC 041 and 051 (Consolidated Reports of Condition and Income) for year-end 2025.

[89] *See* 12 CFR part 225, app. C.

[90] 12 U.S.C. 4802(a).

[91] 12 U.S.C. 4802(b).

[92] 5 U.S.C. 553(b)(4).

[93] 44 U.S.C. 3501 note.

12 CFR Part 239

Administrative practice and procedure, Banks, Banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

Authority and Issuance

For the reasons set forth in the preamble, the Board of Governors of the Federal Reserve System proposes to amend chapter II of title 12 of the Code of Federal Regulations as follows:

PART 217—CAPITAL ADEQUACY OF BANK HOLDING COMPANIES, SAVINGS AND LOAN HOLDING COMPANIES, AND STATE MEMBER BANKS (REGULATION Q)

■ 1. The authority citation for part 217 is revised to read as follows:

Authority: 12 U.S.C. 248(a), 321–338a, 481–486, 1462a, 1467a, 1818, 1828, 1831n, 1831o, 1831p–1, 1831w, 1835, 1844(b), 1851, 3904, 3906–3909, 4808, 5365, 5368, 5371, and 5371 note, and 15 U.S.C. 9050.

Subpart C—Definition of Capital

■ 2. Amend 217.20 by revising the introductory text of paragraph (b)(1), the introductory text of paragraph (c)(1), and the introductory text of paragraph (d)(1) to read as follows:

§ 217.20 Capital components and eligibility criteria for regulatory capital instruments.

* * * * *

(b) * * *

(1) Any common stock instruments (plus any related surplus) issued by the Board-regulated institution, net of treasury stock, and any capital instruments issued by mutual banking organizations (such as mutual capital certificates or mutual special deposits), that meet all the following criteria:

* * * * *

(c) * * *

(1) Instruments (including any instruments issued by mutual banking organizations such as mutual capital certificates or mutual special deposits), plus any related surplus, that meet the following criteria:

* * * * *

(d) * * *

(1) Instruments (including any instruments issued by mutual banking organizations such as mutual capital certificates or mutual special deposits), plus any related surplus, that meet the following criteria:

* * * * *

■ 3. Appendix B to part 217 is added to read as follows:

Appendix B to Part 217—Key Terms for Mutual Capital Certificates Qualifying as Common Equity Tier 1 Capital

1. Background

This appendix sets out key terms for special instruments or capital certificates, issued by mutual banking organizations, eligible to qualify as common equity tier 1 capital, pursuant to section 217.20(b) of the Board's Regulation Q (12 CFR 217.20(b)). Banking organizations are encouraged to seek legal advice and consider additional legal requirements, such as state law or regulatory requirements, that may be applicable to the offering of mutual capital certificates. These key terms are offered as one method of complying with the requirements of section 217.20(b) for mutual-form banking organizations specifically. Banking organizations are encouraged to reach out to Federal Reserve staff if they have questions.

■ 2. *Key Terms*

(a) *Issuer.* Mutual-Form Bank Holding Company, Mutual-Form Savings and Loan Holding Company, or Mutual-Form State Member Bank (''Mutual Banking Organization'').

(b) *Certificates Offered.* Certificates are instruments, issued by the Mutual Banking Organization, representing paid-in capital, the paid-in amount of which shall be classified as equity under U.S. Generally Accepted Accounting Principles. Certificates constitute a claim in liquidation, receivership, insolvency, or similar proceeding, on the residual assets of the Mutual Banking Organization, after the payment in full of all depositors, general creditors, subordinated debt holders, or other senior claimants.

(c) *Ordinary Distributions.*

(1) The Mutual Banking Organization may make distributions on the Certificates only if declared by its board of directors (or a duly authorized committee of the board), to be paid out of the Mutual Banking Organization's net income, retained earnings, or surplus related to other common equity tier 1 instruments, after other legal obligations have been satisfied. The Mutual Banking Organization retains full discretion at all times to cancel distributions on the instrument without triggering an event of default, a requirement to make a payment-in-kind, or an imposition of other restrictions, except in relation to any distribution to holders of instruments that are on parity with the Certificates.

(2) Distributions on Certificates will not be cumulative, are not mandatory, and are not based on a specific distribution rate specified at issuance.[1] Issuers may disclose to investors target distribution rates, provided however, issuers also clearly disclose that such distribution target rates will not be cumulative or mandatory.

(d) *Maturity.* Certificates are perpetual and have no maturity date.

(e) *Redemption.* Certificates have no maturity date, and holders of Certificates do not have the right to require redemption. The Mutual Banking Organization may, in its discretion, redeem the Certificates with the prior approval of the Board of Governors of the Federal Reserve System (''Board'').

(f) *Ranking.* Certificates must be subordinated to all liabilities and other obligations, both with respect to payments and in a receivership, insolvency, liquidation, or similar proceeding. Certificates are not secured, nor covered by any guarantee of the Mutual Banking Organization or of an affiliate of the Mutual Banking Organization, and Certificates are not subject to any other arrangement that legally or economically enhances the seniority of the instrument.

(g) *Voting Rights.* Certificate holders can be granted voting rights to the extent permitted by the charter of the Mutual Banking Organization and applicable federal and state law. However, Certificate holders are not considered members of the Mutual banking Organization solely because they hold Certificates.

(h) *Conflicts of Interest and Financing.* The Mutual Banking Organization, or an entity that the Mutual Banking Organization controls, may not purchase or, directly or indirectly, fund the purchase of the Certificates.

(i) *Listing.* Not required. Certificates can be listed or not listed.

(j) *Reorganization, Recapitalization, and Merger.* Except in the event of insolvency, liquidation, or receivership, the Certificates may survive any reorganization, recapitalization, or merger in accordance with their terms.

Correspondence of Key Terms to Regulatory Requirements

[1] State member banks are subject to other legal restrictions on reductions in capital resulting from distributions, including out of the capital surplus account, under 12 U.S.C. 324 and 12 CFR 208.5.

TABLE 1 TO APPENDIX B

Citation to 12 CFR 217.20	Regulatory text requirement	Term
217.20(b)(1)(i)	The instrument is paid-in, issued directly by the Board- regulated institution, and represents the most subordinated claim in a receivership, insolvency, liquidation, or similar proceeding of the Board-regulated institution.	Certificates Offered; Ranking.
217.20(b)(1)(ii)	The holder of the instrument is entitled to a claim on the residual assets of the Board-regulated institution that is proportional with the holder's share of the Board-regulated institution's issued capital after all senior claims have been satisfied in a receivership, insolvency, liquidation, or similar proceeding.	Certificates Offered; Ranking.
217.20(b)(1)(iii)	The instrument has no maturity date, can only be redeemed via discretionary repurchases with the prior approval of the Board to the extent otherwise required by law or regulation, and does not contain any term or feature that creates an incentive to redeem.	Maturity; Redemption.
217.20(b)(1)(iv)	The Board-regulated institution did not create at issuance of the instrument through any action or communication an expectation that it will buy back, cancel, or redeem the instrument, and the instrument does not include any term or feature that might give rise to such an expectation.	Maturity; Redemption.
217.20(b)(1)(v)	Any cash dividend payments on the instrument are paid out of the Board-regulated institution's net income, retained earnings, or surplus related to common stock, and are not subject to a limit imposed by the contractual terms governing the instrument. State member banks are subject to other legal restrictions on reductions in capital resulting from cash dividends, including out of the capital surplus account, under 12 U.S.C. 324 and 12 CFR 208.5.	Distributions.
217.20(b)(1)(vi)	The Board-regulated institution has full discretion at all times to refrain from paying any dividends and making any other distributions on the instrument without triggering an event of default, a requirement to make a payment-in-kind, or an imposition of any other restrictions on the Board- regulated institution.	Distributions.
217.20(b)(1)(vii)	Dividend payments and any other distributions on the instrument may be paid only after all legal and contractual obligations of the Board-regulated institution have been satisfied, including payments due on more senior claims.	Distributions.
217.20(b)(1)(viii)	The holders of the instrument bear losses as they occur equally, proportionately, and simultaneously with the holders of all other common stock instruments before any losses are borne by holders of claims on the Board-regulated institution with greater priority in a receivership, insolvency, liquidation, or similar proceeding.	Distributions; Redemption.

■ 4. Appendix C to part 217 is added to read as follows:

Appendix C to Part 217—Key Terms for Mutual Capital Certificates Qualifying as Additional Tier 1 Capital

1. Background

This appendix sets out key terms for special instruments or capital certificates, issued by mutual banking organizations, eligible to qualify as additional tier 1 capital, pursuant to section 217.20(c) of the Board's Regulation Q (12 CFR 217.20(c)). Banking organizations are encouraged to seek legal advice and consider additional legal requirements, such as state law or regulatory requirements, that may be applicable to the offering of mutual capital certificates. These key terms are offered as one method of complying with the requirements of section 217.20(c) for mutual-form banking organizations specifically. Banking organizations are encouraged to reach out to Federal Reserve staff if they have questions.

2. Key Terms

(a) *Issuer.* Mutual-Form Bank Holding Company, Mutual-Form Savings and Loan Holding Company, or Mutual-Form State Member Bank (''Mutual Banking Organization'')

(b) *Certificates Offered.* Certificates are instruments, issued by the Mutual Banking Organization, representing paid-in capital, the paid-in amount of which shall be classified as equity under U.S. Generally Accepted Accounting Principles.

(c) *Ordinary Distributions.*

(1) The Mutual Banking Organization may make distributions on the Certificates only if declared by its board of directors (or a duly authorized committee of the board), to be paid out of the Mutual Banking Organization's net income, retained earnings, or surplus related to other additional tier 1 instruments. The Mutual Banking Organization retains full discretion at all times to cancel distributions on the instrument without triggering an event of default, a requirement to make a payment-in-kind, or an imposition of other restrictions, except in relation to any distribution to holders of instruments that are on parity with the Certificates.

(2) Distributions on Certificates will not be cumulative and are not mandatory. The Mutual Banking Organization has flexibility to choose and disclose to investors an appropriate target distribution rate, including rates that are adjusted periodically independent of a Mutual Banking Organization's credit quality, in relation to general market interest rates. However, distribution rates cannot reset based in whole or in part on the Mutual Banking Organization's credit quality, nor contain a ''step- up'' feature or other terms that create an incentive to redeem the instruments early.

(d) *Maturity.* Certificates are perpetual and have no maturity date.

(e) *Redemption.*

(1) Certificates do not have any maturity date, and holders of Certificates will not have the right to require redemption. The Mutual Banking Organization may, in its discretion, redeem the Certificates with the prior approval of the Board of Governors of the Federal Reserve System (''Board'').

(2) The Certificates may be callable by their terms, provided the Certificates may be called by the Mutual Banking Organization only after a minimum of five years following issuance, except that the Certificates may allow it to be called earlier than five years upon the occurrence of a regulatory event that precludes the instrument from being included in additional tier 1 capital, a tax event, or if the issuing entity is required to register as an investment company pursuant to the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*). The Mutual Banking Organization must receive prior approval from the Board to exercise any call option on the Certificates. Prior to exercising the call option, or immediately thereafter, the Mutual Banking Organization must either replace the Certificates to be called with an equal amount of instruments that satisfy the criteria under section 217.20(b) or (c), or demonstrate to the satisfaction of the Board that, following redemption, the Mutual Banking Organization will continue to hold capital commensurate with its risks.

(f) *Ranking.* Certificates must be subordinated to depositors, general creditors, and subordinated debt holders, both with respect to payments and in a receivership, insolvency, liquidation or similar

proceeding. The Certificates are not secured, nor covered by any guarantee of the Mutual Banking Organization or of an affiliate of the Mutual Banking Organization, and Certificates are not subject to any other arrangement that legally or economically enhances the seniority of the instrument. The Certificates can be senior to any rights based on membership in the Mutual Bank Organization.

(g) *Liquidation Rights.* In the event the Mutual Banking Organization voluntarily or involuntarily liquidates, dissolves, or winds up its affairs, holders of Certificates may be entitled to receive an amount per certificate, plus any ordinary distributions that have been declared but not paid prior to the date of payment of distributions to Certificate holders. Distributions can be made only to the extent the Mutual Banking Organization has assets that are available for distribution to Certificate holders, after payment or provision for payment of more senior obligations.

(h) *Voting Rights.* Certificate holders can be granted voting rights to the extent permitted by the charter of the Mutual Banking Organization and applicable federal and state law. However, Certificate holders are not considered members of the Mutual banking Organization solely because they hold Certificates.

(i) *Conflicts of Interest and Financing.* The Mutual Banking Organization, or an entity that the Mutual Banking Organization controls, may not purchase or, directly or indirectly, fund the purchase of the Certificates.

(j) *Preemptive Rights.* The Certificates do not have any features that would limit or discourage additional issuance of capital by the Mutual Banking Organization, such as provisions that require the Mutual Banking Organization to compensate holders of the Certificates if a new instrument is issued at a lower price during a specified time frame.

(k) *Listing.* Not required. Certificates can be listed or not listed.

(l) *Reorganization, Recapitalization, and Merger.* Except in the event of insolvency, liquidation, or receivership, the Certificates may survive any reorganization, recapitalization, or merger in accordance with their terms.

[1] State member banks are subject to other legal restrictions on reductions in capital resulting from distributions, including out of the capital surplus account, under 12 U.S.C. 324 and 12 CFR 208.5.

3. Correspondence of Key Terms to Regulatory Requirements

TABLE 1 TO APPENDIX C

Citation to 12 CFR 217.20	Regulatory text requirement	Term
217.20(c)(1)(i)	The instrument is issued and paid-in	Certificates Offered.
217.20(c)(1)(ii)	The instrument is subordinated to depositors, general creditors, and subordinated debt holders of the Board- regulated institution in a receivership, insolvency, liquidation, or similar proceeding.	Certificates Offered; Liquidation Rights; Ranking.
217.20(c)(1)(iii)	The instrument is not secured, not covered by a guarantee of the Board-regulated institution or of an affiliate of the Board-regulated institution, and not subject to any other arrangement that legally or economically enhances the seniority of the instrument.	Ranking.
217.20(c)(1)(iv)	The instrument has no maturity date and does not contain a dividend step-up or any other term or feature that creates an incentive to redeem.	Maturity; Ordinary Distributions; Redemption.
217.20(c)(1)(v)	If callable by its terms, the instrument may be called by the Board-regulated institution only after a minimum of five years following issuance, except that the terms of the instrument may allow it to be called earlier than five years upon the occurrence of a regulatory event that precludes the instrument from being included in additional tier 1 capital, a tax event, or if the issuing entity is required to register as an investment company pursuant to the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*). In addition: A. The Board-regulated institution must receive prior approval from the Board to exercise a call option on the instrument. B. The Board-regulated institution does not create at issuance of the instrument, through any action or communication, an expectation that the call option will be exercised. C. Prior to exercising the call option, or immediately thereafter, the Board-regulated institution must either: Replace the instrument to be called with an equal amount of instruments that meet the criteria under paragraph (b) of this section or this paragraph (c); or demonstrate to the satisfaction of the Board that following redemption, the Board-regulated institution will continue to hold capital commensurate with its risk.	Redemption.
217.20(c)(1)(vi)	Redemption or repurchase of the instrument requires prior approval from the Board	Redemption.

PART 239—MUTUAL HOLDING COMPANIES (REGULATION MM)

■ 5. The authority citation for part 239 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1464, 1467a, 1828, and 2901.

Subpart A—General Provisions

■ 6. Amend § 239.2 by:

■ a. Redesignating paragraphs (b) through (cc) as paragraphs (c) through (dd);

■ b. Adding paragraph (b); and

■ c. Revising paragraphs (c) and (d), the introductory text of paragraph (f), paragraph (g), paragraphs (p) through (u), and the introductory text of paragraph (v).

The addition and revisions read as follows:

§ 239.2 Definitions.

* * * * *

(b) *Acquiree mutual holding company* means a mutual holding company that would be acquired or controlled by another mutual holding company as a result of a merger or acquisition.

* * * * *

(c) *Acting in concert* has the same meaning as in 12 CFR 238.31(b).

(d) *Affiliate* has the same meaning as in 12 CFR 238.2(a).

* * * * *

(f) *Company* means any corporation, partnership, trust, association, joint venture, pool, syndicate, unincorporated organization, joint-stock company or similar organization, as defined in this section; but a company does not include:

* * * * *

(g) *Control* has the same meaning as in 12 CFR 238.2(e).

* * * * *

(p) *Reorganization Plan* means a plan to reorganize into the mutual holding company form containing the information required by § 239.6.

(q) *Reorganizing association* means a mutual savings association that

proposes to reorganize to the mutual holding company form pursuant to this part.

(r) *Resulting association* means a savings association in the stock form that is organized as a subsidiary of a mutual holding company to receive the substantial part of the assets and liabilities (including all deposit accounts) of the reorganizing association upon consummation of the reorganization.

(s) *Savings account* means any withdrawable account, including a demand account, except this term does not mean a tax and loan account, a note account, a United States Treasury general account, or a United States Treasury time deposit-open account.

(t) *Savings association* has the same meaning as in 12 CFR 238.2(l).

(u) *Savings and loan holding company* has the same meaning as specified in section 10(a)(1) of the HOLA and 12 CFR 238.2(m).

(v) *Similar organization* for purposes of paragraph (f) of this section means a combination of parties with the potential for or practical likelihood of continuing rather than temporary existence, where the parties thereto have knowingly and voluntarily associated for a common purpose pursuant to identifiable and binding relationships which govern the parties with respect to either:

* * * * *

Subpart B—Mutual Holding Companies

■ 7. Amend § 239.3 by removing in paragraph (a)(2) the text ''§ 238.14 of this chapter'' and adding in its place the text ''12 CFR 238.14''.

■ 8. Amend § 239.4 by:

■ a. Revising paragraph (c)(1); and

■ b. Removing in paragraph (d) the text ''§ 238.14 of this chapter'' wherever it appears and adding in its place the text ''12 CFR 238.14''.

The revision reads as follows:

§ 239.4 Grounds for disapproval of reorganizations.

* * * * *

(c) * * *

(1) *Managerial resources.* The factors specified in 12 CFR 238.15(c)(1)(i) through (vi) shall give rise to a rebuttable presumption that the managerial resources test of paragraph (a)(2) of this section is not met. For this purpose, each place the term *acquiror* appears in 12 CFR 238.15(c)(1)(i) through (vi), it shall be read to mean the reorganizing association or any acquiree association, and the reference in 12 CFR 238.15(c)(1)(v) of this chapter to filings under this part shall be deemed to include filings under either 12 CFR part 238 or this part.

* * * * *

■ 9. Amend § 239.5 by:

■ a. Revising the introductory text of paragraph (a);

■ b. Adding paragraph (a)(5); and

■ c. Revising paragraph (b).

The revisions and addition read as follows:

§ 239.5 Membership rights.

(a) *Depositors and borrowers of resulting associations, acquiree associations, and associations in mutual or stock form when acquired.* The charter of a mutual holding company must:

* * * * *

(5) Confer upon the members of any acquiree mutual holding company the same membership rights in the acquiring mutual holding company as are conferred upon the members of the acquiring mutual holding company.

(b) *Depositors and borrowers of associations in the stock form when acquired.* A mutual holding company that acquires a savings association in the stock form, other than a resulting association or an acquiree association, shall not confer any membership rights upon the depositors and borrowers of such association, unless;

(1) such association is merged into an association from which the mutual holding company draws members, in which case the depositors of the stock association shall receive the same membership rights as other depositors of the association into which the stock association is merged; or

(2) such association is the subsidiary of another mutual holding company that, while in the mutual form, is acquired by the mutual holding company, and the acquiring mutual holding company chooses to operate the acquired savings association separately from its resulting association.

■ 10. Amend § 239.6 by revising paragraphs (a), (g), and (i) to read as follows:

§ 239.6 Contents of Reorganization Plans.

(a) Provide for amendment of the charter and bylaws of the reorganizing association, and attach and incorporate such charter and bylaws;

* * * * *

(g) Provide that each depositor in the reorganizing association or any acquiree association immediately prior to the reorganization shall upon consummation of the reorganization receive, without payment, an identical account in the resulting association or the acquiree association, as the case may be (with appropriate modifications made to this provision if savings associations are being merged as a part of the reorganization);

* * * * *

(i) Provide that the Reorganization Plan shall be terminated if not completed within a specified period of time (where the time period shall not be more than 24 months from the date upon which the members of the reorganizing association or the date upon which the members of any acquiree association, whichever is earlier, approve the Reorganization Plan and may not be extended by the reorganizing or acquiree association); and

* * * * *

■ 11. Amend § 239.7 by:

■ a. Removing in paragraph (a)(1) the text ''§ 238.11 of this chapter'' and adding in its place the text ''12 CFR 238.11'';

■ b. Revising paragraphs (a)(2)(iii), (a)(2)(iv), and (a)(3);

■ c. Removing in paragraph (a)(4) the text ''§ 238.11 of this chapter'' and adding in its place the text ''12 CFR 238.11''; and

■ d. Removing in paragraph (a)(5) the text ''§§ 238.41 and 238.11 of this chapter'' and adding in its place the text ''12 CFR 238.41 and 238.11''.

The revisions read as follows:

§ 239.7 Acquisition and disposition of savings associations, savings and loan holding companies, and other corporations by mutual holding companies.

(a) * * *

(2) * * *

(iii) The necessary approvals are obtained from the Board, including approval pursuant to 12 CFR 238.11, and any other approvals required to form an interim association, to amend the charter and bylaws of the association being acquired, or to amend the charter and bylaws of the mutual holding company consistent with § 239.6(a); and

(iv) The approval of the members of the mutual holding company is obtained, if the Board advises the mutual holding company in writing that such approval will be required. In determining whether members' approval will be required, the Board shall consider:

(A) The corporate governance structure of the mutual holding company;

(B) The ability of members to vote on any future mutual-to-stock conversion of the acquiring mutual holding company;

(C) The supervisory condition of the mutual savings association that would be acquired; and

(D) The burden and cost associated with obtaining the members' approval.

(3) *Mutual holding companies.*

(i) A mutual holding company that is not a subsidiary holding company may not acquire control of another mutual holding company, including a subsidiary holding company, by merging with or into such company, unless the necessary approvals are obtained from the Board, including approval pursuant to 12 CFR 238.11.

(ii) The approval of the members of one or both of the mutual holding companies shall also be obtained if the Board advises the mutual holding companies in writing that such approval will be required. In determining whether the members' approval will be required, the Board shall consider:

(A) The corporate governance structure of the mutual holding company;

(B) The ability of members to vote on any future mutual-to-stock conversion of the resulting mutual holding company;

(C) The supervisory condition of the acquiree mutual holding company; and

(D) The burden and cost associated with obtaining the members' approval.

* * * * *

■ 12. Amend § 239.8 by:

■ a. Removing in paragraph (a) the text ''§§ 238.53(c) or 238.54(b) of this chapter'' and adding in its place the text ''12 CFR 238.53(c) or 238.54(b)'';

■ b. Revising paragraph (c)(1)(i);

■ c. Removing in paragraph (c)(1)(iii) the word ''or'';

■ d. Revising paragraph (c)(1)(iv);

■ e. Adding paragraph (c)(1)(v);

■ f. Revising paragraphs (c)(2), (d)(2)(iv), and (d)(4)(iii);

■ g. Deleting paragraph (d)(4)(v);

■ h. Redesignating paragraphs (d)(4)(vi) through (d)(4)(ix) as (d)(4)(v) through (d)(4)(viii); and

■ i. Removing in paragraph (f) the text ''parts 207, 228, and 238 of this chapter'' and adding in its place the text ''12 CFR Parts 207, 228, and 238''.

The revisions and addition read as follows:

§ 239.8 Operating restrictions.

* * * * *

(c) * * *

(1) * * *

(i) Is in compliance with the requirements set forth in § 239.63(c)–(d) as if the share issuance had been a conversion;

* * * * *

(iv) Is purchased in the open market by a tax-qualified or non-tax-qualified employee stock benefit plan of the savings association (or of a subsidiary holding company) in an amount reasonable and appropriate to fund such plan; or

(v) Is conducted under circumstances consistent with the circumstances indicated in the subsidiary holding company's Stock Issuance Plan related to a proposed purchase of shares within one year of the date of issuance of the shares.

(2) No mutual holding company may purchase shares of its subsidiary savings association or subsidiary holding company within one year after a stock issuance, except if the purchase is conducted under circumstances consistent with the circumstances indicated in the subsidiary holding company's Stock Issuance Plan related to a proposed purchase of shares within one year of the date of issuance of the shares complies with § 239.63. For purposes of this section, the reference in § 239.63 to five percent refers to minority shareholders.

(d) * * *

(2) * * *

(iv) An affirmation that all mutual members of the mutual holding company received at some prior time disclosure containing a detailed description of dividend waivers by the mutual holding company and the reasons the board of directors waives the mutual holding company's right to receive dividends declared by a subsidiary of the mutual holding company.

* * * * *

(4) * * *

(iii) Within the ten years prior to the declaration date of the dividend by the subsidiary of the mutual holding company, the mutual members of the mutual holding company have approved the waiver of dividends by the mutual holding company by a majority of votes cast during a member vote. Any proxy statement used in connection with the member vote must contain—

(A) A detailed description of the proposed waiver of dividends by the mutual holding company and the reasons the board of directors requested the waiver of dividends; and

(B) The disclosure of any mutual holding company director's ownership of stock in the subsidiary declaring dividends and any actions the mutual holding company and board of directors have taken to eliminate the conflict of interest, such as the directors waiving their right to receive dividends;

* * * * *

■ 13. Amend § 239.9 by:

■ a. Revising paragraphs (b)(2) and (b)(3); and

■ b. Deleting paragraph (c).

The revisions read as follows:

§ 239.9 Conversion or liquidation of mutual holding companies.

* * * * *

(b) * * *

(2) Except as provided in paragraph (b)(3) of this section, the net proceeds of any liquidation of any mutual holding company shall be transferred to the members of the mutual holding company, in accordance with the charter of the mutual holding company, and, if applicable, the stock holders of the subsidiary holding company in accordance with the charter of the subsidiary holding company.

(3) If the FDIC incurs a loss as a result of the default of any subsidiary savings association of a mutual holding company and that mutual holding company is liquidated pursuant to paragraph (b)(1) of this section, the FDIC shall succeed to the membership interests of the members of the mutual holding company to the extent of the FDIC's loss.

■ 14. Amend § 239.10 by:

■ a. Removing in paragraph (b) the text ''§ 238.14 of this chapter'' wherever it appears and adding in its place the text ''12 CFR 238.14'';

■ b. Removing in paragraph (c)(2) the text ''§ 238.14 of this chapter'' and adding in its place the text ''12 CFR 238.14'';

■ c. Revising paragraph (c)(3);

■ d. Removing in paragraph (e) the text ''§ 238.14 of this chapter'' and adding in its place the text ''12 CFR 238.14'';

■ e. Removing in paragraph (e) the text ''§§ 238.14(f) and (g) of this chapter'' and adding in its place the text ''12 CFR 238.14(f) and (g)'';

■ f. Removing in paragraph (f) the text ''§ 238.14(b) of this chapter'' and adding in its place the text ''12 CFR 238.14(b)''; and

■ g. Removing in paragraph (f) the text ''§ 238.14 of this chapter'' and adding in its place the text ''12 CFR 238.14''.

The revision reads as follows:

§ 239.10 Procedural requirements.

* * * * *

(c) * * *

(3) *Public notice, public comment, and meetings.* Mutual holding company reorganizations are subject to applicable public notice, public comment, and meeting requirements under the Home Owners' Loan Act regulations at 12 CFR 238.11 and 12 CFR 238.14.

* * * * *

■ 15. Amend § 239.11 by revising paragraph (c) to read as follows:

§ 239.11 Subsidiary holding companies.

* * * * *

(c) *Charters and bylaws for subsidiary holding companies.* The charter and bylaws of a subsidiary holding company may be in the form set forth in Appendices B and D, respectively. A subsidiary holding company may be chartered by the Board or by any state, as defined by 12 CFR 238.2(nn).

■ 16. Amend § 239.12 by revising paragraph (b)(5), the introductory text of paragraph (b)(6), and the introductory text of paragraph (b)(7) to read as follows:

§ 239.12 Communication between members of a mutual holding company.

* * * * *

(b) * * *

(5) The reply shall provide either—

(i) The number of the mutual holding company's members and the estimated reasonable cost to the mutual holding company of sending to them the proposed communication; or

(ii) Notification that the mutual holding company has determined not to send the communication because it is ''improper'', as defined in paragraph (c) of this section;

(6) After receiving the amount of the estimated costs of sending and sufficient copies of the communication, the mutual holding company shall send the communication to all members, either—

* * * * *

(7) If the mutual holding company refuses to send the proposed communication, it shall return the requesting member's materials together with a written statement of the specific reasons for refusal, and shall simultaneously send to the appropriate Reserve Bank a copy of each of the requesting member's materials, the mutual holding company's written statement, and any other relevant material. The materials shall be sent within:

* * * * *

■ 17. Amend § 239.13 by revising paragraphs (a) and (b) to read as follows:

§ 239.13 Charters.

(a) *Charters.* The charter of a mutual holding company may be in the form set forth in appendix A of this part and may be amended pursuant to this paragraph.

(b) *Corporate title.* The corporate title of each mutual holding company shall include the term ''mutual'' or the abbreviation ''MHC'' or ''M.H.C.''

* * * * *

■ 18. Amend § 239.14 by:

■ a. Removing in paragraph (a)(2)(i) the text ''§ 238.14 of this chapter'' and adding in its place the text ''12 CFR 238.14''; and

■ b. Revising the introductory text of paragraph (b) and paragraph (b)(2).

The revisions read as follows:

§ 239.14 Charter amendments.

* * * * *

(b) *Approval.* Any charter amendment filed pursuant to paragraph (a)(2)(ii) of this section shall automatically be approved 30 days from the date of filing of such amendment with the appropriate Reserve Bank, provided that the mutual holding company follows the requirements of its charter in adopting such amendment, unless the Reserve Bank or the Board notifies the mutual holding company prior to the expiration of such 30-day period that such amendment is rejected or is deemed to be filed under the provisions of paragraph (a)(2)(i) of this section. Notwithstanding anything in paragraph (a) of this section to the contrary, the following charter amendments shall be effective and deemed approved at the time of adoption, if adopted without change and filed with Board, within 30 days after adoption, provided the mutual holding company follows the requirements of its charter in adopting such amendments.

* * * * *

(2) *Maximum number of votes.* A mutual holding company may amend the Capital Stock section of its charter by substituting the maximum number of votes per member to any number from 1 to 1000.

* * * * *

■ 19. Amend § 239.15 by:

■ a. Revising paragraph (b)(3);

■ b. Removing in paragraph (c)(ii) the text ''§ 238.14 of this chapter'' and adding in its place the text ''12 CFR 238.14''; and

■ c. Removing in paragraph (c)(iii) the sentence ''The Board may amend the model bylaws provided in appendix C to this part.''

The revision reads as follows:

§ 239.15 Bylaws.

* * * * *

(b) * * *

(3) *Notice of meeting of members.* Notice specifying the date, time, and place of the annual or any special meeting and adequately describing any business to be conducted shall be published for two successive weeks immediately prior to the week in which such meeting shall convene in a newspaper of general circulation in the city or county in which the principal place of business of the subsidiary savings association is located, or shall be sent to each of the members of record at least 15 days and not more than 45 days prior to the date on which such meeting shall convene. A similar notice shall be posted in a conspicuous place in each of the offices of the subsidiary savings association during the 14 days immediately preceding the date on which such meeting shall convene. The bylaws may permit a member to waive in writing any right to receive personal delivery of the notice. When any meeting is adjourned for 30 days or more, notice of the adjournment and reconvening of the meeting shall be given as in the case of the original meeting.

* * * * *

■ 20. Amend § 239.16 by revising paragraphs (a)(2) and (b) to read as follows:

§ 239.16 Voluntary dissolution.

(a) * * *

(2) Dissolution in a manner proposed by the directors that appropriately takes into account the impact of the proposed dissolution on the mutual holding company's members and other relevant parties.

(b) The plan, and a statement of reasons for proposing dissolution and for proposing the plan, shall be submitted to the appropriate Reserve Bank for approval. The Board will approve the plan if the Board believes dissolution is appropriate under the circumstances, taking into account the impact of the proposed dissolution on the mutual holding company's members and other relevant parties. If the Board considers the plan inappropriate, the Board may either make recommendations to the mutual holding company concerning the plan or disapprove it. When the plan is approved by the mutual holding company's board of directors and by the Board, it shall be submitted to the mutual holding company's members at a duly called meeting and, when approved by a majority of votes cast at that meeting, shall become effective. After dissolution in accordance with the plan, a certificate evidencing dissolution, supported by such evidence as the Board may require, shall immediately be filed with the Board. When the Board receives such evidence satisfactory to the Board, it will terminate the corporate existence of the dissolved mutual holding company and the mutual holding company's charter shall thereby be canceled.

Subpart C—Subsidiary Holding Companies

■ 21. Amend § 239.21 by:

■ a. Revising paragraph (a); and

■ b. Removing in paragraph (b)(2) the text ''§ 12 CFR 238.12(a)(7) of this chapter'' and adding in its place the text ''12 CFR 238.12(a)(6)''.

The revision reads as follows:

§ 239.21 Charters.

(a) *Charters.* The charter of a subsidiary holding company of a mutual holding company may be in the form set forth in appendix B of this part and may be amended pursuant to § 239.22.

* * * * *

■ 22. Amend § 239.22 by:
■ a. Revising the introductory text of paragraph (a) and paragraph (a)(2)(i);
■ b. Removing in paragraph (a)(2)(ii) the word ''mailed'' and adding in its place the word ''sent'';
■ c. Revising the introductory text of paragraph (b);
■ d. Removing in paragraph (b)(2) the text ''in section 2 of its charter'';
■ e. Removing in paragraph (b)(3) the text ''Section 5 of'';
■ f. Removing in paragraph (b)(4) the text ''by revising Section 5'' and the number ''5'' wherever it appears;
■ g. Revising paragraph (b)(5); and
■ h. Removing in paragraph (b)(6) the text ''Section 5'' and adding in its place the text ''the section on Capital Stock'';
■ i. Removing in paragraph (b)(8) the text ''section 8'' wherever it appears and adding in its place the text ''section'';
■ j. Removing in paragraph (b)(8) the text ''Section 8'' wherever it appears and adding in its place the text ''Section''; and
■ k. Revising paragraphs (c) and (d).

The revisions appear as follows:

§ 239.22 Charter amendments.

(a) *General.* In order to adopt a charter amendment, a subsidiary holding company that is chartered by the Board must comply with the following requirements:

* * * * *

(2) * * *

(i) *Application requirement.* If the proposed charter amendment would render more difficult or discourage a merger, tender offer, proxy contest, the assumption of control by a holder of a block of the subsidiary holding company's stock, or the removal of incumbent management, or would involve a significant issue of law or policy, the subsidiary holding company shall file the proposed amendment with and shall obtain the prior approval of the Board according to the procedures in 12 CFR 238.14; and

* * * * *

(b) *Approval.* Any charter amendment filed by a Board-chartered subsidiary holding company pursuant to paragraph (a)(2)(ii) of this section shall automatically be approved 30 days from the date of filing of such amendment, provided that the subsidiary holding company follows the requirements of its charter in adopting such amendment, unless the Board notifies the mutual holding company prior to the expiration of such 30-day period that such amendment is rejected or is deemed to be filed under the provisions of paragraph (a)(2)(i) of this section. In addition, the following charter amendments, including the adoption of the charter as set forth in appendix B of this part, shall be approved at the time of adoption, if adopted without change and filed with the Board within 30 days after adoption, provided the Board-chartered subsidiary holding company follows the requirements of its charter in adopting such amendments.

* * * * *

(5) *Limitations on subsequent issuances.* A subsidiary holding company may amend its charter to require shareholder approval of the issuance or reservation of common stock or securities convertible into common stock under circumstances which would require shareholder approval under the rules of the stock exchange on which its shares were listed.

* * * * *

(c) *Anti-takeover provisions.* The Board may grant approval to a charter amendment not listed in paragraph (b) of this section regarding the acquisition by any person or persons of its equity securities provided that the Board-chartered subsidiary holding company shall file as part of its application for approval an opinion, acceptable to the Board, of counsel independent from the subsidiary holding company that the proposed charter provision would be permitted to be adopted by a corporation chartered by the state in which the principal office of the subsidiary holding company is located. Any such provision must be consistent with applicable statutes, regulations, and Board policies. Further, any such provision that would have the effect of rendering more difficult a change in control of the Board-chartered subsidiary holding company and would require for any corporate action (other than the removal of directors) the affirmative vote of a larger percentage of shareholders than is required by this part, shall not be effective unless adopted by a percentage of shareholder vote at least equal to the highest percentage that would be required to take any action under such provision.

(d) *Reissuance of charter.* A Board-chartered subsidiary holding company that has amended its charter may apply to have its charter, including the amendments, reissued by the Board. Such requests for reissuance should be filed with the appropriate Reserve Bank, and contain signatures required by the charter in appendix B to this part, together with such supporting documents as needed to demonstrate that the amendments were properly adopted.

■ 23. Amend § 239.23 by removing in paragraph (b)(1)(ii) the text ''§ 12 CFR 238.14 of this chapter'' and add in its place the text ''12 CFR 238.14''.
■ 24. Amend § 239.24 by:
■ a. Revising the introductory text of paragraph (a) and paragraphs (a)(4) and (a)(7);
■ b. Deleting paragraph (a)(9); and
■ c. Revising paragraphs (c)(6)(i) and (c)(8).

The revisions read as follows:

§ 239.24 Issuances of stock by subsidiary holding companies of mutual holding companies.

(a) *Requirements.* No subsidiary holding company of a mutual holding company may issue stock to persons other than its mutual holding company parent in connection with a mutual holding company reorganization, or at any time subsequent to the subsidiary holding company's acquisition by the mutual holding company, unless the subsidiary holding company obtains advance approval of each such issuance from the Board. Approval of a mutual holding company reorganization filed pursuant to § 239.3(a) shall be deemed to constitute approval of any stock issuance specifically applied for pursuant to this section in connection with the reorganization, unless otherwise specified by the Board. The proposed issuance must meet each of the following criteria:

* * * * *

(4) The proposed price or price range of the stock to be issued is reasonable. The Board shall review the reasonableness of the proposed price or price range, if applicable. To the extent the proposed issuance is solely to a stock benefit plan, employee stock ownership plan, stock option plan, or management recognition plan, the Board will review the reasonableness of the terms of such plan.

* * * * *

(7) The Board will review the Stock Issuance Plan and the compliance record of the subsidiary holding company and its subsidiary savings association under the regulations applicable to those entities to determine how the stock issuance would affect the convenience and needs of its communities.

(i) Based on this review, the Board may approve the application, deny the application, or approve the application

on the condition that the subsidiary holding company will improve the Community Reinvestment Act (CRA) performance of its subsidiary savings association or will address the particular credit or lending needs of one of more of the communities that it serves.

(ii) The Board may deny the application if the Stock Issuance Plan does not demonstrate that the proposed stock issuance would help the subsidiary holding company meet the credit and lending needs of the communities that it serves.

* * * * *

(c) * * *

(6) * * *

(i) Comply with § 239.59 as if the stock issuance were being conducted as part of a conversion and, to the extent applicable, the form or forms specified by the Board; and

* * * * *

(8) As part of a reorganization, a reasonable amount of shares or proceeds may be contributed to a charitable organization that complies with §§ 239.64(b) to 239.64(f), provided such contribution does not result in any taxes on excess business holdings under section 4943 of the Internal Revenue Code of 1986, as amended (Internal Revenue Code) (26 U.S.C. 4943).

* * * * *

■ 25. Amend § 239.25 by:

■ a. Revising paragraphs (a)(1) through (a)(3);

■ b. Deleting paragraphs (a)(4) through (a)(7);

■ c. Adding paragraph (a)(4);

■ d. Redesignating paragraph (a)(8) as paragraph (a)(5);

■ e. Revising paragraph (a)(5);

■ f. Deleting paragraph (a)(9);

■ g. Redesignating paragraphs (a)(10) through (a)(22) as paragraphs (a)(6) through (a)(18); and

■ h. Revising paragraphs (a)(7), (a)(8), (a)(10), (a)(13), (a)(18), (b)(1), (b)(4), and (c).

The revisions and addition read as follows:

§ 239.25 Contents of Stock Issuance Plans.

(a) * * *

(1) Provide that, except with respect to a proposed issuance solely to a stock benefit plan, employee stock ownership plan, stock option plan, or management recognition plan, the stock shall be sold at a total price equal to the estimated *pro forma* market value of such stock, based upon an independent valuation;

(2) Provide that the aggregate amount of outstanding common stock of the subsidiary holding company owned or controlled by persons other than the subsidiary holding company's mutual holding company parent at the close of the proposed issuance shall be less than fifty percent of the subsidiary holding company's total outstanding common stock (although this provision may be omitted if the proposed issuance will be conducted by a subsidiary holding company that was in the stock form when acquired by its mutual holding company parent);

(3) Provide that all stock benefit plans, employee stock ownership plans, stock option plans, or management recognition plans may not, at any given time, hold in the aggregate more than either 4.9 percent of the outstanding shares of the subsidiary holding company's common stock or 4.9 percent of the subsidiary holding company's stockholders' equity;

(4) Provide that, following completion of the proposed issuance, the amount of stock authorized to be issued or acquired by all stock benefit plans, employee stock ownership plans, stock option plans, or management recognition plans may not exceed, in the aggregate, 25 percent of the outstanding shares of the subsidiary holding company's common stock or 25 percent of the subsidiary holding company's stockholders' equity.

(5)

(i) Provide that the aggregate amount of common stock that may be acquired by all insiders of the subsidiary holding company and subsidiary savings association and associates of insiders of the subsidiary holding company and subsidiary savings association, must not exceed the following percentages of common stock or stockholders' equity of the subsidiary holding company, held by persons other than the subsidiary holding company's mutual holding company parent at the close of the proposed issuance:

Institution size	Officer and director purchases (percent)
$ 50,000,000 or less	35
$ 50,000,001–100,000,000	34
$100,000,001–150,000,000	33
$150,000,001–200,000,000	32
$200,000,001–250,000,000	31
$250,000,001–300,000,000	30
$300,000,001–350,000,000	29
$350,000,001–400,000,000	28
$400,000,001–450,000,000	27
$450,000,001–500,000,000	26
Over $500,000,000	25

(ii) The percentage limitations contained in paragraph 5(i) of this section may be exceeded provided that all stock acquired by or awarded to insiders and associates of insiders in excess of those limitations is acquired in the secondary market.

(iii) In calculating the number of shares held by insiders and their associates under this provision, shares awarded but not delivered under a stock benefit plan, employee stock ownership plan, stock option plan, or management recognition plan that are attributable to such persons shall not be counted as being acquired by such persons.

* * * * *

(7) Provide that, except with respect to a proposed issuance solely to a stock benefit plan, employee stock ownership plan, stock option plan, or management recognition plan, the sales price of the shares of stock to be sold in the issuance shall be a uniform price determined in accordance with § 239.24;

(8) Provide that, if at the close of the stock issuance the subsidiary holding company has more than thirty-five shareholders of any class of stock, the subsidiary holding company shall promptly register that class of stock pursuant to the Securities Exchange Act of 1934 (15 U.S.C. 78a–78jj), and undertake not to deregister such stock for a period of three years thereafter;

* * * * *

(10) Provide that, for a period of three years following the proposed issuance, no insider of the subsidiary holding company or his or her associates shall purchase, without the prior written approval of the Board, any stock of the subsidiary holding company except from a broker or dealer registered with the U.S. Securities and Exchange Commission, except that the foregoing restriction shall not apply to:

(i) Negotiated transactions involving more than one percent of the outstanding stock in the class of stock; or

(ii) Purchases of stock made by and held by any stock benefit plan, employee stock ownership plan, stock option plan, or management recognition plan, even if such stock is attributable to insiders of the subsidiary holding company and subsidiary savings association or their associates;

* * * * *

(13) Provide that, except with respect to a proposed issuance to a stock benefit plan, employee stock ownership plan, stock option plan, or management recognition plan, the subsidiary holding company will not offer or sell any of the stock proposed to be issued to any person whose purchase would be financed by funds loaned, directly or indirectly, to the person by the subsidiary holding company;

* * * * *

(18) Provide that the subsidiary holding company may make scheduled discretionary contributions to a stock benefit plan, employee stock ownership plan, stock option plan, or management recognition plan provided such contributions do not cause the subsidiary holding company to fail to meet any of its regulatory capital requirements.

* * * * *

(b) * * *

(1) Provide that, in the event the proposed stock issuance is part of a Reorganization Plan, the stock offering may be commenced concurrently with or at any time after sending any proxy statement(s) to the members of the reorganizing association and any acquiree association. The offering may be closed before the required membership vote(s), provided the offer and sale of the stock shall be conditioned upon the approval of the Reorganization Plan and Stock Issuance Plan by the members of the reorganizing association and any acquiree association;

* * * * *

(4) Provide that, in connection with a reorganization, the subsidiary holding company may reserve shares representing up to ten percent of the proposed offering for issuance in connection with a stock benefit plan, employee stock ownership plan, stock option plan, or management recognition plan.

(c) *Applicability of provisions of § 239.63(a)(1) to minority stock issuances.* Notwithstanding § 239.24(d), § 239.63(a)(1)(ii) does not apply to minority stock issuances, because the permissible sizes of stock benefit plan, employee stock ownership plans, stock option plans, and management recognition plans are subject to the requirements set forth in paragraph (a) of this section. However, the other provisions of Section 239.63(a)(1) apply for one year after the subsidiary holding company engages in a minority stock issuance that is conducted in accordance with the purchase priorities set forth in subpart E of this part.

■ 26. Amend § 239.26 by revising paragraphs (b) and (d)(2) to read as follows:

§ 239.26 Shareholders.

* * * * *

(b) *Notice of shareholder meetings.* Written notice stating the place, day, and hour of the meeting and the purpose or purposes for which the meeting is called shall be sent not fewer than 20 nor more than 50 days before the date of the meeting, by or at the direction of the chairman of the board, the president, the secretary, or the directors, or other natural persons calling the meeting, to each shareholder of record entitled to vote at such meeting. If mailed, such notice shall be deemed to be sent when deposited in themail, addressed to the shareholder at the address appearing on the stock transfer books or records of the subsidiary holding company as of the record date prescribed in paragraph (c) of this section, with postage thereon prepaid. When any shareholders' meeting, either annual or special, is adjourned for 30 days or more, notice of the adjourned meeting shall be given as in the case of an original meeting. Notwithstanding anything in this section, however, a subsidiary holding company that is wholly owned shall not be subject to the shareholder notice requirement.

* * * * *

(d) * * *

(2) In lieu of making the shareholders list available for inspection by any shareholders as provided in paragraph (d)(1) of this section, the board of directors may perform such acts as required by paragraphs (a) and (b) of Rule 14a-7 of the General Rules and Regulations under the Securities Exchange Act of 1934 (17 CFR 240.14a-7) as may be duly requested in writing, with respect to any matter which may be properly considered at a meeting of shareholders, by any shareholder who is entitled to vote on such matter and who shall defray the reasonable expenses to be incurred by the subsidiary holding company in performance of the act or acts required.

* * * * *

■ 27. Amend § 239.27 by revising paragraph (j) to read as follows:

§ 239.27 Board of directors.

* * * * *

(j) *Presumption of assent.* A director of the subsidiary holding company who is present at a meeting of the board of directors at which action on any subsidiary holding company matter is taken shall be presumed to have assented to the action taken unless his or her dissent or abstention shall be entered in the minutes of the meeting or unless a written dissent to such action shall be filed with the individual acting as the secretary of the meeting before the adjournment thereof or shall be forwarded by electronic mail or registered mail to the secretary of the subsidiary holding company within five days after the date on which a copy of the minutes of the meeting is received. Such right to dissent shall not apply to a director who voted in favor of such action.

* * * * *

■ 28. Amend § 239.30 by revising paragraph (a) to read as follows:

§ 239.30 Annual reports; books and records.

(a) *Annual reports to stockholders.* A subsidiary holding company not wholly owned by a holding company shall, within 130 days after the end of its fiscal year, send to each of its stockholders entitled to vote at its annual meeting an annual report containing financial statements that satisfy the requirements of rule 14a-3 under the Securities Exchange Act of 1934. (17 CFR 240.14a-3). Concurrently with such transmission, a certification of such transmission signed by the chairman of the board, the president, or a vice president of the subsidiary holding company, together with a copy of the report, shall be sent by the subsidiary holding company to the appropriate Reserve Bank.

* * * * *

Subpart D—Indemnification; Employment Contracts

■ 29. Amend § 239.40 by revising paragraphs (b)(1), (c), and (d) to read as follows:

§ 239.40 Indemnification of directors, officers and employees.

* * * * *

(b) * * *

(1) Any amount for which that person becomes liable under a judgment in such action; and

* * * * *

(c) *Requirements.* Indemnification shall be made to such person under paragraph (b) of this section only if:

(1) Final judgment on the merits is in the person's favor; or

(2) In case of:

(i) Settlement,

(ii) Final judgment against the person, or

(iii) Final judgment in the person's favor, other than on the merits, if a majority of the disinterested directors of the mutual holding company determine that the person was acting in good faith within the scope of the person's employment or authority as the person could reasonably have perceived it under the circumstances and for a purpose the person could reasonably have believed under the circumstances was in the best interests of the mutual holding company or its members.

However, no indemnification shall be made unless the mutual holding company gives the Board at least 60

days' notice of its intention to make such indemnification. Such notice shall state the facts on which the action arose, the terms of any settlement, and any disposition of the action by a court. Such notice, a copy thereof, and a certified copy of the resolution containing the required determination by the board of directors shall be sent to the appropriate Reserve Bank, who shall promptly acknowledge receipt thereof. The notice period shall run from the date of such receipt. No such indemnification shall be made if the Board advises the mutual holding company in writing, within such notice period, of its objection to the indemnification.

(d) *Insurance.* A mutual holding company may obtain insurance to protect it and its directors, officers, and employees from potential losses arising from claims against any of them for alleged wrongful acts, or wrongful acts, committed in their capacity as directors, officers, or employees. However, no mutual holding company may obtain insurance which provides for payment of losses of any individual incurred as a consequence of the individual's willful or criminal misconduct.

* * * * *

■ 30. Amend § 239.41 by revising the introductory text of paragraph (b)(2) and paragraphs (b)(3), (b)(4), and (b)(6)(i) to read as follows:

§ 239.41 Employment contracts.

* * * * *

(b) * * *

(2) If the officer or employee is suspended or temporarily prohibited from participating in the conduct of the mutual holding company's affairs by a notice served under section 8 (e)(3) or (g)(1) of the Federal Deposit Insurance Act (12 U.S.C. 1818 (e)(3) and (g)(1)) the mutual holding company's obligations under the contract shall be suspended as of the date of service unless stayed by appropriate proceedings. If the charges in the notice are dismissed, the mutual holding company may in its discretion:

* * * * *

(3) If the officer or employee is removed or permanently prohibited from participating in the conduct of the mutual holding company's affairs by an order issued under section 8(e)(4) or (g)(1) of the Federal Deposit Insurance Act (12 U.S.C. 1818(e)(4) or (g)(1)), all obligations of the mutual holding company under the contract shall terminate as of the effective date of the order, but vested rights of the contracting parties shall not be affected.

(4) If the subsidiary savings association is in default (as defined in section 3(x)(1) of the Federal Deposit Insurance Act (12 U.S.C. 1813(x)(1))), all obligations under the contract shall terminate as of the date of default, but this paragraph (b) shall not affect any vested rights of the contracting parties: *Provided,* that this paragraph (b) need not be included in an employment contract if prior written approval is secured from the Board.

* * * * *

(6) * * *

(i) By the Board, at the time the Federal Deposit Insurance Corporation enters into an agreement to provide assistance to or on behalf of the subsidiary savings association under the authority contained in section 13(c) of the Federal Deposit Insurance Act (12 U.S.C. 1823(c)); or

* * * * *

Subpart E—Conversions From Mutual to Stock Form

■ 31. Amend § 239.50 by revising paragraph (b) to read as follows:

§ 239.50 Purpose and scope.

* * * * *

(b) *Prescribed forms.* A mutual holding company must use the forms prescribed under this subpart and provide such information as the Board may require under the form by regulation or otherwise. The forms required under this subpart include: Form AC (Application for Conversion) and Form PS (Proxy Statement).

* * * * *

■ 32. Amend § 239.52 by revising paragraphs (j) and (m) to read as follows:

§ 239.52 Definitions.

* * * * *

(j) *Qualifying deposit* is the total balance in an account holder's eligible savings accounts at the close of business on the eligibility or supplemental eligibility record date. The mutual holding company's plan of conversion may provide that only savings accounts with total deposit balances of $50 or more will qualify.

* * * * *

(m) *Solicitation* and *solicit* is a request for a proxy, whether or not accompanied by or included in a form of proxy; a request to execute, not execute, or revoke a proxy; or the furnishing of a form of proxy or other communication reasonably calculated to cause the members to procure, withhold, or revoke a proxy. Solicitation or solicit does not include providing a form of proxy at the unsolicited request of a member, the acts required to send communications to members, or ministerial acts performed on behalf of a person soliciting a proxy.

* * * * *

■ 33. Amend § 239.53 by:

■ a. Revising paragraph (b)(2); and

■ b. Removing in paragraph (d)(2) the text ''The mutual holding company must file its business plan as a confidential exhibit to the Form AC''.

The revision reads as follows:

§ 239.53 Prior to conversion.

* * * * *

(b) * * *

(2) The business plan must include projected financial statements that do not include returns of capital or special dividends in any part of the business plan. The business plan may include additional projections that include returns of capital, special dividends, or both.

* * * * *

■ 34. Amend § 239.54 by revising paragraphs (a) and (c)(1) to read as follows:

§ 239.54 Plan of conversion.

(a) *Adoption by the board of directors.* Prior to filing an application for conversion, the board of directors of the mutual holding company must adopt a plan of conversion that conforms to §§ 239.59 through 239.62 and 239.63(b). The board of directors must adopt the plan by at least a two-thirds vote.

* * * * *

(c) * * *

(1) *Notice.* The mutual holding company must promptly notify its members that the board of directors adopted a plan of conversion and that a copy of the plan is available for the members' inspection in the mutual holding company's home office and in each of the subsidiary savings association's branch offices. The mutual holding company must send a letter to each member or publish a notice in the local newspaper in every local community where the savings association has an office. The mutual holding company may also issue a press release. The Board may require broader publication, if necessary, to ensure adequate notice to the members.

* * * * *

■ 35. Amend § 239.55 by:

■ a. Revising paragraphs (a), (b)(1)(v), (b)(1)(vi), (c)(2), (d), (f)(1)(i), (f)(2), (g)(1)(iii), and (g)(3)(i); and

■ b. Deleting paragraph (h).

The revision reads as follows:

§ 239.55 Filing requirements.

(a) *Applications under this subpart.* Any filing with the Board required under this subpart must be filed in

accordance with 12 CFR 238.14. The Board will review any filing made under this subpart in accordance with 12 CFR 238.14.

* * * * *

(b) * * *

(1) * * *

(v) The documents and information required by Form AC.

(vi) Where indicated, written consents, signed and dated, of any accountant, attorney, investment banker, appraiser, or other professional who prepared, reviewed, passed upon, or certified any statement, report, or valuation for use.

* * * * *

(c) * * *

(2) Upon receipt of an application under this subpart, the Reserve Bank will promptly furnish notice and a copy of the application to the primary federal supervisor of any subsidiary savings association. The primary federal supervisor will have 30 calendar days from the date of the letter giving notice in which to submit its views and recommendations to the Board.

* * * * *

(d) *Confidential treatment of portions of an application for conversion.* The confidentiality of information submitted to the Board under this section and related materials shall be determined in accordance with applicable exemptions under the Freedom of Information Act (5 U.S.C. 552(b)) and the Board's Rules Regarding Availability of Information (12 CFR part 261).

* * * * *

(f) * * *

(1) * * *

(i) The mutual holding company must publish a public notice of the application for conversion in accordance with the procedures in 12 CFR 238.14. The mutual holding company must simultaneously prominently post the notice in its home office and in all of the branch offices of its subsidiary savings associations.

* * * * *

(2) *Public comments.* Commenters may submit comments on the application in accordance with the procedures in 12 CFR 238.14. A commenter must file any comments with the appropriate Reserve Bank.

* * * * *

(g) * * *

(1) * * *

(iii) The conversion will not result in a taxable reorganization under the Internal Revenue Code.

* * * * *

(3) * * *

(i) Based on this review, the Board may approve the application, deny the application, or approve the application on the condition that the resulting stock holding company will improve the CRA performance of its subsidiary savings association or will address the particular credit or lending needs of the communities that it will serve.

* * * * *

■ 36. Amend § 239.56 by redesignating paragraphs (c)(2) and (c)(3) as paragraphs (c)(1) and (c)(2).

■ 37. Amend § 239.57 by:

■ a. Revising paragraph (b)(8);

■ b. Removing the word ''mail'' wherever it appears and adding in its place the word ''send'';

■ c. Removing the word ''mailing'' wherever it appears and adding in its place the word ''sending'';

■ d. Removing in paragraph (f)(2) the text ''or otherwise furnish''; and

■ e. Revising paragraph (f)(3).

The revisions read as follows:

§ 239.57 Proxy solicitation.

* * * * *

(b) * * *

(8) A way for the member to specify by ballot whether the member whether he or she approves or disapproves of each matter that members will vote upon.

* * * * *

(f) * * *

(3) The mutual holding company must send proxy solicitation material to the designated members promptly after the member furnishes the materials and, if mail is to be used, any envelopes (or other containers) or postage (or payment for postage), to the mutual holding company.

* * * * *

■ 38. Amend § 239.58 by:

■ a. Removing in paragraph (a)(1) the text ''and Form OC. The mutual holding company may obtain Form OC from the Reserve Bank and the Board's website (*http://www.federalreserve.gov*)'';

■ b. Removing in paragraph (a)(3) the text ''Form OC'' and adding in its place the text ''offering circular'';

■ c. Removing in paragraph (b)(1) the word ''mails'' and adding in its place the word ''sends''; and

■ d. Revising paragraph (c)(2).

The revision read as follows:

§ 239.58 Offering circular.

* * * * *

(c) * * *

(2) After the U.S. Securities and Exchange Commission declares the post-effective amendment effective, the mutual holding company must immediately send the amendment to each person who subscribed for or ordered shares in the offering.

* * * * *

■ 39. Amend § 239.59 by:

■ a. Removing in paragraph (b)(1) the text ''Securities and Exchange Commission'' and adding in its place the text ''U.S. Securities and Exchange Commission'';

■ b. Deleting paragraphs (c)(2) through (c)(5);

■ c. Redesignating paragraph (c)(6) as paragraph (c)(2);

■ d. Removing in paragraph (d)(5) the text ''and Form OF. The mutual holding company may obtain Form OF from the Reserve Bank and from the Board's website (*www.federalreserve.gov*)'';

■ e. Removing in paragraph (e)(3)(ii) the text ''of the'';

■ f. Revising paragraphs (f)(1), (f)(2), (h)(2), and (i);

■ g. Deleting paragraph (m)(2);

■ h. Redesignating paragraphs (m)(3) and (m)(4) as paragraphs (m)(2) and (m)(3);

■ i. Revising paragraph (m)(3); and

■ j. Adding paragraph (q).

The revisions and addition read as follows:

§ 239.59 Offers and sales of stock.

* * * * *

(f) * * *

(1) A subscriber may purchase conversion shares with cash, by a withdrawal from a savings account, or by a withdrawal from a certificate of deposit. If a subscriber purchases conversion shares by a withdrawal from a certificate of deposit, the mutual holding company or its subsidiary savings association may not assess a penalty for the withdrawal.

(2) The mutual holding company may not extend credit to any person, other than a tax-qualified employee stock benefit plan of the mutual holding company or its subsidiary, to purchase the conversion shares, subject to all other regulatory requirements.

* * * * *

(h) * * *

(2) The mutual holding company must give subscription rights to purchase shares to each supplemental eligible account holder in the same amount as described in paragraph (h)(1) of this section, except that the mutual holding company must use the following fraction instead of the fraction described in paragraph (h)(1)(iii) of this section: the numerator is the total qualifying deposit of the supplemental eligible account holder, and the denominator is the total qualifying deposits of all supplemental eligible account holders.

(i) *Officers, directors, and their associates as eligible account holders.* The officers, directors, and their associates of the mutual holding

company and subsidiary savings association may be eligible account holders. However, if an officer, director, or an associate of an officer or director receives subscription rights based on increased deposits in the year before the eligibility record date, the mutual holding company must subordinate subscription rights for these deposits to subscription rights exercised by other eligible account holders.

* * * * *

(m) * * *

(3) The mutual holding company may include stock contributed to a charitable organization in the conversion in the calculation of the total offering of conversion shares under paragraph (m)(1) of this section, unless the Board objects on supervisory grounds.

* * * * *

(q) *Securities Registration Requirements.*

(1) Notwithstanding the requirements contained in paragraphs (d), (h), and (j) of this section, a mutual holding company that does not meet the standards to register its shares on a national or regional securities exchange need not offer and register its shares in a state, as defined in 12 CFR 238.2(nn), in which less than 5 percent of eligible account holders, supplemental eligible account holders, and other voting members eligible to purchase conversion shares reside. Nothing contained in this paragraph shall limit a mutual holding company from registering its shares in any state where less than 5 percent of eligible account holders, supplemental eligible account holders, and other voting members reside.

(2) Only a mutual holding company that does not meet the standards to register shares on a national or regional securities exchange may qualify for the treatment in paragraph (p)(1) of this section.

■ 40. Amend § 239.62 by revising paragraph (b)(1) to read as follows:

§ 239.62 Liquidation accounts.

* * * * *

(b) * * *

(1) * * *

(i) The resulting stock holding company determines the initial sub-account balance for a savings account held by an eligible account holder, for a savings account not held by the eligible account holder on the supplemental eligibility record date, by multiplying the initial balance of the liquidation account by the following fraction: The numerator is the qualifying deposit in the savings account expressed in dollars on the eligibility record date, and the denominator is the calculation in paragraph (b)(1)(iv) of this section.

(ii) The resulting stock holding company determines the initial sub-account balance for a savings account held by a supplemental eligible account holder, for a savings account not held by the supplemental eligible account holder on the eligibility record date, by multiplying the initial balance of the liquidation account by the following fraction: The numerator is the qualifying deposit in the savings account expressed in dollars on the supplemental eligibility record date, and the denominator is the calculation in paragraph (b)(1)(iv) of this section.

(iii) For a savings account held on both the eligibility record date and the supplemental eligibility record date, the amount of the qualifying deposits for purposes of calculating the initial liquidation sub-account is the higher account balance of the savings account on either the eligibility record date or the supplemental eligibility record date. The resulting stock holding company determines the initial sub-account balance for a savings account held on both the eligibility record date and the supplemental eligibility record date, by multiplying the initial balance of the liquidation account by the following fraction: The numerator is the higher amount of the qualifying deposit in the savings account on either the eligibility record date or the supplemental eligibility record date, expressed in dollars, and the denominator is the calculation in paragraph (b)(1)(iv) of this section.

(iv) The denominator for calculating the initial liquidation sub-account balance of each eligible and supplemental eligible account holder is the sum of the numerator calculations in paragraphs (b)(1)(i), (b)(1)(ii), and (b)(1)(iii) of this section.

(v) If an account holder holds a savings account on the eligibility record date and a separate savings account on the supplemental eligibility record date, the resulting stock holding company must compute separate sub-accounts for the qualifying deposits in the savings account on each record date.

* * * * *

■ 41. Amend § 239.63 by:

■ a. Revising the introductory text of paragraph (a) and paragraphs (a)(1), (a)(2), and (b)(1);

■ b. Removing in paragraph (b)(4) the text ''Securities and Exchange Commission'' and adding in its place the text ''U.S. Securities and Exchange Commission'';

■ c. Revising the introductory text of paragraph (c)(1) and paragraph (c)(1)(ii);

■ d. Removing in paragraph (c)(1)(iv) the text ''tax qualified'' and adding in its place the text ''tax-qualified'';

■ e. Adding paragraph (c)(1)(v);

■ f. Removing in the introductory text of paragraph (c)(3) the text ''.'' and adding in its place the text '':'';

■ g. Revising the introductory text of paragraph (d)(1) and paragraphs (f)(2), (f)(3)(iii), and (f)(3)(v);

■ h. Removing in paragraph (g)(1) the text '', as amended''; and

■ i. Revising paragraph (g)(3).

The revisions read as follows:

§ 239.63 Post-conversion.

(a) *Stock benefit plans, employee stock ownership plans, stock option plans, and management recognition plans.*

(1) During the 12 months after the conversion, the resulting stock holding company may implement a stock benefit plan, employee stock ownership plan, stock option plan, or management recognition plan, provided the resulting stock holding company meets all of the following requirements:

(i) The resulting stock holding company discloses the plans in the proxy statement and offering circular.

(ii) The aggregate holdings of any stock benefit plan, employee stock ownership plan, stock option plan, and management recognition plan do not exceed more than fifteen percent of the number of shares that the resulting stock holding company issued in the conversion.

(iii) No individual receives more than 25 percent of the shares or options under any plan.

(iv) The resulting stock holding company does not grant stock options at less than the market price at the time of grant.

(v) The resulting stock holding company does not fund the option plan or management recognition plan at the time of the conversion.

(vi) The plan does not begin to vest earlier than one year after the conversion and does not vest at a rate exceeding 20 percent per year.

(vii) The plan permits accelerated vesting only for disability or death, or if the resulting stock holding company undergoes a change of control.

(viii) The plan provides that the executive officers or directors must exercise or forfeit their options in the event the institution becomes critically undercapitalized under the applicable regulatory capital requirements, is subject to Board enforcement action, or receives a capital directive under § 263.83 of this chapter.

(2) The resulting stock holding company may provide dividend

equivalent rights or dividend adjustment rights to allow for stock splits or other adjustments to the stock in the stock benefit plan, employee stock ownership plan, stock option plan, or management recognition plan.

* * * * *

(b) * * *

(1) Directors and officers who purchase conversion shares may not sell the shares for one year after the date of purchase, except that, in the event of the death of the officer or director, the successor in interest may sell the shares.

* * * * *

(c) * * *

(1) The resulting stock holding company may not repurchase its shares in the first year after the conversion except under one of the following circumstances:

* * * * *

(ii) The resulting stock holding company may repurchase qualifying shares of a director or conduct a repurchase with the approval of the Board pursuant to an offer made to all shareholders of the stock holding company.

* * * * *

(v) The resulting stock holding company may repurchase its shares if such purchase would be consistent with the company's strategy for deploying conversion proceeds under the business plan filed with the application to convert to stock form and where that submitted business plan included projections to repurchase such stock.

* * * * *

(d) * * *

(1) To repurchase stock in the first year following conversion, other than repurchases under paragraphs (c)(1)(iii), (c)(1)(iv), or (c)(1)(v) of this section, the resulting stock holding company must file a written notice with the appropriate Reserve Bank. The resulting stock holding company must provide the following information:

* * * * *

(f) * * *

(2) A person acquires beneficial ownership of more than ten percent of a class of shares when he or she holds any combination of the stock or revocable or irrevocable proxies under circumstances that give rise to a conclusive control determination or rebuttable control determination under subpart C of 12 CFR 238. The Board will presume that a person has acquired shares if the acquiror entered into a binding written agreement for the transfer of shares. For purposes of this section, an offer is made when it is communicated. An offer does not include non-binding expressions of understanding or letters of intent regarding the terms of a potential acquisition.

* * * * *

(3) * * *

(iii) A corporation whose ownership is, or will be, substantially the same as the ownership of the resulting stock holding company may acquire or offer to acquire more than ten percent of the common stock, if it makes the offer or acquisition more than one year after the resulting stock holding company converts.

* * * * *

(v) An acquiror does not have to file a separate application to obtain Board approval under paragraph (f)(1) of this section, if the acquiror files an application under 12 CFR part 238 that specifically addresses the criteria listed under paragraph (f)(4) of this section and the resulting stock holding company does not oppose the proposed acquisition.

* * * * *

(g) * * *

(3) Use best efforts to list the shares on a national or regional securities exchange or on the National Association of Securities Dealers Automated Quotation system.

* * * * *

■ 42. Amend § 239.64 by:

■ a. Removing in paragraph (c) the text ''second step stock'';

■ b. Removing in paragraph (d) the text ''§ 238.62 of this chapter'' and adding in its place the text ''12 CFR 238.2'';

■ c. Revising the introductory text of paragraph (e) and paragraphs (e)(3) and (e)(4); and

■ d. Removing in paragraph (f)(1)(ii)(C) the text ''The mutual holding company may obtain Form AC from the appropriate Reserve Bank and the Board's website at *http://www.federalreserve.gov*.''

The revisions read as follows:

§ 239.64 Contributions to charitable organizations.

* * * * *

(e) *Charitable organization requirements.* The charter (or trust agreement) of a charitable organization formed by a mutual holding company converting to stock form and gift instrument must provide that:

* * * * *

(3) For at least five years after its organization, one seat on the charitable organization's board of directors (or board of trustees) is reserved for an independent director (or trustee) from the local community. This director may not be an officer, director, or employee of the mutual holding company or resulting stock holding company, or an officer, director, or employee of an affiliate of the mutual holding company or resulting stock holding company, and should have experience with local community charitable organizations and grant making; and

(4) For at least five years after its organization, one seat on the charitable organization's board of directors (or board of trustees) is reserved for a director from the board of directors or the board of directors of an acquiror or resulting institution in the event of a merger or acquisition of the mutual holding company or resulting stock holding company.

* * * * *

■ 43. Amend § 239.65 by:

■ a. Removing in paragraph (g)(4)(i) the text ''Thrift Financial Report'' and adding in its place the text ''relevant regulatory financial reports''; and

■ b. Revising paragraph (g)(7)(ii).

The revision reads as follows:

§ 239.65 Voluntary supervisory conversions.

* * * * *

(g) * * *

(7) * * *

(ii) Any required Home Owners' Loan Act application or Change in Bank Control Act of 1978 (12 U.S.C. 1817(j)) notice under 12 CFR part 238.

* * * * *

■ 44. Amend § 239.66 by removing in paragraph (b)(1) the text ''.'' and adding in its place the text '':''.

Appendix A to Part 239—Mutual Holding Company Model Charter

■ 45. Amend Appendix A by:

■ a. Revising section 4; and

■ b. Removing the text ''for calendar year 1989'' wherever it appears.

The revision reads as follows:

Appendix A to Part 239—Mutual Holding Company Model Charter

Federal Mutual Holding Company Charter

* * * * *

Section 4: Capital. The Mutual Holding Company shall have no capital stock. However, the Mutual Holding Company shall have the authority to issue mutual capital certificates, consistent with the Home Owners' Loan Act and all applicable state and federal law.

* * * * *

Appendix C to Part 239—Mutual Holding Company Model Bylaws

■ 46. Amend Appendix C by:

■ a. Removing in paragraph 3 the text ''mailed postage prepaid'' and adding in its place the word ''sent'';

■ b. Removing in paragraph 3 the text ''at the last address appearing on the

books of the mutual holding company''; and

■ c. Removing in paragraph 6 the text ''(Board)'' and adding in its place the text ''(''Board'')''.

Appendix D to Part 239—Subsidiary Holding Company of a Mutual Holding Company Model Bylaws

■ 47. Amend Appendix D by:

■ a. Removing in section 5 of article II the word ''delivered'' wherever it appears and adding in its place the word ''sent'';

■ b. Removing in section 5 of article II the text ''either personally or by mail,'';

■ c. Deleting section 4 of article III;

■ d. Redesignating section 5 of article III through section 14 of article III as section 4 of article III through section 13 of article III;

■ e. Deleting in section 5 of article III the text ''by telegram'' and adding in its place the text ''through electronic mail'';

■ f. Deleting in section 5 of article III the text ''when delivered to the telegraph company if sent by telegram,'';

■ g. Removing in section 12 of article III the text ''by registered mail'' and adding in its place the text ''by electronic mail or registered mail''; and

■ h. Deleting in section 1 of article IV the text ''Article IV'' and adding in its place the text ''article IV''.

By order of the Board of Governors of the Federal Reserve System.

Benjamin W. McDonough,

Secretary of the Board.

[FR Doc. 2026–15774 Filed 8–3–26; 8:45 am]

BILLING CODE 6201–01–P

FEDERAL REGISTER

Vol. 91 Tuesday,

No. 148 August 4, 2026

Part III

Federal Reserve System

12 Parts 215 and 225

Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks; Bank Holding Companies; Proposed Rule

FEDERAL RESERVE SYSTEM

12 CFR Parts 215 and 225

[Regulations O and Y; Docket No. R–1896]

RIN 7100–AH27

Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks; Bank Holding Companies

AGENCY: Board of Governors of the Federal Reserve System (Board).

ACTION: Notice of proposed rulemaking with request for public comment.

SUMMARY: The Board is inviting public comment on proposed amendments to Regulation O, which governs loans by member banks to their insiders and insiders of their affiliates. The proposed amendments would update and modernize the regulation, increase transparency by clarifying requirements and incorporating existing interpretations, and promote efficiency by reducing regulatory burden. The proposed amendments also would incorporate existing statutory requirements that are not currently reflected in the regulation. Moreover, the proposed amendments would update several outdated dollar-based thresholds in Regulation O and index these thresholds going forward. In addition, the proposed amendments would address the application of Regulation O to member banks that lend to companies that are presumed to be controlled by large asset management companies through passive investment funds. Finally, the proposed amendments would revise and reorganize the regulation to streamline the text and make it more accessible.

DATES: Comments must be submitted on or before October 5, 2026.

ADDRESSES: You may submit comments, identified by Docket No. R–1896 and RIN 7100–AH27, by any of the following methods:

- *Agency Website: https://www.federalreserve.gov/apps/proposals/.* Follow the instructions for submitting comments, including attachments. *Preferred Method.*
- *Mail:* Benjamin W. McDonough, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.
- *Hand Delivery/Courier:* Same as mailing address.
- *Other Means: publiccomments@frb.gov.* You must include the docket number in the subject line of the message.

Comments received are subject to public disclosure. In general, comments received will be made available on the Board's website at *https://www.federalreserve.gov/apps/proposals/* without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure. Public comments may also be viewed electronically or in person in Room M–4365A, 2001 C St. NW, Washington, DC 20551, between 9 a.m. and 5 p.m. during Federal business weekdays.

FOR FURTHER INFORMATION CONTACT: Jay Schwarz, Deputy Associate General Counsel, (202) 452–2970, Daniel Hickman, Senior Counsel, (202) 973–7432, Jasmin Keskinen, Counsel, (202) 853–7872, Legal Division; or Anna Lee Hewko, Associate Director, (202) 250–1577, Missaka Nuwan Warusawitharana, Manager, (202) 452–3461, Helen Xu, Manager, (202) 452–2555, Lesley Chao, Lead Financial Institution Policy Analyst, (202) 974–7063, Li Gu, Senior Economist, (202) 912–4655, Division of Supervision and Regulation; Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
II. Overview of Proposed Rule
III. Proposed Revisions To Modernize Regulation O
  A. Updating Dollar-Based Thresholds in Regulation O
  B. Rebuttable Presumptions of Control
  C. Dodd-Frank Act and Updating Definition of ''Extension of Credit''
  D. Valuation Principles for Extensions of Credit
  E. Other Revisions to the Definition of ''Extension of Credit''
  F. Dodd-Frank Act and the Purchase or Sale of an Asset Between an Insider and a Bank
  G. Modernizing Definition of ''Executive Officer''
  I. Lending Limit and Collateralization Requirements for Undrawn Lines of Credit
  J. Harmonizing Certain Definitions in Regulation O With Definitions in the Board's Regulation Y
  K. Residence Exception to Limits for Extensions of Credit to Executive Officers of a Bank
  L. Regulation O Requirements for Extensions of Credit to Insiders of Correspondent and Respondent Banks
  M. Simplification of Certain Disclosure and Reporting Requirements
IV. Proposed Codifications of the Board's Application of Regulation O
  A. Application of Regulation O to Extensions of Credit Made to a Noninsider that Later Becomes an Insider
  B. Application of Regulation O to Trusts and Estates
  C. Application of Additional Restrictions on Loans to Executive Officers to Certain Related Interests of Executive Officers
  D. Clarifying the Scope of the Definition of ''Principal Shareholder''
  E. Treatment of Subsidiaries of Banks
  F. Prior Approval Requirement and Abstention by All Interested Directors
  G. Safe Harbor for Affiliate and Correspondent Recordkeeping Requirements
V. Technical Revisions To Update and Streamline Regulation O
  A. Separating the Requirements in Section 215.4 of Regulation O
  B. Insiders of Affiliates Exempt From Sections 215.4, 215.6, and 215.8 of Regulation O
  C. Overdrafts
  D. Definition of ''Unimpaired Capital and Unimpaired Surplus''
  E. Disclosure Requirements for Extensions of Credit Secured by Shares of a Bank or Bank Holding Company
  F. Repeal of Existing Section 215.7 of Regulation O
  G. Application of Regulation O to Insured Branches of Foreign Banking Organizations
  H. Definition of ''Appropriate Federal Banking Agency''
  I. Other Revisions to Improve Readability
VI. Economic Analysis
VII. Regulatory Analysis
  A. Paperwork Reduction Act
  B. Regulatory Flexibility Act
  C. Riegle Community Development and Regulatory Improvement Act of 1994
  D. Solicitation of Comments on the Use of Plain Language

12 CFR Part 215

I. Background

Section 22(h) of the Federal Reserve Act restricts the amount and terms of extensions of credit from a member bank to its executive officers, directors, and principal shareholders and to any company or any political or campaign committee controlled by these individuals or entities (collectively, insiders).[1] Section 22(g) of the Federal Reserve Act imposes additional limitations on extensions of credit made by member banks to their executive officers.[2] An ''extension of credit'' includes, among other things, the making or renewing of any loan, granting a line of credit, or entering into any similar transaction.[3]

[1] 12 U.S.C. 375b.

[2] 12 U.S.C. 375a.

[3] 12 U.S.C. 375b(9)(D)(i)(I); 12 CFR 215.3.

The Board's Regulation O[4] implements sections 22(g) and 22(h)[5] and requires, among other things, that:

- Extensions of credit to an insider be on substantially the same terms that the member bank would offer to a person not affiliated with the bank, not present more than normal risk to the bank, and be made based on underwriting standards that are not less stringent than those used for a person not affiliated with the bank;[6]
- A member bank's board of directors approve certain large extensions of credit to insiders;[7]
- The amount of all extensions of credit from a member bank to any one insider and the amount of extensions of credit to all insiders remain below a percentage of the bank's unimpaired capital and unimpaired surplus;[8] and
- Member banks maintain records to document compliance with all of these restrictions and make certain disclosures concerning extensions of credit subject to the rule.[9]

The statute and Regulation O also prohibit an insider from knowingly receiving an extension of credit that does not comply with the requirements of Regulation O.[10]

Sections 22(g) and 22(h), and Regulation O, apply to all banks that are members of the Federal Reserve System.[11] Other federal law subjects federally insured state non-member banks and insured savings associations to sections 22(g) and 22(h) in the same manner and to the same extent as if they were member banks.[12] Accordingly, these insured depository institutions generally are subject to Regulation O, as enforced by their appropriate Federal banking agency. For ease of reference in this **SUPPLEMENTARY INFORMATION**, the term bank is used to refer to all insured depository institutions subject to the rule.

II. Overview of Proposed Rule

Sections 22(g) and 22(h), and Regulation O, have been longstanding features of the banking regulatory framework.[13] These statutory provisions and the regulation are designed to protect banks against potential harm from the conflicts of interest of, and self-dealing by, insiders who are in a position to put their personal or business self-interest ahead of the interests of the banks.[14] Over the years, these statutory provisions and the regulation have been significantly revised and interpreted. This has increased the complexity of complying with the regulation. In addition, the passage of time and structural changes in the market have resulted in the need to update regulatory thresholds and modernize the framework consistent with the purpose of protecting banks against potential harm from self-dealing by insiders.

The Board previously stated that it would periodically review Regulation O and adopt any modifications to the regulation that are shown by experience to be necessary or appropriate to carry out the intent of Congress in this area or to prevent evasions of the statute.[15] The Board conducted a comprehensive review, including feedback received through Economic Growth and Regulatory Paperwork Reduction Act (EGRPRA) public notices and public outreach meetings.[16] This proposal (the proposed rule) includes several revisions that are responsive to that feedback, including proposals to update, modernize, increase the transparency of, and reduce unnecessary burden of the rule. The proposed rule would incorporate statutory revisions addressing insider transactions, provide greater clarity with respect to the application of certain requirements, incorporate certain longstanding interpretations,[17] and harmonize Regulation O with other regulations. In addition, the proposed rule would increase outdated dollar-based thresholds to account for economic growth and inflation and other market developments, as well as index these thresholds to economic growth going forward. The proposed rule also would improve the ability of banks to make extensions of credit to certain publicly traded companies (portfolio companies) in which companies that sponsor, advise, and manage investment funds (fund complexes) have accumulated significant holdings.[18] Finally, the proposed rule includes several technical amendments to Regulation O, including a reorganization to make it more user-friendly.

The Board has consulted with the Office of the Comptroller of the Currency (OCC) and the Federal Deposit Insurance Corporation (FDIC) (together with the Board, the Federal banking agencies) on the proposed rule.

In view of the extensive proposed changes and reorganization, the Board is restating Regulation O in its entirety as amended, rather than proposing revised regulation text only for the portions of Regulation O that would change.[19] The details of each proposed amendment are described below. The Board invites comments on all aspects of the proposed rule.

---

[4] 12 CFR part 215.

[5] The Board may prescribe such rules and regulations, including definitions of terms, as it determines to be necessary to effectuate the purposes and prevent evasions of sections 22(g) and 22(h). *See* 12 U.S.C. 375a(8) and 375b(10).

[6] 12 U.S.C. 375b(2)(A); 12 CFR 215.4(a). Section 22(h) and Regulation O also prohibit banks from paying overdrafts to executive officers and directors unless certain exceptions apply. 12 U.S.C. 375b(6); 12 CFR 215.4(e). The overdraft prohibition does not apply to principal shareholders, unless the principal shareholder is also an executive officer or director. The prohibition also does not apply to the related interests of an executive officer or director. The exceptions to the prohibition include an exception for inadvertent overdrafts, as defined in Regulation O. *See* 12 CFR 215.4(e).

[7] 12 U.S.C. 375b(3); 12 CFR 215.4(b).

[8] *See* 12 U.S.C. 375b(4)–(5); 12 CFR 215.4(c)–(d). The individual lending limit is based on the lending limits applicable to national banks in 12 U.S.C. 84 and is therefore 15 percent of the bank's unimpaired capital and unimpaired surplus in the case of loans that are not fully secured and an additional 10 percent of the bank's unimpaired capital and unimpaired surplus in the case of loans that are fully secured. 12 U.S.C. 375b(4); 12 CFR 215.2(i). In calculating this limit, all of the bank's loans to the insider and the insiders' related interests are aggregated. In general, the aggregate lending limit is 100 percent of the bank's unimpaired capital and unimpaired surplus. 12 U.S.C. 375b(5)(A); 12 CFR 215.4(d).

[9] 12 CFR 215.8–.10.

[10] 12 U.S.C. 375b(7); 12 CFR 215.6.

[11] 12 U.S.C. 375b(1) (''No member bank may . . .''); *id.* 375a (same); *see also* 12 CFR 215.4–.5.

[12] 12 U.S.C. 1828(j) (insured non-member banks); 12 U.S.C. 1468(b) (insured savings associations); 12 CFR 337.3 (insured state non-member banks and state savings associations); 12 CFR 31.2 (insured national banks and federal savings associations). *See also* 12 CFR 215.12 (insured savings associations).

[13] Congress adopted section 22(g) as part of the Banking Act of 1933. 48 Stat. 162, 182 (June 16, 1933); 21 FRB No. 12, 854 (Dec. 1935). Congress adopted section 22(h) as part of the Financial Institutions Regulatory and Interest Rate Control Act of 1978 (FIRA). Public Law 95–630, 92 Stat. 3641; 44 FR 12959, 12962 (Mar. 9, 1979).

[14] *See* Insider Lending Restrictions, J. Virgil Mattingly, 3 Ann. Rev. Banking L. 21, 26–28 (1984) (noting that section 22(h) was based on concerns about insufficient protections against self-dealing by bank insiders and providing discussion of the impetus behind the legislation and citations to relevant Congressional record).

[15] 44 FR 12959, 12963 (Mar. 9, 1979).

[16] Public Law 104–208, Div. A, Title II, section 2222, 110 Stat. 3009–414, (1996) (codified at 12 U.S.C. 3311). *See also* Regulatory Publication and Review Under the Economic Growth and Regulatory Paperwork Reduction Act of 1996, 89 FR 62679 (Aug. 1, 2024).

[17] Existing interpretations not incorporated into the regulation would continue to apply, unless they are inconsistent with the proposed rule.

[18] For purposes of the proposed rule, investment fund means an investment company registered under the Investment Company Act of 1940, such as mutual funds and exchange traded funds, as well as collective investment trusts, separately managed institutional accounts and other pooled investment vehicles.

[19] The proposed rule will result in a fairly significant renumbering and reordering of Regulation O sections and citations. The Regulation O citations used throughout this **SUPPLEMENTARY INFORMATION** are to the existing text of Regulation O.

III. Proposed Revisions To Modernize Regulation O

A. Updating Dollar-Based Thresholds in Regulation O

The Board last adjusted certain dollar-based thresholds in Regulation O in 1994, while apparently choosing not to adjust others.[20] The proposed rule would increase the dollar-based thresholds in Regulation O to adjust for economic growth and inflation since 1994 and provide a methodology for indexing these thresholds going forward.[21] In addition, the proposed rule would clarify that certain extensions of credit should be aggregated when determining whether a given threshold is met and would simplify the applicable thresholds.

1. One-Time Adjustment to Dollar-Based Thresholds

The proposed rule would increase the dollar-based limits in Regulation O. Specifically, the proposed rule would increase the limit:

- For the amount of certain credit card debt that is exempt from the definition of ''extension of credit,'' from $15,000 to $60,000.[22]
- For the amount of indebtedness arising from certain interest-bearing overdraft credit plans that are exempt from the definition of ''extension of credit,'' from $5,000 to $20,000.[23]
- For the inadvertent overdraft exception from the prohibition against paying an overdraft to an executive officer or director, from $1,000 to $4,000.[24]
- For the ''other purpose'' exception from the special prohibitions applicable to extensions of credit to an executive officer, from $100,000 to $400,000.[25]
- For the size of an extension of credit to an insider that requires prior approval by a bank's board of directors, from $500,000 to $2 million.[26]

These dollar-based thresholds in Regulation O have become obsolete, particularly in light of inflation and economic growth since the Board last revised them. The proposed increases reflect inflation and economic growth since 1994. As such, these updates would restore the thresholds to their originally intended level of stringency and would reduce unnecessary regulatory burden. Raising these thresholds is particularly important for community banks because the outdated limits may pose particular hardship in smaller communities and rural markets. In these communities, bank directors typically are active business persons whose businesses have credit requirements. Choosing to join a bank board can impose meaningful frictions in their access to credit, while simultaneously depriving the bank of creditworthy local customers. In addition, in these communities, a bank's insiders have fewer alternative credit sources, making it more likely that they will need to obtain credit from a direct local competitor of the bank.

To determine the new thresholds, Board staff adjusted the existing thresholds based on changes in seasonally adjusted U.S. nominal gross domestic product (nominal GDP), as calculated quarterly by the U.S. Bureau of Economic Analysis.[27] The Board adjusted each threshold using nominal GDP from the fourth quarter of 1994 to the fourth quarter of 2025. The fourth quarter of 1994 is used as the start date because 1994 is the most recent year in which the Board considered adjusting any of the thresholds.[28] The Board chose not to adjust several of the thresholds in 1994. This uniform start date is used for updating all the thresholds in order to maintain the relative relationship increase across the thresholds. To simplify compliance with the thresholds, as adjusted for nominal GDP, the proposed thresholds are rounded down to simple whole numbers that are multiples of the existing thresholds.

Threshold	Value in 1994	Proposed value
Credit card exception	$15,000	$60,000
Overdrafts with credit plan exception	5,000	20,000
Inadvertent overdrafts exception	1,000	4,000
Extensions of credit to executive officers not subject to another exception	100,000	400,000

[20] 59 FR 8831, 8835–36 (Feb. 24, 1994) (updating credit card threshold but declining to update an overdraft threshold and the ''other purpose'' exception for lending to executive officers).

[21] In response to the EGRPRA comment solicitation, commenters requested the Board update the outdated dollar-based thresholds in Regulation O.

[22] To qualify for the exemption, the indebtedness must arise from an arrangement whereby the member bank (i) acquires charge or time credit accounts, or (ii) makes payments to or on behalf of participants in a bank credit card plan, check credit plan, or similar open-end credit plan, provided that (A) the indebtedness does not involve prior individual clearance or approval by the bank other than for the purposes of determining authority to participate in the arrangement and compliance with any dollar limit under the arrangement; and (B) the indebtedness is incurred under terms that are not more favorable than those offered to the general public. 12 CFR 215.3(b)(5). The Board last revised this limit in 1994. 59 FR 8831, 8835 (Feb. 24, 1994).

[23] To qualify for the exemption, the indebtedness must arise by reason of a written, preauthorized, interest-bearing overdraft extension of credit plan that specifies a method of repayment or a written, preauthorized transfer of funds from another account of the account holder at the bank. 12 CFR 215.3(b)(6). The Board last revised this limit in 1979. 44 FR 12959, 12960, 12965–66 (Mar. 9, 1979). The Board chose not to revise this limit in 1994 when it revised the threshold for credit card debt. 59 FR 8831, 8835 (Feb. 24, 1994).

[24] Regulation O generally prohibits a member bank from paying an overdraft on the account of an executive officer or director. 12 CFR 215.4(e)(1). However, the prohibition does not apply to payment of inadvertent overdrafts on an account in an aggregate amount of $1,000 or less, provided that (i) the account is not overdrawn for more than 5 business days; and (ii) the member bank charges the executive officer or director the same fee charged any other customer of the bank in similar circumstances. 12 CFR 215.4(e)(2). The Board last revised this limit in 1979. 44 FR 12959, 12960, 12965–66 (Mar. 9, 1979).

[25] Regulation O generally prohibits a member bank from extending credit to any of its executive officers. 12 CFR 215.5(a). The Board last revised this limit in 1983. 48 FR 42804 (Sept. 20, 1983). The Board chose not to revise this limit in 1994 when it revised the threshold for credit card debt. 59 FR 8831, 8836 (Feb. 24, 1994). This limit is set by the Board, FDIC, and OCC separately for their supervised institutions. 12 U.S.C. 375a(4). One exception to this prohibition is for extensions of credit that do not qualify for another exception, if the aggregate amount of extensions of credit to the executive officer does not exceed the higher of 2.5 percent of the bank's unimpaired capital and unimpaired surplus or $25,000, but in no event more than $100,000. 12 CFR 215.5(c)(4). Extensions of credit not subject to this prohibition nevertheless are subject to the other requirements in Regulation O.

[26] Regulation O generally requires the board of directors of a member bank to approve an extension of credit to an insider that, together with all other extensions of credit to that insider, exceeds (i) the higher of $25,000 or 5 percent of the member bank's unimpaired capital and unimpaired surplus; or (ii) $500,000. Such an extension of credit must be approved by a majority of the entire board of directors, and the interested party must abstain from participating directly or indirectly in the voting. 12 CFR 215.4(b)(2). The Board last revised this limit in 1983. 48 FR 42804 (Sept. 20, 1983). This limit is set by the Board, FDIC, and OCC separately for their supervised institutions. 12 U.S.C. 375b(3). The proposed rule would also increase the identical threshold used for related public disclosure requirements in section 12 CFR 215.9(b) of Regulation O, from $500,000 to $2 million, pursuant to the authorization to issue reporting and disclosure related rules and regulations. 12 U.S.C. 1817(k). This limit is set by the Board, FDIC, and OCC separately for their supervised institutions. *Id.*

[27] U.S. Bureau of Economic Analysis, account code: A191RC, Gross Domestic Product [GDP], retrieved from FRED, Federal Reserve Bank of St. Louis; *https://fred.stlouisfed.org/series/GDP,* May 1, 2026.

[28] *See* 59 FR 8831, 8835 (Feb. 24, 1994) (updating credit card threshold but declining to update other thresholds).

Threshold	Value in 1994	Proposed value
Prior approval by board of directors	500,000	2,000,000
Public disclosure requirement	500,000	2,000,000

Question 1: What are the advantages and disadvantages of using a nominal GDP deflator calculation to adjust the dollar-based thresholds? What are the advantages and disadvantages of using an alternative methodology or source of data, such as using a deflator based on the Consumer Price Index published by the U.S. Bureau of Labor Statistics (CPI)? If available, provide data and proposed alternative methodology.

Question 2: What are the advantages and disadvantages of alternative approaches, such as not using absolute dollar thresholds and instead relying solely on thresholds set by a percentage of the bank's unimpaired capital and unimpaired surplus? What would be an appropriate percent to use for each threshold and why?

Question 3: To what extent should the Board consider easing certain requirements or increasing the thresholds even further for certain well capitalized and well managed community banks? If so, which requirements or thresholds should be revised and why?

Question 4: Would a date other than 1994 be appropriate as the baseline for indexing the thresholds? For example, the Board last revised the thresholds for loans to executive officers not otherwise specifically authorized under section 22(g) and to insiders requiring prior approval by the board of directors under section 22(h) in 1983. If so, what date would be more appropriate and why?

2. Periodic Indexing of Dollar-Based Thresholds by Nominal GDP

As discussed above, without periodic adjustments, dollar-based thresholds become obsolete and undermine the purpose of Regulation O by restricting more extensions of credit than Congress intended in light of inflation and real economic growth. To limit the need for future adjustments through rulemaking, the proposal would adopt a mechanism to automatically adjust the dollar-based thresholds periodically going forward.

Specifically, under the proposal, the Board would adjust the dollar-based thresholds of Regulation O every five years to reflect real economic growth and inflation. Notice of the new thresholds would be published in the **Federal Register**. The five-year time period was chosen to balance the compliance burden of firms implementing new thresholds against the potential for misalignment with the thresholds' objective over time. The periodic adjustment would be based on five years of cumulative growth of nominal GDP. Indexing under this approach would help ensure that changes in the dollar-based thresholds are reflective of inflation and the size of the U.S. economy. The proposed mechanism would not adjust the thresholds if the five-year cumulative growth of nominal GDP is negative. This approach would reduce the potential for procyclicality during a prolonged period of economic contraction.

To ensure an accurate and predictable measure of gross domestic product, the Board generally would use the most current estimate of nominal GDP for a given calendar year published by the Bureau of Economic Analysis on or before September 30 of the year of the publication of the scalar.[29] At the end of every consecutive five-year period, the Board would calculate the value for the GDP growth adjustment scalar as a ratio of the nominal GDP estimate for the calendar year preceding the year in which the scalar is published, divided by the nominal GDP for the calendar year preceding the effective date of any final rule for which estimates are available. For example, if the Board were to adopt a final rule with an effective date of 2027 for the updated dollar-based thresholds described above, the Board would calculate and publish the GDP growth adjustment scalar in 2032 by dividing the nominal GDP at end of calendar year 2031 by the nominal GDP at end of the calendar year 2026.[30] The Board would calculate and publish a GDP growth adjustment scalar, along with updated dollar-based thresholds, every five years. Additionally, thresholds adjusted under the proposed indexing methodology would be rounded based on the size of the threshold (*e.g.,* millions, thousands), generally, to the nearest two significant digits.[31]

The Board would expect the initial scalar to be 1 and to publish that in connection with the final rule.

Question 5: What are the advantages and disadvantages of indexing the dollar-based thresholds based on nominal GDP? What alternative approaches, for example indexing the dollar-based thresholds based on CPI, should the Board consider, and why?

Question 6: What are the advantages and disadvantages of the proposed approach to indexing the dollar-based thresholds so that they do not change to reflect a period of negative average nominal GDP growth? Under what circumstances, if any, should the update to a dollar-based threshold reflect negative average nominal GDP growth, and why?

Question 7: What, if any, operational challenges are associated with the proposed approach? What adjustments could the Board make to the proposed approach to address such challenges?

Question 8: What is the appropriate frequency for updating the dollar amounts (for example updated every 5 years)?

Question 9: What alternative rounding methodology, if any, should the Board adopt for the proposed ongoing adjustments to the dollar-based thresholds? For example, what would be the advantages or disadvantages of rounding different-sized thresholds in different ways (such as rounding thresholds in the millions to the nearest two significant digits and rounding thresholds in the thousands to the nearest significant digit)?

3. Clarification To Apply Certain Limits on an Aggregate Basis

Regulation O contains limited exceptions from the definition of ''extension of credit'' for certain charge or time credit accounts, credit card plans, check credit plans, or similar open-ended plans, and overdrafts up to a specified amount. Consistent with a longstanding interpretation, the proposed rule would clarify that the dollar-based limit for each exception applies to the aggregate of all such extensions of credit to the same insider.[32] For example, the proposed

[29] *See* Bureau of Economic Analysis, A191RC, Gross Domestic Product [GDP], retrieved from FRED, Federal Reserve Bank of St. Louis; *https://fred.stlouisfed.org/series/GDP.* The Board may elect to use a comparable value in instances such as where a nominal U.S. GDP growth estimate from the Bureau of Economic Analysis is unavailable.

[30] The proposal would include a definition of the GDP growth adjustment, which sets forth the way in which the adjustment would be calculated.

[31] For example, a threshold that otherwise would be calculated as $5.964 million would be rounded to $6.0 million, or the nearest $0.1 million.

[32] 12 CFR 215.3(b)(5)–(6). When it adopted these thresholds, the Board stated that they were meant to limit the aggregate amount of each category of extension of credit in the threshold. *See* 44 FR 12959, 12960, 12965–66 (Mar. 9, 1979).

rule would make explicit that, when determining whether extensions of credit arising by reason of an interest-bearing overdraft credit plan are excepted from the definition of ''extension of credit,'' a bank must aggregate all outstanding balances owed by an insider and compare that aggregate number to the dollar-based limit. The proposed rule would make the same change to the inadvertent overdraft exemption from the prohibition on paying overdrafts in section 215.4(e)(2) of Regulation O.

4. Streamlining Limits on Loans to Executive Officers and Prior Approval by Bank Boards of Directors for Certain Large Loans

The exception from section 215.5 for an extension of credit to an executive officer for purposes other than a home mortgage or a child's education is currently subject to three different limits.[33] To streamline the procedure for calculating the applicable limit, the proposed rule would condense the overlapping thresholds. The revised provision would allow for extensions of credit to executive officers for purposes other than a home mortgage or a child's education up to the lesser of 2.5 percent of the bank's unimpaired capital and unimpaired surplus or $400,000.[34]

Similarly, the requirement that a bank's board of directors provide prior approval for an extension of credit to an insider is currently subject to three different thresholds.[35] The proposed rule would consolidate and streamline the thresholds and require prior approval if an extension of credit, when aggregated with all extensions of credit to an insider, exceeds the lesser of 5 percent of the bank's unimpaired capital and unimpaired surplus, or $2,000,000.[36] These revisions to streamline the applicable thresholds will make the requirements of Regulation O easier to understand and administer.

B. Rebuttable Presumptions of Control

Section 22(h) and Regulation O restrict the amount and terms of extensions of credit from a bank to companies controlled by an executive officer, director, or principal shareholder of the bank (related interests).[37] The term ''control'' is defined in section 22(h) as directly or indirectly, or acting through or in concert with one or more persons: (i) owning, controlling, or having the power to vote 25 percent or more of any class of voting securities of the company or bank; (ii) controlling in any manner the election of a majority of the directors of the company or bank; or (iii) having the power to exercise a controlling influence over the management or policies of the company or bank.[38] Section 22(h) also defines a principal shareholder of a bank as ''any person that directly or indirectly, or acting through or in concert with one or more persons, owns, controls, or has the power to vote more than 10 percent of any class of voting securities of a member bank.'' [39] In addition, Regulation O presumes that a person is a related interest of a principal shareholder if the principal shareholder directly or indirectly owns, controls, or has the power to vote more than 10 percent of any class of voting securities of the company and no other person owns, controls, or has the power to vote a greater percentage of that class of voting securities (presumption of control).[40]

1. Exemption From Presumption of Control for Portfolio Companies of Fund Complexes That Meet Certain Criteria

Because of the increasing popularity of passive investing through index funds, fund complexes have acquired, or have approached acquiring, more than 10 percent of a class of voting securities of a wide range of public companies, including bank and non-bank companies. Upon acquiring more than 10 percent of a class of voting securities of a banking organization, a fund complex becomes a ''principal shareholder'' of the bank (principal shareholder fund complex).[41] This is not a presumption; it is a statutory definition. In addition, under Regulation O, any portfolio company in which a principal shareholder owns more than 10 percent of a class of voting securities would be presumed to be a ''related interest'' of the principal shareholder if the principal shareholder is the largest shareholder of the company because it would trigger the presumption of control.[42] In that event, the portfolio companies presumed to be controlled by the principal shareholder would be considered related interests of the principal shareholder of the bank under Regulation O. Accordingly, the bank's lending to such portfolio companies of the principal shareholder would be subject to the lending limits and other restrictions and standards of Regulation O.

As detailed below, it is highly unlikely that Congress foresaw or intended for section 22(h) to apply to extensions of credit to portfolio companies of passive fund complexes or the heavy compliance burden that this would create based on the presumption of control in Regulation O, which is not in the statute.[43] The relationship between the portfolio companies of passive fund complexes and a bank for which the passive fund complex is a principal shareholder generally does not give rise to the type of conflict of interest and self-dealing issues that section 22(h) and Regulation O were designed to address because the portfolio companies of these fund complexes have been accumulated largely as passive investments and the fund complexes are not actively engaged in the management of their portfolio companies. This stands in contrast to most related interests captured by Regulation O, which normally are closely held companies over which a principal shareholder of a bank exerts significant influence. If portfolio companies held by these fund complexes are deemed to be a bank's insiders, the bank would be required to develop extensive monitoring and recordkeeping systems to ensure that any extensions of credit to these portfolio companies comply with Regulation O, including adherence to applicable approvals and lending limits.

[33] Section 215.5(c)(4) of Regulation O states that exception ''* * * does not exceed at any one time the higher of 2.5 percent of the bank's unimpaired capital and unimpaired surplus or $25,000, but in no event more than $100,000.''

[34] The limit would be $400,000 rather than $100,000 because the proposed rule would raise the $100,000 threshold to $400,000, as discussed in section III.A.1 of this **SUPPLEMENTARY INFORMATION**.

[35] Section 215.4(b) of Regulation O states that prior approval is required if the aggregate extensions of credit to an insider ''exceed the higher of $25,000 or 5 percent of the member bank's unimpaired capital and unimpaired surplus [and] in no event may a member bank extend credit to any insider [that] exceeds $500,000 [without prior approval.]''

[36] The limit would be $2,000,000 rather than $500,000 because the proposed rule would raise the $500,000 threshold to $2,000,000, as discussed in section III.A.1 of this **SUPPLEMENTARY INFORMATION**. Conforming edits are being proposed to the related public disclosure requirements in section 12 CFR 215.9(b) of Regulation O.

[37] 12 CFR 215.2(n). Related interest also covers any political or campaign committee that is controlled by that person or the funds or services of which will benefit that person.

[38] 12 U.S.C. 375b(9)(B).

[39] 12 U.S.C. 375b(9)(F).

[40] 12 CFR 215.2(c)(2)(ii).

[41] 12 U.S.C. 375b(9)(F); 12 CFR 215.2(m). In the case of a fund complex, the shares of a bank held by different investment funds in the same group generally are treated as shares controlled by the fund complex. *See* Letter from Scott G. Alvarez, Board General Counsel, to Robert L. Tortoriello, Esq. (Sept. 29, 2006).

[42] 12 CFR 215.2(c)(2)(ii).

[43] In response to the EGRPRA comment solicitation, commenters highlighted this issue and recommended the Board carve out certain portfolio companies of passive investment funds from the rebuttable presumption of control in Regulation O.

Index funds make investment decisions to buy and sell shares of companies on behalf of investors to closely mirror the risk and return characteristics of underlying third-party indices. These index-based funds, unlike actively managed funds, are less likely to seek to influence the lending decisions of banks for which they are principal shareholders to make preferential extensions of credit to their other portfolio companies.[44] For this reason, the proposed rule would provide the exception only to fund complexes that overall exhibit passive investment qualities—that is, those fund complexes that hold investments primarily through investment funds with an investment objective of replicating the risk and return characteristics of a third-party index (passive fund complex).

In addition, the proposed rule would reduce unnecessary compliance burden. Passive fund complexes hold a wide array of portfolio companies at any given point in time and their ownership interests can fluctuate daily based on market dynamics. Banks often rely heavily on insiders to self-identify their related interests, particularly when a principal shareholder has a vast network of related interests.[45] Banks and fund complexes may be forced to rely on publicly available information to determine levels of third-party ownership in publicly traded companies.[46] Since this information may not be timely or complete, it can be particularly problematic for a bank to determine who is a related interest of a passive fund complex when applying the presumptions of control to portfolio companies, particularly the presumption of control based on whether the passive fund complex owner is the largest shareholder. As such, many banking organizations could be operating with an incomplete or outdated list of insiders. When a passive fund complex that is a principal shareholder of a bank has numerous related interests, establishing a framework that captures all of the related interests could take considerable time and effort. The proposed revision would mitigate the regulatory burden arising from this asymmetry of information by reducing the number of potential portfolio companies captured as related interests of principal shareholder fund complexes.

In December 2019, the federal banking agencies issued a joint statement acknowledging this issue and providing temporary relief to allow banks to continue to lend to portfolio companies presumed to be controlled by certain fund complexes while the Board considered whether to amend Regulation O.[47] Since then the Federal banking agencies have extended that temporary relief to allow additional time for regulatory changes addressing the underlying issue.[48]

The proposed rule would not apply the presumption of control in Regulation O to the portfolio companies of fund complexes if the fund complex meets certain requirements designed to ensure that the relationship between the fund complex and the bank is sufficiently passive (qualifying fund complex). The proposed rule would look to the status of the relationship between the fund complex and the bank to determine whether the portfolio companies of the fund complex should be presumed to be related interests of a principal shareholder fund complex for purposes of Regulation O. The Board has authority to define the scope of the presumption of control in Regulation O and is proposing to exempt the portfolio companies of qualifying fund complexes from the presumption of control. While the ability to qualify for the status of a qualifying fund complex is based on the relationship between the bank and the fund complex, the Board is only altering the presumption of control with respect to the relationship between the fund complex and its portfolio companies. This focus on the relationship between the fund complex and the bank is consistent with the purpose of Section 22(h), which is concerned with potential influence on bank lending decisions. The Board is not able to alter the threshold for when a fund complex is considered an insider of a bank because the definition of principal shareholder is statutory. Nevertheless, focus on the fund complex's ability to control the bank as a basis for the relief would allow Regulation O to discourage the principal shareholder fund complex from improperly influencing the bank's lending for the benefit of the principal shareholder's other portfolio companies. In particular, under the proposed rule, the presumption of control would not apply to determine whether a portfolio company is a related interest of a fund complex that is a principal shareholder of a bank if:

(1) The fund complex is not (and is not affiliated with) a depository institution or holding company supervised and regulated by the Board, FDIC, or OCC (regulated company);

(2) No individual investment fund in the fund complex owns or controls more than 10 percent of any class of voting securities of a regulated company;

(3) Investment funds in the fund complex that are not index funds[49] do not in the aggregate own or control more than 10 percent of any class of voting securities of a regulated company; and

(4) The fund complex does not meet any of the conditions that would give rise to a rebuttable presumption of control under the Board's Regulation Y control rule[50] with respect to a regulated company.

The effect of this proposed exception for qualifying fund complexes would be to permit lending relationships between banks and portfolio companies held by qualifying fund complexes to continue free from the limitations in Regulation O, because portfolio companies held by qualifying fund complexes would no longer be captured by the presumption of control. Pursuant to section 22(h) and

[44] Index funds typically include prospectus and investment objectives stating that the fund does not seek to acquire control over management decisions of companies held by the fund.

[45] For example, Regulation O permits a member bank to meet some of its recordkeeping requirements by issuing an annual survey to insiders to identify extensions of credit to the insider, including its related interests; or to rely on borrowers to identify themselves as insiders of the bank when receiving an extension of credit from the bank. *See* 12 CFR 215.8(c)(1)–(2).

[46] Fund complexes are subject to applicable federal securities laws which require, among other things, the public disclosure of beneficial ownership stakes under various conditions. These disclosure obligations may change based on several factors, including whether the fund complex is acquiring the securities with the purpose or effect of ''changing or influencing the control of the issuer.'' Fund complexes should consult the rules and guidance of the Securities and Exchange Commission (SEC) to determine their disclosure obligations given the facts and circumstances around whether an investor or group would be viewed as acquiring or holding the securities with the purpose or effect of changing or influencing the control of an issuer under the SEC's rules.

[47] *See* Status of Certain Investment Funds and Their Portfolio Investments for Purposes of Regulation O and Reporting Requirements under Part 363 of FDIC Regulations, SR 19–16 (Dec. 27, 2019). *See also* OCC Bulletin 2019–65 (Dec. 27, 2019); FDIC FIL 85–2019 (Dec. 27, 2019).

[48] *See* Status of Certain Investment Funds and Their Portfolio Investments for Purposes of Regulation O and Reporting Requirements under Part 363 of FDIC Regulations, SR 25–6 (Dec. 19, 2025). *See also* OCC Bulletin 2025–47 (Dec. 18, 2025); FDIC FIL–61–2025 (Dec. 18, 2025).

[49] For purposes of the proposed rule, an ''index fund'' is a fund that has an investment objective of tracking the risk and return characteristics of a previously specified third-party broad-based index by holding all, or a representative and preset sample of, the securities of the index in approximately the same proportions as their representation in the index and uses rules-based investing to track that broad-based market index in order to replicate the risk and return characteristics of the broad-based market index. A third-party broad-based market index provides investors with a performance indicator of the overall applicable securities market, is not focused on any specific industries or sectors, and is not published or managed by the investment fund, its investment advisor, or any of their respective affiliates.

[50] *See* 12 CFR 225.32.

the proposed rule, however, any portfolio company of a qualifying fund complex would continue to be a related interest of the fund complex if the complex directly, indirectly, or acting in concert owns or controls, or has the power to vote, 25 percent or more of any class of the portfolio company's voting securities; controls in any manner the election of a majority of the portfolio company's directors; or has the power to exercise a controlling influence over the management or policies of the portfolio company.[51]

If a qualifying fund complex attempts to influence the lending decisions of any bank in its portfolio in favor of its other portfolio companies, the Board could find that the portfolio company is a related interest of the fund complex because the fund complex no longer qualifies for the exemption from the presumption of control with respect to the portfolio company. All of the fund complex's portfolio companies would immediately become related interests of the fund complex and thus insiders of each bank of which the fund complex is a principal shareholder. In addition, any outstanding extensions of credit to the portfolio companies would count towards each bank's Regulation O lending limits and all future extensions of credit would be subject to all of the requirements in Regulation O. Each bank also would be required to maintain records of future extensions of credit to the portfolio companies, and the fund complex would be liable for knowingly permitting any of the portfolio companies to receive a future extension of credit from one of the banks.

This proposed exception is intended to align the proposed rule with the purpose of the insider lending restrictions and the nature of a qualifying fund complex's ownership of portfolio companies. The purpose of the insider lending restrictions is to protect banks against potential harm from self-dealing by insiders by providing safeguards aimed at mitigating the potential for conflicts of interest from individuals who may be in a position to influence a bank's lending decisions for personal advantage.[52] These concerns are not implicated when fund complexes offer investment funds that acquire ownership in a wide array of publicly traded companies (including banks) for investment purposes based primarily on tracking third-party broad-based market indices. While many fund complexes also offer actively managed funds, the popularity of index funds has been the primary source of the increasing ownership of publicly traded companies that has resulted in the application of Regulation O to these lending relationships.[53] This investment structure and market dynamic was not prevalent at the time that the statutory framework underpinning Regulation O was enacted or when the regulation was last amended. As such, the insider lending restrictions were not drafted with the purpose of governing lending relationships between banks and portfolio companies where a principal shareholder fund complex does not have an ability or intent to influence bank lending decisions for the benefit of portfolio companies.

The exception from the presumption of control for qualifying fund complexes would apply only for purposes of determining whether a qualifying fund complex controls another portfolio company. The exception would not apply for the purposes of determining whether a fund complex is a principal shareholder of a bank or whether a person controls a qualifying fund complex. Under the proposed rule, a person would continue to be presumed to control a qualifying fund complex if the person directly or indirectly owns, controls, or has the power to vote more than 10 percent of any class of voting securities of the qualified fund complex and no other person owns, controls, or has the power to vote a greater percentage of that class of voting securities.

Question 10: What are the advantages and disadvantages of using the Board's control rule for evaluating controlling influence by fund complexes over regulated companies? What would be the advantages and disadvantages of considering other specific factors, such as:

A fund complex may not, directly or indirectly, or acting in concert with one or more others:

(1) Have more than one director interlock with the regulated company (that is, one person serving as director for both the fund complex and regulated institution) or appoint more than one director of the regulated company as a representative of the fund complex;

(2) Have any officer or employee interlock with the regulated company;

(3) Propose a director or slate of directors in opposition to any nominee proposed by the management or board of directors of the regulated company;

(4) Attempt to influence the dividend policies; loan, credit, or investment decisions or policies; pricing of services; personnel decisions; operations activities (for example location of any offices or branches or hours of operation, etc.); or any similar activities or decisions of the regulated company or any of its subsidiaries;

(5) Enter into any agreement with the regulated company that substantially limits the discretion of the regulated company's management over major policies or decisions;

(6) Solicit or participate in soliciting proxies with respect to any matter presented to the shareholders of the regulated company or any of its subsidiaries; or

(7) Dispose or threaten to dispose (explicitly or implicitly) of equity interests of the regulated company or any of its subsidiaries as a condition or inducement of specific action or non-action by the regulated company or any of its subsidiaries.

Question 11: What alternative ways to address the application of Regulation O to portfolio companies of passive fund complexes should the Board consider? For example, (1) raising the presumption of control percentage threshold from 10 percent to a higher amount (for example 15, 20 or 25 percent), (2) eliminating the presumption of control (subject to certain passivity criteria such as no board representation or management agreements), or (3) adopting the control framework from Regulation Y? If available, provide data to support proposed alternative options.

Question 12: Would it be necessary and appropriate to extend the exception for a qualifying fund complex to the rebuttable presumption of control in section 215.2(c)(2)(i) of Regulation O? For example, is it possible for a qualifying fund complex to be an executive officer or director of a company or regulated company?

Question 13: Who is the appropriate party to maintain records to verify that a fund complex is a qualified fund complex? Is the principal shareholder that is a qualified fund complex the appropriate party to be responsible for asserting and supporting that it is a qualified fund complex? Should the rule require these principal shareholders to provide the supporting information to a bank in the principal shareholder's

[51] 12 U.S.C. 375b(9).

[52] *See e.g.,* House Hearing; Comm. on Banking; Sep/Oct 1977 hearings on H.R. 9086 (Part 3), at 1631, Testimony of Chairman St. Germain (noting that the provision is designed to remove the appearance of conflicts of interest and preferential treatment related to insider loans); Senate Hearing; Senate Banking Comm.; May 1977 (Part 1), Statement of George A. LeMaistre, Chairman, FDIC, at 40–41 (highlighting the issue of self-dealing by bank insiders and seeking more explicit statutory limitations to prevent banks from incurring undue risks by lending excessive amounts to insiders and related businesses).

[53] *See* section VI of this **SUPPLEMENTARY INFORMATION**.

portfolio and/or the Federal banking agencies?

Question 14: What would be the advantages or disadvantages of providing a grace period for application of the presumption of control when a principal shareholder temporarily trips the presumption of control with respect to a portfolio company due to events outside its control or that do not become known immediately? If a grace period were applied what would be an appropriate amount of time (for example 90 days)?

Question 15: Would it be necessary or appropriate to continue to require market terms for lending between banks and portfolio companies that are no longer subject to the presumption of control? For example, should the proposed rule prohibit banks from knowingly making an extension of credit to a portfolio company that would be covered by the existing presumption of control, unless the terms of such extension of credit are on substantially the same terms as those prevailing for comparable transactions with unaffiliated third parties and do not involve more than normal risk of repayment or present other unfavorable features?

2. Appropriate Federal Banking Agency Determination Regarding a Rebuttal of Presumptions of Control

The proposed rule would continue to permit insiders to rebut the presumptions of control.[54] While compliance with Regulation O is enforced by the individual Federal banking agencies, the underlying regulation is promulgated by the Board. This has caused some confusion and insiders have asked which Federal banking agency is the appropriate agency to make a determination regarding a rebuttal of a presumption. For purposes of determining a rebuttal of control, the appropriate Federal banking agency, as defined in 12 U.S.C. 1813(q), is the relevant Federal agency.[55] However, in light of the Board's statutory responsibility to issue regulations implementing sections 22(g) and (h), the other Federal banking agencies often consult with the Board when considering evidence presented in a rebuttal of a presumption of control. To facilitate coordination of the review of arguments presented to rebut presumptions and enhance consistency in interpretation of the presumptions of control, the proposed rule would note that the appropriate Federal banking agency should consult with the Board when making a determination regarding a rebuttal of a presumption of control.

This clarification is not intended to impact how the Federal banking agencies process rebuttals of a presumption of control, including any delegations of authority that the agencies may have made with respect to this provision of Regulation O. The change would note only that the party's appropriate Federal banking agency should consult with the Board. This change also would not undo any determinations regarding any rebuttals of presumptions of control in Regulation O issued prior to the finalization of the proposed rule.

Question 16: What are the advantages and disadvantages related to the clarification that the Board should be consulted regarding a rebuttal of a presumption of control?

C. Dodd-Frank Act and Updating Definition of ''Extension of Credit''

Section 614 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) amended the definition of ''extension of credit'' in section 22(h) to include ''having credit exposure to the person arising from a derivative transaction . . . , repurchase agreement, reverse repurchase agreement, securities lending transaction, or securities borrowing transaction between the [ ] bank and the person.'' [56] However, the Dodd-Frank Act did not define the term ''credit exposure'' or otherwise prescribe a methodology for the valuation of a credit exposure arising from these types of transactions. The proposed rule would set forth valuation methodologies for credit exposures arising from derivatives transactions and from securities borrowing or lending transactions, repurchase agreements, and reverse repurchase agreements (collectively, securities financing transactions). The Board invites comment on the proposed methodology for the valuation of credit exposures caused by derivatives transactions and securities financing transactions, and on possible alternatives discussed in greater detail below.

In Board staff's experience, banks and their insiders rarely engage in derivatives transactions or securities financing transactions. Nevertheless, for ease of reference, the proposed rule would set forth the valuation methodologies. The proposed rule also would eliminate paragraph (a)(1) of section 215.3 of Regulation O, which specifies that an extension of credit includes ''a purchase under repurchase agreement of securities, other assets, or obligations.'' [57] This paragraph no longer would be necessary because the proposal would set forth a new methodology for banks to value extensions of credit attributable to repurchase agreements.

The Dodd-Frank Act also amended section 23A of the Federal Reserve Act [58] so that credit exposures to an affiliate from derivatives transactions and securities financing transactions are similarly treated as extensions of credit for purposes of that section.[59] Section 22(h) and section 23A both apply to all insured depository institutions, regardless of size. Given the similarities in the amendments made by the Dodd-Frank Act to sections 22(h) and 23A, the Board is considering whether any valuation methodologies in the proposed rule for Regulation O should also be used to value those same credit exposures for purposes of section 23A and the Board's Regulation W.[60] The adoption of a methodology to value credit exposures for purposes of section 23A and Regulation W would occur in a separate rulemaking.

Question 17: What are the advantages and disadvantages of using the same methodology to value credit exposures from derivative transactions and securities financing transactions for purposes of Regulation O and Regulation W? What would be the reasons for these regulations to use different methods?

Question 18: To what extent do banks enter into derivative and securities financing transactions with their insiders or insiders of their affiliates (including the related interests of such insiders)?

1. Negative Credit Exposures

The proposed rule would value only credit exposures of a bank to its insider, and would not include credit exposures of an insider to the bank. Specifically,

[54] Regulation O permits a person to rebut a presumption by submitting to the appropriate Federal banking agency (as defined in 12 U.S.C. 1813(q)) written materials that, in the agency's judgment, demonstrate an absence of control. 12 CFR 215.2(c)(4).

[55] As discussed in section V.H. of this **SUPPLEMENTARY INFORMATION**, the proposed rule also would create a definition of ''appropriate Federal banking agency'' in the definition section.

[56] *See* Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 614, 124 Stat. 1376 (2010) (codified at 12 U.S.C. 375b(9)(D)(i)(II)).

[57] 12 CFR 215.3(a)(1).

[58] 12 U.S.C. 371c.

[59] Section 608 of the Dodd-Frank Act (codified at 12 U.S.C. 371c(b)(7)(G)). Because covered transactions under section 23A also are subject to section 23B of the Federal Reserve Act, credit exposures from derivatives and securities financing transactions also are subject to the requirements of section 23B. 12 U.S.C. 371c–1.

[60] 12 CFR part 223.

the proposed rule would not permit a credit exposure from an insider to the bank to count towards either the individual or aggregate lending limits of the bank. This would be consistent with the focus of the insider lending restrictions on credit risk to a bank from an insider, regardless of any credit risk the insider might have to the bank. For example, section 22(h) and Regulation O do not permit a bank to reduce the aggregate amount of extensions of credit to a single insider by accounting for extensions of credit made by the insider to the bank. This also would be consistent with the definition of ''extension of credit'' in section 22(h) and Regulation O, which includes an insider owing money or its equivalent to a bank; not the reverse.[61]

2. Credit Exposure From Derivative Transactions and Derivative Netting Sets

The proposed rule would allow banks to value the credit exposure arising from a derivative transaction using any method it is authorized to use under the Federal banking agencies' risk-based capital rule. Similarly, any credit exposure associated with a derivative netting set could be valued using any method a bank is permitted to use under the Federal banking agencies' risk-based capital rule. The proposed valuation methodology would leverage the significant consideration given to the valuation of derivative transactions generally for purposes of regulatory capital requirements by the Federal banking agencies, including with the benefit of public comment. This proposed methodology also would allow banks to rely on their existing systems and processes for calculating regulatory capital requirements to ensure compliance with Regulation O, minimizing cost to the banks.

The proposed rule also would permit a bank to offset any resulting credit exposure arising from a derivative or derivative netting set with the value of cash held in a segregated, earmarked deposit account with the member bank for the sole purpose of securing credit transactions between the member bank and the insider that is identified as such, and any obligations of, or fully guaranteed as to principal and interest by, the United States or its agencies, received by the bank from the insider as collateral for the derivative or derivative netting set. Limiting the types of collateral that can offset a credit exposure for derivatives to cash and U.S. obligations provides the greatest protection for a bank from credit risk it may face from a derivative with its insiders. This limitation also would be consistent with the preference in section 22(h) for cash and U.S. government obligations. Specifically, extensions of credit secured by this collateral are not subject to the individual lending limit.[62]

Consistent with section 22(h), the proposed rule would define derivative transaction to have the same meaning given in 12 U.S.C. 84(b).[63]

Question 19: What are the advantages and disadvantages of using methodologies in the Federal banking agencies' risk-based capital rules to measure credit exposures from derivative transactions and derivative netting sets? Would another methodology be more useful or accurate? For example, should the proposed rule value credit exposures at current exposure, which reflects a bank's present obligations under a derivative transaction?

Question 20: What would be the advantages and disadvantages to expanding the scope of collateral that can offset a credit exposure from a derivative transaction to include more than cash and U.S. government obligations?

Question 21: Are there other types of collateral that have sufficiently reliable value and liquidity that they should be permitted to offset a derivative exposure between a bank and an insider? For example, should a bank be able to offset an exposure for the assets that constitute ''eligible collateral'' as defined in the Board's Single Counterparty Credit Limit rule, 12 CFR 252, subparts H and Q, or ''financial collateral'' as defined in the Federal banking agencies' risk-based capital rules? Should convertible bonds that convert into publicly traded securities be included?

Question 22: Should cash that can be used to reduce a credit exposure be required to be held in a segregated earmarked deposit account at the bank? Would a bank's interest in cash that is used as collateral for a derivative transaction be sufficiently protected without these requirements or under alternate arrangements?

Question 23: What would be the benefit of limiting cash collateral that can be used to offset a credit exposure arising from a derivative transaction or securities financing transaction to certain currencies? For example, would it be beneficial to limit eligible cash collateral to U.S. dollars or a currency that matches the denomination of the asset being secured?

3. Valuation of Credit Derivative Transactions and Similar Derivative Transactions

Under the Board's Regulation W, certain credit derivatives in which a member bank provides credit protection to the nonaffiliate with respect to an obligation of an affiliate of the member bank are guarantees by the member bank on behalf of that affiliate.[64] Similarly, the proposed rule would treat certain credit derivatives as guarantees on behalf of an insider. Because of this treatment, the proposed rule would value these credit derivatives differently than other derivatives. Specifically, the proposed rule would value credit exposures arising from these derivatives at the greater of (i) the notional principal amount or (ii) the maximum potential loss to the member bank on the transaction.

The proposed rule also would include in the scope of derivatives that are treated as guarantees any equity derivative or total return swap (whether funded or unfunded) that is functionally similar to a guarantee. Equity derivative agreements under which a bank, in exchange for a fee, agrees to compensate a third-party for any depreciation in the value of the underlying equity securities issued by an insider of the bank effectively serve as a price guarantee for those underlying securities. Similarly, total return swaps can be structured to provide a similar guarantee on a funded or unfunded basis. Where the securities issued by a bank's insider(s) represent only a portion of the reference assets, the valuation would be limited to the amount of the guarantee provided by the bank with respect to the obligations of its insider(s).

The Board observes that credit derivatives in which a bank provides credit protection to an affiliate and similar equity derivatives or total return swaps (whether funded or unfunded) subject the bank to similar risk of loss as if the bank had purchased the reference asset itself. As a result, the proposed methodology would treat this synthetic asset purchase similarly to Regulation O's valuation of an asset purchase by a member bank from an affiliate by valuing the transaction at the greater of (i) the total notional exposure or (ii) the maximum potential loss to the member bank on the transaction.

[61] 12 U.S.C. 375b(9)(D)(i)(I); 12 CFR 215.3(a).

[62] 12 U.S.C. 375b(4); 12 CFR 215.4(c). The individual lending limit permits extensions of credit in amounts that are excepted from the lending limit in the National Bank Act. The National Bank Act lending limit excepts the entire amount of loans secured by certain cash and U.S. government obligations from the limit. 12 U.S.C. 84(c)(4)–(6).

[63] *See* 12 U.S.C. 375b(9)(D)(i)(II).

[64] 12 CFR 223.33(c).

Question 24: The Board invites comment on the proposed treatment of, and valuation for, equity derivatives and total return swaps. What alternative treatment for or additional clarifications should the Board consider?

4. Credit Exposure From Securities Financing Transactions

To value credit exposures from securities financing transactions, the proposed rule would seek to measure the risk of loss that a bank may face by entering into such a transaction with an insider. In general, this risk can be separated into two subcomponents. First, the risk that an insider is unable to give back to the bank what is owed, either in the form of cash or securities (credit risk). Second, where securities are involved, the risk that the value of securities fluctuates to the detriment of the bank (market risk).

To achieve this purpose, the proposed rule would allow a bank to use any methodology that it is authorized to use under the Federal banking agencies' risk-based capital rules to measure credit exposures arising from securities financing transactions. By relying on the Federal banking agencies' risk-based capital rules, this method inherently achieves the purpose of measuring a bank's credit and market risks given the sensitivity of the capital rules to these risks. This alignment also would minimize compliance burdens as banks already are familiar with the Federal banking agencies' risk-based capital rules. Further, the proposed valuation of credit exposure from securities financing transactions would be consistent with the treatment of derivatives.

This proposed approach for valuing credit exposures from a securities financing transaction may not be relevant for smaller banks that have elected to use the community bank leverage ratio framework to comply with their risk-based capital requirements. Accordingly, the proposed rule also would provide a simplified option to determine credit exposures arising from securities financing transactions. All banks would be permitted to use this simplified method, including those that have not elected to use the community bank leverage ratio framework. This simplified amount would equal the sum of cash and the fair market value of securities transferred by the bank to the insider, minus the sum of cash and the fair market value of U.S. government obligations transferred from the insider to the bank in connection with that transaction. This method has the benefit of being simpler than the amounts calculated by using the Federal banking agencies' risk-based capital rules and also provides a reasonable measure of the risk faced by a bank when entering into a securities financing transaction with an insider (that is, the dollar value of what the bank is owed less the dollar value of reliable collateral provided by the insider). This method also acknowledges the preference that Congress expressed for credit exposures collateralized by cash and U.S. government obligations.[65] Consistent with this intent, the proposed rule also would require that any cash collateral used by banks to offset its exposure to an insider be in a segregated deposit account with the bank over which the bank has a perfected security interest.

Q*uestion 25: Should the definition of* ''*securities financing transaction*'' *be revised or expanded to include any other transactions (e.g., margin loans)?*

Question 26: What would be the advantages and disadvantages of requiring all banks to use the same method to determine credit exposure from a securities financing transaction? For example, should all banks be required to determine the amount of a credit exposure from a securities financing transaction using the simplified method set forth in the proposed rule for banks that use the community bank leverage ratio framework, or should all banks be required to use the methods they are authorized to use under their applicable capital requirements?

Question 27: What would be the advantages and disadvantages of expanding or narrowing the scope of eligible collateral? For example, would it be better for eligible collateral to include all of the assets that are ''*financial collateral*'' *as defined in the Federal banking agencies' risk-based capital rules? Should convertible bonds that convert into publicly traded securities be included?*

Question 28: Are there any circumstances where securities issued by an insider or, more likely, an insider's related interest, should be permitted to qualify as eligible collateral?

Question 29: Should cash that can be used to reduce a credit exposure be required to be held in a segregated earmarked deposit account at the bank? Would a bank's interest in cash that is used as collateral for a derivative transaction be sufficiently protected without these requirements or under alternate arrangements?

Question 30: Should the proposed rule specify that securities issued by an insider (or, more likely, an insider's related interest) cannot be used to offset a credit exposure from a securities financing transaction? For example, should the proposed rule require a bank to assign a value of zero to any such securities when using the Federal banking agencies' risk-based capital rules to value the credit exposure?

D. Valuation Principles for Extensions of Credit

As discussed above, the proposed rule would include a method for determining the credit exposure of a derivative or securities financing transaction. To provide similar clarity on how banks should value other extensions of credit under Regulation O, the proposed rule would set forth valuation principles for various types of extensions of credit and purchases and sales of assets. In order to minimize compliance burdens with this change, the proposed rule would rely on the valuation principles currently in Regulation W, with which banks already are familiar.

1. Extensions of Credit Originated by a Bank

For extensions of credit, the proposed rule would set forth valuation methodologies for extensions of credit originated by a bank, purchased by a bank, and made through a bank's acquisition of a debt security of an insider. For extensions of credit originated by a bank, the proposed rule generally would value the transaction as the amount of funds provided by a bank to, or on behalf of, an insider plus any additional amounts that the bank could be required to provide to, or on behalf of the insider. Specifically, the proposed rule would value such a transaction at the greater of (i) the principal amount of the extension of credit; (ii) the amount owed by the insider to the bank under the extension of credit; or (iii) the sum of the amount provided by the bank to, or on behalf of, an insider plus any additional amount that the bank could be required to provide to, or on behalf of, the insider. Regulation W sets forth examples for using these methodologies.[66] Banks may look to these examples to help understand the

[65] Extensions of credit secured by certain cash and U.S. government obligations are not subject to the individual lending limit in section 22(h) or Regulation O. 12 U.S.C. 375b(4); 12 CFR 215.4(c). The individual lending limit permits extensions of credit in amounts that are excepted from the lending limit in the National Bank Act. The National Bank Act lending limit excepts the entire amount of loans secured by certain cash and U.S. government obligations from the limit. 12 U.S.C. 84(c)(4)–(6).

[66] 12 CFR 223.21(a)(4)(i)–(iv).

valuation methodologies in the proposed rule.

The first prong (''the principal amount of the extension of credit'') likely would determine the valuation of a transaction in which a bank purchases a zero-coupon note issued by an insider. Such an extension of credit should be valued at the amount the insider ultimately is obligated to pay to the bank, rather than the amount of funds initially advanced by the bank. For example, a bank that purchases from an insider for $50 a 10-year zero-coupon note issued by the insider with a face value of $100 would be required to value the extension of credit at $100.

The second prong (''the amount owed by the insider'') likely would determine the valuation of a transaction in which an insider fails to pay a bank when a fee is due to the bank. This second prong is not intended to include amounts not yet due to the bank, including accrued interest not yet due. This would ensure that the value of an extension of credit equals the full amount of the exposure from the bank to the insider.

The third prong (''the sum of the amount provided by the bank to, or on behalf of, an insider plus any additional amount that the bank could be required to provide to, or on behalf of, the insider'') likely will determine the value of most extensions of credit made by a bank to an insider. Under this prong, for example, a $100 term loan is a $100 extension of credit, a $300 revolving credit facility is a $300 extension of credit (regardless of the amount of the facility drawn down by the insider), and a guarantee backstopping a $500 debt issuance by an insider is a $500 extension of credit.

Question 31: How should guarantees provided by a bank to an insider when the bank acts as agent for the insider to engage in a trade with a clearinghouse be valued for purposes of Regulation O? When the trade is a derivative transaction and the bank guarantees performance of the insider on the derivative contract, what would be the advantages and disadvantages of valuing the guarantee as an extension of credit or as a derivative, in each case pursuant to the methods set forth in the proposed rule?

2. Extensions of Credit Acquired by a Bank

Banks may extend credit to insiders by acquiring an extension of credit to an insider that was made by a third-party. In these cases, the proposed rule would value the transaction as the price paid by the bank for the extension of credit plus any additional amount that the bank could be required to provide to, or on behalf of, the insider under the terms of the agreement governing the extension of credit. For example, if a bank pays a third-party $90 for a $100 term loan that the third-party made to an insider of the bank (for example, because the loan was at a fixed rate and had declined in value due to a rise in the general level of interest rates), the extension of credit amount is $90 rather than $100. This lower amount reflects the fact that the bank's maximum loss on the transaction is $90, rather than the original principal amount of the loan. By way of additional illustration, if a bank pays a third-party $70 for a $100 line of credit to an insider of which the insider had drawn $70, the amount of the extension of credit would be $100, which is the purchase price paid plus the remaining amount of the line of credit that the bank could be required to lend under the purchased credit line.

3. Extensions of Credit Through the Purchase of or Investment in a Debt Security

As discussed in section III.D.2 of this **SUPPLEMENTARY INFORMATION**, the proposed rule would include in the definition of ''extension of credit'' a bank's acquisition by purchase, discount, exchange, or otherwise of a note or other obligation, including commercial paper or other debt securities of an insider, upon which an insider is liable as maker, drawer, endorser, guarantor, or surety. For the purchase of or investment in the debt securities of an insider, the proposed rule would value this extension of credit as the greater of the bank's purchase price or the carrying value of the debt securities. Accordingly, a bank that paid no consideration in exchange for the debt securities of an insider would nevertheless be required to value the extension of credit at no less than the bank's carrying value of the securities. The carrying value of the security would be the amount at which the securities are carried on the GAAP financial statements of the bank. In addition, if the bank's carrying value of the securities increased or decreased after the bank's initial investment, the amount of the extension of credit would increase or decrease to reflect the bank's changing financial exposure to the insider. In no case could the amount of the extension of credit fall below the amount paid by the bank for the securities. Regulation W includes examples of this valuation principle, which banks may look to in order to understand the valuation principle in the proposed rule.[67]

Valuing the purchase of or investment in debt securities of an insider at the carrying value of the securities would be consistent with GAAP, which requires a bank to reflect its investment in securities issued by an insider at the carrying value throughout the life of the investment, even if the bank paid no consideration for the securities. As noted above, this approach also would be consistent with Regulation W, so banks would be able to rely on existing compliance systems to value extensions of credit for purposes of Regulation O. Lastly, this approach would be consistent with the purposes of section 22(h)—that is, limiting the financial exposure of banks to their insiders.

As noted, the proposed rule would set a floor for the value of an extension of credit resulting from the investment in or purchase of debt securities of an insider at the consideration paid by the bank for the securities. Although this approach would not be consistent with GAAP, it would ensure that the amount of the extension of credit never falls below the amount of funds actually transferred by the bank to the insider. The floor also would limit the ability of a bank to provide additional funding to an insider in circumstances where the insider approaches insolvency.

E. Other Revisions to the Definition of ''Extension of Credit''

Section 22(h) and Regulation O define ''extension of credit'' to mean the making or renewal of any loan, a granting of a line of credit, or entering into any similar transaction.[68] Regulation O also provides a non-exhaustive list of transactions that are extensions of credit, including ''[a]ny other similar transaction as a result of which a person becomes obligated to pay money (or its equivalent) to a bank, whether the obligation arises directly or indirectly, or because of an endorsement on an obligation or otherwise, or by any means whatsoever.'' [69] Over the years, the Board and Board staff have identified transactions that fall within the scope of this provision. The proposed rule would expand the non-exhaustive list of transactions that are extensions of credit to include these additional identified transactions, as described in this section.

A number of the proposed additions to the definition of extension of credit would use similar or identical language found in Regulation W. The Board would seek to interpret similar language between the proposed rule and

[67] 12 CFR 223.23(a)(2)(i).

[68] 12 U.S.C. 375b(9)(D); 12 CFR 215.3(a).

[69] 12 CFR 215.3(a).

Regulation W consistently where possible.

Question 32: What would be the advantages and disadvantages of using interpretations of language in Regulation W to interpret similar language in the proposed rule?

1. Leases That Are the Functional Equivalent of an Extension of Credit

The proposed rule would include as an extension of credit a lease that is the functional equivalent of an extension of credit. These leases involve money or its equivalent being owed to a bank, and, by definition, are substantially similar to a loan. This treatment would be a codification of an existing interpretation [70] and would be consistent with the definition of ''extension of credit'' in Regulation W.[71]

A lease that is the functional equivalent of an extension of credit also would include a full-payout net lease permissible for a national bank under 12 U.S.C. 24(Seventh) and 12 CFR part 23.[72] In most cases, a full-payout net lease results in the payment of rent and tax benefits to the lessor bank that return to the lessor bank the full initial value of the rented property plus some additional amount. This additional amount normally is comparable to an interest rate that would be charged on a traditional loan for the same property and with a maturity equal to the life of the non-operating lease.[73] This treatment also would be consistent with the Board's interpretation of ''leases that are the functional equivalent of an extension of credit'' for purposes of Regulation W.[74]

The Board would continue to assess, on a case-by-case basis, whether other leases also constitute extensions of credit. In other contexts, Board staff has noted that the following factors may contribute to a determination that a lease is an extension of credit: (1) the agreement contains a Uniform Commercial Code financing statement of the type normally filed in connection with a secured credit transaction, (2) many attributes of ownership of the equipment, such as responsibility for servicing, insuring, licensing and assumption of risk of loss, pass to the lessee, (3) the lessee has the right to purchase the equipment at the end of the lease period, and (4) the useful life of the equipment is of such a short duration that the lessor must look to the terms of the agreement, rather than to the equipment's resale value, as the primary source of recovery for the investment.[75] These and other relevant factors could contribute to an analysis of whether a lease is an ''extension of credit'' for purposes of the proposed rule.

Question 33: What are the advantages and disadvantages of the proposed factors that may be used to determine whether a lease is an extension of credit? What other factors may be relevant in considering whether a lease is an ''extension of credit''? For example, should the Board consider the accounting treatment of the lease under GAAP?

2. Investments in Debt Securities

The proposed rule would include as an extension of credit an investment in debt securities of an insider. When a bank invests in the debt securities issued by an insider that is not a natural person, the investment gives rise to an obligation by the insider to pay funds to the bank in satisfaction of the debt security. The bank therefore has credit exposure to the insider. The bank also has credit exposure to the insider because performance on the security would be reflected on the bank's balance sheet. Therefore, investments in debt securities of an insider are viewed as extensions of credit. This addition also would be consistent with Regulation W, which specifies that a purchase of or investment in debt securities issued by an affiliate constitutes an extension of credit.[76]

Question 34: What are the advantages and disadvantages of including an investment in debt securities issued by an insider as an extension of credit?

Question 35: Should an investment in securities other than debt securities issued by an insider constitute an extension of credit? Should the scope of securities be expanded or reduced?

3. Modifications to Existing Extensions of Credit

The proposed rule would expand the list of transactions that are extensions of credit to include an increase in the amount of, extension of maturity of, or adjustment to the interest rate term or other material term of, an existing extension of credit to an insider. This language comes from the definition of ''extension of credit'' in Regulation W, which also treats modifications as an extension of credit.[77] This revision would clarify when modifications made to an existing extension of credit would constitute a new extension of credit that must comply with the requirements of Regulation O. The proposed revision is intended to address significant modifications to an existing extension of credit that economically amount to a new extension of credit. A bank's credit risk could be materially altered if a bank and insider modify an extension of credit in one of these ways. Failure to treat these events as a new extension of credit also would create a significant opportunity for evasion of the insider lending restrictions. If such events did not constitute an extension of credit, an insider and bank seeking to grant the insider favorable treatment could approve an extension of credit that is compliant with the proposed rule, only to later revise the extension of credit in a manner inconsistent with the proposed rule. This revision would codify the Board's existing interpretation of treatment for these modifications as a new extension of credit. By using the same language that currently exists in Regulation W, the proposed rule also would create efficiencies for banks by using the same standard in both regulations.

The list of transactions that are extensions of credit in Regulation O already includes ''[a]n increase of an existing indebtedness.'' [78] Regulation O excepts increases of an existing indebtedness for certain accrued interest and incidental expenses from the definition of ''extension of credit.'' [79] Because the proposed rule would modify the definition of extension of credit to include an increase in the amount, extension of maturity, or adjustment to the interest rate term or other material term, of an extension of credit, the existing inclusion of ''[a]n increase of an existing indebtedness'' in the list of transactions that are extensions of credit would not be necessary. Accordingly, the proposed rule would eliminate this language from the list. However, the proposed rule would preserve the exception for certain

[70] *See* Staff Opinion, April 8, 1976, FRRS 3–1080.

[71] *See* 12 CFR 223.3(o)(3).

[72] The same treatment would apply for a full-payout net lease permissible for a federal savings association under 12 CFR 160.41.

[73] *See* Staff Opinion, April 8, 1976, FRRS 3–1080 (holding that full-payout nonoperating leases are extensions of credit).

[74] Transactions Between Member Banks and Their Affiliates, 67 FR 76560, 76570 (Dec. 12, 2002).

[75] *See* FRRS 3–1190.1 (noting that an equipment lease agreement is essentially a financing arrangement for purposes of section 23A if, based on a combination of factors, it is the equivalent of a loan or extension of credit).

[76] 12 CFR 223.3(o)(4) (defining ''extension of credit'' to include ''[a]n acquisition by purchase, discount, exchange, or otherwise of a note or other obligation, including commercial paper or other debt securities, of an affiliate'').

[77] *See* 12 CFR 223.3(o)(5).

[78] 12 CFR 215.3(a)(5) (An extension of credit includes ''[a]n increase of an existing indebtedness, but not if the additional funds are advanced by the bank for its own protection for: (i) [a]ccrued interest; or (ii) [t]axes, insurance, or other expenses incidental to the existing indebtedness'').

[79] *Id.*

accrued interest and incidental expenses by adding a new separate exception from the definition of extension of credit.

Question 36: What are the advantages and disadvantages to specifying that an extension of credit includes an increase in the amount, extension of maturity, or adjustment to the interest rate term or other material term, of an extension of credit?

4. Exception for Inadvertent Overdrafts

In 1968, the Board excepted certain inadvertent overdrafts that are promptly repaid from the definition of ''extension of credit.'' [80] The Board expanded this exception in 1979 to apply to the prohibition against overdrafts in section 22(h), noting that ''[t]he Board intends that this provision be used solely in the unusual case of an inadvertent overdraft.'' [81] Regulation O still contains this exception, provided that all inadvertent overdrafts to an insider do not amount in the aggregate to more than $1,000.[82] There is a separate broader exception with respect to indebtedness of $5,000 or less arising by reason of an interest-bearing overdraft credit plan.[83] Over the years, there has been confusion over the relationship between these two similar and overlapping exceptions.

To avoid confusion, the proposed rule would eliminate the exception for inadvertent overdrafts from the definition of ''extension of credit'' while retaining the broader exception for interest-bearing overdraft credit plans. This change would recognize that, since the exception was adopted in 1968, banking practices with respect to overdrafts have changed. Banks are more likely to have overdraft protection plans, and account holders often enter into arrangements with their banks that would prevent the bank from paying an overdraft that would not be automatically repaid. This change also would be consistent with Regulation W, which does not provide an exception for inadvertent overdrafts made by a bank's affiliates.

However, the proposed rule would not eliminate the separate exception for inadvertent overdrafts with respect to the prohibition against overdrafts to executive officers and directors.[84] This would permit banks to pay inadvertent overdrafts to executive officers and directors provided that they meet the requirements that apply to all extensions of credit and the terms of the exception (specifically, below the specified amount, not more than 5 business days, and third-party fees). Eliminating the inadvertent overdraft exception for executive officers and directors would be overly punitive because a bank would immediately be in violation of Regulation O for these overdrafts which, by definition, are small and unintentional. As noted above, the proposed rule would increase the inadvertent overdraft threshold to $4,000.

Question 37: What are the advantages and disadvantages of eliminating the exception for inadvertent overdrafts as part of the definition of ''extension of credit'' (section 215.3(b)(2) of Regulation O)?

Question 38: In the alternative, what would be the advantages and disadvantages of retaining but narrowing the exception to cover qualified custodial overdrafts (for example ordinary course of business in connection with payment transactions, settlement services, or futures, derivatives, and securities clearing)? If revised, what criteria would constitute appropriate limitations? For example, should these criteria include consideration of a repayment timeline (for example 5 business days), concerns about repayment, policies and procedures, or something else?

Question 39: What other clarifications, if any, should the Board consider for the treatment of inadvertent overdrafts?

5. Guarantees and Similar Transactions by a Bank on Behalf of an Insider

Section 215.3(a)(3) of Regulation O specifies that a standby letter of credit (or other similar arrangement regardless of name or description) or an ineligible acceptance are extensions of credit. The proposed rule would expand this provision to include additional similar transactions using the language from the definition of ''covered transaction'' in Regulation W. Specifically, the proposed rule would include the issuance of a guarantee, acceptance, or letter of credit, including an endorsement on behalf of an insider, and a confirmation of a letter of credit issued by an insider as extensions of credit.[85]

Like standby letters of credit or ineligible acceptances, these additional transactions expose a bank to the credit risk of an insider. These transactions also are the types of credit transactions for which an insider could be incentivized to exert undue influence over the decision to issue a guarantee, acceptance, or letter of credit because of the benefit provided by the transaction to the insider. In addition, harmonizing the scope of terminology with Regulation W would have the added benefit of decreasing compliance costs for banks because they already are familiar with and likely have developed policies for compliance with Regulation W.

Consistent with Regulation W, the proposed rule would clarify that a credit derivative between a bank and a third-party in which the bank provides credit protection to the third-party with respect to an obligation of an insider of the bank is a guarantee by a bank on behalf of an insider for purpose of Regulation O. The proposed rule would specify that credit derivatives would include: (i) an agreement under which the bank, in exchange for a fee, agrees to compensate the third-party for any default of the underlying obligation of the insider; (ii) an agreement under which the bank, in exchange for payments based on the total return of the underlying obligation of the insider, agrees to pay the third-party a spread over funding costs plus any depreciation in the value of the underlying obligation of the insider; (iii) an equity derivative under which the bank, in exchange for a fee, agrees to compensate a third-party for any depreciation in the value of an equity security of the insider; and (iv) a total return swap, whether funded or unfunded, under which the bank, in exchange for a fee, agrees to compensate a third-party for any loss or depreciation in the value of a security or debt obligation issued by an insider.

Question 40: What are the advantages and disadvantages of expanding the list of extensions of credit so that it includes the issuance of a guarantee, acceptance, or letter of credit, including an endorsement, on behalf of an insider, and a confirmation of a letter of credit issued by an insider, as extensions of credit?

Question 41: Should the Board consider adding any other items to the non-exhaustive list of examples of extensions of credit? If so, which items should be added?

6. Application of the Tangible Economic Benefit Rule to Spouses and Trusts and Estates

Section 215.3(f) of Regulation O includes the tangible economic benefit rule, which treats extensions of credit

[80] 33 FR 2837 (Feb. 10, 1968).

[81] 44 FR 12959, 12964 (Mar. 9, 1979).

[82] 12 CFR 215.3(b)(2).

[83] 12 CFR 215.3(b)(6).

[84] 12 CFR 215.4(e)(2).

[85] *See* 12 CFR 223.3(h)(5); *see also* 12 U.S.C. 371c(b)(7)(E). As noted in section III.C of this **SUPPLEMENTARY INFORMATION**, the definition also would include derivative transactions, cross-insider netting arrangements, and securities financing transactions.

made to a borrower as having been made to another person, to the extent that the proceeds are transferred to the person or are used for the tangible economic benefit of the person.[86] The proposed rule would codify the Board's longstanding practice of applying this rule so that extensions of credit to the spouse of an insider or to an estate or trust in which an insider has a substantial beneficial interest are treated as having been made to the insider.

i. Spouses of Insiders

The proposed rule would codify previous interpretations by treating extensions of credit to the spouse of an insider, or to the related interest of a spouse of the insider, as having been made to the insider, unless the extension of credit meets the conditions described below. Extensions of credit to the spouse of an insider or the related interest of a spouse of an insider typically indirectly inure to the insider's benefit given the sharing of financial resources that is common between spouses. This default treatment is aimed at preventing a significant source of potential evasion by ascribing extensions of credit to an insider when the extension of credit is made to the insider's spouse or the spouse's related interest. This treatment also would reduce the undue influence and conflict of interest concerns that the insider lending restrictions are meant to mitigate.

The proposed rule would not treat an extension of credit to an insider's spouse as having been made to the insider, however, if (i) the spouse is independently creditworthy, and (ii) repayment of the extension of credit is not predicated on the insider's income. An extension of credit to the related interest of an insider's spouse would not be treated as an extension of credit to the insider if, in addition to the two conditions in the preceding sentence, (i) the insider does not have a financial or ownership interest in the company, and (ii) the insider does not participate in management of the company. These conditions would help to mitigate the risk that a bank would be exposed to the credit risk of an insider arising indirectly through the insider's spouse. This exception also would ensure that Regulation O does not impede the ability of a spouse of an insider to obtain credit for the spouse's own business ventures independently of the insider. An extension of credit that meets these conditions could still be treated as an extension of credit to the insider if, for example, the proceeds of the extension of credit are transferred to or used for the tangible economic benefit of the insider-spouse, or if the business is a related interest of the insider.

If both spouses in a relationship are insiders of the same bank, an extension of credit by the bank to one insider would be treated as having been made separately to both insiders if the exception above does not apply to the extension of credit. Accordingly, the extension of credit would need to satisfy the requirements in Regulation O with respect to both insiders.

Question 42: What are the advantages and disadvantages of treating an extension of credit made to the spouse of an insider, or a related interest of a spouse of an insider, as an extension of credit to the insider?

Question 43: What are the advantages and disadvantages of the proposed factors? Are there any other conditions under which an extension of credit to the spouse of an insider, or a related interest of a spouse of an insider, should not be treated as having been made to the insider? For example, could a spouse provide some type of evidence showing that the proceeds of a loan would not be used for the tangible economic benefit of the insider?

ii. Beneficiaries of Trusts and Estates

The proposed rule would codify the Board's previous interpretation of the tangible economic benefit rule that renders some extensions of credit to a trust or estate to be deemed as having been made to a beneficiary of the trust or estate.[87] A beneficiary of a trust or an estate has an interest in the property of the trust or estate. When the trust or estate receives an extension of credit, the proceeds inure to the benefit of the beneficiary because they often are used to preserve or enhance the value of other assets held by the trust or estate. Specifically, the proposed rule would treat an extension of credit to a trust or estate in which an insider has a 25 percent or more present or contingent beneficial interest as being made to the insider because it is a sufficiently large interest in a trust or estate that it could give rise to a motivation for the beneficiary to attempt to exert undue influence on the decision of a bank to lend to the trust or estate.

In addition, use of the 25 percent threshold is consistent with other thresholds in banking statutes and regulations. For example, both section 22(h) and the BHC Act define control to include ownership of 25 percent or more of a class of voting securities.[88] Among other things, this statutory requirement implies that, when a company owns 25 percent or more of a class of voting securities of a bank, it is sufficiently interested in the performance of the bank that it should be subject to certain requirements with respect to the bank. Accordingly, a 25 percent or more present or contingent beneficial interest in an estate or trust could be viewed similarly as giving rise to a sufficient interest in the estate or trust for extensions of credit to be attributed to beneficiaries that are insiders.

In the alternative, the Board could set the threshold lower at 10 percent. A beneficial interest of 10 percent might give rise to sufficient motivation for the beneficiary to attempt to exert undue influence on the lending decisions of the bank. Section 22(h) and Regulation O already deem the 10 percent threshold sufficient to render a person an insider and, thus, subject to the prohibitions of the insider lending restrictions. The 10 percent threshold also is consistent with other statutory thresholds that the Board has deemed sufficient to trigger heightened scrutiny. For example, prior notice is required in certain circumstances where an individual acquires 10 percent or more of a bank or bank holding company,[89] and Regulation O sets forth presumptions of control when an individual owns more than 10 percent of a bank.[90]

Question 44: What are the advantages and disadvantages to this proposed clarification regarding when an extension of credit to a trust or an estate should be treated as having been made to a beneficiary of the trust or estate?

Question 45: Is the proposed 25 percent threshold appropriate or should the proposed beneficial interest threshold be set at a different level? For example, should the threshold be set at 10 percent, 33.3 percent, or some other value between 10 percent and 100 percent?

[86] 12 CFR 215.3(f).

[87] *See, e.g.,* FRRS 3–1062.1 (citing a letter from Neal L. Petersen, General Counsel of the Board, to John P. Amershadian (May 23, 1980), available at *https://www.federalreserve.gov/supervisionreg/legalinterpretations/letter-from-petersen-to-amershadian-may-23-1980.pdf*). In addition, as noted in section IV.B of this **SUPPLEMENTARY INFORMATION**, a trust can be a related interest of an insider if the insider controls the trust and the proposed rule will indicate that trustees are presumed to control a trust, and settlors, appointers, or beneficiaries can be presumed to control a trust under certain circumstances.

[88] 12 U.S.C. 375b(9)(B); 12 U.S.C. 1841(a)(2)(A).

[89] *See* 12 CFR 225.41(c)(2).

[90] *See* 12 CFR 215.2(c)(2). As discussed in sections III.B and IV.B of this **SUPPLEMENTARY INFORMATION**, the proposed rule would amend these presumptions.

F. Dodd-Frank Act and the Purchase or Sale of an Asset Between an Insider and a Bank

The proposed rule would include the requirements of section 615 of the Dodd-Frank Act, which added paragraph (z) to 12 U.S.C. 1828. Section 615 prohibits a depository institution from purchasing or selling an asset from or to an insider unless (i) the transaction is on ''market terms;'' and (ii) if the transaction represents more than 10 percent of the capital stock and surplus of the institution, the transaction has been approved in advance by a majority of the members of the board of directors of the institution ''who do not have an interest in the transaction.'' [91]

As required by 12 U.S.C. 1828(z), the Board has consulted with the OCC and FDIC regarding this portion of the proposed rule.

1. ''Market Terms''

The proposed rule would interpret market terms, as it is used in 12 U.S.C. 1828(z), to mean the terms described in section 23B of the Federal Reserve Act.[92] Section 23B requires that the terms of a transaction between a bank and its affiliates be ''the same, or at least as favorable to such bank or its subsidiary, as those prevailing at the time for comparable transactions with or involving other nonaffiliated companies.'' [93] In the event there are no such comparable transactions, section 23B requires that the proposed affiliate transaction be on terms that the bank would offer to nonaffiliates in good faith.[94]

The proposed rule would use the same standard as in section 23B but substitute insiders and non-insiders for affiliates and nonaffiliates, as appropriate. This standard is intended to ensure that the sale or purchase of an asset between a bank and an insider would not be disadvantageous to the bank relative to similar transactions between the banks and non-insiders. This standard also would create consistency between the market terms requirements in two of the Board's regulations governing transactions between banks and related parties, namely Regulation O and Regulation W. Using the same standard in Regulation O that already is in Regulation W should decrease compliance costs for banks because they already are familiar with and likely have developed policies for compliance with section 23B that could be modified for purposes of Regulation O more easily than developing policies for a new standard. Because the language used in the two regulations would be similar, the Board would seek to interpret the language consistently when possible.

Question 46: What are the advantages and disadvantages of interpreting ''market terms'' to mean the standard set forth in section 23B?

Question 47: What would be the advantages and disadvantages of requiring that a purchase or sale of assets strictly be on fair market terms? Should it be impermissible for a bank to sell or purchase an asset from an insider on terms that are more favorable to the bank than could be expected for a similar transaction with a noninsider?

Question 48: What would be the advantages and disadvantages of defining ''market terms'' to be consistent with the ''prevailing comparable transactions'' terms requirement in section 22(h) and section 215.4(a)(1) of Regulation O? [95]

Question 49: What alternative standard could the Board consider adopting to define ''market terms?''

Question 50: What would be the advantages and disadvantages of using interpretations of the market terms standard in section 23B to interpret the similar standard in the proposed rule?

2. Indirect Participation by an Interested Party

The proposed rule also would make clear that approval of a purchase or sale of an asset between an insider and a bank by a majority of directors cannot include an interested party's participation in the discussion or any attempt to influence the voting of the board of directors regarding the transaction. This requirement is the same as that imposed currently by Regulation O to implement the prior approval requirement in section 22(h).[96]

Absent this requirement, the purpose of the statute—to prevent an insider from participating in approval by the board of directors of a transaction that presents a conflict of interest for the insider—would not be discharged. This is because an interested party could exert undue influence on the approval of a transaction by a bank's board of directors other than by participating in the voting. For example, directors that are not interested parties could be less likely to speak openly in a meeting to discuss a proposed transaction that is attended by the interested party. An interested party also could encourage other directors to approve a proposed transaction or monopolize a conversation about the transaction, which could limit the amount of time that directors who are not interested in the transaction are able to discuss any concerns related to the transaction.

The Board proposes adopting the same standard to clarify participation in the voting for purposes of 12 U.S.C. 1828(z) as in section 22(h) to maintain consistency in the regulation, for simplicity, and also to avoid creating a new standard for banks to interpret.

While the proposed rule would seek to align the prior approval requirements in section 22(h) and 12 U.S.C. 1828(z) when possible, there is one notable statutory difference between them. Section 22(h) requires approval by a majority of a bank's ''*entire* board of directors'' whereas 12 U.S.C. 1828(z) requires approval by a majority of ''the members of the board of directors . . . *who do not have an interest in the transaction*.'' [97] For purposes of determining what number of directors constitutes a majority, section 22(h) does not exclude directors with an interest in the transaction. For example, if two directors out of seven have an interest in a transaction, section 22(h) would require four directors to vote in favor of the transaction (that is, a majority of the entire board of directors); whereas, 12 U.S.C. 1828(z) would require three (that is, a majority of the five uninterested directors).

3. ''Purchase of Asset'' Definition

For purposes of this section, the proposed rule would define the term ''purchase of asset'' generally in line with the term ''purchase of an asset'' in Regulation W.[98] Regulation W states that ''[p]urchase of an asset by a member bank from an affiliate means the acquisition by a member bank of an asset from an affiliate in exchange for cash or any other consideration, including an assumption of liabilities. The merger of an affiliate into a member bank is a purchase of assets by the member bank from an affiliate if the member bank assumes any liabilities of the affiliate or pays any other form of

[91] 12 U.S.C. 1828(z).

[92] 12 U.S.C. 371c–1.

[93] 12 U.S.C. 371c–1(1)(A).

[94] 12 U.S.C. 371c–1(1)(B).

[95] *See* 12 U.S.C. 375b(1)(a)(i); 12 CFR 215.4(a)(1). The ''prevailing comparable transactions'' terms requirement in Regulation O requires any extension of credit by a bank to an insider to be (i) ''made on substantially the same terms (including interest rates and collateral) as, and following credit underwriting procedures that are not less stringent than, those prevailing at the time for comparable transactions by the bank with other persons that are not covered by this part and who are not employed by the bank''; and (ii) ''not involve more than the normal risk of repayment or present other unfavorable features.'' 12 CFR 215.4(a)(1)(i) and (ii).

[96] 12 CFR 215.4(b)(4).

[97] *Compare* 12 U.S.C. 375b(3)(B) *with* 12 U.S.C. 1828(z)(1)(B) (emphasis added).

[98] 12 CFR 223.3(dd).

consideration in the transaction.'' For purposes of Regulation O, the proposal would use the term ''insured depository institution'' in place of ''member bank'' and the term ''insider'' in the place of ''affiliate.'' General alignment with the Regulation W definition in this manner would ensure consistent treatment of these concepts in the Regulation W and Regulation O contexts.

G. Modernizing Definition of ''Executive Officer''

Regulation O defines ''executive officer,'' in part, by providing a list of titles that, if held by a person, would presumptively render them an ''executive officer.'' [99] The proposed rule would revise this list to remove ''every vice president,'' ''the cashier,'' and ''the secretary.'' Accordingly, persons with these titles would no longer be presumed to be executive officers for purposes of Regulation O.[100] The proposed rule also would add to the list of titles the chief executive officer, chief financial officer, chief lending officer, and chief investment officer.

These changes would modernize this list, which has remained essentially unchanged since 1935.[101] Banking practices, including the responsibilities of persons with certain titles, have changed since that time. For example, the title of vice president has become widely used, particularly at large banking organizations, to cover a range of officials with limited policymaking responsibilities.[102] Similarly, the scope and use of the titles of the secretary and the cashier have changed significantly over time, and no longer reliably connote an individual who participates in major policymaking functions of a bank. For example, the role of a board secretary typically involves ministerial functions such as maintaining minutes from meetings and certifying passed resolutions. These functions do not constitute participation in major policymaking decisions of a bank. The titles that would be added to the proposed rule identify persons who typically participate in the policymaking decisions of a company.

These revisions should reduce regulatory burden by decreasing the number of individuals covered by the title presumption. Currently, a bank may overcome this presumption if the bank board adopts a resolution meeting certain requirements set forth in Regulation O.[103] The proposed rule would negate the need to complete this exercise for persons no longer included in the list. Although the proposed rule would add titles that are presumed to be executive officers, persons with these titles likely already are treated as executive officers under the existing standard and requirement.

The proposed rule otherwise would not change the definition, including the functional analysis portion of the definition specifying that anyone who in practice participates in major policymaking functions of the bank is an executive officer. Accordingly, a person could be an ''executive officer'' regardless of title if the nature of the person's duties and role concern major policymaking functions. A person also could be an ''executive officer'' regardless of whether a bank has adopted a resolution excluding the person from major policymaking functions if the person *in fact* participates in major policymaking functions of the bank or other company.

Question 51: Is elimination of the title of the cashier and the secretary appropriate? Are there any other titles that are outdated which should be removed or revised?

Question 52: Is elimination of the title of vice president appropriate? Should senior vice president or other similar title be added?

Question 53: Should any other titles be included? For example, should additional or all C-suite officers be presumed to be ''executive officers?''

Question 54: What would be the advantages or disadvantages of aligning the scope of titles that are presumed to be executive officers with definitions of ''executive officer'' in other Board regulations, including, for example, the definition in the Board's capital rule [104] *or the definition included in the proposed rule on incentive-based compensation arrangements?* [105] *How might it differ from this proposal?*

Question 55: What would be the advantages or disadvantages of aligning the scope of titles that are presumed to be executive officers with definition of ''senior executive officer'' in section 914 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA)? How might it differ from this proposal? In particular, how should the Board consider Congress's use of term ''senior executive officer'' in FIRREA versus ''executive officer'' in sections 22(g) and 22(h), as well as the statutory definition of ''executive officer'' in section 22(h)? [106]

Question 56: Do any other terms need to be clarified (for example ''authority to participate,'' ''other than in the capacity of a director''). If so, how?

H. Lending Limit and Collateralization Requirements for Undrawn Lines of Credit

The proposed rule would modify the collateralization requirements applicable to the undrawn portion of a line of credit. Lines of credit are extensions of credit subject to Regulation O and, thus, the entire amount (that is both the drawn and undrawn portions) of a line of credit counts towards the individual lending limit in section 215.4(c) of Regulation O.[107] When a bank grants a line of credit to an insider in an amount that, together with all extensions of credit to the insider, amounts to more than 15 percent of the bank's unimpaired capital and unimpaired surplus, Regulation O requires the bank to (i) count the entire amount of the line of credit when determining the amount of collateral that the insider must provide; and (ii) obtain collateral for the entire amount of all extensions of credit to the insider in excess of 15 percent, including undrawn portions of the line of credit.

For example, suppose a bank grants a line of credit (and no other extensions of credit) to an insider equal to 20 percent of the bank's unimpaired capital and unimpaired surplus. Regulation O would require the bank to collect qualifying collateral from the insider equal to 5 percent of the face amount of the line of credit, immediately upon granting the line of credit.[108] This is

[99] 12 CFR 215.2(e)(1) (''The chairman of the of the board, the president, every vice president, the cashier, the secretary, and the treasurer of a company or bank are considered executive officers. . .'').

[100] These persons could nevertheless be ''executive officers'' in practice because Regulation O defines the term to include any ''person who participates or has authority to participate (other than in the capacity of a director) in major policymaking functions of the company or bank, whether or not: the officer has an official title; the title designates the officer an assistant; or the officer is serving without salary or other compensation.'' 12 CFR 215.2(e)(1).

[101] The list of official titles that would be considered executive officers was first included in the definition of executive officer in 1935. The titles were switched to presumptions in 1938 and the definition was slightly updated in 1968 by among other things removing the title of trust officer. *See* 21 FRB No. 12, 854 (Dec. 1935); 25 FRB p. 636 (1939); 33 FR 2837 (Feb. 10, 1968).

[102] The Board previously highlighted this trend by acknowledging that resolutions to exclude officers from participation in major policymaking functions might be particularly appropriate for the many vice presidents of large banks. 33 FR 2837 (Feb. 10, 1968).

[103] 12 CFR 215.2(e)(1).

[104] 12 CFR 217.2.

[105] 81 FR 37670, 37808 (June 10, 2016) (proposed to be codified at 12 CFR 236.2(gg)).

[106] 12 U.S.C. 375b(9)(C).

[107] 12 CFR 215.4(c). The entire amount of a line of credit also counts against the aggregate lending limit. *Id.* 215.4(d).

[108] The lending limit for an insider equals 15 percent of a bank's unimpaired capital and

Continued

true regardless of whether the insider draws on the line of credit.

The proposed rule would provide a new exception to this requirement. Specifically, the proposed rule would not require a bank to collect collateral from an insider for the unused portion of a line of credit, if the bank does not have any legal obligation to advance funds under the line of credit until the insider has posted the required collateral. Under this condition, securing the unused portion of a line of credit would be unnecessary for the protection of the bank because the insider would be unable to require the bank to advance additional funds without posting the additional collateral required by section 22(h). This treatment also would be consistent with similar treatment provided for the unused portion of certain extensions of credit made by a bank to an affiliate in Regulation W.[109] The unused portion of a line of credit would continue to count towards the 15 percent limit for unsecured extensions of credit and the 25 percent limit for all extensions of credit in the proposed rule. A bank could not advance funds under a line of credit until it collects any collateral required by the proposed rule.

For example, suppose the aggregate amount of extensions of credit granted by a bank to an insider amounts to 15 percent of the bank's unimpaired capital and unimpaired surplus, and that none of these extensions of credit are a line of credit. Suppose further that the bank then grants a line of credit to the same insider equal to 10 percent of the bank's unimpaired capital and unimpaired surplus. So long as the line of credit remains undrawn and the bank does not have any legal obligation to advance additional funds under the line of credit until the insider has posted the required collateral, the proposed rule would not require the bank to collect collateral from the insider until the insider draws on the line of credit. However, the insider would be required to provide qualifying collateral for any drawn amount. Furthermore, the bank would be unable to make an additional extension of credit to the insider because the amount of extensions of credit to the insider, including the face amount of the line of credit, meet the limit set forth in section 22(h), or 25 percent of the bank's unimpaired capital and unimpaired surplus.

This exception would represent a change from the current requirement in Regulation O that the entire amount of a line of credit, whether drawn or undrawn, be collateralized. This is because the existing requirement may be unduly burdensome and unnecessary to protect the bank as it requires collateralization of a credit that has not been extended. The proposed exception would provide equivalent protection to a bank because a bank would not provide proceeds of a line of credit until the bank has collateral. Accordingly, the bank would not risk advancing funds to an insider on an uncollateralized basis. The proposed new approach to collateralization of lines of credit is appropriate because it would reduce burden and preserve the protection that Regulation O currently affords a bank.

Question 57: What are the advantages and disadvantages of this proposed treatment for collateralization of the unused portion of lines of credit?

J. Harmonizing Certain Definitions in Regulation O With Definitions in the Board's Regulation Y

The proposed rule would define two new terms that Regulation O uses but does not define. Specifically, the proposed rule would define the terms ''acting in concert'' and ''class of voting securities.'' Regulation O uses both terms in the definitions of ''control'' and ''principal shareholder.'' [110] The proposed rule would define these terms by using definitions of these terms from Regulation Y.[111] This change would provide a clearer standard for when two parties should aggregate their voting securities for purposes of determining control and principal shareholder status.

The proposed rule would define ''acting in concert'' to be the same as the definition in section 225.41(b)(2) of Regulation Y, which is used for the portion of Regulation Y implementing the Change in Bank Control Act.[112] The term also would incorporate the rebuttable presumptions of concerted action in section 225.41(d) of Regulation Y.[113] One of the presumptions concerns ''immediate family'', which is defined differently between Regulation O and Regulation Y.[114] The proposed rule would rely on the existing definition of ''immediate family'' set forth in Regulation O. Accordingly, when determining for purposes of Regulation O the scope of family members that are presumed to be acting in concert pursuant to section 225.41(d)(2) of Regulation Y, a person should look to the definition of ''immediate family'' in section 215.2 of Regulation O.

The proposed rule also would define ''class of voting securities'' by cross referencing to the definition of the same term in section 225.2 of Regulation Y.[115]

Historically, Board staff often has consulted the definition of ''acting in concert'' and the rebuttable presumptions for acting in concert in Regulation Y to determine when two parties could be considered to be acting through or in concert with one another for purposes of Regulation O.[116]

---

unimpaired surplus, in the case of uncollateralized extensions of credit. The limit can be as high as 25 percent of the bank's unimpaired capital and unimpaired surplus, but only if the insider provides collateral for any amount of an extension of credit above 15 percent. 12 CFR 215.2(i). Accordingly, in the example cited here, the insider must collateralize 20 − 15 = 5 percent.

[109] *See* 12 CFR 223.14(f)(2).

[110] *See* 12 CFR 215.2(c) and (m)(1).

[111] This approach is consistent with the legislative history of the underlying terms. Congress added the terms acting in concert and class of voting securities to both section 22(h) and the Change in Bank Control Act at the same time as part of the adoption of the FIRA in 1978. *See* Public Law 95–630, 92 Stat. 3641.

[112] 12 CFR 225.41(b)(2) (''Acting in concert includes knowing participation in a joint activity or parallel action towards a common goal of acquiring control of a state member bank or bank holding company whether or not pursuant to an express agreement.'').

[113] 12 CFR 225.41(d). As noted, the proposed rule, however, would not revise the definition of ''immediate family.'' 12 CFR 215.2(g).

[114] *Compare* 12 CFR 215.2(g) *with* 12 CFR 225.41(b)(3).

[115] 12 CFR 225.2(q)(1)–(3). The text of these paragraphs is as follows:

''(1) *Voting securities* means shares of common or preferred stock, general or limited partnership shares or interests, or similar interests if the shares or interest, by statute, charter, or in any manner, entitle the holder:

(i) To vote for or to select directors, trustees, or partners (or persons exercising similar functions of the issuing company); or

(ii) To vote on or to direct the conduct of the operations or other significant policies of the issuing company.

(2) *Nonvoting shares.* Preferred shares, limited partnership shares or interests, or similar interests are not voting securities if:

(i) Any voting rights associated with the shares or interest are limited solely to the type customarily provided by statute with regard to matters that would significantly and adversely affect the rights or preference of the security or other interest, such as the issuance of additional amounts or classes of senior securities, the modification of the terms of the security or interest, the dissolution of the issuing company, or the payment of dividends by the issuing company when preferred dividends are in arrears;

(ii) The shares or interest represent an essentially passive investment or financing device and do not otherwise provide the holder with control over the issuing company; and

(iii) The shares or interest do not entitle the holder, by statute, charter, or in any manner, to select or to vote for the selection of directors, trustees, or partners (or persons exercising similar functions) of the issuing company.

(3) *Class of voting shares.* Shares of stock issued by a single issuer are deemed to be the same class of voting shares, regardless of differences in dividend rights or liquidation preference, if the shares are voted together as a single class on all matters for which the shares have voting rights other than matters described in paragraph (o)(2)(i) of this section that affect solely the rights or preferences of the shares.''

[116] *See* 12 CFR 225.41(d).

Similarly, Board staff has used the definitions for ''voting securities,'' ''nonvoting securities,'' and ''class of voting securities'' in Regulation Y to evaluate the term ''class of voting securities'' in Regulation O. The proposed rule would reflect this approach, which would increase transparency by clarifying what ''acting in concert'' and ''class of voting securities'' mean for purposes of Regulation O. Using definitions already in Regulation Y also would simplify compliance with the proposed rule, given existing familiarity with the definitions in Regulation Y.

Question 58: What are the advantages and disadvantages of using of the definition and presumptions for acting in concert in Regulation Y? Does adopting these definitions and presumptions present any challenges? If so, how should they be addressed?

Question 59: Should the definition of immediate family in Regulation O be harmonized with the Regulation Y definition?[117]

Question 60: What are the advantages and disadvantages of using the Regulation Y definitions for class of voting securities? Does adopting the Regulation Y definitions present any challenges? If so, how should they be addressed?

Question 61: Should the definition of nonvoting shares in Regulation Y be included in Regulation O?

Question 62: Are there any other terms in Regulation O that need greater clarification? If so, would it be helpful to harmonize such terms with similar terms in Regulation Y?

K. Residence Exception to Limits for Extensions of Credit to Executive Officers of a Bank

Section 22(g) and section 215.5 of Regulation O generally prohibit a bank from making an extension of credit to an executive officer, with four exceptions.[118] One exception is for extensions of credit secured by a first lien on a single ''residence'' that is ''owned'' by the executive officer (home mortgage exception).[119] The proposed rule would revise the home mortgage exception to better ensure that the exception is used for a ''residence'' as required by the statute. The proposed revisions would not substantively alter the Board's current interpretation of the home mortgage exception, but rather incorporate in a transparent manner how the home mortgage exception has been interpreted and implemented.[120] The proposed rule also would make a technical revision to make more explicit that the exception is available only for one residence of the executive officer.

1. Whether a Property Is a ''Residence''

The proposed rule would add two conditions for the home mortgage exception that would further ensure the exception is used only for a residence.[121] First, an executive officer would be required to live in the property for at least three months each year. The legislative history for section 22(g) indicates that Congress intended the home mortgage exception to be used for an executive officer's ''home.'' [122] An officer must reside at a property for some period of time for it to qualify as a home. Read most permissively, a residence that is a home could mean a property that is distinguishable from a property used as a temporary shelter, like a hotel or other accommodation. A minimum period of one month each year could establish that an executive officer uses the property differently than a temporary shelter. Read more conservatively, a ''residence'' that is a home could mean the property where a person lives for a majority of the year, or at least six months.

The proposed rule would require that an executive officer live in a property for three months each year to use the home mortgage exception. This number falls in the middle of the range of reasonable values discussed above. The proposed rule would not use a lower value within this range in recognition of the apparent interest of Congress that the exception be used for a home, rather than a property that may be only an occasional place where an executive officer stays. The proposed rule would not use the highest value in the range to prevent the home mortgage exception from being unduly restrictive. This value also would be consistent with Board staff's interpretations of the home mortgage exception that it is available for a second home, but not a vacation property.[123]

An executive officer would not be required to live at the property for the three-month period consecutively. For example, an executive officer could satisfy the requirement by spending two months at the property and another month at a later time, provided all three months occur within the same 12-month period.[124]

Second, the proposed rule would require that the property not be a property for investment purposes, including renting or leasing out all, or a portion, of the property for income. This condition would prevent an insider from using the home mortgage exception for purposes not contemplated by section 22(g), which limits the exception to mortgage loans on properties used by an insider as a residence only.[125]

Question 63: What period of time living in a property is sufficient to indicate that the property is a ''residence'' of a person? What period between one and six months should be required to qualify for the home mortgage exception?

Question 64: What would be the advantages or disadvantages of interpreting ''residence'' to mean the place where an executive officer is most likely to be found or where he or she spends the majority of the year?

Question 65: What would be the advantages or disadvantages of interpreting residence to mean a place where an executive officer can be found for more than a de minimis amount of time each year, but a small fraction of the year? For example, could a residence include a place that a person lives for only one month each year?

Question 66: What would be the advantages and disadvantages to requiring an executive officer to live in a residence for three months of every calendar year, rather than three months during a rolling 12-month period?

Question 67: Are there other ways to determine whether a property is a residence, for example, reliance on tax rules? If so, what are the advantages and disadvantages of such an approach?

2. Mortgage Exception for Executive Officers Available Only for One Dwelling

Section 22(g) and section 215.5 of Regulation O state that the home mortgage exception is available for a residence. Board staff has received a significant number of inquiries from

[117] *See* 12 CFR 225.41(b)(3).

[118] *See* 12 U.S.C. 375a; 12 CFR 215.5(a).

[119] *See* 12 U.S.C. 375a(2); 12 CFR 215.5(c)(2).

[120] *See, e.g.,* 57 FR 22417, 22423 (May 28, 1992) (dropping term primary from residence exception). A second home, for example used for vacation, can count as a residence for purposes of section 215.5(c)(2) of Regulation O so long as the executive officer annually resides at the home for some period of time during the year.

[121] *See* 12 CFR 215.5(c)(2)(i)–(ii).

[122] *See e.g.,* S. Rep. No. 165 at 1 (Apr. 12, 1967) (discussing an exception to the lending restrictions for executive officers for ''a first mortgage loan on a *home*'') (emphasis added).

[123] Letter from Elisabeth L. Carmichael to Robert L. Jaynes (Oct. 11, 1967) (''The staff of the Board considers this authority to be limited to a loan to provide housing for an executive officer, and would not include a loan secured by a lien on a vacation home''); Letter from J. Virgil Mattingly to Charles R. Haley (Mar. 30, 1995).

[124] The first 12-month period would begin when a bank extends credit pursuant to the home mortgage exception.

[125] 12 U.S.C. 375a(2)(A).

banks and their executive officers about whether the bank may make extensions of credit pursuant to the home mortgage exception to the same executive officer for two different properties. Standing alone, section 22(g)(2)(A) is ambiguous because it refers to ''a dwelling,'' which could mean any dwelling. But section 22(g)(2)(B) resolves this ambiguity by limiting the exception to a single mortgage loan to an executive officer.[126] To resolve any residual ambiguity, the proposed rule would replace ''a residence'' in the home mortgage exception with ''a single residence.'' [127] The Board notes that the single residence restriction applies only to a mortgage loan made to an executive officer. The single residence restriction does not apply to a mortgage loan made to a director or principal shareholder, or to a related interest of a director, principal shareholder, or executive officer.

L. Regulation O Requirements for Extensions of Credit to Insiders of Correspondent and Respondent Banks

1. The Requirements in 12 U.S.C. 1972

The proposed rule would incorporate existing requirements for restrictions on extensions of credit from banks to the insiders [128] of correspondent banks and from correspondent banks to insiders of their respondent banks set forth in section 106(b)(2) of the Bank Holding Company Act Amendments of 1970 (BHC Act Amendments).[129] The correspondent lending restrictions generally require that extensions of credit by a bank to the insider of its respondent bank or correspondent bank (i) be made on substantially the same terms, including interest rates and collateral, as those prevailing at the time for comparable transactions with other persons; and (ii) not involve more than the normal risk of repayment or present other unfavorable features.[130] The restrictions also prohibit a bank from opening a correspondent account at a second bank if either bank has any outstanding extensions of credit to insiders of the other that do not meet these same qualitative requirements. Congress adopted these restrictions in response to banks providing favorable loans to their insiders by allowing their correspondent bank to make the loan and taking the respondent bank's correspondent account as collateral.[131]

The proposed rule is intended to codify the correspondent lending requirements, including their scope of application, as set forth in the statute. Incorporating these restrictions in the proposed rule should benefit banks by consolidating requirements related to insider lending into one regulation.

For purposes of the requirements for extensions of credit involving correspondent banks, the proposed rule also would define ''bank'' and ''correspondent account.'' Consistent with section 106(b) of the BHC Act Amendments, the proposed rule would define ''bank'' to have the meaning given in the BHC Act and also to include a mutual savings bank, savings bank, and savings association, as each are defined in 12 U.S.C. 1813.[132] The term ''bank'' also would include a subsidiary of any of these entities, consistent with the definition of ''member bank'' applicable to other parts of Regulation O and with Board staff's past interpretations of the definition of ''bank'' in section 106.[133] The proposed rule would define ''correspondent account'' to mean an account maintained by a bank with another bank for the deposit or placement of funds. Consistent with the intent of Congress to prevent banks from using their correspondent accounts to circumvent the insider lending restrictions, this broad definition would capture most, if not all, accounts at a correspondent bank that banks could use to enhance an extension of credit made by the correspondent bank.

The proposed rule also would eliminate paragraph (b)(4) of section 215.1 of Regulation O. This paragraph, which states that banks are subject to the requirements of 12 U.S.C. 1972(2) would no longer be necessary in light of the proposed incorporation of the correspondent lending restrictions into Regulation O.

2. Recordkeeping Requirements for Correspondent Lending Restrictions

Because the correspondent lending restrictions would be codified in Regulation O, the Board is proposing to specify the applicable records maintenance expectations, as it does for other requirements in the regulation.[134] However, these relationships are fundamentally different that those addressed elsewhere in Regulation O, as there is an additional layer of separation between the lending bank and the insider because the relevant borrowers are insiders of an unaffiliated third—party. Taking this into consideration, the proposed rule would set forth two specific methods for banks to adequately maintain records for the correspondent lending restrictions. First, a bank could send an annual survey to its correspondent and respondent banks asking for a list of the relevant insiders of such banks (the ''survey method''). Second, a bank could require, as part of all extensions of credit that it makes, that the borrower indicate whether the borrower is an insider of the bank's respondent or correspondent bank (the ''borrower inquiry method''). These methods are similar to the methods set forth in Regulation O for a bank to maintain records to ensure compliance with Regulation O with regard to loans to insiders of the bank's affiliates.[135] As discussed in section IV.G of this

[126] 12 U.S.C. 375a(2) (''A member bank may make a loan to any executive officer of the bank if . . . it is secured by a first lien on *a dwelling* . . . *used by him as his residence* [and] ''*no other loan* by the bank to the officer under authority of this paragraph is outstanding.'') (emphasis added). This reading is also supported by legislative history suggesting that the provision was not meant to cover loans for multiple properties. H.R. Rep 90–262, 90th Cong. ., 1st Sess. 1967 (noting that a bank officer could not borrow, for example, $18,000 from his bank for a year-round residence and another $12,000 for a vacation residence.'').

[127] While section 22(g) and Regulation O limit, and the proposed rule would limit, the home mortgage exception to a single property, a person that serves as an executive officer at two different banks may receive one extension of credit from each bank pursuant to the home mortgage exception. The extensions of credit must otherwise comply with Regulation O and the conditions of the home mortgage exception. Generally, if two banks share an executive officer and contemplate merging, neither bank should make an extension of credit on the basis of the home mortgage exception if one of the banks already has made an extension of credit in reliance on the exception.

[128] The proposed rule would define ''insiders'' for purposes of the correspondent lending restrictions using the same definition of ''director'', ''executive officer'', and ''related interest'' as apply for the rest of Regulation O. However, the ''principal shareholder'' definition would not be included because the statute does not use the term ''principal shareholder'' and instead applies the restrictions to ''any person who directly or indirectly or acting through or in concert with one or more persons owns, controls, or has the power to vote more than 10 per centum of any class of voting securities of'' a bank. 12 U.S.C. 1972(2)(A)–(D).

[129] 12 U.S.C. 1972(2). These restrictions apply to banks that maintain a correspondent account for another bank and for banks that open and maintain a correspondent account at another bank. Section 106(b)(2) of the BHC Act Amendments applies by its terms to insured banks, mutual savings banks, savings banks, and savings associations. These restrictions have been interpreted to also apply to extensions of credit by subsidiaries of these entities. *See* Letter from J. Virgil Mattingly to James M. Mataya (Sept. 26, 1997).

[130] A bank may select any reasonably prudent method to ensure compliance with these restrictions. For example, a bank may establish policies and procedures to request additional information about a borrower's relationships with correspondent banks when the bank determines that a prospective extension of credit to the borrower will be on preferential terms. 72 FR 30470, 30472 (June 1, 2007).

[131] *See e.g.,* H. Rep. No. 95–1383 at 13 (July 20, 1978).

[132] 12 U.S.C. 1972(2)(G)(i).

[133] *See e.g.,* Letter from J. Virgil Mattingly to James M. Mataya (Sept. 26, 1997).

[134] *See* 12 CFR 215.8(a).

[135] *See* 12 CFR 215.8(c)(1) and (2).

SUPPLEMENTARY INFORMATION, a bank that uses either the survey method or borrower inquiry method will have discharged its responsibility with respect to the recordkeeping requirements for the correspondent lending restrictions.

3. Bankers' Banks

The correspondent lending restrictions apply by statute to bankers' banks (banks established by other financial institutions to provide services to the financial institutions that own them). Bankers' banks often maintain correspondent accounts for their bank-customers and make loans to the holding companies of their respondent banks. These holding companies would be treated as insiders of the respondent banks,[136] so loans by a bankers' bank to the holding company of a respondent bank are subject to the correspondent lending restrictions. Because bankers' banks generally serve only other financial institutions, a significant portion of their lending activity can be subject to the correspondent lending restrictions. This has led to questions about how a bankers' bank would comply with the requirement that loans subject to the restriction be on substantially the same terms, including interest rate and collateral, as those prevailing at the time for comparable transactions with other persons.

To comply with this requirement, a bankers' bank would have to demonstrate that the terms of a loan are substantially comparable to terms of loans it already has made to borrowers who are not subject to the correspondent lending requirement. It would not require identical terms and would not require all transactions to have the same terms. For bankers' banks, loans to insured depository institutions likely could be compared to loans to holding companies to determine compliance with this standard.[137] If a loan by a bankers' bank to the holding company of a respondent bank is on substantially the same terms, including interest rate and collateral, as a loan by the bankers' bank to similarly situated insured depository institutions and meets the other conditions of the correspondent lending restrictions, the loan generally would be compliant with these restrictions.

As reflected in the following questions, the Board is seeking input on the value of incorporating the restrictions of 12 U.S.C. 1972(2) into Regulation O. In particular, the Board is interested in feedback on the impact of the associated recordkeeping requirements on community banks.

Question 68: What are the advantages and disadvantages to incorporating the requirements of 12 U.S.C. 1972(2) into Regulation O?

Question 69: What are the advantages and disadvantages of the proposed definitions of ''bank'' and ''correspondent account?'' Should the definition of ''correspondent account'' be limited to accounts used for certain purposes, like payment or other transaction services with a third-party? Should the definition align with the definition used for anti-money laundering and anti-terrorist financing purposes?

Question 70: How do ''bankers' banks'' currently manage the correspondent bank requirements in 12 U.S.C. 1972? What are the potential risks and benefits of not applying these requirements to a loan by a correspondent bank to a company that owns the respondent bank, including any parent bank holding company?

Question 71: What other methods could a bank use to identify the insiders of its correspondent and respondent banks?

Question 72: What would be the advantages and disadvantages of exempting certain institutions from the recordkeeping requirements for the correspondent lending restrictions? At what point might the benefits of uniform recordkeeping requirements be outweighed by the burden of having to comply with those specific requirements?

M. Simplification of Certain Disclosure and Reporting Requirements

Regulation O requires a bank, in response to a written request from the public, to provide the names of each executive officer and principal shareholder that had extensions of credit outstanding from the bank, including extensions of credit made to the related interests of the executive officer or principal shareholder, if the total amount of such extensions of credit were a certain size as of the end of the latest previous quarter.[138] This requirement includes separate definitions for ''principal shareholder'' and ''related interest.'' The proposed rule would eliminate these separate definitions so that the requirement would instead rely on the definitions used in the rule's main definition section.

1. Principal Shareholder

Compared to the definition of ''principal shareholder'' applicable to most of Regulation O, the definition in the disclosure requirement notably does not exclude a company of which the bank is a subsidiary.[139] This appears to be because the Board adopted the disclosure requirement when the statutory source of authority for the requirement did not use the term ''principal shareholder'' from section 22(h) or otherwise provide an exclusion for a bank's holding company.[140] Congress later amended this authority to include the term ''principal shareholder'' and to permit the Federal banking agencies to define terms for reporting and public disclosure of information by a bank concerning extensions of credit to executive officers and principal shareholders of a bank.[141]

The definition of ''principal shareholder'' in the disclosure requirement also provides an explicit exception for foreign banks. When it adopted this exception, the Board stated that it did not believe that ''normal and routine interbank transactions were the type of transactions for which the reporting requirements were designed or which they can adequately accommodate.'' [142] At that time, the definition of ''principal shareholder'' in the disclosure requirement also was used for other more burdensome reporting requirements that no longer are required.[143]

The proposed rule would eliminate the special definition of ''principal shareholder'' in the disclosure requirement. This change would permit banks to exclude their holding companies from a disclosure mandated by the disclosure requirement. The benefit of simplifying the regulation by eliminating the special definition outweighs the benefit to the public of receiving confirmation that an extension

[136] Holding companies generally are treated as insiders for purposes of the correspondent lending restrictions. As discussed in section IV.D of this **SUPPLEMENTARY INFORMATION**, holding companies are not treated as insiders for purposes of the rest of Regulation O.

[137] A loan to an insured depository institution likely would not be subject to the correspondent lending restrictions because the institution likely is not an insider of a bank. The bank also would not be a ''related interest'' of an insider of the bank because a related interest must be a ''company'' and the correspondent lending restrictions exclude an insured depository institution from the definition of ''company.'' *See* 12 U.S.C. 1972(2)(G)(ii) and (iii).

[138] 12 CFR 215.9. As noted above, the proposed rule would raise the threshold from $500,000 to $2,000,000.

[139] *Compare* 12 CFR 215.2(m) *with* 12 CFR 215.9(a)(1).

[140] *See* FIRA, Public Law 95–630, 901, 92 Stat. 3641, 3693–94 (1978).

[141] *See* Garn-St. Germain Depository Institutions Act of 1982, Public Law 97–320, 429, 96 Stat 1469, 1527 (1982).

[142] Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks, 44 FR 67973, 67976 (Nov. 28, 1979).

[143] *See* 12 CFR 215.10(b) (1980).

of credit exists between a bank and its holding company because the disclosure requirement may only be used rarely. Furthermore, extensions of credit between a bank and its holding company are sufficiently common that disclosing the existence of these extensions likely does not reveal new information in most circumstances.

The change also would eliminate the exception from disclosure requirement for foreign banks. The Board adopted the exception in the definition when the disclosure and reporting requirements were substantially more complicated and burdensome. Now that the requirements are limited to simple disclosure of the existence of extensions of credit by a bank to a foreign bank that is a principal shareholder, it no longer would be unduly burdensome to scope foreign banks into the requirement. In addition, a foreign bank that is the disclosing bank's holding company would not be subject to the requirement, as described above.

2. Related Interest

The Board excluded foreign banks from the special definition of ''related interest'' in the disclosure requirement for the same reason that foreign banks were excluded from the definition of ''principal shareholder'' in the requirement. That is, the Board was concerned that including transactions between a bank and any affiliated foreign bank in the disclosure requirements would be unduly burdensome.[144] Including foreign banks in the definition of ''related interest'' would no longer create undue hardship on banks because the only requirement that remains is the relatively simple disclosure requirement, not the complex reporting requirements that were required by Regulation O in 1980.

Question 73: What are the advantages and disadvantages of these proposed simplifications?

IV. Proposed Codifications of the Board's Application of Regulation O

A. Application of Regulation O to Extensions of Credit Made to a Noninsider That Later Becomes an Insider

The proposed rule would specify when the prohibitions in the proposed rule apply to extensions of credit made to a person that becomes an insider after the bank made the extension of credit (transition loans). Section 215.3(d) of Regulation O states that an extension of credit is considered to have been made ''at the time the bank enters into a binding commitment to make the extension of credit.'' [145] Board staff has received a significant number of questions related to this provision, particularly how it applies to transition loans. These revisions would codify existing interpretations of Regulation O.[146]

1. Transition Loan Treatment

The proposed rule would specify that (i) transition loans need not conform to Regulation O until such extensions are renewed, revised, or extended, at which time the extensions of credit would be treated as a new extension of credit, and that (ii) the amount of these transition loans must be included in the calculation of the individual and aggregate lending limits as soon as the borrower becomes an insider. For example, a person that is not an insider of a bank would not be required to modify or unwind loans from the bank if the person later becomes an insider and the loan does not meet a requirement in Regulation O. However, the bank would be required to count the amount of the loans towards all applicable quantitative limits in the rule, including, for example, the limit on extensions of credit to a single insider and the insider's related interests. If this amount, together with all other extensions of credit to the person, exceeds any quantitative limit in the rule, the bank would not be required to unwind the loans, but the insider would not be able to receive an additional extension of credit subject to that limit.

This treatment strikes a balance between not imposing undue burden on persons who become insiders and ensuring that a bank has limited credit exposure to its insiders. On the one hand, requiring insiders and banks to modify transition loans could be overly burdensome because it would require an insider and a bank to renegotiate the terms of any outstanding extensions of credit made to the insider at the time that the person becomes an insider. This burden could discourage qualified persons who have preexisting lending relationships with a bank from becoming an insider of the bank. This problem could be particularly acute in small communities, where local banks often provide credit to a large portion of the local business community, including many persons that could be helpful as directors or executive officers. On the other hand, one purpose of the insider lending restrictions is to limit a bank's credit exposure to its insiders. The proposed rule would accommodate both of these concerns by generally not requiring an insider or a bank to modify transition loans, and also by prohibiting the bank from extending additional credit to the insider if the amount of transition loans to the insider exceeds the individual or aggregate lending limits.

To prevent evasion of the proposed rule, this treatment would not be available for transition loans made by a bank in contemplation of a borrower becoming an insider.[147] Such extensions of credit would undermine the purpose of sections 22(h) and (g) and the proposed rule, because a person whose extensions of credit will become or could become subject to Regulation O may be able to exert undue influence on bank staff. For example, a loan officer may be inclined to offer favorable terms to a person that will become the loan officer's boss, or a director or significant shareholder of the bank.

Question 74: What are the advantages and disadvantages of the proposed application of requirements in the proposed rule to transition loans?

Question 75: What would be the advantages and disadvantages of providing a transition treatment for the requirements of Regulation O that apply only to certain types of insiders? For example, should loans made to an insider that is not an executive officer be immediately subject to the restrictions for executive officers as soon as the insider becomes an executive officer?

Question 76: What would be the advantages and disadvantages of requiring a bank to maintain records with respect to transition loans before they lose their transition loan status?

2. Lines of Credit

The proposed rule also would specify that transition loans that are lines of credit to an insider would be subject to the treatment set forth above, but for only 14 months after the date the borrower becomes an insider. At that time, the line of credit would need to comply with all requirements of the proposed rule.

In practice, this requirement already exists for most lines of credit and the proposed rule simply would make this result more explicit. Section 215.4(b)(3) of Regulation O requires prior approval for advances made pursuant to a line of

[144] Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks, 44 FR 67973, 67977 (Nov. 28, 1979).

[145] 12 CFR 215.3(d).

[146] *See e.g.,* Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks; Loans to Holding Companies and Affiliates, 62 FR 13294, 13296 fn. 11 (Mar. 20, 1997); FRRS 3–1036 (citing 1936 Fed. Res. Bull. 121).

[147] The Board has authority to write rules to prevent the evasion of sections 22(h) and 22(g). 12 U.S.C. 375a(8) and 375b(10).

credit, unless the line of credit has been approved by a bank's board of directors in the 14 months preceding the advance. In other words, an insider readily may draw on a line of credit only if the bank's board of directors approves the line of credit every 14 months. In each case, such approval would constitute a new extension of credit.[148] Accordingly, if a transition loan is a line of credit, the bank's board of directors generally must approve the line of credit within 14 months of the borrower becoming an insider, at which time the transition loan becomes a new extension of credit.

This treatment for lines of credit also addresses unique characteristics posed by lines of credit. Unlike other extensions of credit, lines of credit sometimes do not mature. Instead, many lines of credit persist until the lender or borrower terminates the line. This would create the possibility that a line of credit could remain a transition loan that would not need to conform to the requirements of the proposed rule in perpetuity. This result would be inconsistent with the purposes that the insider lending restrictions seek to address.

The proposed rule would apply this treatment to all transition loans that are lines of credit, not just the larger lines of credit which are subject to the prior approval requirement in section 215.4(b) of Regulation O. As noted above, without this requirement, an insider could have a line of credit that does not conform to the proposed rule in perpetuity. For example, such a line of credit would not be subject to the requirement that an extension of credit to an insider not be on favorable terms, present more than the normal risk of repayment, or have other unfavorable features. The proposed rule would use the 14-month benchmark to be consistent with the 14-month threshold for lines of credit subject to the prior approval requirement. This consistency should reduce the complexity of the rule and facilitate compliance. Fourteen months also should give a person who becomes an insider sufficient time to work with its bank to modify the line of credit, if necessary, to comply with the proposed rule.

Question 77: What are the advantages and disadvantages of requiring a transition loan that is a line of credit to comply with the requirements in the proposed rule no later than 14 months after a bank extends the line of credit?

Question 78: Should the proposed treatment for transition loans end no later than 14 months for extensions of credit other than lines of credit?

Question 79: What are the advantages or disadvantages of the 14 month reapproval for a line of credit (section 215.4(b)(3) of Regulation O)? Should it be replaced with an alternative process that is less burdensome, such as a notification requirement with certain criteria? If so, what criteria might be useful for obtaining the same consideration?

B. Application of Regulation O to Trusts and Estates

Over the years, the Board has issued interpretations in response to a significant number of inquiries concerning the application of Regulation O to trusts and estates. The proposed rule would codify some of these longstanding interpretations. This section IV.B of this **SUPPLEMENTARY INFORMATION** also restates existing interpretations regarding the current application of Regulation O that would continue to apply after adoption of the proposed rule.

1. When a Trust Is a Related Interest of an Insider

Section 22(h) and Regulation O explicitly define ''company'' to include business or other trusts. Accordingly, a trust can be a related interest of an insider, if the insider controls the trust. The proposed rule would set forth two rebuttable presumptions of control for when a person controls a trust.

First, the proposed rule would include a rebuttable presumption that a person controls a trust if the person is a trustee of the trust. This addition would be consistent with the Board's 2020 revisions to Regulation Y concerning presumptions of control. As part of those revisions, the Board included a rebuttable presumption that one company controls another if the first company enters into any agreement making the first company a trustee of the second.[149] The Board reasoned that trust agreements often grant to trustees the ability to direct or exercise significant influence over the management or operations of a company.[150] This change also would be consistent with the definition of ''control'' in section 10 of the Home Owners' Loan Act, which deems a person to control a trust if the person is a trustee of the trust.[151]

This revision to Regulation O would overturn an interpretation that Board staff issued in a 1980 letter stating that ''[a]n extension of credit by a [bank] to an estate or trust for which a director of the [bank] is executor or trustee . . . is not considered made directly to the director . . . solely by reason of the director's status as executor of the estate or trustee of the trust.'' [152] Since Board staff issued this specific interpretation, the Board's thinking about control of a trust has evolved, including with the changes to Regulation Y noted above. For the same reasons discussed in the rulemaking record for those revisions and for the reasons discussed above, the Board believes it is appropriate to presume that a person who is a trustee of a trust controls the trust.

Second, the proposed rule would create a new rebuttable presumption of control that a person that is a settlor, appointer, or beneficiary of a trust controls the trust if the person has the power to (i) remove or replace a trustee of the trust and (ii) limit a trustee's power to make, sell, change, or exchange any investment or asset of the trust. The ability to remove or replace trustees enables a person to exert influence over the trustees because a trustee may not act freely out of fear that the person will remove the trustee. The power to limit a trustee's power to make, sell, change, or exchange any investment or asset of the trust also is a significant power because, while it does not enable a person to take an affirmative action with respect to the investments or assets of a trust, it enables the person to prevent the trustee from doing so. This amounts to a power to veto important decisions of the trustee. Taken together, these powers amount to sufficient control for purposes of the insider lending restrictions. A person with these powers that also is an insider of a bank has sufficient control of the trust to raise conflict of interest concerns about the insider attempting to influence the bank to extend credit to the trust.

These presumptions of control would not comprehensively define the scope of circumstances under which a settlor, appointer, or beneficiary would control a trust. Consistent with its past practice, the Board would continue to evaluate the specific facts and circumstances of a case to determine whether a person controls a trust.

Question 80: What are the advantages and disadvantages of the proposed presumptions of control for when a person controls a trust?

Question 81: What would be the advantages and disadvantages of the

[148] *See* 12 CFR 215.3(a) (''[a]n extension of credit is a making or *renewal* . . .'') (emphasis added).

[149] 12 CFR 225.32(b).

[150] *See* Control and Divestiture Proceedings, 85 FR 12398 (Mar. 2, 2020).

[151] 12 U.S.C. 1467a(a)(2)(C).

[152] FRRS 3–1062.1 (citing the letter from Neal L. Petersen to John P. Amershadian (May 23, 1980)).

proposed rule incorporating a portion of or the entire framework for presuming that a person controls a company set forth in the Board's control rule, section 225.32 of Regulation Y?

Question 82: Are there other circumstances where a person should be presumed to control a trust?

2. Application of Regulation O to Executors of Estates

The proposed rule would presume that a person controls any company or bank that is controlled by an estate for which the person serves as executor. The proposed rule also would clarify that a person owns, controls, or has the power to vote more than 10 percent of any class of voting securities of a bank or company when an estate for which the person serves as an executor owns, controls, or has the power to vote such shares. These presumptions would codify long-standing application of Regulation O.[153]

Companies controlled by an estate are indirectly controlled by the estate's executor because executors generally have the same authority over such companies as the estate itself. If an estate controls a company and an executor has authority over the estate and the estate's powers, the executor similarly has control over the companies controlled by the estate. For the same reasons, executors of an estate have sufficient control over shares controlled by the estate to also be considered to control the shares. As a result of this clarification, a person would be a principal shareholder of a bank if an estate for which the person serves as executor owns, controls, or has the power to vote more than 10 percent of any class of voting securities of the bank.

An estate generally would not be treated as a related interest of an insider because an estate often more closely resembles an individual than a company.[154] Accordingly, an estate normally would not meet the definition of ''related interest,'' which includes only certain ''companies'' and ''political or campaign committees.''

Question 83: What are the advantages and disadvantages of treating a company or shares of a company controlled by an estate as being controlled by an executor of the estate?

Question 84: Are there specific circumstances where an executor should not be treated as controlling a company or shares controlled by an estate because, for example, the agreements governing the estate limit the executor's or executors' authority?

C. Application of Additional Restrictions on Loans to Executive Officers to Certain Related Interests of Executive Officers

In general, the additional restrictions for extensions of credit made to executive officers set forth in section 22(g) and section 215.5 of Regulation O apply to extensions of credit made directly to executive officers and not their related interests. However, to prevent evasions of these requirements, the proposed rule would apply these restrictions to extensions of credit made to the related interest of an executive officer if the related interest is merely the alter ego of the executive officer and has no independent means to repay the extension of credit. Under these circumstances, there is a greater risk that an executive officer is using a related interest to evade the requirements of section 22(g).

Whether a related interest is considered an alter ego of an executive officer would be determined by the facts and circumstances of a particular case and generally with reference to general principles of corporate law setting forth when a company is the mere alter ego of another person. This analysis could consider, among other things, (i) the executive officer's ownership interest and management responsibilities with respect to the related interest, (ii) whether the related interest was created to perpetrate a fraud, (iii) whether the related interest is organized and operated as a mere tool or business conduit for the executive officer, (iv) whether the related interest appears to have been formed to evade legal obligations of the executive officer, (v) the capitalization of the related interest, (vi) the failure of the related interest or its management to observe corporate formalities, and (vii) the intermingling of funds of the executive officer and the related interest.

Similarly, whether a related interest has independent means to repay the extension of credit would be evaluated by the facts and circumstances of the case and would focus on whether the related interest has sources for funds other than the executive officer.

Question 85: What are the advantages and disadvantages of treating extensions of credit to certain related interests of an insider as subject to the requirements of section 22(g) as proposed?

Question 86: Are general principles of corporate law sufficient to determine when a related interest is an alter ego of an insider? Should other factors be included to ensure that an insider does not use a related interest to evade the requirements of section 22(g)?

Question 87: What factors should be used to establish whether a related interest has a means of repayment independent from an insider?

D. Clarifying the Scope of the Definition of ''Principal Shareholder''

The proposed rule would revise the definition of ''principal shareholder'' to clarify that a person is not a principal shareholder of a bank *or any affiliates* of the bank if the bank is a subsidiary of such person. This change would mean that a company that controls the bank would not be treated as a principal shareholder of any of the company's subsidiaries and, thus, extensions of credit by the bank to such subsidiaries would not be subject to the proposed rule.[155]

This change would result in a definition of ''principal shareholder'' in the proposed rule that better aligns with section 22(h).[156] This change also would be consistent with the Board's previous statements that it had intended to exclude from the definition of ''principal shareholders'' companies of which a bank is a subsidiary, as well as the related interests of such companies.[157]

Question 88: What are the advantages and disadvantages of revising the definition of ''principal shareholder'' as proposed?

Question 89: To what extent should transactions subject to Regulation W also be subject to Regulation O?

E. Treatment of Subsidiaries of Banks

The proposed rule would clarify that extensions of credit by a bank to its

[153] FRRS 3–1062.1 (citing the letter from Neal L. Petersen to John P. Amershadian (May 23, 1980)). Pursuant to the definition of ''extension of credit'' under Regulation O and the proposed rule, if an insider guarantees a loan or the proceeds of a loan are transferred to the insider, then the loan would be an extension of credit to the insider.

[154] While an estate is not listed in the definition of ''company'' in Regulation O, an estate can be treated as a company for purposes of section 22(h) and Regulation O if it takes on characteristics of a company or is part of an association.

[155] Regulation O specifies that a company of which a member bank is a subsidiary is not a principal shareholder, but only with respect to the member bank. 12 CFR 215.2(m)(2) (''A principal shareholder *of a member bank* does not include a company of which a member bank is a subsidiary.'') (emphasis added). Accordingly, the holding company of a bank could be treated as a principal shareholder of an affiliate of the bank, even if it is not treated as a principal shareholder of the bank itself, which would inadvertently subject extensions of credit to the holding company to Regulation O.

[156] 12 U.S.C. 375b(9)(F)(ii) (''Principal shareholder . . . does not include a company of which a member bank is a subsidiary.'').

[157] ''Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks; Loans to Holding Companies and Affiliates,'' 57 FR 60979 (Dec. 23, 1992).

subsidiaries are not subject to the proposed rule, and that extensions of credit by the subsidiaries of banks would be treated as loans made by the bank itself. The proposed rule also would exempt extensions of credit made by a bank to insiders of an operating subsidiary of the bank from the proposed rule, and would treat extensions of credit to the insiders of a financial subsidiary the same as an extension of credit to an insider of an affiliate of the bank.

1. Extensions of Credit Made by and to Subsidiaries of a Bank

The proposed rule would modify the definition of ''subsidiary'' so that it does not exclude subsidiaries of banks. Section 22(h) and Regulation O define ''member bank'' to include any subsidiary of a member bank.[158] Accordingly, an extension of credit made by a subsidiary of a bank to an insider of the bank or its affiliates has been treated as subject to the requirements of Regulation O. However, there has been confusion about this treatment because the definition of ''subsidiary'' in Regulation O excludes subsidiaries of banks.[159] The proposed revision should resolve this ambiguity, and also would be consistent with the plain language of section 22(h).

The Board excluded the subsidiaries of a bank from the definition of ''subsidiary'' in 1979 to make clear that extensions of credit by a bank to its subsidiaries were not subject to Regulation O.[160] The Board reasoned that the regulation need not apply to transactions among these affiliates because Regulation W already provided restrictions for such transactions that are sufficient to protect the bank. To ensure that the proposed rule would continue to not inadvertently apply to extensions of credit by a bank to its subsidiaries, the proposed rule would revise the definition of ''principal shareholder'' to exclude member banks. This proposed change will prevent a bank from being treated as an insider.

2. Extensions of Credit to Insiders of a Subsidiary of a Bank

Because the proposed rule would amend the term ''subsidiary'' to no longer exclude the subsidiaries of a bank, such subsidiaries would meet the definition of ''affiliate'' in Regulation O. Accordingly, the restrictions in the proposed rule that apply to extensions of credit to insiders of affiliates would apply to extensions of credit made to insiders of subsidiaries of the bank. This would be an unintentional change to the Board's position of not applying Regulation O to extensions of credit made by a bank to the insider of an operating subsidiary. To maintain the Board's existing approach, the proposed rule would exclude operating subsidiaries of a bank from the definition of ''affiliate.'' The proposed rule would define ''operating subsidiary'' to mean a subsidiary that is not a ''financial subsidiary'' as that term is defined in section 223.3(p) of Regulation W.[161]

This treatment would be consistent with relief provided by the Board for operating subsidiaries in Regulation O, Regulation W,[162] and Regulation Y.[163] Compared to financial subsidiaries, operating subsidiaries are subordinate to their parent banks and often engage in only a subset of activities in which their parent banks may engage. An insider of such a subsidiary likely does not have sufficient influence over the lending decisions of the bank to warrant application of the proposed rule, absent other factors. By contrast, financial subsidiaries engage in activities in which banks themselves may not engage directly. These subsidiaries engage in separate business lines that are not a subset of the bank's activities. Insiders of these subsidiaries are more similar to insiders of affiliates of a bank that are not operating subsidiaries. Therefore, the proposed rule would apply to extensions of credit to insiders of financial subsidiaries in the same manner and to the same extent as it would apply to extensions of credit to insiders of affiliates of the bank that are not operating subsidiaries of the bank. If the insider of an operating subsidiary is an insider of the bank or another affiliate of the bank, extensions of credit to the insider would continue to be subject to the proposed rule.

The proposed rule would rely on the definition of ''financial subsidiary'' in Regulation W to identify operating subsidiaries. This definition identifies the scope of subsidiaries that engage in the activities in which a bank itself may not engage. Relying on a definition in another one of the Board's rules would create consistency and allow banks to leverage their existing systems for classifying operating and financial subsidiaries for purposes of the proposed rule.

Question 90: What are the advantages and disadvantages of revising the definitions of ''member bank,'' ''subsidiary,'' and ''principal shareholder'' as proposed? Are there consequences to these changes apart from the purposes discussed here?

Question 91: What would be the advantages and disadvantages of subjecting extensions of credit to insiders of certain subsidiaries of savings associations to Regulation O? For example, should extensions of credit to the insiders of subsidiaries of savings associations that engage in the activities of financial subsidiaries of national banks be subject to Regulation O?

F. Prior Approval Requirement and Abstention by All Interested Directors

Section 22(h) and 12 U.S.C. 1828(z) require a vote by a bank's board of directors before the bank may engage in certain transactions with the bank's insider. Both sections also require any director with an interest in the transaction to abstain from participating in the vote.[164]

Consistent with Board staff's longstanding interpretation, the proposed rule would clarify that, for both prior approval requirements, all directors that are interested parties must abstain from participating directly or indirectly in the approval vote. In the past, some banks have asked whether the prior approval requirement in Regulation O requires only one director with an interest in a transaction to abstain. Clarifying that all directors who are interested in a transaction must abstain from a prior approval vote would recognize that more than one insider could have an interest in the same extension of credit, and that all such insiders would be required to abstain from the required approval process for such transactions. To allow any directors with an interest in the transaction to participate in the vote would undermine the purpose of the requirement of excluding any persons with a conflict of interest from participating in a vote required by these sections.[165]

[158] 12 U.S.C. 375b(9)(E); 12 CFR 215.2(j).

[159] 12 CFR 215.2(o).

[160] *See* ''Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks,'' 44 FR 12959, 12961–62 (Mar. 9, 1979).

[161] Regulation W provides that the definition of ''financial subsidiary'' does not apply to subsidiaries of savings associations. 12 CFR 223.72(b) (item 8). To maintain consistency with Regulation W, the proposed rule would not treat subsidiaries of savings associations as financial subsidiaries (that is, the proposed rule would treat them as operating subsidiaries).

[162] In general, transactions between a member bank and its operating subsidiary are not subject to the requirements of Regulation W. *See* 12 CFR part 223.

[163] In general, a bank holding company is not required to provide notice pursuant to section 4 of the BHC Act for the activities of an operating subsidiary. *See* 12 CFR 225.22(e).

[164] 12 U.S.C. 375b(3)(B) and 1828(z)(1)(B).

[165] As noted in section III.F.2 of this **SUPPLEMENTARY INFORMATION**, the proposed rule would seek to align the prior approval requirements in section 22(h) and 12 U.S.C. 1828(z) as much as

Continued

Question 92: What are the advantages and disadvantages of clarifying the prior approval requirements?

G. Safe Harbor for Affiliate and Correspondent Recordkeeping Requirements

In general, banks are required to maintain records necessary to ensure compliance with the requirements in Regulation O.[166] However, the Board has acknowledged that banks may not have easy access to the information concerning extensions of credit to persons that are not insiders of the bank.[167] To help banks meet their recordkeeping requirements for extensions of credit to the insiders of affiliates, the Board adopted in 1994 two specific methods for banks to maintain necessary records.[168] The Board also stated that an ''implicit safe harbor exists'' for banks that use one of these two recordkeeping options.[169] The proposed rule would codify this safe harbor for the recordkeeping requirements related to insiders of a bank's affiliates. The proposed rule also would extend this safe harbor to the new recordkeeping requirements for the correspondent lending restrictions discussed in section III.L of this **SUPPLEMENTARY INFORMATION** for banks that use one of the two recordkeeping requirements set forth in the proposed rule.

Compared to information related to insiders of a bank, information regarding insiders of other institutions, including the bank's affiliates and correspondent and respondent banks, is more difficult for a bank to obtain. A bank has greater access to information concerning its own insiders through shareholder and employment records because such information normally belongs to the bank. By contrast, a bank may not own information about the insiders of its affiliates or insiders of the bank's respondent or correspondent banks, and the burden of obtaining such information could, in some instances, outweigh the benefit of having the information. It also would be unreasonable in these circumstances to hold banks liable for recording information that is not entirely within their power to obtain.

Question 93: What are the advantages and disadvantages of providing such a safe harbor?

Question 94: Are there other circumstances where a safe harbor might be appropriate? If so, explain and provide examples.

V. Technical Revisions To Update and Streamline Regulation O

The proposed rule would include a series of technical amendments that are designed to streamline the regulation and make it more understandable and user-friendly. Among other things, these revisions and reorganizations would adopt language that would be more understandable and eliminate unnecessary cross-references and footnotes. The proposed rule also would include new subsections to reorganize the regulation. These technical revisions are not intended to have substantive effect. In view of the extensive proposed changes and reorganization, the Board would restate Regulation O in its entirety as amended, rather than proposing revised regulation text only for portions of Regulation O that would change.[170]

Question 95: Are the proposed technical revisions and reorganizations helpful?

Question 96: Are there any other ways that Regulation O could be made more understandable and user-friendly?

A. Separating the Requirements in Section 215.4 of Regulation O

The proposed rule would separate the five requirements in the general prohibitions section of Regulation O (12 CFR 215.4) into four new sections so that each requirement, with the exception of the individual and aggregate lending limits, would be stated in its own section. The proposed rule would state the individual and aggregate lending limits in one combined section.

The collection of these separate requirements in one section of Regulation O can be confusing. Some of these requirements are qualitative in nature, others are quantitative, and still others are procedural. Some of these requirements apply to all insiders, as in the case of the creditworthiness requirements, whereas others apply to only some insiders, as in the case of the overdraft prohibitions. The proposed revision would shorten section 215.4 of Regulation O and more intuitively categorize the requirements of the proposed rule.

B. Insiders of Affiliates Exempt From Sections 215.4, 215.6, and 215.8 of Regulation O

The proposed rule would define a new term ''exempt official'' for directors and officers that already are excluded from the definitions of director and officer in Regulation O for the purposes of sections 215.4, 215.6, and 215.8.[171] The proposed rule would use this term in sections 215.11–13, .21, .23, and .30, and eliminate the exclusion in the definitions of director and executive officer. The scope of application of the proposed rule to directors and executive officers would not be different from the scope of application in Regulation O as a result of these changes.

Regulation O excludes directors and executive officers of the affiliates of banks from the scope of the requirements in section 215.4, 215.6, and 215.8 if: (i) the director or executive officer is excluded by a resolution of the bank's board of directors from participating in the policymaking functions of the bank, (ii) the director or executive officer in fact does not participate in the policymaking functions of the bank, (iii) the affiliate does not control the bank, (iv) the assets of the affiliate do not cross a certain threshold, and (v) the director or executive officer is not otherwise subject to sections 215.4, 215.6, and 215.8 of Regulation O. The proposed definition of ''exempt official'' would use the same criteria. The revision would shorten Regulation O. The term ''exempt official'' would be included in the new section dedicated to the definition of the term ''insider,'' discussed in greater detail above.

C. Overdrafts

The Board also proposes to simplify the requirements in the proposed rule related to overdrafts. Section 215.4(e) of Regulation O prohibits banks from paying overdrafts to certain insiders. Various portions of Regulation O cross reference to certain portions of this prohibition. For example, the definition of ''extension of credit'' in Regulation O includes two exceptions for certain types of overdrafts. These exceptions

possible, but one statutory difference between them is worth noting. Section 22(h) requires approval by a majority of a bank's ''entire board of directors'' whereas 12 U.S.C. 1828(z) requires approval by a majority of ''the members of the board of directors . . . who do not have an interest in the transaction.'' For purposes of determining what number of directors constitutes a majority, section 22(h) does not exclude directors with an interest in the transaction. For example, if two directors out of seven have an interest in a transaction, section 22(h) would require four directors to vote in favor of the transaction (that is, a majority of the entire board of directors, or seven); whereas, 12 U.S.C. 1828(z) would require three (that is, a majority of uninterested directors, or five).

[166] 12 CFR 215.8(a).

[167] *See e.g.,* Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks; Loans to Holding Companies and Affiliates, 59 FR 8831, 8833 (Feb. 24, 1994).

[168] *Id.*

[169] *Id.* at 8834.

[170] The proposed rule would result in a fairly significant renumbering and reordering of Regulation O sections and citations. The Regulation O citations used throughout this **SUPPLEMENTARY INFORMATION** are to the existing text of Regulation O.

[171] 12 CFR 215.2(d)(2) and (e)(2).

both refer to types of overdrafts ''described in section 215.4.'' To eliminate this cross reference, the proposed rule would replace the language directing a reader to look to section 215.4 with language describing the type of overdraft that is being referenced.

Some portions of Regulation O that refer to overdrafts use language that differs from the definition of ''pay an overdraft on an account'' in the regulation's definition section. The proposed rule also would amend these references to better align with the definition. This proposed revision is not intended to alter the substance of any portion of the proposed rule that refers to an ''overdraft.''

D. Definition of ''Unimpaired Capital and Unimpaired Surplus''

The proposed rule would create a new definition for the term ''capital stock and surplus'' and remove the definition of the term from the definition of ''lending limit.'' This reorganization would not substantively change the meaning of the terms ''lending limit'' or ''capital stock and surplus'' as they are used in Regulation O. Instead, the proposed reorganization would separate the two terms within the text of the regulation to improve the readability of the regulation and to make it easier to revise one definition without affecting the other, should such a revision be necessary in the future.

E. Disclosure Requirements for Extensions of Credit Secured by Shares of a Bank or Bank Holding Company

Section 306(o) of the Federal Deposit Insurance Corporation Improvement Act of 1991 requires that an executive officer or director of a bank and its holding company report annually to the board of directors of his or her institution the outstanding amount of any extensions of credit secured by shares of the bank and its holding company, if the shares of the institution are not publicly traded.[172] The Board previously codified portions of this requirement in section 215.10 of Regulation O for extensions of credit secured by stock of the bank, and in section 225.4(e) of Regulation Y for extensions of credit secured by stock of the bank holding company.[173] The proposed rule would consolidate these requirements in Regulation O. Consistent with section 306(o), the proposed rule also would make explicit that an executive officer or director of an insured depository institution must disclose the outstanding balance of an extension of credit if the extension of credit is secured by stock of the insured depository institution or such institution's holding company and that an executive officer or director of a holding company must disclose the outstanding balance of an extension of credit secured by stock of the holding company or the subsidiary lending bank. The Board also proposes to eliminate section 225.4(e) of Regulation Y, as that requirement would be incorporated into the proposed rule.

This revision would not substantively change the requirements of the proposed rule relative to Regulation O or Regulation Y, but would reorganize them for ease of reference and to more closely align this disclosure requirement in the proposed rule with section 306(o). Consistent with Regulation Y and Board staff's past interpretations for Regulation O, the proposed rule would specify that a company's shares are publicly traded if any class of equity securities of the company are registered securities under section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 78*l*).[174]

The proposed rule also would clarify that disclosure is required for extensions of credit to an executive officer or director of a bank, when the extension of credit is secured by bank holding company shares that are not publicly traded.[175]

Question 97: Should Regulation O require that a director or executive officer of a bank or holding company disclose extensions of credit secured by shares of either the bank or holding company? Or, should Regulation O require that a director or executive officer of a bank disclose only extensions of credit secured by shares of the bank, and that a director or executive officer of a holding company disclose only extensions of credit secured by shares of the holding company?

F. Repeal of Existing Section 215.7 of Regulation O

Section 215.7 of Regulation O set forth a transition period for compliance with the regulation for extensions of credit made prior to March 10, 1979, that either matured on or after that same date. The relief expired on March 10, 1980, and, therefore, no longer applies to any extensions of credit. Accordingly, the proposed rule would eliminate this section to streamline and shorten the regulation.

G. Application of Regulation O to Insured Branches of Foreign Banking Organizations

The proposed rule would revise the definition of ''member bank'' to include the insured branches of foreign banks. Regulation O already applies to the insured branches of foreign banks by statute, but the existing definition of ''member bank'' has caused confusion about this application because it states that ''[t]he term does not include any foreign bank that maintains a branch in the United States, whether or not the branch is insured. . . .''[176] This language has been misread to specify the scope of application of Regulation O to foreign branches, rather than the foreign bank to which a branch belongs. To improve clarity, the proposed rule would be revised to reflect the relevant statutory language, which specifies that ''[t]he term does not include any foreign bank solely because the foreign bank has an insured branch, but the term does include an insured branch.''

H. Definition of ''Appropriate Federal Banking Agency''

Regulation O refers to ''appropriate Federal banking agency'' in several instances but does not separately define the term in the definition section of the rule. The proposed rule would add the term to the definition section and define it to mean, ''with respect to a member bank or company, [ ] the meaning given in 12 U.S.C. 1813.'' This change to the regulation text is not intended to impact the meaning of the term in the proposed rule.

12 U.S.C. 1813 provides that the appropriate Federal banking agency means:

The OCC, in the case of:

- Any national banking association;
- Any Federal branch or agency of a foreign bank; and
- Any Federal savings association;

The FDIC, in the case of:

- Any State nonmember insured bank;
- Any foreign bank having an insured branch; and
- Any State savings association; and

The Board, in the case of:

- Any State member bank;

[172] Section 306(o) Public Law 102–242 (1991), codified in a note to 12 U.S.C. 375b. While the statute uses the term reporting, that term is typically used for information provided to regulators. The proposed rule would change the term to disclosure to align with the label typically used when information is provided to third-parties such as the bank's board of directors.

[173] 12 CFR 215.10; 12 CFR 225.4(e).

[174] 15 U.S.C. 78*l*. *See also* 12 CFR 225.41(c)(2)(i).

[175] *See* Letter from J. Virgil Mattingly to C. Romain (Aug. 18, 1992).

[176] 12 CFR 215.2(j); 12 U.S.C. 1828(j)(3)(B) (noting that the requirements of 12 U.S.C. 375a and 375b ''shall not apply with respect to a foreign bank solely because the foreign bank has an insured branch, but shall apply with respect to the insured branch.''). *See also* FRRS 3–1085.5 (Apr. 21, 1993).

- Any branch or agency of a foreign bank with respect to any provision of the Federal Reserve Act which is made applicable under the International Banking Act of 1978;
- Any foreign bank which does not operate an insured branch;
- Any agency or commercial lending company other than a Federal agency;
- Supervisory or regulatory proceedings arising from the authority given to the Board of Governors under section 7(c)(1) of the International Banking Act of 1978, including such proceedings under the Financial Institutions Supervisory Act of 1966;
- Any bank holding company and any subsidiary (other than a depository institution) of a bank holding company; and
- Any savings and loan holding company and any subsidiary (other than a depository institution) of a savings and loan holding company.[177]

I. Other Revisions To Improve Readability

The proposed rule also would include various changes to simplify and modernize the language of Regulation O and to enhance its organization. For example, the proposed rule includes new subheadings and has replaced the term ''interest-bearing extension of credit plan'' in the section discussing the prohibition on overdrafts to certain insiders with ''interest bearing overdraft protection plan.''

VI. Economic Analysis

This section analyzes the potential economic impact of the proposed amendments to Regulation O. The economic analysis focuses on the effects of two key components of the proposal: (1) providing relief from the unintended application of insider lending restrictions to portfolio companies of qualifying fund complexes, and (2) adjusting dollar-based thresholds to account for inflation and economic growth, along with establishing an automatic indexing methodology. The analysis considers both the benefits and costs of these changes relative to the baseline. The proposal also provides clarifications and codifies existing interpretations of Regulation O, enhancing transparency and facilitating compliance by banks. The section does not further analyze these benefits.

The economic analysis is structured as follows. Section A provides an overview of the baseline, describing the current state of Regulation O and recent trends in fund complex ownership. Section B summarizes the proposed policy changes, with references to the detailed descriptions in Sections III.A and III.B of this **SUPPLEMENTARY INFORMATION**. Section C analyzes the economic impact of providing relief for qualifying fund complexes, and Section D analyzes the economic impact of adjusting and indexing dollar-based thresholds. Section E concludes.

Baseline

The baseline considers the current state of Regulation O, which imposes constraints on bank lending to insiders, including principal shareholders and related interests of principal shareholders, in order to mitigate potential for self-dealing. Under Regulation O, if a fund complex holds aggregate ownership of more than 10 percent in a bank, the fund complex becomes a principal shareholder of the bank directly subject to the insider lending limits and requirements. Additionally, any other company that a principal shareholder controls (holding at least 25 percent) or is presumed to control (holding more than 10 percent of and being the largest shareholder) becomes a ''related interest'' of the bank and is subject to these limits and requirements. In that event, the principal shareholder fund complex and its controlled portfolio companies would be considered insiders of the bank under Regulation O. Accordingly, the bank's lending to the principal shareholder fund complex and its fund-complex controlled portfolio companies would be subject to the lending limits and other restrictions and standards of Regulation O.

The rise in assets under management by index funds has significantly increased the number of firms subject to Regulation O, creating unintended regulatory consequences. As of April 2026, indexed mutual funds and exchange traded funds hold 63.6 percent of the total combined domestic equity held by the nation's long-term active and index mutual funds and exchange traded funds, representing nearly two-thirds of long-term fund assets in domestic equity and demonstrating the importance of passive investment strategies.[178] Despite this substantial share, index funds do not pose the risk of self-dealing that Regulation O was designed to mitigate. Passive investment strategies, by their nature, do not involve the type of active control or influence that would create conflicts of interest or opportunities for preferential treatment, yet index funds holding a significant share of market equity are subject to the same restrictions as active investors who may exert significant influence over portfolio companies.

To assess the magnitude of this trend and its impact on the application of Regulation O, the analysis relies on institutional ownership holding data from the S&P Global Capital IQ Ownership database.[179] The Board used this database to calculate the ownership of domestic banks and global non-bank portfolio companies for each fund group in aggregate.[180] [181]

As Table 1 shows, from the fourth quarter of 2004 to the fourth quarter of 2025, the number of banks of which fund groups hold more than 10% has increased sharply (by 247 percent). This growth is also observed for their holdings in non-banks (by 44 percent). Due to the data limitations noted above, these results may underestimate the number of entities potentially affected by Regulation O requirements. This trend suggests that the rapid growth of investment fund groups is at least partly responsible for the classification of fund complexes as principal shareholders of many banks.

[177] 12 U.S.C. 1813(q).

[178] Statistical report by the Investment Company Institute. *https://www.ici.org/research/stats/combined_active_index_0426#:~:text=Total%20Net%20Assets%20Long%2DTerm,53.4.*

[179] Note that the aggregation of holdings in all underlying subsidiary funds for a given fund manager may not match the holdings at the parent company level specified in S&P's database for a few reasons. Preliminarily, this disparity may be attributed to regulatory guidelines and governing bodies' mandates, which do not require all portfolio managers to report their holdings; therefore, S&P largely attributes this disparity to the discretion exercised by individual portfolio managers and mandated by regulatory thresholds. Furthermore, S&P omits fund-level holdings in the detailed view because institutional managers typically report total holdings on an issuer, encompassing fund holdings along with direct holdings. The presentation of parent-level holdings is based on specific logic considering relationships between entities within the same business line to prevent duplication. Additionally, variations arise due to different reporting dates, Principal Executive Officers, and filing sources.

[180] Following academic and regulatory research, the RSSD ID (assigned by the Federal Reserve's National Information Center as a universal identifier for financial institutions) is used to separate banks vs. non-banks. A financial institution is typically considered a ''bank'' if (i) it has an RSSD or (ii) it controls an institution with an RSSD and as a result the definition would include certain entities without an RSSD such as industrial loan companies, trust companies, and credit card banks. There are data limitations due to difficulties in identifying entities that meet the second criteria (ii) but the impact is likely small. Using one quarter report of total number of controlled banks provided by one fund complex, the discrepancy of missing entities that meet the second criteria (ii) is 9%.

[181] 9-character CUSIP (Committee on Uniform Securities Identification Procedures) identifiers are used to identify domestic companies.

TABLE 1—GROWTH OF FUND GROUP OWNERSHIP OF BANKS AND NON-BANK COMPANIES

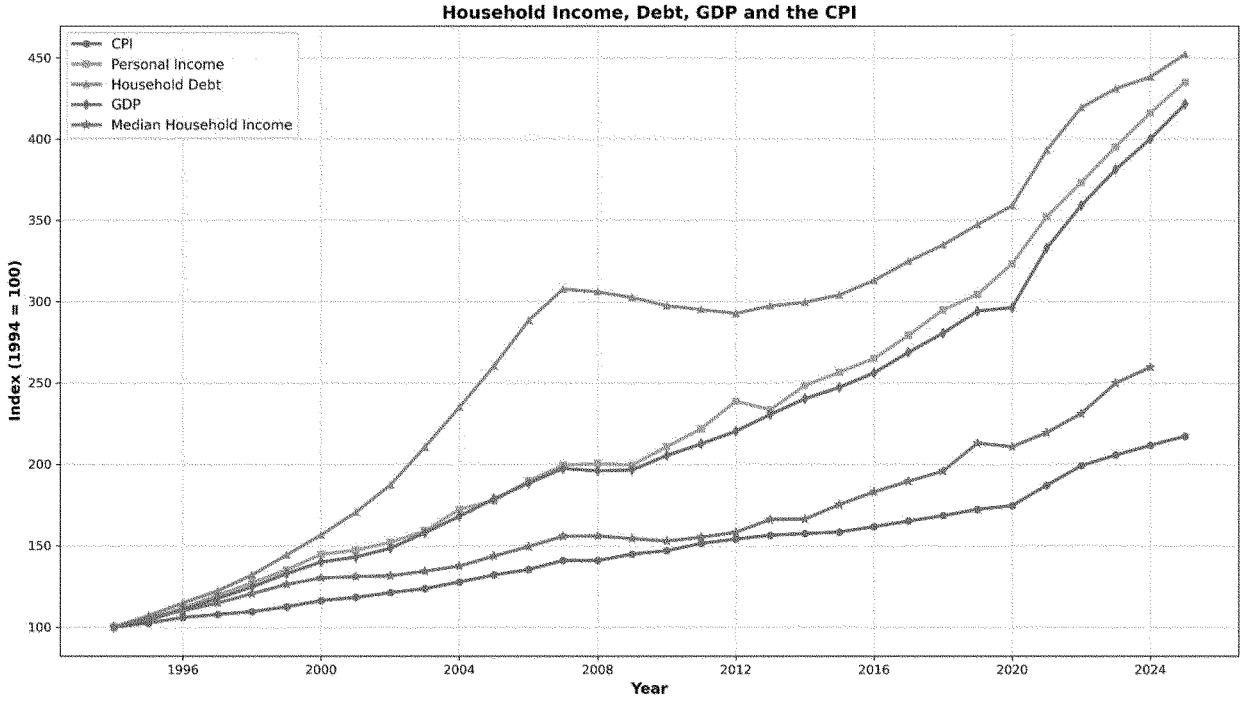
Sample period	Number of banks held by fund groups >= 10%	Number of non-bank companies held by fund groups >=10% [182]
2004Q4	19	1,423
2025Q4	66	2047
Increase/(Decrease), No.	47	624
Increase/(Decrease), %	247%	44%

As described above, there are lending limits that apply to insiders and the companies they are presumed to control.[183] In light of the sharp rise in assets under management at these investment fund groups, if lending to all of these non-bank companies is counted against these lending limits it is possible that a bank may exceed the lending limits. Recognizing this issue, in December 2019, the Federal banking agencies issued a joint statement providing temporary relief to allow banks to continue to lend to certain fund complex-controlled portfolio companies, and this temporary relief has been extended through 2026. The proposal would provide permanent relief from this unintended consequence of Regulation O.

Next, the baseline analysis considers the fixed nominal thresholds that apply to certain loans and transactions with insiders. These thresholds have been unchanged since the Board last considered Regulation O in 1994.

Over time, increase in loan demand occurs due to both inflation, which drives up the cost, and economic activity, which increases the quantity of goods and services produced. For determining the appropriate indexed levels for the Regulation O dollar-based thresholds, staff considered data on household debt (need to borrow) and household income (ability to pay), relative to a number of different macroeconomic indicators such as GDP and the consumer price index (CPI).

The figure below depicts the evolution of five series: Personal Income, household debt, median household income, nominal GDP, and the CPI. All series are normalized to 100 as of 1994. The source data for these series are various U.S. statistical agencies, and the data are accessed via the St. Louis Fed's FRED® database.[184]



This figure shows that household debt has grown at a faster rate than nominal GDP over this period. In the early part of the period, one observes a rapid runup in household borrowing prior to the financial crisis. Personal Income tends to closely track GDP over this period, reflecting that the former is the largest single component of Gross Domestic Income. Median household income has grown at a somewhat slower pace than GDP over this period,[185] due to the accumulation of economic gains by high-income individuals and because GDP includes population growth effects while median household income is measured per household. Nonetheless, these series demonstrate significantly

[182] The data did not allow for determination of whether a specific fund complex is the largest shareholder so the number of non-banks subject to the presumption of control may be smaller than the amounts provided in the table.

[183] In particular, the individual lending limit, which allows for up to 15 percent of bank capital and surplus for unsecured lending and an additional 10 for secured lending, applies to a principal shareholder and *all* of its related interests.

[184] The specific series obtained from the FRED® database are PI, CMDEBT, MEHOINUSA646N, GDP, and CPIAUCSL, respectively.

[185] Data on median household income are available only up to 2024.

more growth over this period than the price level, with the CPI only growing by a factor just above 2 from 1994 to 2025. An examination of the indexed values for aggregate income, debt, and GDP at the end of 2025 indicate that, for a given nominal threshold, demand for loan products that exceed that threshold may have increased by a factor of 4 or more from 1994 to 2025, demonstrating the need for revising these thresholds.

Proposed Policy Changes

The proposal includes two major policy changes that are analyzed in this economic analysis.

First, as discussed in Section III.B, the proposal would provide relief from the unintended application of Regulation O to qualifying fund complexes by exempting their portfolio companies from the presumption of control. A qualifying fund complex must meet specific criteria designed to ensure that the relationship between the fund complex and the bank is sufficiently passive such that section 22(h) and Regulation O conflict of interest concerns are minimized. These criteria include requirements that the fund complex not be affiliated with a bank, that no individual fund hold more than 10 percent of any bank, that non-index funds not aggregately hold more than 10 percent of any bank, and that the fund complex not trigger any of the control presumptions under the Board's Regulation Y.

Second, as discussed in Section III.A, the proposal would increase various dollar-based thresholds in Regulation O to adjust for economic growth and inflation since the regulation was last updated. The proposal would also establish a methodology for automatically indexing these thresholds every five years going forward based on nominal GDP growth. This indexing mechanism would reduce unnecessary regulatory burden while retaining safeguards against self-dealing and conflicts of interest.

Effects of Proposed Approach To Address Ownership by Fund Complexes

This section analyzes the economic effects of the qualifying fund complex exemption described in Section III.B of this **SUPPLEMENTARY INFORMATION**. The primary benefits include maintaining access to conventional banking relationships for portfolio companies, reducing credit rationing, improving capital allocation efficiency, and substantially lowering compliance costs for both banks and fund complexes that would otherwise face burdensome monitoring, information collection, and procedural requirements. The costs are expected to be minimal, consisting primarily of regulatory arbitrage risks that are substantially mitigated by the proposal's multiple qualifying criteria. Overall, the proposal generates significant net benefits by refocusing Regulation O on its core purpose of mitigating potential for self-dealing while eliminating unnecessary restrictions on genuinely passive investors that are seeking exposure to a broad-based stock index.

Benefits

The proposed changes would address the unintended consequences of the regulatory presumption of control on lending to companies held by fund groups.

As a result of the proposal, portfolio companies of qualifying fund complexes would retain access to conventional banking relationships that would have been unnecessarily restricted by the insider lending requirements, maintaining their ability to secure financing for ordinary business operations. Many of these portfolio companies are large, publicly traded firms with substantial credit needs and banks naturally seek to lend to creditworthy borrowers in their markets. Such relationships could become curtailed due to the unintended application of Regulation O constraints. As shown in Table 1, the proposal would directly affect a substantial volume of potential lending relationships. As of Q4 2025, fund complexes are principal shareholders of approximately 66 banks, and fund complexes might be presumed to control approximately 2047 portfolio companies. Each of the 66 affected banks could potentially have lending relationships with any of the 2047 affected portfolio companies, representing up to 135,102 (66 multiplied by 2047) possible bank-borrower pairs subject to Regulation O restrictions. While not all potential relationships would be covered or materialize into actual loans, the analysis suggests that a meaningful number of lending relationships could be affected by the current regulatory structure. Even if a small fraction of these potential relationships represent actual or desired lending relationships, the proposal could exempt a significant number of relationships between banks and portfolio companies that are otherwise affected by the requirements of Regulation O.

Facilitating lending relationships between the banks and portfolio companies currently subject to unintended Regulation O requirements will eliminate an unintended constraint on lending relationships across portfolio companies and improve economic efficiency. In the case that banks cannot lend freely to creditworthy portfolio companies due to Regulation O constraints, both banks and borrowers face costs. Banks lose profitable lending opportunities with creditworthy borrowers while portfolio companies may face reduced access to bank credit, forcing them to use more expensive alternative financing. Such unintended restrictions on lending could prevent efficient capital allocation and some companies may forego productive investments or face delays in financing.

Reducing unnecessary barriers to lending will allow capital to flow more efficiently to productive uses, supporting business growth and economic activity. The improved capital allocation could potentially lead to more sustainable economic activity and support competitive banking markets.

Reduced Compliance Costs

Banks and fund complexes would also benefit from the reduced administrative costs associated with monitoring and managing related interest restrictions. All banks with principal shareholder fund complexes exempted from the Regulation O constraints under the proposal would benefit by avoiding costs associated with continuously monitoring ownership changes, obtaining prior board approvals for certain large loans, and collecting information about related interests across potentially thousands of portfolio companies. While the Board does not have sufficient information to quantify all aspects of these savings, the proposal would likely generate significant compliance cost reductions, as discussed below.

Banks and fund complexes would face significant costs in attempting to determine whether specific portfolio companies qualify as related interests under Regulation O's existing presumptions of control. This determination requires banks to assess whether a fund complex is the largest shareholder of a portfolio company, obtain real-time ownership levels across multiple funds and portfolio companies, and monitor whether ownership changes have created or eliminated ''related interest'' relationships. Banks must also maintain complex systems to aggregate exposures across numerous related interests and coordinate with fund complexes to obtain timely ownership information. The proposal would reduce these monitoring burdens and information collection costs by eliminating the need for banks to make ongoing determinations about whether

portfolio companies of qualifying fund complexes trigger the presumption of control. Banks will no longer need to continuously monitor whether a qualifying fund complex remains the largest shareholder of each portfolio company or track ownership percentage changes under 25 percent.

Under current Regulation O, large extensions of credit to insiders require approval by a majority of the bank's board of directors, with interested parties required to abstain from voting. Each board approval requires preparation of materials describing the proposed extension of credit, board member time to review and vote on the transaction, and documentation of the approval process. For banks with numerous fund complex-controlled portfolio companies that are classified as related interests, compliance with this requirement could involve many such board approvals annually. The proposal would provide benefits to banks with principal shareholder fund complexes by essentially eliminating this procedural requirement for all portfolio companies where the fund complex holds less than 25 percent of voting securities. These portfolio companies would no longer be classified as related interests subject to the prior approval requirement. This reduced procedural requirement could result in meaningful cost savings.

As noted above, based on Table 1, as of the first quarter of 2025, fund complexes are principal shareholders of 66 banks and these fund complexes might be presumed to control 2047 portfolio companies. This suggests that a meaningful number of banks would benefit from the proposed compliance cost reductions.

Costs

The proposed exception for qualifying fund complexes is expected to impose minimal costs relative to the substantial benefits described above. The primary costs arise from regulatory arbitrage risks that the exception could inadvertently permit some forms of preferential treatment or conflict of interest, though the proposal includes safeguards designed to prevent such outcomes.

The proposal creates a theoretical risk that fund complexes could restructure their operations or organizational forms to qualify for the exception while maintaining some degree of influence over bank lending decisions. Fund complexes might restructure voting arrangements, modify fund structures, or adjust ownership levels across individual funds in ways designed to meet the qualifying criteria while preserving elements of control or coordination that the exception is intended to exclude. However, the proposal includes multiple qualifying criteria designed to ensure that fund complexes benefiting from the exception are genuinely passive investors. Specifically, the proposal requires that no individual fund hold more than 10 percent of any bank, that non-index funds not aggregately hold more than 10 percent of any bank, and that the fund complex not be presumed to control the bank pursuant to the Board's existing control rule Regulation Y. These multiple, overlapping criteria substantially reduce the opportunity for fund complexes to restructure in ways that would qualify for the exception while maintaining meaningful control, and the Board expects that the probability of regulatory arbitrage is low. In addition, the proposal does not impact the Board's authority to determine that a fund complex has ''the power to exercise a controlling influence'' over a portfolio company even if the fund complex does not meet the rebuttable presumptions of control,[186] which provides an additional safeguard against attempts to exercise control through subtle or indirect means.

Effects of Proposed Adjustment of Thresholds

This section analyzes the economic effects of the threshold adjustments and indexing methodology described in Section III.A of the **SUPPLEMENTARY INFORMATION**. The primary benefits include a meaningful reduction in administrative burden for banks by decreasing the frequency with which routine transactions trigger regulatory requirements, such as approvals from a bank's board of directors, as well as ongoing benefits from automatic indexing that would maintain appropriate threshold values as the economy grows. Banks of all sizes would benefit from the reduced compliance costs, and insiders would maintain appropriate access to banking services without unnecessary regulatory restrictions on certain transactions. The costs include potential increase in the risks related to insider lending. However, safeguards remain in place to mitigate potential risks from higher thresholds, including requirements that all extensions of credit to insiders be made on substantially the same terms as to non-insiders and subject to individual and aggregate lending limits.

[186] *See* 12 U.S.C. 375b(9)(B)(iii).

Benefits

Banks would benefit from raising the dollar thresholds that have not kept pace with inflation and economic growth since 1994. The proposal would reduce administrative burden by decreasing the frequency with which certain transactions with insiders trigger regulatory requirements and would establish automatic indexing to maintain appropriate threshold values as the economy grows.

As the economy has grown, the dollar size of typical banking transactions has increased, causing the outdated thresholds to apply to more routine transactions than originally intended. The proposed threshold increases would address this problem by updating the values to be more reflective of current economic conditions, thereby reducing the administrative burden associated with regulatory requirements that have become unnecessarily restrictive. For example, the proposed increase in the prior approval threshold from $500,000 to $2 million would substantially reduce the number of insider transactions requiring heightened review. Each board approval requires preparation of materials describing the proposed extension, scheduling of board meetings or obtaining written consents, board member time to review and vote on the transaction, documentation of the approval process, and associated recordkeeping. Banks' current processes to ensure timely board review could be simplified for transactions falling between the current and proposed thresholds. The savings would be particularly significant for banks with existing insider lending relationships, as these banks could experience significant reductions in the number of board approvals required annually.

Beyond addressing the immediate burden created by outdated thresholds, the proposal would establish a methodology for indexing Regulation O thresholds based on changes in nominal GDP, which would provide ongoing benefits by automatically adjusting thresholds to reflect economic activity over time. This indexing methodology would prevent the erosion of threshold values that has occurred over the past several decades when thresholds remained fixed in nominal terms. By linking thresholds to nominal GDP growth, the proposal would eliminate the need for periodic rulemakings to update threshold values as economic activity and thus transactions over a given amount increase. Without indexing, banks would face a gradually increasing number of transactions

triggering regulatory requirements solely because nominal transaction sizes grow with the economy while thresholds remain fixed. The proposed indexing would prevent this inadvertent tightening of regulatory standards.

The proposed threshold adjustments are expected to benefit member banks of all sizes, though the distribution of benefits would vary based on the scale and nature of each bank's insider lending relationships. The proposal would also benefit insiders of banks by maintaining their access to banking services at their own bank without unnecessary regulatory restrictions on routine transactions. Executive officers and directors would be able to obtain credit cards with higher limits, maintain overdraft protection plans with higher limits, and access more business credit without triggering prior approval requirements for transactions that fall within the updated thresholds. This would be particularly beneficial in small and rural markets where alternative banking relationships may be limited and where insiders' business credit needs have grown substantially with the economy over the decades since the thresholds were last updated. Moreover, one bank may be reluctant to lend to an insider of another bank, as they could potentially worry about an adverse selection problem. As such, the proposal removes an impediment to these banks attracting and retaining skilled executive officers and directors.

Costs

The proposed threshold increases are designed to maintain the original calibration of regulatory requirements by adjusting for nominal GDP growth since the thresholds were last updated, thereby restoring them to approximately the same value relative to the economy as when they were originally established. However, the nominal increases could create potential risks that banks could extend larger amounts of credit to insiders without board approval or other safeguards that apply above the current thresholds. The proposal increases multiple thresholds, all by approximately fourfold to reflect nominal GDP growth since they were last updated. Most notably, under the proposal, a bank could extend $2 million to an insider without board approval, compared to $500,000 under current requirements. Additionally, executive officers could obtain extensions of credit for purposes other than home mortgages or education loans up to $400,000 (from $100,000), credit card debt up to $60,000 (from $15,000) would be exempt from the definition of ''extension of credit,'' and inadvertent overdrafts up to $4,000 (from $1,000) would be permitted. These increased thresholds could potentially allow for larger transactions that present conflicts of interest or self-dealing concerns to occur without the board oversight or other safeguards that the current requirements are designed to provide.

These potential risks are mitigated by several factors that ensure the threshold adjustments do not create meaningful new opportunities for self-dealing or conflicts of interest. First, the thresholds account for the increase in economic activity from the fourth quarter of 1994 to the fourth quarter of 2025, meaning that transactions requiring board approval today represent the same relative size and risk profile as transactions requiring board approval when the thresholds were last considered. Thus, the proposed thresholds are specifically calibrated to maintain the original value and the original regulatory requirements rather than creating new opportunities for larger transactions relative to typical bank capital levels and commercial lending activity in the economy. Second, all extensions of credit to insiders remain subject to the fundamental requirement that they be made on substantially the same terms as extensions to non-insiders and not involve more than normal risk of repayment, regardless of the size of the extension. Third, extensions of credit remain subject to the individual and aggregate lending limits in Regulation O, which constrain the total amount of credit that can be extended to any insider regardless of whether board approval is required. These continuing requirements ensure that the threshold adjustments do not create meaningful new risks of self-dealing or conflicts of interest.

In addition, the ongoing indexing of thresholds would create compliance costs by requiring banks to update their systems and procedures every five years to reflect adjusted threshold amounts based on changes in nominal GDP. However, this cost is expected to be marginal.

Conclusion

The proposed amendments to Regulation O are expected to generate substantial benefits by addressing two significant issues with the current regulatory framework. First, the exemption for portfolio companies of qualifying fund complexes from the presumptions of control would maintain access to conventional banking relationships for portfolio companies, improve capital allocation efficiency, and substantially reduce compliance costs for both banks and fund complexes, while preserving Regulation O's core purpose of preventing self-dealing through multiple qualifying criteria and safeguards. Second, the adjustment of dollar-based thresholds to reflect nominal GDP growth from the fourth quarter of 1994 to the fourth quarter of 2025 would reduce administrative burden for banks by making thresholds more reflective of current economic conditions. The establishment of ongoing indexing based on nominal GDP growth would prevent future erosion through a transparent, predetermined method.

The proposed threshold adjustments are designed to maintain the original calibration of regulatory requirements by restoring thresholds to approximately the same value relative to the economy in 1994, thereby preserving prudential safeguards against self-dealing and conflicts of interest. In addition to updating the calibration, the proposal preserves important safeguards by requiring that all extensions of credit to insiders be made on substantially the same terms as to non-insiders and remain subject to individual and aggregate lending limits.

Overall, the analysis demonstrates that the benefits of the proposal justify the costs, as the proposal refocuses Regulation O on transactions that genuinely present conflicts of interest while reducing unnecessary restrictions on passive investors and routine transactions that have grown with the economy.

VII. Regulatory Analysis

A. Paperwork Reduction Act

Certain provisions of the proposal contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) (PRA). In accordance with the requirements of the PRA, the Board may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The information collection affected by this rulemaking is the Recordkeeping and Disclosure Requirements Associated with Regulation O (FR O; OMB No. 7100–0382). This Board proposes to extend this information collection for three years, with revision. The Board reviewed the proposal under the authority delegated to the Board by OMB.

Comments are invited on:

a. Whether the collections of information are necessary for the proper

performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the information collections, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of the information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

All comments will become a matter of public record. Comments on aspects of this notice that may affect reporting, recordkeeping, or disclosure requirements and burden estimates should be sent to the addresses listed in the **ADDRESSES** section of this document. A copy of the comments may also be submitted to the OMB desk officer for the Board by mail to U.S. Office of Management and Budget, 725 17th Street NW, #10235, Washington, DC 20503; facsimile to (202) 395–6974; or email to *oira_submission@omb.eop.gov,* Attention, Federal Banking Agency Desk Officer.

Current Actions

The proposed rule would modify the disclosure requirement currently codified in section 215.9 of Regulation O. This section requires a bank, in response to a written request from a member of the public, to identify the executive officers and principal shareholders of the bank (and the related interests of such persons) that have outstanding extensions of credit in an amount equal to the lower of 5 percent of the bank's capital and unimpaired surplus or $500,000 as of the end of the latest previous quarter. No disclosure is required if the amount of the extensions of credit to a person and the person's related interests does not exceed $25,000.[187]

The proposed rule, restated at 215.31, would amend the threshold in this section for the amount of extensions of credit to be the lesser of 5 percent of the bank's unimpaired capital and unimpaired surplus and $2.0 million. The proposed rule would continue not to require disclosure when the amount of extensions of credit to an executive officer or principal shareholder, or to their related interests, does not exceed $25,000. The proposed rule also would amend the definition of ''principal shareholder'' for purposes of the disclosure requirement. Specifically, a bank's holding company no longer would be a principal shareholder. In addition, a foreign bank no longer would be excluded from the definition of principal shareholder. Taken together, the list of persons that must be disclosed by banks subject to Regulation O likely will be smaller under the proposed rule than under Regulation O as it currently is written.

The proposed rule also would create recordkeeping and disclosure requirements to ensure compliance by banks with the correspondent lending restrictions in 12 U.S.C. 1972. Under the proposal, member banks would be required to maintain records of extensions of credit to insiders of the member bank's correspondent or respondent bank. The proposed rule would permit banks with correspondent or respondent banks to use one of two methods prescribed by the rule to procure the information necessary to satisfy these recordkeeping requirements, or to propose an alternative to the bank's appropriate federal banking agency. The two methods set forth by the proposed rule are the survey method, whereby a bank sends an annual survey to each of its correspondent or respondent banks to identify their insiders; or the borrower inquiry method, whereby a bank asks all persons seeking an extension of credit to identify whether they are insiders of the bank's respondent or correspondent banks. Each of these methods would require the member bank to request the disclosure by third-parties of certain information to the bank.

The proposed amendments also relate to certain existing data items collected in the Federal Financial Institutions Examination Council (FFIEC) Reports of Condition and Income (Call Reports; FFIEC 031, 041, and 051). Any amendments to the Call Reports would be proposed separately by the FFIEC.

Proposed Extension for Three Years, With Revision, of the Following Information Collection

Collection title: Recordkeeping and Disclosure Requirements Associated with Regulation O.

Collection identifier: FR O.

OMB control number: 7100–0382.

General description of collection: The Board's Regulation O—Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks (12 CFR part 215) governs any extension of credit made by a member bank to an executive officer, director, or principal shareholder of the member bank and any related interests of such persons or entities (insiders). Regulation O prohibits such extensions of credit to insiders unless they are made on substantially the same terms (including interest rates and collateral) as those prevailing at the time for comparable transactions by the bank with other persons who are not employed by the bank and do not involve more than the normal risk of repayment or present other unfavorable features. In addition, Regulation O limits extensions of credit by a member bank to individual insiders and to all insiders, requires a member bank's board of directors to approve certain large extensions of credit, and sets forth recordkeeping and disclosure requirements.

Pursuant to section 215.8 of the current Regulation O, respondents must maintain records necessary for compliance with the regulation. Under section 215.9 of the current Regulation O, upon receipt of a written request from the public, a respondent must make available certain information regarding extensions of credit that exceed a certain threshold. These two provisions are restated at 215.30 and .31.

Frequency: Event-generated.

Respondents: Insured depository institutions and uninsured member banks.

Total estimated number of respondents:

Recordkeeping

Section 215.30—4,464.
Section 215.31—608.

Disclosure

Section 215.31—608.

Estimated average hours per response:

Recordkeeping

Section 215.30—3.
Section 215.31—1.

Disclosure

Section 215.31—2.

Total estimated annual burden hours: 15,216.

B. Regulatory Flexibility Act

The Board is providing an initial regulatory flexibility analysis with respect to this proposed rule. The Regulatory Flexibility Act[188] (RFA), requires an agency to consider whether the rules it proposes will have a significant economic impact on a substantial number of small entities.[189]

[187] 12 CFR 215.9.

[188] 5 U.S.C. 601 *et seq.*

[189] Under regulations issued by the U.S. Small Business Administration (SBA), a small entity

Continued

In connection with a proposed rule, the RFA generally requires an agency to prepare and invite comment on an initial regulatory flexibility analysis describing the impact of the rule on small entities, unless the agency certifies that the proposed rule, if promulgated, would not have a significant economic impact on a substantial number of small entities. An initial regulatory flexibility analysis must contain (1) a description of the reasons why action by the agency is being considered; (2) a succinct statement of the objectives of, and legal basis for, the proposed rule; (3) a description of, and, where feasible, an estimate of the number of small entities to which the proposed rule will apply; (4) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; (5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap with, or conflict with the proposed rule; and (6) a description of any significant alternatives to the proposed rule which accomplish its stated objectives and minimize any significant economic impact of the proposed rule on small entities.[190]

The Board has considered the potential impact of the proposed rule on small entities in accordance with the RFA. Based on its analysis and for the reasons stated below, the Board believes that this proposed rule will not have a significant economic impact on a substantial number of small entities. Nevertheless, the Board is publishing and inviting comment on this initial regulatory flexibility analysis.

As discussed in this **SUPPLEMENTARY INFORMATION**, the proposed rule would amend Regulation O to incorporate existing statutory requirements that are not currently reflected in the regulation and would clarify certain definitions, exemptions, and other matters to reflect longstanding interpretations and to harmonize Regulation O with other Board regulations. The proposed amendments also would update several outdated dollar-based thresholds in Regulation O and index these thresholds going forward. In addition, the proposed amendments would address the application of Regulation O to member banks that lend to companies that are presumed to be controlled by large asset management companies through passive investment funds. Finally, the proposed amendments would revise and reorganize the regulation to streamline the text and make it more accessible. Some of these changes may require changes to reporting forms that would occur separately from this rulemaking.

The Board has broad authority under sections 22(g) and 22(h) to establish regulations restricting extensions of credit from a bank to its insiders, consistent with statutory requirements. The Board has codified these restrictions into its Regulation O. However, subsequent interpretations and statutory updates have clarified and expanded restrictions on bank extensions of credit. The proposed regulatory amendments would conform Regulation O to existing statutes and interpretations and, therefore, would provide necessary clarity to banks regarding their obligations.

Regulation O applies, by its terms, to all member banks, regardless of their size. The regulation affects all insured depository institutions, however, because other Federal law subjects insured nonmember banks and insured savings associations to sections 22(g) and 22(h) as if they were member banks. The rule also applies indirectly to the ''insiders'' of insured depository institutions, which, for RFA purposes, includes only insiders that are either (1) small business concerns; (2) small organizations, which are not-for-profit enterprises that are independently owned and operated and not dominant in their field; or (3) small governmental jurisdictions. The number of small entities affected by Regulation O is estimated to include 3,134 depository institutions.[191] The Board does not collect data on all insiders of depository institutions at this time. Accordingly, the exact number of small entities affected by the rule would require additional surveys or reports, which would increase the burden on the public and are not necessary for implementation of the rule. However, as discussed in more detail in section VII.A. of this **SUPPLEMENTARY INFORMATION**, the proposal would not include additional reporting requirements imposing any measurable burden. Any changes to reporting requirements would be limited to codifying existing statutory requirements, simplifying definitions applicable to disclosure requirements in Regulation O, scoping foreign banks into disclosure requirements as a result of Regulation O simplification, and consolidating certain disclosure requirements codified in Regulation O and Regulation Y into Regulation O. Although there is an additional recordkeeping requirement resulting from the codification of statutory correspondent lending restrictions, these methods are nearly identical to the methods set forth in Regulation O for a bank to maintain records to ensure compliance with Regulation O of loans to insiders of the bank's affiliates.

The Board is aware of no other Federal rules that duplicate, overlap, or conflict with the proposed changes to Regulation O. In addition, as indicated above, the proposal would not include additional reporting requirements imposing any measurable burden and, with respect to the proposed amendments to exempt portfolio companies of qualifying fund complexes from the presumptions of control and to adjust and index the dollar-based thresholds to account for economic growth and inflation, the proposal would provide relief and reduce regulatory burden. Accordingly, the Board is aware of no significant alternatives to the proposed rule that would reduce economic impact on small entities supervised by the Board.

For these reasons, the proposed rule is not expected to have a significant economic impact on a substantial number of small entities.

The Board welcomes written comments regarding this initial regulatory flexibility analysis, and requests that commenters describe the nature of any impact on small entities and provide empirical data to illustrate and support the extent of the impact.

C. Riegle Community Development and Regulatory Improvement Act of 1994

Pursuant to section 302(a) of the Riegle Community Development and Regulatory Improvement Act (RCDRIA),[192] in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions (IDIs), the federal banking agencies must consider, consistent with the principle of safety and soundness and the public interest, any

includes a depository institution with total assets of $850 million or less. *See* 13 CFR 121.201. Consistent with the SBA's General Principles of Affiliation, the Board includes the assets of all domestic and foreign affiliates toward the applicable size threshold when determining whether to classify a particular entity as a small entity. *See* 13 CFR 121.103. As of the first quarter of 2026, there were approximately 3,134 small state member banks, based on Call Report data as of March 31, 2026.

[190] 5 U.S.C. 603(b)–(c).

[191] Small entity information is from Call Report data as of March 31, 2026.

[192] 12 U.S.C. 4802(a).

administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations. In addition, section 302(b) of RCDRIA requires new regulations and amendments to regulations that impose additional reporting, disclosures, or other new requirements on IDIs generally to take effect on the first day of a calendar quarter that begins on or after the date on which the regulations are published in final form, with certain exceptions, including for good cause.[193]

The proposed rule would modify the disclosure requirements related to extensions of credit by banks to their principal shareholders and executive officers, and any related interests of such persons, as discussed in section VII.A of this **SUPPLEMENTARY INFORMATION**. This modification likely will decrease the amount of information that most banks must disclose under the rule. The proposed rule otherwise does not include additional reporting requirements.

The proposed amendments relate to certain existing data items collected in the Federal Financial Institutions Examination Council (FFIEC) Reports of Condition and Income (Call Reports; FFIEC 031, 041, and 051). Any amendments to the Call Reports would be proposed separately by the FFIEC.

The Board invites comment on all aspects of the proposed rule and analysis related to RCDRIA.

D. Solicitation of Comments on the Use of Plain Language

Section 722 of the GLB Act requires the federal banking agencies to use plain language in proposed and final rulemakings published after January 1, 2000.[194] The Board has sought to present the proposed rule in a simple and straightforward manner and invites comment on the use of plain language in this proposal.

Question 98: Has the Board organized the proposal in a clear way? If not, how could the proposal organized more clearly?

Question 99: Are the requirements of the proposed rule clearly stated? If not, how could they be stated more clearly?

Question 100: Does the proposal contain unclear technical language or jargon? If so, which language requires clarification?

Question 101: Would a different format (such as a different grouping and ordering of sections, a different use of section headings, or a different organization of paragraphs) make the regulation easier to understand? If so, what changes would make the proposal clearer?

Question 102: What else could the Board do to make the proposal clearer and easier to understand?

E. Providing Accountability Through Transparency Act of 2023

The Providing Accountability Through Transparency Act of 2023 (*5 U.S.C. 553(b)(4)*) requires that a NPR include the internet address of a summary of not more than 100 words in length of the proposed rule, in plain language, that shall be posted on the internet website under section 206(d) of the E-Government Act of 2002 (*44 U.S.C. 3501 note*).

In summary, the Board proposes to amend its Regulation O (Loans To Executive Officers, Directors, And Principal Shareholders Of Member Banks) to update and modernize the regulation, clarify requirements and incorporate existing interpretations, and reduce regulatory burden. The proposal also would incorporate existing statutory requirements; update, and index going forward, several outdated dollar-based thresholds in Regulation O; and address the application of Regulation O to member banks that lend to companies presumed to be controlled by large asset management companies through passive investment funds. Finally, the proposal would revise and reorganize the regulation to make it more accessible.

The proposal and such a summary can be found at *https://www.regulations.gov* and *https://www.federalreserve.gov/supervisionreg/reglisting.htm.*

List of Subjects in 12 CFR Part 215

Administrative practice and procedure, Banks, Banking, Credit, Federal Reserve System, Holding Companies, Investments, Penalties, Reporting and recordkeeping requirements, and Securities.

Authority and Issuance

For the reasons stated in the **SUPPLEMENTARY INFORMATION**, the Board of Governors of the Federal Reserve System proposes to amend 12 CFR chapter II as follows:

■ 1. Revise Part 215 to read as follows:

PART 215—LOANS TO EXECUTIVE OFFICERS, DIRECTORS, AND PRINCIPAL SHAREHOLDERS OF MEMBER BANKS (REGULATION O)

Sec.

Subpart A—General Provisions

§ 215.1 Authority, purpose, and scope.
§ 215.2 Definitions.
§ 215.3 Extension of credit.
§ 215.4 Timing of application of requirements.
§ 215.5 Valuation principles.

Subpart B—Requirements for Extensions of Credit to All Insiders

§ 215.11 Terms and creditworthiness.
§ 215.12 Prior approval.
§ 215.13 Lending limits.
§ 215.14 Prohibition on knowingly receiving an unauthorized extension of credit.

Subpart C—Requirements for Extensions of Credit and Other Transactions With Certain Insiders

§ 215.20 Additional restrictions on extensions of credit to executive officers of a member bank.
§ 215.21 Additional restrictions on paying overdrafts on accounts of directors and executive officers of a member bank and its affiliates.
§ 215.22 Additional restrictions for extensions of credit related to existing and potential correspondent accounts.
§ 215.23 Prohibitions on asset purchases and sales between an insured depository institution and an insider.

Subpart D—Recordkeeping and Disclosure Requirements

§ 215.30 Records of member banks.
§ 215.31 Disclosure of credit from member banks to executive officers and principal shareholders.
§ 215.32 Disclosure requirement for credit secured by certain bank and holding company stock.

Subpart E—Civil Penalties

§ 215.40 Civil penalties.

Authority: 12 U.S.C. 248(a), 375a(10), 375b(9) and (10), 1468, 1817(k), 1828(z), 1972(2), and 5412; Pub. L. 102–242, 105 Stat. 2236 (1991) (12 U.S.C. 1811 note).

Subpart A—General Provisions

§ 215.1 Authority, purpose, and scope.

(a) *Authority.* This part is issued pursuant to sections 11(a), 22(g), and 22(h) of the Federal Reserve Act (12 U.S.C. 248(a), 375a, and 375b), 12 U.S.C. 1817(k), section 306 of the Federal Deposit Insurance Corporation Improvement Act of 1991 (Pub. L. 102–242, 105 Stat. 2236 (1991)), section 11 of the Home Owners' Loan Act (12 U.S.C. 1468), section 106 of the Bank Holding Company Act Amendments of 1970 (12 U.S.C. 1972), and sections 312(b)(2)(A) and 615(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (12 U.S.C. 1828(z)(2) and 5412).

(b) *Purpose and scope*—(1) This part governs:

(i) Any extension of credit by a member bank to an executive officer,

[193] 12 U.S.C. 4802.

[194] 12 U.S.C. 4809(a).

director, or principal shareholder of the member bank or of any affiliate of the member bank;

(ii) Any extension of credit by a member bank to a company controlled by such a person, or to a political or campaign committee that benefits or is controlled by such a person;

(iii) Asset purchases and sales between an insured depository institution and an insider of the insured depository institution described in paragraph (b)(1) or (2) of this section; and

(iv) Extensions of credit by a depository institution to an executive officer, director, or principal shareholder of another depository institution (or to a related interest of such person), if either institution maintains or seeks to maintain a correspondent account with the other institution.

(2) The Federal Deposit Insurance Act (12 U.S.C. 1828(j)) applies sections 22(g) and 22(h) of the Federal Reserve Act to insured State nonmember banks and insured branches of foreign banks in the same manner and to the same extent as if they were member banks, and the Home Owners' Loan Act (12 U.S.C. 1468(b)) applies sections 22(g) and 22(h) to insured savings associations in the same manner and to the same extent as if they were member banks.

(3) This part also implements the reporting and disclosure requirements of 12 U.S.C. 1817(k) concerning extensions of credit by a member bank to its executive officers or principal shareholders (or to the related interests of such persons).

§ 215.2 Definitions.

For purposes of this part, the following definitions apply unless otherwise specified:

Acting in concert has the meaning given in § 225.41(b)(2) of this chapter. For purposes of this part, the persons set forth in § 225.41(d)(1)–(6) of this chapter are presumed to be acting in concert, except that, for purposes of § 225.41(d)(2) of this chapter, the term ''immediate family'' has the meaning given in this section.

Affiliate means any company of which a member bank is a subsidiary or any other subsidiary of that company, but does not include a subsidiary of the member bank that is not a financial subsidiary (as defined in § 223.3 of this chapter).

Appropriate Federal banking agency with respect to a member bank or company has the meaning given in 12 U.S.C. 1813.

Board means the Board of Governors of the Federal Reserve System.

Carrying value with respect to a security means (unless otherwise provided) the value of the security on the financial statements of the member bank, determined in accordance with GAAP.

Class of voting securities has the meaning given in § 225.2 of this chapter.

Company means any corporation, limited liability company, partnership, trust (business or otherwise), association, joint venture, pool syndicate, sole proprietorship, unincorporated organization, or any other form of business entity not specifically listed herein. However, the term does not include:

(1) An insured depository institution; or

(2) A corporation, the majority of the shares of which are owned by the United States or by any State.

Control of a company or bank (1) means that a person directly or indirectly, or acting through or in concert with one or more persons:

(i) Owns, controls, or has the power to vote 25 percent or more of any class of voting securities of the company or bank;

(ii) Controls in any manner the election of a majority of the directors of the company or bank; or

(iii) Has the power to exercise a controlling influence over the management or policies of the company or bank.

(2) A person is presumed to have control, including the power to exercise a controlling influence over the management or policies, of a company or bank if:

(i) (A) The person is an executive officer or director of the company or bank; and

(B) The person directly or indirectly owns, controls, or has the power to vote more than 10 percent of any class of voting securities of the company or bank; or

(ii) (A) The person directly or indirectly owns, controls, or has the power to vote more than 10 percent of any class of voting securities of the company or bank; and

(B) No other person owns, controls, or has the power to vote a greater percentage of that class of voting securities;

(iii) In the case of a company or bank that is a trust:

(A) The person is a trustee of the trust; or

(B) The person is a settlor, appointer, or beneficiary of the trust, and has the power to:

(*1*) Remove or replace a trustee of the trust; and

(*2*) Limit the power of a trustee of the trust to purchase, sell, or exchange any investment or asset of the trust; and

(iv) The company or bank is controlled by an estate for which the person serves as executor.

(3) The presumptions of control in paragraph (2) of this definition do not apply for the purpose of determining whether a qualified fund complex controls a company through one or more investment funds for purposes of determining whether the company is a related interest of the qualified fund complex that is a principal shareholder of a member bank.

(4) An individual is not considered to have control, including the power to exercise a controlling influence over the management or policies, of a company or bank solely by virtue of the individual's position as an officer or director of the company or bank.

(5) A person may rebut a presumption established by paragraph (2) of this definition by submitting to the appropriate Federal banking agency written materials that, in the agency's judgment, demonstrate an absence of control. The appropriate Federal banking agency should consult with the Board in considering such a request.

Derivative transaction has the meaning given in 12 U.S.C. 84(b).

Derivative netting set means all derivative transactions with an individual counterparty that are governed by a qualifying master netting agreement (as defined in § 217.2 of this chapter).

Director of a company or bank means any director of the company or bank, whether or not receiving compensation. An advisory director is not considered a director if the advisory director:

(1) Is not elected by the shareholders of the company or bank;

(2) Is not authorized to vote on matters before the board of directors; and

(3) Provides solely general policy advice to the board of directors.

(4) Notwithstanding the definition of ''member bank'' in this section, a person is not a director of a member bank solely because the person is a director of a subsidiary of the member bank.

Executive officer of a company or bank (1) means a person who participates or has authority to participate (other than in the capacity of a director) in major policymaking functions of the company or bank, whether or not the officer has an official title, the title designates the officer an assistant, or the officer is serving without salary or other compensation.

(2) The chair of the board, president, treasurer, chief executive officer, chief

financial officer, chief lending officer, and chief investment officer of a company or bank are considered executive officers, unless the officer is excluded, by resolution of the board of directors or by the bylaws of the company or bank, from participation (other than in the capacity of a director) in major policymaking functions of the company or bank, and the officer does not actually participate therein.

(3) Executive officer of a company or bank does not include persons who may have official titles and may exercise a certain measure of discretion in the performance of their duties, including discretion in the making of loans, but who do not participate in the determination of major policies of the company or bank and whose decisions are limited by policy standards fixed by the senior management of the company or bank.

(4) Executive officer of a company or bank does not include a manager or assistant manager of a branch of the company or bank unless that individual participates, or is authorized to participate, in major policymaking functions of the bank or company.

(5) Notwithstanding the definition of ''member bank'' in this section, a person is not an executive officer of a member bank solely because the person is an executive officer of a subsidiary of the member bank.

Exempt official (1) means a person that:

(i) Is a director or executive officer of an affiliate of a member bank;

(ii) Is not a director or executive officer of the member bank; and

(iii) With respect to all positions as director or executive officer of an affiliate of a member bank:

(A) The director or executive officer is excluded, by resolution of the board of directors or by the bylaws of the member bank, from participation in major policymaking functions of the member bank, and the director or executive officer does not actually participate in such functions;

(B) The affiliate does not control the member bank; and

(C) As determined annually, the assets of the affiliate do not constitute more than 10 percent of the consolidated assets of the company that:

(*1*) Controls the member bank; and

(*2*) Is not controlled by any other company.

(2) For purposes of paragraph (1)(iii)(A) of this definition, a resolution of the board of directors or a corporate bylaw may:

(i) Include the director (by name or by title) in a list of persons excluded from participation in such functions; or

(ii) Not include the director in a list of persons authorized (by name or by title) to participate in such functions.

Foreign bank has the meaning given in 12 U.S.C. 3101(7).

GAAP means generally accepted accounting principles as used in the United States.

GDP growth adjustment means the most recent scalar published by the Board equal to the ratio of:

(1) The nominal United States gross domestic product in the 4th quarter of the calendar year prior to publication of the scalar, as reflected by the most current estimates published by the Bureau of Economic Analysis on or before September 30th of the year of the publication of the scalar, or a comparable value; to

(2) The nominal United States gross domestic product in the 4th quarter of the calendar year prior to [the effective date of a final rule], as reflected by the most current estimates published by the Bureau of Economic Analysis.

Immediate family means the spouse of an individual, the individual's minor children, and any of the individual's children (including adults) residing in the individual's home.

Insider of a member bank or company means:

(1) An executive officer or director of the member bank or company (other than an exempt official);

(2) A principal shareholder of the member bank or company; and

(3) Any related interest of a person described in paragraphs (1) or (2) of this definition.

Insured depository institution has the meaning given in 12 U.S.C. 1813.

Investment fund means an investment company registered under the Investment Company Act of 1940, as well as collective investment trusts, separately managed institutional accounts, and other pooled investment vehicles.

Member bank means any banking institution that is a member of the Federal Reserve System and includes any subsidiary of such banking institution. The term includes insured branches of foreign banks, as defined by 12 U.S.C. 1813(s), but does not otherwise include a foreign bank that maintains a branch in the United States.

Non-index fund (1) means an investment fund that does not:

(i) Have an investment objective of tracking the risk and return characteristics of a previously specified third-party broad-based market index by holding all, or a representative and preset sample of, the securities of the index in approximately the same proportions as their representation in the index; and

(ii) Use rules-based investing to track that broad-based market index by holding all of its constituent assets or an automatically selected representative sample of those assets in order to replicate the risk and return characteristics of the index.

(2) A third-party broad-based market index provides investors with a performance indicator of the overall applicable securities market, is not focused on any specific industries or sectors, and is not published or managed by the investment fund, its investment advisor, or any of their respective affiliates;

Pay an overdraft on an account means to pay an amount upon the order of an account holder in excess of funds on deposit in the account.

Person means an individual or a company.

Principal shareholder (1) means a person that directly or indirectly, or acting through or in concert with one or more persons, owns, controls, or has the power to vote more than 10 percent of any class of voting securities of a member bank or company. For clarification, shares owned or controlled by a member of an individual's immediate family are considered to be owned or controlled by the individual.

(2) A principal shareholder of a member bank or company does not include:

(i) A company of which the member bank is a subsidiary; or

(ii) The member bank.

Qualified fund complex (1) means a company that:

(i) Sponsors, manages, or advises investment funds that invest in voting securities of a regulated company;

(ii) Is not, and is not affiliated with, a bank holding company (as defined in § 225.2 of this chapter) or savings and loan holding company (as defined in § 238.2 of this chapter);

(iii) Does not meet any of the conditions that would give rise to a rebuttable presumption of control over a regulated company under § 225.32 of this chapter;

(iv) Does not sponsor, manage, or advise any investment fund that owns or controls more than 10 percent of any class of voting securities of a regulated company; and

(v) Does not sponsor, manage, or advise non-index funds that in the aggregate own or control more than 10 percent of any class of voting securities of a regulated company.

(2) For purposes of paragraph (1)(iv) of this definition, investment funds that share the same or substantially the same

investment objective and asset composition are treated as a single investment fund.

Regulated company means an insured depository institution, a bank holding company (as defined in § 225.2 of this chapter), or a savings and loan holding company (as defined in § 238.2 of this chapter).

Related interest of a person means:

(1) A company that is controlled by that person; or

(2) A political or campaign committee that is controlled by that person or the funds or services of which will benefit that person.

Securities financing transaction means any repurchase agreement, reverse repurchase agreement, securities borrowing transaction, or securities lending transaction, including a transaction in which a member bank acts as agent for a customer and indemnifies the customer against loss caused by the default of the bank's counterparty.

Subsidiary has the meaning given in 12 U.S.C. 1841(d).

Unimpaired capital and unimpaired surplus of a member bank equals the sum of:

(1) The bank's tier 1 and tier 2 capital included in the bank's risk-based capital under the capital rule of the appropriate Federal banking agency, based on the bank's most recent consolidated report of condition filed under 12 U.S.C. 1817(a)(3); and

(2) The balance of the bank's allowance for loan and lease losses or adjusted allowance for credit losses, as applicable, not included in the bank's tier 2 capital for purposes of the calculation of risk-based capital by the appropriate Federal banking agency, based on the bank's most recent consolidated report of condition filed under 12 U.S.C. 1817(a)(3).

(3) For a bank that is subject to the community bank leverage ratio framework (as defined in the capital rule of the appropriate Federal banking agency), unimpaired capital and unimpaired surplus means the bank's tier 1 capital (as defined in the capital rule of the appropriate Federal banking agency and as calculated in accordance with the community bank leverage ratio framework of the appropriate Federal banking agency) plus allowance for loan and lease losses or adjusted allowance for credit losses, as applicable.

§ 215.3 Extension of credit.

(a) An extension of credit to an insider is a making or renewal of any loan to an insider, a granting of a line of credit to an insider, or an extending of credit in any manner whatsoever to an insider, and includes:

(1) An advance to an insider by means of paying an overdraft on an account, cash item, or otherwise;

(2) Issuance of a guarantee, acceptance (including an ineligible acceptance as defined in § 208.24 of this chapter), or letter of credit, including an endorsement or standby letter of credit (as defined in § 208.24 of this chapter), on behalf of an insider, or a confirmation of a letter of credit issued by an insider;

(3) An advance to an insider of unearned salary or other unearned compensation for a period in excess of 30 days;

(4) A lease to an insider that is the functional equivalent of an extension of credit;

(5) An acquisition by purchase, discount, exchange, or otherwise of a note or other obligation, including commercial paper or debt securities, upon which an insider is liable as maker, drawer, endorser, guarantor, or surety;

(6) Any increase in the amount of, extension of maturity of, or adjustment to the interest rate term or other material term of, an extension of credit to an insider;

(7) A derivative transaction, derivative netting set, or securities financing transaction with an insider, the value of which (as calculated pursuant to § 215.5) is greater than zero; and

(8) Any other similar transaction as a result of which an insider becomes obligated to pay money (or its equivalent) to the member bank, whether the obligation arises directly or indirectly, or because of an endorsement on an obligation or otherwise, or by any means whatsoever.

(b) An extension of credit does not include:

(1) An advance to an insider against accrued salary or other accrued compensation, or an advance to an insider for the payment of authorized travel or other expenses incurred or to be incurred on behalf of the bank;

(2) A receipt by a bank of a check deposited in or delivered to the bank in the usual course of business, unless it results in the carrying of a cash item for an insider or the paying of an overdraft on an account to an insider;

(3) An acquisition of a note, draft, bill of exchange, or other evidence of indebtedness of an insider through:

(i) A merger or consolidation of banks or a similar transaction by which a bank acquires assets and assumes liabilities of another bank or similar organization; or

(ii) Foreclosure on collateral or similar proceeding for the protection of the bank, provided that such indebtedness is not held for a period of more than three years from the date of the acquisition, subject to extension by the appropriate Federal banking agency for good cause;

(4) (i) An endorsement or guarantee by an insider for the protection of a bank of any loan or other asset previously acquired by the bank in good faith; or

(ii) Any indebtedness of the insider to a bank for the purpose of protecting the bank against loss or of giving financial assistance to it;

(5) Aggregate indebtedness of an insider of $60,000, multiplied by the GDP growth adjustment, or less arising by reason of any general arrangement by which a bank:

(i) Acquires charge or time credit accounts; or

(ii) Makes payments to or on behalf of participants in a bank credit card plan, check credit plan, or similar open-end credit plan, provided:

(A) The indebtedness does not involve prior individual clearance or approval by the bank other than for the purposes of determining authority to participate in the arrangement and compliance with any dollar limit under the arrangement; and

(B) The indebtedness is incurred under terms that are not more favorable than those offered to the general public;

(6) Aggregate indebtedness of an insider of $20,000, multiplied by the GDP growth adjustment, or less arising by reason of a written, preauthorized, interest-bearing overdraft protection plan that specifies a method of repayment;

(7) A discount of promissory notes, bills of exchange, conditional sales contracts, or similar paper owned by an insider, without recourse to the insider; or

(8) An advance of funds that increases an existing indebtedness of an insider, if the additional funds are advanced by the bank for its own protection for:

(i) Accrued interest; or

(ii) Taxes, insurance, or other expenses incidental to the existing indebtedness.

(9) Except for purposes of § 215.20 of this part, a loan:

(i) Made pursuant to the ''Paycheck Protection Program'' in which the participation by the Small Business Administration on a deferred basis is 100 percent;

(ii) For which material terms, including the maturity and the interest rate, are set by the Small Business Administration;

(iii) That is made during the ''covered period,'' as that term is defined in 15 U.S.C. 636(a)(36)(A)(iii), but in no case later than March 31, 2022; and

(iv) That would not be prohibited by 13 CFR 120.110(o) or rules or interpretations thereof issued by the Small Business Administration.

(c) Non-interest-bearing deposits to the credit of a bank are not considered loans, advances, or extensions of credit to the bank of deposit; nor is the giving of immediate credit to a bank upon uncollected items received in the ordinary course of business considered to be a loan, advance or extension of credit to the depositing bank.

(d) A participation without recourse is considered to be an extension of credit by the participating bank, not by the originating bank.

(e) *Tangible economic benefit rule*—(1) *In general.* An extension of credit is considered made to an insider to the extent that the proceeds are transferred to the insider or are used for the tangible economic benefit of the insider.

(2) *Beneficiaries of trusts and estates.* For purposes of this part, the proceeds of an extension of credit to a trust or estate are treated as being transferred to an insider or used for the tangible economic benefit of the insider if the insider has a 25 percent or more present or contingent beneficial interest in the trust or estate.

(3) *Spouse of an insider.* For purposes of this part, the proceeds of an extension of credit to a spouse of an insider or to the related interest of such spouse are treated as being transferred to the insider or used for the tangible economic benefit of the insider, unless:

(i) The spouse or related interest is independently creditworthy;

(ii) Repayment of the extension of credit is not predicated on the insider's income or assets; and

(iii) In the case of an extension of credit to a related interest of the spouse of an insider, the insider does not have a financial or ownership interest in, or participate in the management of, the related interest.

(4) *Exception.* An extension of credit is not considered made to an insider under paragraph (e) of this section if:

(i) The credit is extended on terms that would satisfy the standard set forth in § 215.11(a) for extensions of credit to insiders; and

(ii) The proceeds of the extension of credit are used in a bona fide transaction to acquire property, goods, or services from the insider.

§ 215.4 Timing of application of requirements.

(a) *Timing of an extension of credit.* An extension of credit to an insider by a member bank is considered to have been made at the time the bank enters into a binding commitment to make the extension of credit.

(b) *Extensions of credit to noninsiders that later become insiders.* An extension of credit by a member bank to a noninsider that later becomes an insider is not subject to this part if:

(1) The member bank includes the amount of the extension of credit towards any quantitative limit in this part for purposes of determining whether a future extension of credit to the insider would comply with the quantitative limit; and

(2) The member bank did not enter into the transaction in contemplation of the noninsider becoming an insider.

(c) *Lines of credit.* Paragraph (b) of this section ceases to apply to a line of credit beginning 14 months after the date that the noninsider becomes an insider.

§ 215.5 Valuation principles.

(a) *Extensions of credit.* (1) Except as provided in paragraphs (a)(2), (a)(3), (b), or (c) of this section, an extension of credit to an insider must be valued at the greater of:

(i) The principal amount of the extension of credit;

(ii) The amount owed by the insider to the member bank under the transaction; or

(iii) The sum of:

(A) The amount provided to, or on behalf of, the insider in the transaction; and

(B) Any additional amount that the member bank could be required to provide to, or on behalf of, the insider under the terms of the transaction.

(2) If a member bank acquires an extension of credit to an insider, the extension of credit must be valued at the sum of:

(i) The total amount of consideration given (including liabilities assumed) by the member bank in exchange for the extension of credit; and

(ii) Any additional amount that the member bank could be required to provide to, or on behalf of, the insider under the terms of the transaction.

(3) A member bank's purchase of or investment in a debt security issued by an insider must be valued at the greater of:

(i) The total amount of consideration given (including liabilities assumed) by the member bank in exchange for the security, reduced to reflect amortization of the security to the extent consistent with GAAP; or

(ii) The carrying value of the security.

(b) *Derivative transaction or derivative netting set.*

(1) Except as provided in paragraph paragraphs (b)(2) of this section, a credit exposure from a derivative transaction or derivative netting set with an insider must be valued using any of the methods that the member bank is authorized to use under the capital rule issued by the member bank's appropriate Federal banking agency;

(2) A credit derivative between a member bank and a third-party in which the member bank provides credit protection to the third-party with respect to an obligation of an insider of the member bank is a guarantee by a member bank on behalf of an insider for purposes of this regulation. A credit exposure from a transaction in such credit derivatives would be valued at the greater of (i) the notional principal amount or (ii) the maximum potential loss to the member bank on the transaction. Such derivatives would include:

(i) An agreement under which the member bank, in exchange for a fee, agrees to compensate the third-party for any default of the underlying obligation of the insider;

(ii) An agreement under which the member bank, in exchange for payments based on the total return of the underlying obligation of the insider, agrees to pay the third-party a spread over funding costs plus any depreciation in the value of the underlying obligation of the insider;

(iii) An equity derivative under which the member bank, in exchange for a fee, agrees to compensate a third-party for any depreciation in the value of an equity security of the insider; and

(iv) A total return swap, whether funded or unfunded, under which the member bank, in exchange for a fee, agrees to compensate a third-party for any loss or depreciation in the value of a security or debt obligation issued by an insider.

(c) *Securities financing transaction.* A securities financing transaction with an insider must be valued using:

(1) Any of the methods that the member bank is authorized to use under the capital rule issued by the member bank's appropriate Federal banking agency; [195] or

(2) The simplified amount calculated pursuant to paragraph (d) of this section.

(d) *Simplified amount.* The simplified amount for a securities financing transaction equals:

(1) The market value of cash and securities transferred by the member

[195] 12 CFR part 3 (Office of the Comptroller of the Currency); 12 CFR part 208 (Board); 12 CFR part 324 (Federal Deposit Insurance Corporation).

bank to the insider as part of the transaction; *less*

(2) The market value of cash in a segregated deposit account with the member bank in which the bank has a perfected security interest and any obligations of, or fully guaranteed as to principal and interest by, the United States or its agencies, transferred by the insider to the member bank as part of the transaction.

§ 215.6 Indexing dollar-based thresholds.

(a) *In general.* The Board will publish a GDP growth adjustment and adjusted thresholds every five years starting with [the effective date of a final rule].

(b) *Rounding.* When adjusting thresholds under paragraph (a) of this section, each threshold shall be rounded based on the size of the threshold (*e.g.,* thousands, millions) to the nearest number with two significant digits, such that:

(1) Each threshold in the thousands shall be rounded to the nearest number with one significant digit; and

(2) Each threshold in the millions shall be rounded to the nearest number with two significant digits.

(c) *Exception.* Notwithstanding paragraph (a) of this section, the Board will not publish an updated GDP growth adjustment if the five-year cumulative growth of nominal U.S. GDP is negative.

Subpart B—Requirements for Extensions of Credit to All Insiders

§ 215.11 Terms and creditworthiness.

(a) *In general.* A member bank must not extend credit to any insider of the bank or insider of its affiliates unless the extension of credit:

(1) Is made on substantially the same terms (including interest rates and collateral) as, and following credit underwriting procedures that are not less stringent than, those prevailing at the time for comparable transactions by the bank with other persons that are not covered by this part and who are not employed by the bank; and

(2) Does not involve more than the normal risk of repayment or present other unfavorable features.

(b) *Exception.* Nothing in this section or § 215.21(b)(3)(ii) shall prohibit any extension of credit made pursuant to a benefit or compensation program—

(1) That is widely available to employees of the member bank and, in the case of extensions of credit to an insider of its affiliates, is widely available to employees of the affiliates at which that person is an insider; and

(2) That does not give preference to any insider of the member bank over other employees of the member bank and, in the case of extensions of credit to an insider of its affiliates, does not give preference to any insider of its affiliates over other employees of the affiliates at which that person is an insider.

§ 215.12 Prior approval.

(a) A member bank must not extend credit (which term includes granting a line of credit) to any insider of the bank or insider of its affiliates in an amount that, when aggregated with the amount of all other extensions of credit to that person and to all related interests of that person, exceeds the lower of 5 percent of the member bank's unimpaired capital and unimpaired surplus, or $2,000,000, multiplied by the GDP growth adjustment, unless:

(1) The extension of credit has been approved in advance by a majority of the entire board of directors of that bank; and

(2) Any interested party has abstained from participating directly or indirectly in the voting.

(b) Approval by the board of directors under paragraph (a) of this section is not required for an extension of credit that is made pursuant to a line of credit that was approved under paragraph (a) of this section within 14 months of the date of the extension of credit. The extension of credit must also be in compliance with the requirements of § 215.11.

(c) Participation in the discussion, or any attempt to influence the voting, by the board of directors regarding an extension of credit constitutes indirect participation in the voting by the board of directors on an extension of credit.

§ 215.13 Lending limits.

(a) *Individual lending limit*—(1) *In general.* A member bank must not extend credit to an insider of the bank or insider of its affiliates if the amount of the extension of credit, when aggregated with the amount of all other extensions of credit by the bank to that person and to all related interests of that person would exceed:

(i) The limit of loans to a single borrower established by 12 U.S.C. 84(a), which is 15 percent of the bank's unimpaired capital and unimpaired surplus in the case of loans that are not fully secured, and an additional 10 percent of the bank's unimpaired capital and unimpaired surplus in the case of loans that are fully secured by readily marketable collateral having a market value, as determined by reliable and continuously available price quotations, at least equal to the amount of the loan. This limit also includes any higher amounts that are permitted by 12 U.S.C. 84(c) and (d) for the types of obligations listed therein as exceptions to the limit established by 12 U.S.C. 84(a).

(ii) In the case of a State member bank, any lending limit set forth by State law applicable to the bank.

(2) *Line of credit.* For purposes of paragraph (a)(1) of this section, the unused portion of a line of credit will be deemed to have been collateralized if the member bank that makes the line of credit does not have any legal obligation to advance funds pursuant to the line of credit until the insider provides the amount of collateral required by paragraph (a)(1) of this section with respect to the entire used portion (including the amount of the requested draw) of the line of credit.

(b) *Aggregate lending limit*—(1) *General limit.* A member bank must not extend credit to any insider of the bank or insider of its affiliates unless the extension of credit is in an amount that, when aggregated with the amount of all outstanding extensions of credit by that bank to all such insiders, does not exceed the bank's unimpaired capital and unimpaired surplus.

(2) *Member banks with deposits of less than $100,000,000.* (i) A member bank with deposits of less than $100,000,000 may by an annual resolution of its board of directors increase the general limit specified in paragraph (b)(1) of this section to a level not to exceed two times the bank's unimpaired capital and unimpaired surplus, if:

(A) The board of directors determines that such higher limit is consistent with prudent, safe, and sound banking practices in light of the bank's experience in lending to its insiders and is necessary to attract or retain directors or to prevent restricting the availability of credit in small communities;

(B) The resolution sets forth the facts and reasoning on which the board of directors bases the finding, including the amount of the bank's lending to its insiders as a percentage of the bank's unimpaired capital and unimpaired surplus as of the date of the resolution;

(C) The bank meets or exceeds, on a fully-phased in basis, all applicable capital requirements established by the appropriate Federal banking agency; and

(D) The bank received a satisfactory composite rating in its most recent report of examination.

(ii) If a member bank has adopted a resolution authorizing a higher limit pursuant to paragraph (b)(2)(i) of this section and subsequently fails to meet the requirements of paragraph (b)(2)(i)(C) or (b)(2)(i)(D) of this section, the member bank must not extend any

additional credit (including a renewal of any existing extension of credit) to any insider of the bank or its affiliates unless such extension is consistent with the general limit in paragraph (b)(1) of this section.

(3) *Exceptions.* (i) The general limit specified in paragraph (b)(1) of this section does not apply to the following:

(A) Extensions of credit secured by a perfected security interest in bonds, notes, certificates of indebtedness, or Treasury bills of the United States or in other such obligations fully guaranteed as to principal and interest by the United States;

(B) Extensions of credit to or secured by unconditional takeout commitments or guarantees of any department, agency, bureau, board, commission or establishment of the United States or any corporation wholly owned directly or indirectly by the United States;

(C) Extensions of credit secured by a perfected security interest in a segregated deposit account in the lending bank; or

(D) Extensions of credit arising from the discount of negotiable or nonnegotiable installment consumer paper that is acquired from an insider and carries a full or partial recourse endorsement or guarantee by the insider, provided that:

(1) The financial condition of each maker of such consumer paper is reasonably documented in the bank's files or known to its officers;

(2) An officer of the bank designated for that purpose by the board of directors of the bank certifies in writing that the bank is relying primarily upon the responsibility of each maker for payment of the obligation and not upon any endorsement or guarantee by the insider; and

(3) The maker of the instrument is not an insider.

(ii) The exceptions in paragraphs (b)(3)(i)(A) through (b)(3)(i)(C) of this section apply only to the amounts of such extensions of credit that are secured in the manner described therein.

§ 215.14 Prohibition on knowingly receiving an unauthorized extension of credit.

An executive officer, director, or principal shareholder of a member bank or any of its affiliates (other than an exempt official) must not knowingly receive (or knowingly permit any of that person's related interests to receive) from a member bank, directly or indirectly, any extension of credit not authorized under this part.

Subpart C—Requirements for Extensions of Credit and Other Transactions With Certain Insiders

§ 215.20 Additional restrictions on extensions of credit to executive officers of a member bank.

(a) *Scope.* The restrictions in this section on extensions of credit by a member bank to any of its executive officers apply in addition to any restrictions on extensions of credit by a member bank to its insiders or insiders of its affiliates set forth elsewhere in this part. The restrictions of this section apply only to executive officers of the member bank and not to executive officers of its affiliates or to related interests of executive officers of the member bank. For purposes of this section, however, an extension of credit by a member bank to a related interest of an executive officer must be treated as having been made to the executive officer, if the related interest:

(1) Is the alter ego of the executive officer; and

(2) Has no independent means to repay the extension of credit.

(b) A member bank must not extend credit to any of its executive officers, and an executive officer of a member bank must not borrow from or otherwise become indebted to the bank, except in the amounts, for the purposes, and upon the conditions specified in paragraphs (d) and (e) of this section.

(c) A member bank must not extend credit in an aggregate amount greater than the amount permitted in paragraph (d)(4) of this section to a partnership in which one or more of the bank's executive officers are partners and, either individually or together, hold a majority interest. For the purposes of paragraph (d)(4) of this section, the total amount of credit extended by a member bank to such partnership is considered to be extended to each executive officer of the member bank who is a member of the partnership.

(d) A member bank is authorized to extend credit to any executive officer of the bank:

(1) In any amount to finance the education of the executive officer's children;

(2) In any amount to finance or refinance the purchase, construction, maintenance, or improvement of a single residence of the executive officer, provided:

(i) The extension of credit is secured by a first lien on the residence and the residence is owned (or expected to be owned after the extension of credit) by the executive officer;

(ii) The property is not used for investment purposes, including renting or leasing out any portion of the property for income;

(iii) The executive officer lives at the property for at least three months each year; and

(iv) In the case of a refinancing, that only the amount thereof used to repay the original extension of credit, together with the closing costs of the refinancing, and any additional amount thereof used for any of the purposes enumerated in this paragraph (d)(2), are included within this category of credit;

(3) In any amount, if the extension of credit is secured in a manner described in § 215.13(b)(3)(i)(A)–(C); and

(4) For any other purpose not specified in paragraphs (d)(1)–(3) of this section, if the aggregate amount of extensions of credit to that executive officer under this paragraph (d)(4) does not exceed at any one time the lower of 2.5 percent of the member bank's unimpaired capital and unimpaired surplus or $400,000, multiplied by the GDP growth adjustment.

(e) Any extension of credit by a member bank to any of its executive officers must be:

(1) Promptly reported to the member bank's board of directors;

(2) In compliance with the requirements of § 215.11;

(3) Preceded by the submission of a detailed current financial statement of the executive officer; and

(4) Made subject to the condition in writing that the extension of credit will, at the option of the member bank, become due and payable at any time that the officer is indebted to any other bank or banks in an aggregate amount greater than the amount specified for a category of credit in paragraph (d) of this section.

§ 215.21 Additional restrictions on paying overdrafts on accounts of directors and executive officers of a member bank and its affiliates.

(a) *Scope.* This section applies to payments of overdrafts by a member bank on an account of an executive officer or director of the member bank, or on an account of an executive officer or director of its affiliates that is not an exempt official. This section does not apply to payments of overdrafts on an account of a related interest of such an executive officer or director.

(b) A member bank must not pay an overdraft on an account of an executive officer or director of the member bank, or executive officer or director of its affiliates that is not an exempt official, unless the payment is made:

(1) Pursuant to a written, preauthorized, interest-bearing overdraft protection plan that specifies a method of repayment;

(2) Pursuant to a written, preauthorized transfer of funds from another account of the account holder at the member bank; or

(3) Inadvertently, if:

(i) The account is not overdrawn for more than five business days;

(ii) The member bank charges the executive officer or director the same fee charged any other customer of the bank in similar circumstances; and

(iii) The aggregate amount of all payments of overdrafts on an account of the account holder pursuant to paragraph (b)(3) of this section does not exceed $4,000, multiplied by the GDP growth adjustment.

§ 215.22 Additional restrictions for extensions of credit related to existing and potential correspondent accounts.

(a) For purposes of this section:

(1) The term ''bank'' has the meaning given in 12 U.S.C. 1841(c) and includes a mutual savings bank, a savings bank, a savings association (as those terms are defined in 12 U.S.C. 1813), and any subsidiary of the foregoing;

(2) The term ''correspondent account'' means an account that is maintained by a bank with another bank for the deposit or placement of funds; and

(3) The term ''insider'' of a bank means:

(i) An executive officer or director of the bank;

(ii) (A) A person that directly or indirectly, or acting through or in concert with one or more persons, owns, controls, or has the power to vote more than 10 percent of any class of voting securities of the bank;

(B) Shares owned or controlled by a member of an individual's immediate family are considered to be owned or controlled by the individual; and

(iii) Any related interest of a person described in paragraphs (a)(3)(i) and (a)(3)(ii) of this section.

(b) A bank must not extend credit to the insider of a second bank if the bank maintains a correspondent account in the name of the second bank, or the second bank maintains a correspondent account in the name of the bank, unless the extension of credit is made on substantially the same terms, including interest rates and collateral, as those prevailing at the time for comparable transactions with other persons and does not involve more than the normal risk of repayment or present other unfavorable features; and

(c) A bank must not open a correspondent account at a second bank if the bank has an outstanding extension of credit to an insider of the second bank or the second bank has an outstanding extension of credit to an insider of the bank, unless the extension of credit is made on substantially the same terms, including interest rates and collateral, as those prevailing at the time for comparable transactions with other persons and does not involve more than the normal risk of repayment or present other unfavorable features.

§ 215.23 Prohibitions on asset purchases and sales between an insured depository institution and an insider.

(a) For purposes of this section the term ''purchase an asset'' means the acquisition by an insured depository institution of an asset from an insider in exchange for cash or any other consideration, including an assumption of liabilities. The merger of an insider into an insured depository institution is a purchase of assets by the insured depository institution from an insider if the insured depository institution assumes any liabilities of the insider or pays any other form of consideration in the transaction.

(b) An insured depository institution must not purchase an asset from, or sell an asset to, an insider of the institution unless:

(1) The purchase or sale:

(i) Is on terms and under circumstances that are substantially the same, or at least as favorable to the insured depository institution, as those prevailing at the time for comparable transactions with or involving persons that are not insiders of the insured depository institution; or

(ii) In the absence of comparable transactions, is on terms and under circumstances that in good faith would be offered to, or would apply to, persons that are not insiders of the insured depository institution; and

(2) The transaction has been approved in advance by a majority of the members of the board of directors of the insured depository institution who are not an interested party with respect to the transaction, if the amount of the purchase or sale represents more than 10 percent of the unimpaired capital and unimpaired surplus of the insured depository institution.

(c) Participation in the discussion, or any attempt to influence the voting, by the board of directors regarding a purchase or sale of assets subject to this section constitutes indirect participation in the voting by the board of directors on the purchase or sale of assets.

Subpart D—Recordkeeping and Disclosure Requirements

§ 215.30 Records.

(a) *In general.* A member bank must maintain records necessary for compliance with the requirements of this part.

(b) *Safe harbors.*

(1) A member bank that uses one of the methods set forth in paragraphs (d)(1) or (d)(2) of this section satisfies the requirements of paragraph (d) of this section.

(2) A member bank that uses one of the methods set forth in paragraphs (e)(1) or (e)(2) of this section satisfies the requirements of paragraph (e) of this section.

(c) *Recordkeeping for insiders of the member bank.* Any recordkeeping method adopted by a member bank must:

(1) Identify, through an annual survey, all insiders of the bank itself; and

(2) Maintain records of all extensions of credit to insiders of the bank itself, including the amount and terms of each such extension of credit.

(d) *Recordkeeping for insiders of the member bank's affiliates.* Any recordkeeping method adopted by a member bank must maintain records of extensions of credit to insiders of the member bank's affiliates by:

(1) *Survey method.* (i) Identifying, through an annual survey, each insider of the member bank's affiliates; and

(ii) Maintaining records of the amount and terms of each extension of credit by the member bank to such insiders; or

(2) *Borrower inquiry method.* (i) Requiring as part of each extension of credit that the borrower indicate whether the borrower is an insider of an affiliate of the member bank; and

(ii) Maintaining records that identify the amount and terms of each extension of credit by the member bank to borrowers so identifying themselves.

(3) *Alternative recordkeeping methods for insiders of affiliates.* A member bank may employ a recordkeeping method other than those identified in paragraphs (d)(1) and (d)(2) of this section if the appropriate Federal banking agency determines that the bank's method is at least as effective as the identified methods.

(e) *Recordkeeping for insiders of a correspondent or respondent bank.* For purposes of this paragraph (e), the term insider has the meaning set forth in § 215.22(a)(3). Any recordkeeping method adopted by a member bank must maintain records of extensions of credit to insiders of the member bank's correspondent or respondent bank by:

(1) *Survey method.* (i) Identifying, through an annual survey of each correspondent or respondent bank of the member bank, each insider of the member bank's correspondent or respondent bank; and

(ii) Maintaining records of the amount and terms of each extension of credit by the member bank to such insiders; or

(2) *Borrower inquiry method.* (i) Requiring as part of each extension of credit that the borrower indicate whether the borrower is an insider of the member bank's correspondent or respondent bank; and

(ii) Maintaining records that identify the amount and terms of each extension of credit by the member bank to borrowers so identifying themselves.

(3) *Alternative recordkeeping methods.* A member bank may employ a recordkeeping method other than those identified in paragraphs (e)(1) and (e)(2) of this section if the appropriate Federal banking agency determines that the bank's method is at least as effective as the identified methods.

(f) *Special rule for non-commercial lenders.* A member bank that is prohibited by law or by an express resolution of the board of directors of the bank from making an extension of credit to any company or other entity that is covered by this part as a company is not required to maintain any records of the related interests of the insiders of the bank or its affiliates or to inquire of borrowers whether they are related interests of the insiders of the bank or its affiliates.

§ 215.31 Disclosure of credit from member banks to executive officers and principal shareholders.

(a) *Public disclosure.* (1) Upon receipt of a written request from the public, a member bank must make available the names of each of its executive officers and each of its principal shareholders to whom, or to whose related interests, the member bank had outstanding as of the end of the latest previous quarter of the year, an extension of credit that, when aggregated with all other outstanding extensions of credit at such time from the member bank to such person and to all related interests of such person, equaled or exceeded 5 percent of the member bank's unimpaired capital and unimpaired surplus or $2,000,000, multiplied by the GDP growth adjustment, whichever amount is less. No disclosure under this paragraph is required if the aggregate amount of all extensions of credit outstanding at such time from the member bank to the executive officer or principal shareholder of the member bank and to all related interests of such a person does not exceed $25,000.

(2) A member bank is not required to disclose the specific amounts of individual extensions of credit.

(b) *Maintaining records.* Each member bank must maintain records of all requests for the information described in paragraph (a) of this section and the disposition of such requests. These records may be disposed of after two years from the date of the request.

§ 215.32 Disclosure requirement for credit secured by certain bank and holding company stock.

(a) *Bank stock.* Each executive officer or director of a member bank that does not have any class of equity securities registered under section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 78*l*) must disclose annually to the board of directors of the member bank the outstanding amount of any extension of credit to the executive officer or director that is secured by shares of the member bank or by shares of a company of which the member bank is a subsidiary.

(b) *Holding company stock.* Each executive officer or director of a company of which the member bank is a subsidiary and that does not have any class of equity securities registered under section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 78*l*) must disclose annually to the board of directors of the company the outstanding amount of any extension of credit to the executive officer or director that is secured by shares of the company or by shares of the subsidiary member bank. In addition, each executive officer or director of a member bank must disclose annually to the board of directors of the member bank the outstanding amount of any extension of credit to the executive officer or director that is secured by shares of the holding company, if the holding company does not have any class of equity securities registered under section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 78*l*).

Subpart E—Civil Penalties

§ 215.40 Civil penalties.

Any member bank, or any officer, director, employee, agent, or other person participating in the conduct of the affairs of the bank, that violates any provision of this part (other than § 215.31) is subject to civil penalties as specified in section 29 of the Federal Reserve Act (12 U.S.C. 504).

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

■ 2. The authority citation for part 225 continues to read as follows:

12 U.S.C. 1817(j)(13), 1818, 1828(o), 1831i, 1831p–1, 1843(c)(8), 1844(b), 1972(1), 3106, 3108, 3310, 3331–3351, 3906, 3907, and 3909; 15 U.S.C. 1681s, 1681w, 6801 and 6805.

§ 225.4 Corporate practices. (Amended)

■ 3. In § 225.4, remove and reserve § 225.4(e).

Nomenclature Changes

PART 207—(AMENDED)

■ 4. The authority citation for Part 207 continues to read as follows:

Authority: 12 U.S.C. 1831y.

§ 207.11 (Amended)

■ 5. In § 207.11(e), remove ''§ 215.2(e)(1)'' and add ''§ 215.2'' in its place.

PART 208—(AMENDED)

■ 6. The authority citation for Part 208 continues to read as follows:

Authority: 12 U.S.C. 24, 36, 92a, 93a, 248(a), 248(c), 321–338a, 371d, 461, 481–486, 601, 611, 1814, 1816, 1817(a)(3), 1817(a)(12), 1818, 1820(d)(9), 1833(j), 1828(o), 1831, 1831o, 1831p–1, 1831r–1, 1831w, 1831x, 1835a, 1882, 2901–2907, 3105, 3310, 3331–3351, 3905–3909, 5371, and 5371 note; 15 U.S.C. 78b, 78I(b), 78l(i), 780–4(c)(5), 78q, 78q–1, 78w, 1681s, 1681w, 6801, and 6805; 31 U.S.C. 5318; 42 U.S.C. 4012a, 4104a, 4104b, 4106, and 4128.

PART 208—(AMENDED)

■ 7. In the table below, for each part or section indicated in the left column, remove the current section referenced in the middle column from wherever it appears, and add ''§ 215.2'' as indicated in the right column:

Part or section	Remove	Add
§ 207.11(e)	§ 215.2(e)(1)	§ 215.2
Part 208—Appendix D–1(B)(4)	§ 215.2(c)	§ 215.2
Part 208—Appendix D–1(B)(5)	§ 215.2(d)	§ 215.2
Part 208—Appendix D–1(B)(6)	§ 215.2(d)(1)	§ 215.2
Part 208—Appendix D–1(6)	§ 215.2(l)	§ 215.2

PART 238—(AMENDED)

■ 8. The authority citation for Part 238 continues to read as follows:

Authority: 5 U.S.C. 552, 559; 12 U.S.C. 1462, 1462a, 1463, 1464, 1467, 1467a, 1468, 5365; 1813, 1817, 1829e, 1831i, 1972, 15 U.S.C. 78 *l.*

§§ 238.119, 122 (Amended)

■ 9. In the table below, for each part or section indicated in the left column, remove the current section referenced in the middle column from wherever it appears, and add ''§ 215.2'' as indicated in the right column:

Section	Remove	Add
§ 238.119(a)(4)(ii)(B)	§ 215.2(e)(1)	§ 215.2
§ 238.122(a)(4)(ii)(B)	§ 215.2(e)	§ 215.2

PART 248—PROPRIETARY TRADING AND CERTAIN INTERESTS IN AND RELATIONSHIPS WITH COVERED FUNDS (REGULATION VV)

■ 10. The authority citation for Part 248 continues to read as follows:

Authority: 12 U.S.C. 1851, 12 U.S.C. 221 *et seq.,* 12 U.S.C. 1818, 12 U.S.C. 1841 *et seq.,* and 12 U.S.C. 3103 *et seq.*

§ 248.10 (Amended)

■ 11. In § 248.10(d)(3), remove ''§ 215.2(e)'' and add ''§ 215.2'' in its place.

PART 252—ENHANCED PRUDENTIAL STANDARDS (REGULATION YY)

■ 12. The authority citation for Part 252 continues to read as follows:

Authority: 12 U.S.C. 321–338a, 481–486, 1467a, 1818, 1828, 1831n, 1831o, 1831p–1, 1831w, 1835, 1844(b), 1844(c), 3101 *et seq.,* 3101 note, 3904, 3906–3909, 4808, 5361, 5362, 5365, 5366, 5367, 5368, 5371.

§§ 252.22, 252.33, 252.144, 252.147, 252.153, 252.155 (Amended)

■ 13. In the table below, for each part or section indicated in the left column, remove the current section referenced in the middle column from wherever it appears, and add ''§ 215.2'' as indicated in the right column:

Section	Remove	Add
§ 252.22(a)(4)(ii)(B)	§ 215.2(e)(1)	§ 215.2
§ 252.33(a)(4)(ii)(B)	.....	.....
§ 252.144(b)(1)(v)(B)(*2*)	.....	.....
§ 252.147(e)(2)(iv)(B)(*2*)	§ 215.2(e)	§ 215.2
§ 252.155(a)(5)(ii)(B)	.....	.....
§ 252.153(e)(3)(iv)(B)(*2*)	§ 215.2(e)(1)	§ 215.2

By order of the Board of Governors of the Federal Reserve System.

Benjamin W. McDonough,

Secretary of the Board.

[FR Doc. 2026–15777 Filed 8–3–26; 8:45 am]

BILLING CODE 6201–01–P

FEDERAL REGISTER

Vol. 91 Tuesday,

No. 148 August 4, 2026

Part IV

Department of Health and Human Services

45 CFR Part 170

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413 et al.

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Requirements for Quality Programs; Other Policy Changes; and Adoption of Updated Versions of Certain Health Information Technology Standards; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, 415, 419, 495, and 512

Office of the Secretary

45 CFR Part 170

[CMS–1849–F and CMS–0062–F]

RINs 0938–AV79 and 0938–AV44

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Requirements for Quality Programs; Other Policy Changes; and Adoption of Updated Versions of Certain Health Information Technology Standards

AGENCY: Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule will revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals; make changes relating to Medicare graduate medical education (GME) for teaching hospitals; update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs); update and make changes to requirements for certain quality programs; and make other policy-related changes. ONC also adopts certain health information technology (health IT) standards and specifications on behalf of HHS.

DATES: These regulations are effective on October 1, 2026. The incorporation by reference of certain material listed in this rule is approved by the Director of the Federal Register as of October 1, 2026. The incorporation of reference of certain other material listed in the rule was approved by the Director of the Federal Register as of October 1, 2025.

FOR FURTHER INFORMATION CONTACT: Donald Thompson, and Michele Hudson, (410) 786–4487 or *DAC@cms.hhs.gov,* Operating Prospective Payment, MS–DRG Relative Weights, Wage Index, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Sole Community Hospitals (SCHs), Medicare-Dependent Small Rural Hospital (MDH) Program, and Low-Volume Hospital Payment Adjustment.

Emily Lipkin, Jim Mildenberger and Michael Raftery, *DAC@cms.hhs.gov,* Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Lily Yuan, *NTAP@cms.hhs.gov,* New Technology Add-On Payments Issues.

Mady Hue, *marilu.hue@cms.hhs.gov,* and Andrea Hazeley, *andrea.hazeley@cms.hhs.gov,* MS–DRG Classifications Issues.

David O'Reilly, *David.Oreilly@cms.hhs.gov,* Rural Community Hospital Demonstration Program Issues.

Jeris Smith, *jeris.smith@cms.hhs.gov,* Frontier Community Health Integration Project (FCHIP) Demonstration Issues.

Lang Le, *lang.le@cms.hhs.gov,* Hospital Readmissions Reduction Program and Hospital Acquired Condition Reduction Program—Administration Issues.

Ngozi Uzokwe, *ngozi.uzokwe@cms.hhs.gov,* Hospital Acquired Condition Reduction Program and Hospital Readmissions Reduction Program—Measures Issues.

Julia Venanzi, *julia.venanzi@cms.hhs.gov,* Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program—Administration Issues.

Melissa Hager, *melissa.hager@cms.hhs.gov,* and Ngozi Uzokwe, *ngozi.uzokwe@cms.hhs.gov*—Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues.

John Green, *john.green1@cms.hhs.gov,* PPS-Exempt Cancer Hospital Quality Reporting Program—Administration Issues.

Kristina Rabarison, *Kristina.Rabarison@cms.hhs.gov,* PPS-Exempt Cancer Hospital Quality Reporting Program—Measure Issues.

Ariel Cress, *ltchqualityquestions@cms.hhs.gov,* Long-Term Care Hospital Quality Reporting Program—Administration Issues.

Jessica Warren, *jessica.warren@cms.hhs.gov,* and Lisa Marie Gomez, *LisaMarie.Gomez1@cms.hhs.gov,* Medicare Promoting Interoperability Program Issues.

CMMI_TEAM@cms.hhs.gov, Transforming Episode Accountability Model (TEAM) Issues.

CJR–X@cms.hhs.gov, Comprehensive Care for Joint Replacement Expanded (CJR–X) Model Issues.

Katherine McDonald, *katherine.mcdonald@cms.hhs.gov,* Amanda Michael, *amanda.michael@cms.hhs.gov,* and Kellie Shannon, *kellie.shannon@cms.hhs.gov,* Organ Acquisition Payment, Reasonable Cost Payment, and Appeals for Independent Organ Procurement Organizations (IOPOs) and Histocompatibility Laboratories (HCLs) Issues.

Alexander Baker, (202) 260–2048, for ONC Health Information Technology Standards and Specifications Issues.

SUPPLEMENTARY INFORMATION:

Tables Available on the CMS Website

The IPPS tables for this fiscal year (FY) 2027 final rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled ''FY 2027 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2027 final rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1849–F. For further details on the contents of the tables referenced in this final rule, we refer readers to section VI. of the Addendum to this FY 2027 IPPS/LTCH PPS final rule. Readers who experience any problems accessing any of the tables that are posted on the CMS websites, as previously identified, should contact Michael Treitel, *DAC@cms.hhs.gov.*

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This FY 2027 IPPS/LTCH PPS final rule will make payment and policy changes under the Medicare inpatient prospective payment system (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it will make payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). This final rule also will make policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs. We are

also making changes relating to Medicare graduate medical education (GME) and nursing and allied health (NAH) education payments.

We are finalizing the adoption of the Advance Care Planning electronic clinical quality measure (eCQM) in the Hospital Inpatient Quality Reporting and Medicare Promoting Interoperability Programs and finalizing the adoption of the Advance Care Planning eCQM, with a modification, in the PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program. We are finalizing the proposal to adopt five modified claims-based, risk-standardized mortality measures in the Hospital Inpatient Quality Reporting Program as a step towards subsequently modifying these measures in the Hospital Value-Based Purchasing Program.

Other than these cross-program proposals, we did not propose any updates for the Hospital Value-Based Purchasing Program or the Hospital Acquired-Conditions Reduction Program.

In the Hospital Readmissions Reduction Program, we are finalizing the adoption of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure with modifications.

In addition to the cross-program proposals previously listed, in the Hospital Inpatient Quality Reporting Program, we are finalizing the adoption of two new quality measures, removal of three measures, and modification of three current measures. We are also finalizing modifications of data reporting and submission requirements for electronic clinical quality measures (eCQMs) and the Maternal Morbidity structural measure.

In addition to the cross-program proposal previously listed in the PCH Quality Reporting Program, we are finalizing the adoption of an additional new measure, with a modification, and finalizing the removal of one measure. We are also finalizing the adoption of data reporting and submission requirements for eCQMs.

In addition to the cross-program proposal previously listed, in the Medicare Promoting Interoperability Program, we are finalizing the removal of two measures and two attestations; adoption of a measure; modification of one measure; adoption of one additional eCQM in alignment with the Hospital Inpatient Quality Reporting Program; and removal of three eCQMs in alignment with the Hospital Inpatient Quality Reporting Program.

In the LTCH Quality Reporting Program (QRP), we are finalizing removal of two measures, beginning with the FY 2028 LTCH QRP. We also finalize a revision of the LTCH QRP Data Submission Deadlines beginning with the FY 2029 LTCH QRP. Finally, we summarize public comments received on one Request for Information (RFI) on future measure concepts for the LTCH QRP.

The Transforming Episode Accountability Model (TEAM), a mandatory alternative payment model that was finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), aims to improve beneficiary care through financial accountability for episodes categories that begin with one of the following procedures: coronary artery bypass graft (CABG), lower extremity joint replacement (LEJR), major bowel procedure, surgical hip/femur fracture treatment (SHFFT), and spinal fusion. TEAM tests whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. In this final rule, we are finalizing updates to TEAM that will modify policies affecting episode category triggers, quality measure assessment, and the construction of target prices. We also discuss the public comments received from a Request for Information (RFI) about voluntary opt-in opportunity for hospitals with physician ownership (POHs) and our policy intent for future rulemaking.

The Comprehensive Care for Joint Replacement CJR Expanded (CJR–X) Model builds upon the CJR Model test that ran from April 1, 2016 to December 31, 2024. Based on the strength of evidence from the CJR Model, the CMS Innovation Center is expanding the model nationally, including U.S. Territories starting January 1, 2028. The model will focus on improving care and reducing spending for Medicare beneficiaries undergoing lower extremity joint replacement (LEJR) procedures. Participating hospitals will be held accountable for spending and quality of care during an inpatient stay or hospital outpatient procedure and for the 90 days following hospital discharge. The CJR–X Model will be mandatory for acute care hospitals, except for those participating in TEAM, and acute care hospitals located in Maryland. CJR–X includes some modifications to the CJR Model. Some quality measures and payment methodology policies have been updated in response to CJR Model evaluation results, stakeholder feedback, and changes to national care delivery patterns among both CJR and non-CJR hospitals.

Under various statutory authorities, we either discuss continued program implementation or changes to the Medicare IPPS, the LTCH PPS, other related payment methodologies and programs for FY 2027 and subsequent fiscal years, and other policies and provisions included in this final rule. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals; and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of the Balanced Budget Refinement Act of 1999 (BBRA) (Public Law (Pub. L.) 106–113) and section 307(b)(1) of the Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of LTCHs described in section 1886(d)(1)(B)(iv) of the Act.
- Section 1814(l)(4) of the Act requires, beginning with FY 2015, that CAHs that do not successfully demonstrate meaningful use of certified electronic health record technology (CEHRT) for an EHR reporting period for a cost reporting period shall be paid 100 percent of reasonable costs rather than 101 percent of reasonable costs.
- Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of

GME in accordance with section 1886(h) of the Act. Hospitals paid under the IPPS with approved GME programs are paid for the indirect costs of training residents in accordance with section 1886(d)(5)(B) of the Act.

- Section 1886(d)(5)(F) of the Act provides for additional Medicare IPPS payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients (DSH hospitals, or DSH-eligible hospitals). These payments are known as the Medicare disproportionate share hospital (DSH) adjustment, or DSH payment. Section 1886(d)(5)(F) of the Act specifies the methods under which a hospital may qualify for the DSH payment.
- Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, provides for a reduction to DSH payments under section 1886(d)(5)(F) of the Act and for an additional uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act if subsection (r) did not apply (''the empirically justified amount''); and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act, in the absence of section 1886(r) of the Act; (2) 1 minus the percent change in the percent of individuals who are uninsured; and (3) the hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.
- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67) and amended by section 51005(a) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS, with implementation beginning in FY 2016. Section 51005(b) of the Bipartisan Budget Act of 2018 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined in clause (ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2027.
- Section 1899B of the Act, which provides for the establishment of standardized data reporting for certain post-acute care providers, including LTCHs.
- Section 1886(b)(3)(B)(viii) of the Act, which establishes the Hospital Inpatient Quality Reporting Program, requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a subsection (d) hospital for discharges occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.
- Section 1886(b)(3)(B)(ix) of the Act, which establishes payment adjustments under the Medicare Promoting Interoperability Program by requiring downward adjustments to the applicable percentage increase, beginning with FY 2015 (and beginning with FY 2022 for subsection (d) Puerto Rico hospitals), for eligible hospitals that do not successfully demonstrate meaningful use of CEHRT for an EHR reporting period for a payment adjustment year. Additionally, Section 1886(n) of the Act establishes the requirements for an eligible hospital to be treated as a meaningful EHR user of CEHRT for an EHR reporting period for a payment adjustment year or, for purposes of subsection (b)(3)(B)(ix) of the Act, for a fiscal year.
- Section 1866(k) of the Act, which provides for the establishment of a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''
- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program, under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year.
- Section 1886(p) of the Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.
- Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, which establishes the Hospital Readmissions Reduction Program. Under the program, payments for discharges from an applicable hospital as defined under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act directs the Secretary to assess a hospital's performance relative to other hospitals with a similar proportion of beneficiaries who are dually eligible for both Medicare and full Medicaid benefits.
- Section 1886(m)(5) of the Act, which requires the Secretary to reduce by 2 percentage points the annual update to the standard Federal rate for discharges for a long-term care hospital (LTCH) during the rate year for LTCHs that do not submit data on quality measures in the form, manner, and at a time, specified by the Secretary.
- Section 1115A of the Act authorizes the testing of innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries while reducing program expenditures.

2. Summary of the Major Provisions

The following is a summary of the major provisions in this final rule. In general, these major provisions are being finalized as part of the annual update to the payment policies and payment rates, consistent with the applicable statutory provisions. A general summary of the changes in this final rule is presented in section I.D. of the preamble of this final rule.

a. Requirements To Prohibit Unlawful Discrimination by Graduate Medical Education Programs and Nursing and Allied Health Education Programs

In section V.F.2. of the preamble of this final rule, we discuss our finalized proposal to require that, in addition to meeting other applicable requirements, an approved medical residency training program must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. In V.G.3. of the preamble of this final rule, we discuss similar policies with respect to approved nursing and allied health education programs and accreditors.

b. Modifications to the Criteria for New Residency Programs

In section V.F.3. of the preamble of this final rule, we discuss our modifications to the criteria for identifying new residency programs under 42 CFR 413.79(l). Under this policy, in addition to receiving initial

accreditation by the appropriate accrediting body, for a residency program to be considered new, at least 90 percent of the individual residents must not have previous experience training in another program in the same specialty. This requirement includes exceptions for small residency programs, displaced residents, and residents admitted via a binding third-party matching program. In determining whether a program is genuinely new for cap-building purposes, we will also no longer consider the previous employment of the program director or faculty.

c. Hospital Readmissions Reduction Program (HRRP)

In this FY 2027 IPPS/LTCH PPS final rule, we are finalizing the adoption of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure with modifications beginning with 2 years of early look reports for the FY 2028 and FY 2029 program years, and use beginning with the FY 2030 program year.

d. Hospital Value-Based Purchasing (VBP) Program

In this FY 2027 IPPS/LTCH PPS final rule, we are finalizing modifications to five condition-specific and procedure-specific mortality measures beginning with the FY 2032 program year: (1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization measure; (2) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization measure; (3) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization measure; (4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization measure; and (5) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery measure. We sought comments on two topics: (1) measuring emergency room access and timeliness in the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs; and (2) potential future use of the Adult Community-Onset Sepsis Standardized Mortality Ratio measure in the Hospital Inpatient Quality Reporting Program.

e. Hospital Inpatient Quality Reporting Program

In this FY 2027 IPPS/LTCH PPS final rule, we are finalizing several changes to the Hospital Inpatient Quality Reporting Program. We are finalizing the adoption of three new measures: (1) Excess Days in Acute Care After Hospitalization for Diabetes measure beginning with the FY 2029 payment determination; (2) Advance Care Planning eCQM beginning with the FY 2030 payment determination; and (3) Hospital Harm-Postoperative Venous Thromboembolism eCQM beginning with the FY 2030 payment determination. We are also finalizing the adoption of five modified mortality measures in the Hospital Inpatient Quality Reporting Program beginning with the FY 2028 payment determination before subsequently modifying them in the Hospital Value-Based Purchasing Program: (1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following AMI Hospitalization measure; (2) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization measure; (3) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization measure; (4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following COPD Hospitalization measure; and (5) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following CABG Surgery measure. We are finalizing modifications to three claims-based measures beginning with the FY 2028 payment determination: (1) Excess Days in Acute Care after Hospitalization for AMI; (2) Excess Days in Acute Care after Hospitalization for Heart Failure; and (3) Excess Days in Acute Care after Hospitalization for Pneumonia. We are finalizing the removal of three measures beginning with the FY 2030 payment determination: (1) Venous Thromboembolism Prophylaxis (VTE–1) eCQM; (2) Intensive Care Unit Venous Thromboembolism Prophylaxis (VTE–2) eCQM; and (3) Discharged on Antithrombotic Therapy (STK–02) eCQM. We are finalizing changes to data reporting and submission requirements for eCQMs and structural measures: (1) mandatory reporting for the Malnutrition Care Score eCQM beginning with the FY 2030 payment determination; (2) mandatory reporting for the Hospital Harm eCQMs after 2 years of self-selected reporting beginning with the FY 2030 payment determination with modifications; and (3) an update to the reporting of the Maternal Morbidity Structural measure beginning with the FY 2028 payment determination. We sought comments on three topics: (1) measuring emergency room access and timeliness in the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs; (2) potential future use of the Adult Community-Onset Sepsis Standardized Mortality Ratio measure in the Hospital Inpatient Quality Reporting Program; and (3) Birthing-Friendly Hospital designation modification to expand designation criteria.

f. PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program

In this FY 2027 IPPS/LTCH PPS final rule, we are finalizing the adoption of two new measures with modifications: (1) Advance Care Planning eCQM beginning with the FY 2030 program year; and (2) Malnutrition Care Score eCQM beginning with the FY 2030 program year. We are also finalizing the removal of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP COVID–19 Vaccination) measure beginning with the FY 2028 program year. In addition, we finalized the establishment of reporting and submission requirements for eCQMs in this program.

g. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In the LTCH QRP, we finalize removal of two measures, beginning with the FY 2028 LTCH QRP. We also finalize the revision of the LTCH QRP Data Submission Deadlines beginning with the FY 2029 LTCH QRP. We also summarize public comments received on one Request for Information (RFI) on future measure concepts for the LTCH QRP.

h. Medicare Promoting Interoperability Program

We are finalizing several changes to the Medicare Promoting Interoperability Program. Specifically, we are finalizing: (1) revisions to the definition of certified EHR technology (CEHRT) for the Medicare Promoting Interoperability Program based on Office of the National Coordinator for Health Information Technology (ONC) proposals to update the ONC Health IT Certification Program; (2) removal of attestations related to ONC Direct Review and ONC-Authorized Certification Body (ONC–ACB) Surveillance; (3) removal of the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure; (4) modification of the Electronic Prior Authorization measure; (5) adoption of the Unique Device Identifiers (UDIs) for Implantable Medical Devices measure within the Public Health and Clinical Data Exchange objective; (6) adoption of two new eCQMs in alignment with the

Hospital Inpatient Quality Reporting Program; and (7) removal of three eCQMs in alignment with the Hospital Inpatient Quality Reporting Program.

i. Transforming Episode Accountability Model (TEAM)

In section X.A. of the preamble of this final rule, we discuss the changes we are finalizing for the Transforming Episode Accountability Model (TEAM). TEAM is a 5-year mandatory model tested under the authority of section 1115A of the Act, that started on January 1, 2026, and will end on December 31, 2030. We are finalizing changes to a few areas of the model, including: (1) adding 3 Medicare Severity Diagnosis Related Groups (MS–DRGs) that would initiate a spinal fusion anchor hospitalization; (2) clarifying quality measure performance periods for certain quality measures; (3) using a rolling concurrent Composite Quality Score (CQS) baseline period for certain quality measures; (4) adding an Ambulatory Payment Classification (APC) and MS–DRG update factor to target prices; and (5) using the full baseline period to construct the prospective normalization factor. We also discuss the public comments received from a RFI about voluntary opt-in opportunity for hospitals with physician ownership (POHs) and our policy intent for future rulemaking.

j. Comprehensive Care for Joint Replacement Expanded (CJR–X) Model

In section X.C. of the preamble of this final rule, we are finalizing expansion of the CJR Model. The CJR–X Model will be a mandatory model that will be tested under the authority of section 1115A of the Act, beginning on January 1, 2028 for acute care hospitals paid under the IPPS and OPPS with limited exclusions. Participating hospitals will be accountable for the cost and quality of care for LEJR episodes from the hospital inpatient or hospital outpatient admission through 90 days after the beneficiary is discharged from the hospital or hospital outpatient procedure. We are finalizing multiple policies for CJR–X, including: (1) a January 1, 2028 start date; (2) acute care hospitals as the participant and accountable entity; (3) LEJR as the episode of care; (4) five quality measures and a composite quality score (CQS) to assess quality performance; (5) regional risk-adjusted target prices that include capped normalization and trend factors; (6) pricing-specific policies for certain hospitals, such as low volume hospitals and safety net hospitals; (7) provider and beneficiary overlap permitted with most models; (8) allowing participant hospitals to have financial arrangements; (9) waiving certain Medicare Program requirements; (10) permitting beneficiary-identifiable and regional aggregated data sharing; and (11) options for Alternative Payment Model (APM) participation.

3. Summary of Costs and Benefits

The following table provides a summary of the costs, savings, and benefits associated with the major provisions described in section I.A.2. of the preamble of this final rule.

BILLING CODE 4169–69–P

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Update to the IPPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this final rule, acute care hospitals are estimated to experience a $2.9 billion increase in payments in FY 2027, primarily driven by the changes in FY 2027 operating payments, including outlier payments, uncompensated care payments, capital payments, new technology add-on payments, and the expiration of the temporary changes in the low-volume hospital program and the expiration of the MDH program on January 1, 2027.
Update to the LTCH PPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this final rule, based on the best available data for the 319 LTCHs in our analysis, we estimate that the changes to the payment rates and factors that we present in the preamble of and Addendum of this final rule, which reflect the update to the LTCH PPS standard Federal payment rate for FY 2027, will result in an estimated increase in payments in FY 2027 of approximately $54 million.
Requirements to Prohibit Unlawful Discrimination by Graduate Medical Education Programs and Nursing and Allied Health Education Programs	As discussed in Appendix A of this final rule, regarding our policies concerning unlawful discrimination by approved programs and accrediting bodies, as of October 1, 2026, we do not expect that approved programs or accrediting bodies would continue to or newly engage in unlawful discrimination on the basis of race or other protected characteristics.
Changes to the Hospital Readmissions Reduction Program	We estimated that our changes for the Hospital Readmissions Reduction Program will result in no financial impact for the FY 2027 payment determination.
Changes to the Value-based Incentive Payments under the Hospital Value-Based Purchasing Program	We estimate that there will be no net financial impact to the Hospital Value-Based Purchasing Program for the FY 2027 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS-DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS-DRG payment amount reductions for the FY 2027 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2027 discharges is approximately $1.9 billion.
Changes to the Hospital IQR Program	Across 3,050 IPPS hospitals, we estimate that our changes for the Hospital Inpatient Quality Reporting Program will result in an increase of 8,133 hours and $447,803 to the information collection burden for the FY 2030 payment determination and subsequent years.
Changes to the PCH Quality Reporting Program	Across 11 PCHs, we estimated that our changes for the PCH Quality Reporting Program will result in a decrease of 84 hours and $4,975 to the information collection burden for the FY 2028 program year and subsequent years.
Changes to the LTCH QRP	Across 318 LTCHs, we estimated that our changes for the LTCH QRP would result in a total information collection burden decrease of 4,473 hours associated with our policies and updated burden estimates and a total cost decrease of approximately $203,056.74 for the FY 2028 LTCH QRP.
Changes to the Medicare Promoting Interoperability Program	Across 4,550 eligible hospitals and CAHs, we estimated that our changes for the Medicare Promoting Interoperability Program result in a total information collection burden increase of 3,886 hours and $213,962 for the EHR reporting period in CY 2026 and subsequent years.
Transforming Episode Accountability Model (TEAM)	We estimate for the TEAM policies included in this final rule that there would be no significant change from the savings estimate in the FY 2026 IPPS/LTCH PPS final rule.
CJR-X	We estimate that the CJR-X model in this final rule would result in saving the Medicare program $725 million across 5 performance years. We note these estimates represent only a portion of the potential savings CJR-X may generate, as the model does not have a specified end date.

BILLING CODE 4169–69–C

B. Background Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment (COLA) factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it

receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, the disproportionate share hospital (DSH) adjustment discussed earlier in this section, provides for a percentage increase in Medicare payments. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for an additional Medicare payment beginning on October 1, 2013, that considers the amount of uncompensated care furnished by the hospital relative to all other qualifying hospitals.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. In general, to qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment. In addition, certain transformative new devices and certain antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway by demonstrating that, absent an add-on payment, they would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments and, beginning in FY 2023 for IHS and Tribal hospitals and hospitals located in Puerto Rico, the new supplemental payment.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as an isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

With the recent enactment of section 6202 of the Consolidated Appropriations Act (CAA), 2026 (Pub. L. 119–75), under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through December 31, 2026. For discharges occurring on or after October 1, 2007, but before January 1, 2027, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area (or, as amended by the Bipartisan Budget Act of 2018, a hospital located in a State with no rural area that meets certain statutory criteria), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years). As section 6202 of the CAA, 2026 extended the MDH program through December 31, 2026, beginning on January 1, 2027, the MDH program will no longer be in effect absent a change in law. Because the MDH program is not authorized by statute beyond December 31, 2026, beginning January 1, 2027, all hospitals that previously qualified for MDH status under section 1886(d)(5)(G) of the Act will no longer have MDH status and will be paid based on the IPPS Federal rate.

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs. The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); Inpatient psychiatric hospitals (IPF) and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are included along with the IPPS annual update in this document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable cost-based system, subject to a rate-of-increase ceiling on inpatient operating costs. Similarly, extended neoplastic disease care hospitals are paid on a reasonable cost basis, subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to

hospitals described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, effective for LTCH's cost reporting periods beginning in FY 2016 cost reporting period, LTCHs are generally paid for discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS.

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v) of the Act and existing regulations under 42 CFR part 413.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413. Section 1886(d)(5)(B) of the Act provides that prospective payment hospitals that have residents in an approved GME program receive an additional payment for each Medicare discharge to reflect the higher patient care costs of teaching hospitals relative to non-teaching hospitals. The additional payment is based on the indirect medical education (IME) adjustment factor, which is calculated using a hospital's ratio of residents to beds and a multiplier, which is set by Congress. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. The regulations regarding the indirect medical education (IME) adjustment are located at 42 CFR 412.105.

C. Summary of Provisions of Recent Legislation That Are Implemented in This Final Rule—Consolidated Appropriations Act, 2026 (Pub. L. 119–75)

Section 6201 of the Consolidated Appropriations Act (CAA), 2026 extended through the portion of FY 2027 occurring on October 1, 2026, through December 31, 2026, the modified definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals that had been in effect for FYs 2019 through 2025. Specifically, under section 1886(d)(12)(C)(i) of the Act, as amended, for FYs 2019 through 2026 and the portion of FY 2027 occurring on October 1, 2026 through December 31, 2026, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Under section 1886(d)(12)(D) of the Act, as amended, for discharges occurring in FYs 2019 through December 31, 2026, the Secretary determines the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year.

Section 6202 of the CAA, 2026 amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to provide for an extension of the MDH program through the first quarter of FY 2027 (that is, through December 31, 2026).

D. Issuance of a Notice of Proposed Rulemaking and Summary of the FY 2027 IPPS/LTCH PPS Proposed Provisions

The FY 2027 IPPS/LTCH PPS proposed rule appeared in the April 14, 2026 **Federal Register** (91 FR 19312). In the proposed rule, we set forth proposed payment and policy changes to the Medicare IPPS for FY 2027 operating costs and capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2027.

The following is a general summary of the changes that we proposed to make:

1. Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of the proposed rule, we included the following:

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2027.
- Proposed recalibration of the MS–DRG relative weights.
- A discussion of the proposed FY 2027 status of new technologies approved for add-on payments for FY 2026, a presentation of our evaluation and analysis of the FY 2027 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) Pub. L. 108–173, obtained in a town hall meeting for applications not submitted under an alternative pathway) with proposals for certain FDA market authorized technologies that applied under the traditional pathway and a discussion of the proposed status of FY 2027 new technology applicants under the alternative pathways for certain medical devices and certain antimicrobial products.
- A proposal to repeal the alternative pathway for new technology add-on payment and OPPS device pass-through payment applications, and require all applicants for new technology add-on payments and OPPS device pass-through payments to demonstrate that they meet all eligibility requirements to receive add-on payments and/or pass-through payments (as discussed in section II.E.7. of the preamble of the proposed rule).

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III of the preamble of the proposed rule, we proposed revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but are not limited to, the following:

- The proposed FY 2027 wage index update using wage data from cost reporting periods beginning in FY 2023.
- Calculation, analysis, and implementation of the proposed occupational mix adjustment to the wage index for acute care hospitals for

FY 2027 based on the 2022 Occupational Mix Survey.

- Proposed application of the rural, imputed and frontier State floors, and proposed transition for the discontinuation of the low wage index hospital policy.
- Proposed revisions to the wage index for acute care hospitals, based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Proposed adjustment to the wage index for acute care hospitals for FY 2027 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- The proposed transition for the discontinuation of the low wage index hospital policy.
- Proposed labor-related share for applying the FY 2027 wage index.

3. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2027

In section IV. of the preamble of the proposed rule, we discuss the following:

- Proposed calculation of Factor 1 and Factor 2 of the uncompensated care payment methodology.
- Proposed methodology for determining Factor 3 of the uncompensated care payment for FY 2027.
- Proposed methodology for determining the amount of interim uncompensated care payments, using the average of the most recent 3 years of discharge data.

4. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section V. of the preamble of the proposed rule, we discussed proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed inpatient hospital market basket update for FY 2027.
- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- Proposed conforming amendments to reflect the statutory extension of the temporary changes to the low-volume hospital payment adjustment through December 31, 2026.
- Proposed conforming amendments to reflect the statutory extension of the MDH program through December 31, 2026.
- Proposed requirements to prohibit unlawful discrimination by graduate medical education programs and nursing and allied health education programs.
- Proposed modifications to the criteria for identifying new residency programs for purposes of direct graduate medical education (GME) and indirect medical education (IME) payments; proposed clarifications of the methodology for calculating direct GME and IME payments following a teaching hospital merger; and a notice of closure of two teaching hospitals and opportunities to apply for available slots.
- Proposed nursing and allied health (NAH) education program Medicare Advantage (MA) add-on rates and direct GME MA percent reductions for CY 2024; and proposed changes to the regulations for determining net costs of approved NAH education programs and changes to the procedures for allocating indirect NAH costs.
- Proposed update to and revision to the payment adjustment for certain immunotherapy cases.
- Proposed changes to the requirements of the Hospital Readmissions Reduction Program—Updating the proposed estimate of the financial impacts for the FY 2027 Hospital Readmissions Reduction Program.
- Proposed changes to the requirements of the Hospital Value-Based Purchasing Program—Updating the proposed estimate of the financial impacts for the FY 2027 Hospital Value-Based Purchasing Program.
- Proposed changes to the requirements of the Hospital-Acquired Condition Reduction Program—Updating the proposed estimate of the financial impacts for the FY 2027 Hospital-Acquired Conditions Reduction Program.
- Discussion of and proposed changes relating to the implementation of the Rural Community Hospital Demonstration Program in FY 2027.

5. Proposed FY 2027 Policy Governing the IPPS for Capital-Related Costs

In section VI. of the preamble of the proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2027.

6. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VIII. of the preamble of the proposed rule, we discuss the following:

- Proposed changes to payments to certain excluded hospitals for FY 2027.
- Proposed continued implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

7. Proposed Changes to the LTCH PPS

In section VIII. of the preamble of the proposed rule, we set forth proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2027.

8. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section IX. of the preamble of the proposed rule, we proposed the following:

- Changes to the requirements for the Hospital Inpatient Quality Reporting Program.
- Changes to the requirements for the PCH Quality Reporting Program.
- Changes to the requirements for the Long-Term Care Hospital Quality Reporting Program.
- Changes to requirements pertaining to eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

9. Other Proposals and Comment Solicitations Included in This Final Rule

Section X.A. of the preamble of the proposed rule included changes to TEAM that would affect episodes, quality measure assessment, and pricing methodology. We also solicited comment on an ambulatory surgical center episode RFI and a voluntary hospitals with physician ownership RFI.

Section X.B. of the preamble of the proposed rule, included a proposed revision to the provider-based location criteria regulations applicable to off-campus facilities or organizations (§ 413.65).

Section X.C. of the preamble of the proposed rule included proposals for the CJR–X Model with policies affecting participation, episodes, quality measure and assessment, pricing methodology, model overlap, financial arrangements, waivers of Medicare Program requirements, data sharing, and APM options.

Section X.D. of the preamble of the proposed rule, discussed the following proposals:

- To reconcile non-renal organ acquisition costs for independent organ procurement organizations (IOPOs) and histocompatibility laboratories (HCLs), and to require the Medicare Administrative Contractor to establish, adjust if necessary, and publish the IOPO non-renal standard acquisition charges (SACs) and the HCL testing rates.
- To change certain existing policy and to codify certain longstanding

Medicare reasonable cost reimbursement policies, applicable to all providers reimbursed for all or for some of their services on a reasonable cost basis.

- To clarify and codify cost allocation principles.
- To codify the discretionary Administrator review of CMS reviewing official determinations with respect to appeals under § 413.420(g) for IOPOs and HCLs.

10. Other Provisions of the Proposed Rule

Section XI.A. of the preamble of the proposed rule includes our discussion of the MedPAC Recommendations.

Section XI.B. of the preamble of the proposed rule includes a descriptive listing of the public use files associated with the proposed rule.

Section XII. of the preamble of the proposed rule includes the collection of information requirements for entities based on our proposals.

11. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In sections II. and III. of the Addendum of the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2027 prospective payment rates for operating costs and capital-related costs for acute care hospitals, including cost-of-living adjustment (COLA) factors for IPPS hospitals located in Alaska and Hawaii. We proposed to establish the threshold amounts for outlier cases. In addition, in section V. of the Addendum of the proposed rule, we address the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2027 for certain hospitals excluded from the IPPS.

12. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum of the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2027 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2027. We proposed to establish the adjustments for the wage index, labor -related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates.

13. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact the proposed changes would have on affected acute care hospitals, LTCHs, and other entities.

14. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2027 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

15. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2026 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We address these recommendations in Appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2026 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's website at *https://www.medpac.gov.*

E. Public Comments Received in Response to the FY 2027 IPPS/LTCH PPS Proposed Rule

We received approximately 979 timely pieces of correspondence containing multiple comments on the proposed rule that appeared in the April 14, 2026 **Federal Register** (91 FR 19312) titled ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2027 Rates; Requirements for Quality Programs; and Other Policy Changes'' (hereinafter referred to as the FY 2027 IPPS/LTCH PPS proposed rule). We note that some of these public comments were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed with policy responses in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading.

F. Adoption of Health Information Technology Standards and Incorporation by Reference

In section X.E. of preamble of this final rule, the Office of the National Coordinator (ONC) is finalizing certain provisions that were included in the proposed rule that appeared in the April 14, 2026 **Federal Register** (91 FR 19890) titled ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges'' (hereinafter referred to as 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule).

ONC's proposals included adoption updated versions of certain health IT standards and specifications in 45 CFR 170.215 on behalf of HHS and a January 1, 2028 expiration date for versions of the standards and specifications currently in 45 CFR 170.215(j)(1) through (3), (k)(1), (m), and (n), provided that the proposals to adopt the newer versions of these adopted standards are finalized.

Specifically, ONC is finalizing the adoption of certain health IT standards and specifications in 45 CFR 170.215(j) (k), (m), and (n) on behalf of HHS. These standards are referenced in ONC Health IT Certification criteria for electronic prior authorization as well as CMS proposals in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule. ONC is finalizing to replace previously adopted versions of corresponding standards in 45 CFR 170.215(j), (k), (m), and (n) with the finalized updated versions upon the effective date of this final rule.

II. Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. Adoption of the MS–DRGs and MS–DRG Reclassifications

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011 through 2026 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76 FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; 80 FR 49342; 81 FR 56787 through 56872; 82 FR 38010 through 38085; 83 FR 41158 through 41258; 84 FR 42058 through 42165; 85 FR 58445 through 58596; 86 FR 44795 through 44961; 87 FR 48800 through 48891; 88 FR 58654 through 58787; 89 FR 69000 through 69109; and 90 FR 36549 through 36649, respectively).

For discussion regarding our previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case mix, we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 48799 through 48800).

Comment: Multiple commenters summarized the statutory and regulatory history regarding the documentation and coding recoupment adjustments required under section (7)(b) of the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Pub. L. 110–90), as amended. The commenters contend that the total level of adjustments made by CMS under this section took back more than was authorized by Congress and stated that section 7(b)(2) of Public Law 110–90 requires CMS to increase the standardized amount by 0.9412% to avoid carrying over into FY 2026 the −3.9% reduction to the standardized amount that law required between FY 2013 and FY 2017.

Response: As we have discussed in prior rulemaking, including in response to comments in the FY 2026 IPPS/LTCH PPS final rule, as of FY 2023, CMS completed the statutory requirements of section 7(b)(1)(B) of Public Law 110–90 as amended by section 631 of the American Taxpayer Relief Act of 2012 (ATRA, Pub. L. 112–240), section 404 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), and section 15005 of the 21st Century Cures Act (Pub. L. 114–255). As we discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44794 through 44795), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58444 through 58445) and in prior rules, we believe section 414 of the MACRA and section 15005 of the 21st Century Cures Act set forth the levels of positive adjustments for FYs 2018 through 2023. Those adjustments added up to +2.9488 percentage points, not +3.9 percentage points, and we see no evidence that Congress enacted that smaller adjustment schedule with the silent intent that CMS would later make a permanent 0.9412% payment adjustment to reach a total +3.9 percentage point adjustment. To the contrary, section 414 of the MACRA instructs the agency to ''not make the adjustment (estimated to be an increase of 3.2 percent) that would otherwise apply for discharges occurring during fiscal year 2018 by reason of the completion of the adjustments required under clause (ii).'' Because the adjustment ''that would otherwise apply'' in fiscal year 2018 but for clause (1)(B)(iii) was +3.9%, the commenter's suggestion to complete making that adjustment now is inconsistent with the statute's text.

Subparagraph (b)(2) of Public Law 110–90 does not compel a contrary result. As the U.S. Court of Appeals for the D.C. Circuit has explained, that provision simply requires CMS ''to ignore recoupment adjustments'' when ''calculat[ing] and apply[ing] the annual 'percentage increase'' to base rates provided for in the Medicare statute to account for inflation. Fresno Community Hospital & Medical Center v. Cochran, 987 F.3d 158, 163 (D.C. Cir. 2021). The Secretary has complied with that instruction. Similarly, the commenters' citations to statements the agency made in the **Federal Register** about its intent to unwind the reductions to the standardized amount the agency made between FY 2013 and FY 2017 were made before Congress passed clause (1)(B)(iii) and have been countermanded by that provision. We therefore decline the commenters' suggestion to read into section 7(b) of Public Law 110–90 implied authority to increase the standardized payment amount by 0.9412%. For the same reasons, we do not see a basis for exercising the Secretary's exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act.

C. Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for FY 2027 MS–DRG Updates

a. International Classification of Diseases, 10th Revision (ICD–10)

Providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the ICD–10–CM and ICD–10–PCS Official Guidelines for Coding and Reporting.

b. Basis for FY 2027 MS–DRG Updates

The deadline for interested parties to submit MS–DRG classification change requests for FY 2027 was October 20, 2025. All requests are submitted to CMS via Medicare Electronic Application Request Information System™ (MEARIS™), accessed at *https://mearis.cms.gov.* Specifically, as indicated on the MEARIS™ site, the MS–DRG classification change request

process may be used for requests to create, modify, or delete MS–DRGs, change ICD–10–CM diagnosis code(s) severity level designations, change ICD–10–PCS procedure code(s) Operating Room (O.R.) designations, or to review the CC Exclusions List or the surgical hierarchy.

Within MEARIS™, we have built in several resources to support users, including a ''Resources'' section available at *https://mearis.cms.gov/public/resources* with technical support available under ''Useful Links'' at the bottom of the MEARIS™ site. Questions regarding the MEARIS™ system can be submitted to CMS using the form available under ''Contact'', also at the bottom of the MEARIS™ site.

We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the request for MS–DRG classification changes to CMS. The aforementioned burden is subject to the Paperwork Reduction Act (PRA) of 1995 and approved under OMB control number 0938–1431 and has an expiration date of January 31, 2029.

As we have discussed in prior rulemaking, we may not be able to fully consider all of the requests that we receive for the upcoming fiscal year. We have found that, with the implementation of ICD–10, some types of requested changes to the MS–DRG classifications require more extensive research to identify and analyze all of the data that are relevant to evaluating the potential change.

As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36550), beginning with FY 2027 rulemaking, we are no longer summarizing in the proposed and final rules those requests that are not able to be considered for the upcoming FY. We noted that requests that require more extensive analysis may include those involving multiple MS–DRGs, overlapping logic across multiple Major Diagnostic Categories (MDCs), special logic such as diagnosis codes combined with procedure codes, and/or complex logic including code clusters or multiple logic lists. In December 2025, we informed requestors via MEARIS™ if their MS–DRG classification change request was not able to be considered with the FY 2027 rulemaking cycle.

Comment: A commenter (technology association) acknowledged the process that CMS utilizes for accepting MS–DRG requests via MEARIS™ and that some types of requested changes to the MS–DRG classifications require more extensive research to identify and analyze all the data that are relevant to evaluating the potential change. The commenter stated that CMS notified requestors via MEARIS™ if their MS–DRG classification change request was not able to be considered with the FY 2027 rulemaking cycle and they understood that several of their members received such notifications. The commenter also stated that the agency does not publicly disclose the number of MS–DRG applications they receive and review annually. The commenter encouraged CMS to provide greater transparency regarding the overall volume and the nature of the MEARIS™ requests that are submitted to CMS each year. The commenter stated their belief that it is important for CMS to provide transparency into the number of requests that it receives each year to provide stakeholders with an understanding of the volume of requests and potential likelihood of not having their application reviewed in rulemaking the same rulemaking cycle. The commenter further stated that for those applications CMS has stated require additional analysis, CMS should provide the applicant with an expected timeline for review. According to the commenter, absent a clear process for revisiting deferred requests, stakeholders are left without clarity as to when such submissions will receive further consideration. The commenter stated it is important for CMS to establish a transparent timeline for re-evaluation of MS–DRG requests that are not addressed in the year of submission.

The commenter stated they identified two circumstances in which the public comment process could function as a necessary supplement to MEARIS™. In the first example, the commenter stated that when an MS–DRG classification change request has been submitted through MEARIS™ and CMS has been unable to address the request, CMS should recognize the public comment process as an appropriate vehicle for stakeholders to consider the request. The commenter stated they agree that any policy change responsive to public comments, where CMS has not separately proposed the requested change in rulemaking, is appropriately reserved for proposal and finalization in the subsequent rulemaking cycle. The commenter stated this option would be consistent with the agency's general practice for off-cycle ambulatory payment classification, transitional pass-through, and new technology add-on payment determinations. According to the commenter, using this approach would allow the public comment process to operate as a transparency and queue-management mechanism, not as a substitute for proposal and finalization. In the second example, the commenter stated that when CMS has proposed to discontinue the new technology add-on payment for a specific technology, by listing that technology in a designated table within the proposed rule, the agency has put that technology's payment treatment before the public for comment. The commenter stated that the proposed new technology add-on payment discontinuation is itself the proposal. According to the commenter, any public comments addressing the adequacy of the MS–DRG payment for that technology, and a proposed corresponding adjustment to payment when the new technology add-on payment expires, are directly responsive to the action CMS has put before the public; they are not free-standing reassignment requests outside rulemaking. The commenter asserted that MS–DRG assignment is inseparable from the new technology add-on payment action that CMS has proposed. The commenter urged CMS to recognize that for the technologies subject to this scenario, any public comments that include concerns regarding payment adequacy are within the scope of rulemaking and may be considered for action in the same final rule that finalizes a proposed discontinuation of new technology add-on payment. The commenter stated that recognition of these two categories of examples would not displace MEARIS™ as the agency's submission process but could ensure that the public comments function as a supplement because exclusive reliance on MEARIS™ produces outcomes inconsistent with payment accuracy, beneficiary access, and administrative efficiency. The commenter urged CMS to address the public comments submitted for either example to include the requests received, a summary of the supporting evidence, and an explanation of the disposition.

Response: We appreciate the commenter's feedback. In response to the commenter's recommendation that CMS provide greater transparency into the number of requests that it receives each year to afford stakeholders a better understanding of the volume of requests received and the potential likelihood of not having an application reviewed in rulemaking during that same rulemaking cycle, we note that, until the current FY 2027 rulemaking cycle, all prior MS–DRG classification change requests received via MEARIS™ since FY 2024 rulemaking have been reflected in the annual IPPS/LTCH PPS rulemakings; therefore, stakeholders were provided with details regarding

the number and the nature of the MS–DRG classification change requests. We no longer believe that providing an annual summary as part of the annual rulemaking that outlines the number and nature of MS–DRG classification change requests received and for which we are unable to address for the upcoming fiscal year is beneficial because, as reflected in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36550 through 36552), we received public comments in response to such summaries that were included in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18012), urging CMS to finalize changes for requests that we had indicated we were unable to consider for FY 2026 and for which we did not propose a change to the logic for FY 2026. Additionally, providing an annual summary detailing the number and nature of MS–DRG requests received may not completely reflect the complexity of a given request.

We continue to believe that we provide sufficient transparency through our established annual notice and comment rulemaking process. We note that, since the implementation of MEARIS™ for the submission of MS–DRG classification change requests, we have continued efforts towards refining our process for MS–DRG classification change requests. For example, as stated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36549 through 36550), and the preamble of the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19322) and this final rule, beginning with FY 2027 rulemaking, we inform requestors via MEARIS™ if an MS–DRG classification change request is unable to be considered with the upcoming fiscal year's rulemaking cycle and that we will no longer summarize in the proposed and final rules those requests that are not able to be considered for the upcoming fiscal year. As the commenter acknowledged in its submitted comments, several of their members received such notifications. Specifically, we note that for those requests that were unable to be considered for FY 2027 rulemaking, the requestors received an electronic notification that their MS–DRG classification change request was being deferred for the FY 2027 rulemaking cycle; therefore, requestors were made aware that their MS–DRG classification change request was not being considered in the FY 2027 rulemaking cycle. With respect to the commenter's recommendation that CMS should provide the requestors who received notification that their FY 2027 MS–DRG classification change request was deferred with an expected timeline for review, we note that following this FY 2027 rulemaking, we intend to provide additional information to those requestors whose MS–DRG classification change requests were deferred for FY 2027 regarding the status of their FY 2027 MS–DRG classification change request.

In response to the commenter's second example where they asserted that any public comments addressing the adequacy of the MS–DRG payment in connection with the proposed discontinuation of a new technology add-on payment for a specific technology, with a proposed corresponding adjustment to payment, are within the scope of rulemaking and may be considered for action in the same final rule that finalizes a proposed discontinuation of a new technology add-on payment technology, we disagree. Specifically, we note that under our established process, requests for consideration of an MS–DRG classification change must be submitted via MEARIS™ as discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28127) and final rule (87 FR 48800 through 48801). We disagree that the use of MEARIS™ produces outcomes inconsistent with payment accuracy, beneficiary access, and administrative efficiency. As reflected in our annual rulemakings, for the MS–DRG classification change requests we are able to consider, we present a summary of the requests received, the relevant MDC(s), MS–DRG(s), ICD–10–CM diagnosis and ICD–10–PCS procedure codes that are analyzed using the designated MedPAR claims data file and the proposals that are set forth based on the findings from our analysis of claims data and clinical review. In connection with our annual proposed rulemakings, we also provide a test version of the ICD–10 MS–DRG GROUPER software, supplemental mapping files, a draft version of the ICD–10 MS–DRG Definitions Manual and, effective with FY 2025 rulemaking, a draft version of the Definitions of Medicare Code Edits (MCE) Manual, and the associated proposed relative weights file so that the public can better analyze and understand the impact of the proposals included in the proposed rule utilizing these available resources. Therefore, we do not believe it would be appropriate to finalize MS–DRG classification changes in connection with the proposed discontinuation of a new technology add-on payment for a specific technology in the absence of providing our standard data analysis and corresponding resources that are made publicly available under our established rulemaking process.

To provide further transparency in connection with our MS–DRG request process, beginning with the FY 2028 rulemaking cycle, we intend to send notifications to requestors via MEARIS™ if their MS–DRG classification change request(s) will be considered with a status update of ''Under Review'', and for those MS–DRG classification change requests that are unable to be considered for the upcoming fiscal year's rulemaking, we intend to send notifications to requestors via MEARIS™ with a status update of ''Deferred'', followed by additional communication as to why the request is unable to be considered for the upcoming fiscal year's rulemaking cycle. Consistent with our process for the FY 2027 MS–DRG classification change requests, we intend to notify requestors by mid-December if their request is or is not able to be considered for the upcoming fiscal year.

Interested parties should submit any MS–DRG classification change requests, including any comments and suggestions for FY 2028 consideration by October 20, 2026, via MEARIS™ at: *https://mearis.cms.gov/public/home.* As noted, we will inform requestors via MEARIS™ if the MS–DRG classification change request is or is not able to be considered with the upcoming fiscal year rulemaking cycle.

As we did for the FY 2026 IPPS/LTCH PPS proposed rule, for the FY 2027 IPPS/LTCH PPS proposed rule we provided a test version of the ICD–10 MS–DRG GROUPER Software, Version 44, so that the public can better analyze and understand the impact of the proposals included in the proposed rule. We noted that this test software reflected the proposed GROUPER logic for FY 2027. Therefore, it included the new diagnosis and procedure codes that are effective for FY 2027 as reflected in Table 6A.—New Diagnosis Codes—FY 2027 and Table 6B.—New Procedure Codes—FY 2027 associated with the proposed rule and does not include the diagnosis codes that are invalid beginning in FY 2027 as reflected in Table 6C.—Invalid Diagnosis Codes—FY 2027 and Table 6D.—Invalid Procedure Codes—FY 2027 associated with the proposed rule. Those tables were not published in the Addendum to the FY 2027 IPPS/LTCH PPS proposed rule, but are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to the FY 2027 IPPS/LTCH PPS proposed rule. Because the

diagnosis and procedure codes no longer valid for FY 2027 are not reflected in the test software, we made available a supplemental file in Table 6P.1a that includes the mapped Version 44 FY 2027 ICD–10–CM codes and the deleted Version 43 FY 2026 ICD–10–CM codes and Table 6P.1b that includes the mapped Version 44 FY 2027 ICD–10–PCS codes and the deleted Version 43.1 FY 2026 ICD–10–PCS codes that should be used for testing purposes with users' available claims data. Therefore, users had access to the test software allowing them to build case examples that reflect the proposals that were included in the proposed rule. In addition, users were able to view the draft version of the ICD–10 MS–DRG Definitions Manual, Version 44 that contains the documentation for proposed FY 2027 ICD–10 MS–DRG GROUPER Version 44 logic changes and were also able to view a draft version of the Definitions of Medicare Code Edits (MCE) Manual to review any changes that will become effective October 1 for FY 2027. In the proposed rule we also noted that, as a result of new and modified code updates approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting, any further changes to the MCE will be reflected in the finalized Definitions of Medicare Code Edits (MCE) Manual, made available in association with the annual IPPS/LTCH PPS final rule. As such, we made available the draft FY 2027 ICD–10 MCE Version 44 Manual file on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.*

We noted in the proposed rule that the MCE manual is comprised of two chapters: *Chapter 1: Edit code lists* provides a listing of each edit, an explanation of each edit, and as applicable, the diagnosis and/or procedure codes for each edit, and *Chapter 2: Code list changes* summarizes the changes in the edit code lists (for example, additions and deletions) from the prior release of the MCE software. We also stated that the public may submit any questions, comments, concerns, or recommendations regarding the MCE to the CMS mailbox at *MSDRGClassificationChange@cms.hhs.gov* for our review and consideration.

The test version of the ICD–10 MS–DRG GROUPER Software, Version 44, the draft version of the ICD–10 MS–DRG Definitions Manual, Version 44, the draft version of the Definitions of Medicare Code Edits Manual, Version 44, and the supplemental mapping files in Tables 6P.1a and 6P.1b of the FY 2026 and FY 2027 ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

Comment: Commenters expressed appreciation that we provided a test version of the ICD–10 MS–DRG GROUPER Software, Version 44, along with mapping files to assist with analysis, however, the commenters stated that this version essentially only allows for a case-by-case analysis and a minimal batch analysis. The commenters stated that it would be more beneficial to have a Batch z/OS version of the test GROUPER so that it could be better utilized for broader and more meaningful analysis purposes. The commenters requested that availability of a Batch z/OS version of the test GROUPER be made publicly available for all future rulemaking.

Response: We appreciate the commenters' feedback and will take the suggestion into consideration for future rulemaking.

Following are the changes that we proposed to the MS–DRGs for FY 2027. We invited public comments on each of the MS–DRG classification proposed changes, as well as our proposals to maintain certain existing MS–DRG classifications discussed in the FY 2027 IPPS/LTCH PPS proposed rule. In some cases, we proposed changes to the MS–DRG classifications based on our analysis of claims data and clinical appropriateness. In other cases, we proposed to maintain the existing MS–DRG classifications based on our analysis of claims data and clinical appropriateness. As discussed in the FY 2027 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2025 update of the FY 2025 MedPAR file, which contains hospital bills received from October 1, 2024, through September 30, 2025. In our discussion of the proposed MS–DRG reclassification changes, we referred to these claims data as the ''September 2025 update of the FY 2025 MedPAR file.''

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on clinical factors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), we finalized our proposal to expand our existing criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG. Specifically, we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. We stated we believed that applying these criteria to the NonCC subgroup would better reflect resource stratification as well as promote stability in the relative weights by avoiding low volume counts for the NonCC level MS–DRGs. We noted that in our analysis of MS–DRG classification requests for FY 2021 that were received by November 1, 2019, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups.

As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58661), we continue to apply the criteria to create subgroups, including application of the NonCC subgroup criteria, in our annual analysis of MS–DRG classification requests, consistent with our approach since FY 2021 when we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. Accordingly, in our analysis of the MS–DRG classification requests for FY 2027 that we received by October 20, 2025, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups, as described in the following table.

Criteria Number	Three-Way Split 123 (MCC vs CC vs NonCC)	Two-Way Split 1_23 MCC vs (CC+NonCC)	Two-Way Split 12_3 (MCC+CC) vs NonCC
1. At least 500 cases in the MCC/CC/NonCC group	500+ cases for MCC group; and 500+ cases for CC group; and 500+ cases for NonCC group	500+ cases for MCC group; and 500+ cases for (CC+NonCC) group	500+ cases for (MCC+CC) group; and 500+ cases for NonCC group
2. At least 5 percent of the patients are in the MCC/CC/NonCC group	5 percent+ cases for MCC group; and 5 percent+ cases for CC group; and 5 percent+ cases for NonCC group	5 percent+ cases for MCC group; and 5 percent+ cases for (CC+NonCC) group	5 percent+ cases for (MCC+CC) group; and 5 percent+ cases for NonCC group
3. There is at least a 20 percent difference in average cost between subgroups	20 percent+ difference in average cost between MCC group and CC group; and 20 percent+ difference in average cost between CC group and NonCC group	20 percent+ difference in average cost between MCC group and (CC+NonCC) group	20 percent+ difference in average cost between (MCC+ CC) group and NonCC group
4. There is at least a $2,000 difference in average cost between subgroups	$2,000+ difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group	$2,000+ difference in average cost between MCC group and (CC+ NonCC) group	$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
5. The R2 of the split groups is greater than or equal to 3	R2 $\geq$ 3.0 for the three-way split within the base MS-DRG	R2 $\geq$ 3.0 for the two-way 1_23 split within the base MS-DRG	R2 $\geq$ 3.0 for the two-way 12_3 split within the base MS-DRG

In general, once the decision has been made to propose to make further modifications to the MS–DRGs as described previously, such as creating a new base MS–DRG, or in our evaluation of a specific MS–DRG classification request to split (or subdivide) an existing base MS–DRG into severity levels, all five criteria must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. We note that in our analysis of requests to create a new MS–DRG, we typically evaluate the most recent year of MedPAR claims data available. For example, we stated earlier that for the FY 2027 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2025 update of the FY 2025 MedPAR file. However, in our evaluation of requests to split an existing base MS–DRG into severity levels, as noted in prior rulemaking (80 FR 49368), we typically analyze the most recent two years of data. This analysis includes two years of MedPAR claims data to compare the data results from one year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. The first step in our process of evaluating if the creation of a new CC subgroup within a base MS–DRG is warranted is to determine if all the criteria is satisfied for a three-way split. In applying the criteria for a three-way split, a base MS–DRG is initially subdivided into the three subgroups: MCC, CC, and NonCC. Each subgroup is then analyzed in relation to the other two subgroups using the volume (Criteria 1 and 2), average cost (Criteria 3 and 4), and reduction in variance (Criteria 5). If the criteria fail, the next step is to determine if the criteria are satisfied for a two-way split. In applying the criteria for a two-way split, a base MS–DRG is initially subdivided into two subgroups: ''with MCC'' and ''without MCC'' (1_23) or ''with CC/MCC'' and ''without CC/MCC'' (12_3). Each subgroup is then analyzed in relation to the other using the volume (Criteria 1 and 2), average cost (Criteria 3 and 4), and reduction in variance (Criteria 5). If the criteria for both of the two-way splits fail, then a split (or CC subgroup) would generally not be warranted for that base MS–DRG. If the three-way split fails on any one of the five criteria and all five criteria for both two-way splits (1_23 and 12_3) are met, we would apply the two-way split with the highest R2 value. We note that if the request to split (or subdivide) an existing base MS–DRG into severity levels specifies the request is for either one of the two-way splits (1_23 or 12_3), in response to the specific request, we will evaluate the criteria for both of the two-way splits; however, we do not also evaluate the criteria for a three-way split.

We are making the FY 2027 ICD–10 MS–DRG GROUPER and Medicare Code Editor (MCE) Software Version 44, the ICD–10 MS–DRG Definitions Manual files Version 44 and the Definitions of Medicare Code Edits Manual Version 44 available to the public on our CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.*

2. MDC 04 (Diseases and Disorders of the Respiratory System)

a. Short-term External Heart Assist Systems

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19324 through 19328), we discussed a request we received to reassign cases reporting procedure codes describing the insertion of a short-term external heart assist device from MDC 04 MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) to MDC 05 (Diseases and Disorders of the Circulatory System) MS–DRG 215 (Other Heart Assist System Implant). According to the requestor, when patients are admitted with pulmonary conditions, such as pulmonary embolism, and have Impella® Ventricular Support Systems inserted for cardiac support during a thrombectomy procedure, MS–DRGs 163, 164, or 165 are assigned. The requestor stated that cases reporting procedure codes describing the insertion of Impella® Ventricular Support Systems that are assigned to MS–DRGs 163, 164, or 165 require resources similar to cases that are assigned to MS–DRG 215. The requestor further requested that if CMS did not reassign cases reporting procedure codes describing the insertion of a short-term external heart assist device to MS–DRG 215, in the alternative, CMS should consider creating new MS–DRGs for cases reporting procedure codes describing the insertion of a short-term external heart assist device and major chest procedures.

As discussed in the proposed rule, in reviewing this request, we noted that acute massive pulmonary embolism can lead to right ventricular (RV) failure and cardiogenic shock, requiring urgent treatment. Thrombolytic therapy is the standard treatment for high-risk pulmonary embolism in hemodynamically unstable patients. However, in cases where thrombolytics are contraindicated or ineffective, mechanical circulatory support can serve as a rescue therapy. While extracorporeal membrane oxygenation (ECMO) is commonly utilized, Impella® Ventricular Support Systems can offer right ventricular support in patients with pulmonary embolism-induced

cardiogenic shock.[1] Impella® Ventricular Support Systems are temporary heart assist devices intended to provide mechanical circulatory support by temporarily assisting the pumping function of the heart to provide adequate circulation of blood to critical organs while also allowing damaged heart muscle the opportunity to rest and recover in patients who need short-term support.

We noted in the proposed rule that the requestor identified cases reporting procedure codes describing the insertion of a short-term external heart assist device as reporting ICD–10–PCS codes 02HA3RZ (Insertion of short-term external heart assist system into the heart, percutaneous approach) and 5A0221D (Assistance with cardiac output using impeller pump, continuous). We stated that while we agree with the requestor that procedure code 02HA3RZ describes the insertion of a short-term external heart assist device, we note that there are additional ICD–10–PCS codes in the classification that also describe the insertion of a short-term external heart assist device. Therefore, in reviewing this request, we identified the five additional ICD–10–PCS procedure codes that also describe the insertion of a short-term external heart assist device listed in the following table and included these codes in our analysis.

ICD-10-PCS Code	Description
02HA0RS	Insertion of biventricular short-term external heart assist system into heart, open approach
02HA0RZ	Insertion of short-term external heart assist system into heart, open approach
02HA3RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous approach
02HA4RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach
02HA4RZ	Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach

To begin our analysis, as discussed in the proposed rule, we examined claims data from the September 2025 update of the FY 2025 MedPAR file for MS–DRGs 163, 164, and 165 to identify cases reporting ICD–10–PCS codes 02HA0RS, 02HA0RZ, 02HA3RS, 02HA3RZ, 02HA4RS, or 02HA4RZ. We stated in the proposed rule that we agreed with the requestor that when a patient is admitted and has an Impella® external heart assist device inserted, two ICD–10–PCS codes are assigned: a code that describes the insertion of the short-term external heart assist device and code 5A0221D that describes assistance with an impeller pump. Because the assistance with an Impella® is always coded with ICD–10–PCS code 5A0221D, we did not include this code in our analysis as the presence of the code would be expected to be identified in all cases. Our findings are shown in the following table.

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
163	All cases	13,396	8.2	$40,641
	Cases reporting insertion of short-term external heart assist devices	17	8.4	$81,960
164	All cases	14,384	4	$23,393
	Cases reporting insertion of short-term external heart assist devices	0	0	$0
165	All cases	6,431	2.3	$17,981
	Cases reporting insertion of short-term external heart assist devices	0	0	$0

As shown in the table, we identified a total of 13,396 cases within MS–DRG 163 with an average length of stay of 8.2 days and average costs of $40,641. Of these 13,396 cases, there were 17 cases that reported a procedure code describing the insertion of a short-term external heart assist device with an average length of stay of 8.4 days and average costs of $81,960. There were zero cases reporting a procedure code describing the insertion of a short-term external heart assist device in MS–DRGs 164 and 165. The data analysis shows that for the cases in MS–DRG 163 reporting a procedure code describing the insertion of a short-term external heart assist device, the average length of stay is longer, and the average costs are higher when compared to all cases in that MS–DRG.

As discussed in the proposed rule, to further review the consumption of hospital resources for cases reporting a procedure code describing the insertion of a short-term external heart assist device with a principal diagnosis of a pulmonary condition, we reviewed the claims data to identify cases reporting ICD–10–PCS codes 02HA0RS, 02HA0RZ, 02HA3RS, 02HA3RZ, 02HA4RS, or 02HA4RZ in other MS–DRGs in MDC 04 (Diseases and Disorders of the Respiratory System), specifically MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) and MS–DRG 173 (Ultrasound Accelerated and Other Thrombolysis with Principal Diagnosis Pulmonary Embolism). We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 43.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for a complete listing of the MS–DRGs in MDC 04. There were zero cases reporting a procedure code describing the insertion of a short-term external heart assist device with a principal diagnosis of a pulmonary condition in MS–DRGs 166, 167, 168 or MS–DRG 173.

We then reviewed the claims data to further identify the principal diagnoses that were reported to determine what factors may also be contributing to the higher average costs for the subset of cases that reported a procedure code describing the insertion of a short-term

[1] Pandey, Asim MBBS[a,*]; Parajuli, Samriddhi MBBS[b]; Khanal, Prajwal MBBS[c]; Khanal, Kunjan MBBS[d]; Yadav, Ramsinhasan Prasad MBBS[e]. Hemodynamic improvement with Impella RP in acute massive pulmonary embolism: a narrative review of cardiovascular outcomes and pulmonary catheter pressure assessment. Annals of Medicine & Surgery 87(7):p 4303–4309, July 2025. | DOI: 10.1097/MS9.0000000000003431

external heart assist device in MS–DRG 163. Our findings for the principal diagnoses that were reported within the claims data from the September 2025 update of the FY 2025 MedPAR file for this subset of cases are shown in the following table:

DIAGNOSES REPORTED WITH A PROCEDURE CODE DESCRIBING THE INSERTION OF A SHORT-TERM EXTERNAL HEART ASSIST DEVICE IN MS-DRG 163				
ICD-10-CM Code	Description	Number of Times Reported	Average Length of Stay	Average Costs
I26.02	Saddle embolus of pulmonary artery with acute cor pulmonale	3	7.3	$61,956
I26.09	Other pulmonary embolism with acute cor pulmonale	9	7.6	$79,521
I26.92	Saddle embolus of pulmonary artery without acute cor pulmonale	2	11.5	$111,452
I26.99	Other pulmonary embolism without acute cor pulmonale	3	9.7	$89,619
	Total	**17**	**8.4**	**$ 81,960**

As reflected in the table, all 17 cases reported a principal diagnosis of pulmonary embolism. While the results of the claims analysis as previously summarized indicate that the average costs of cases that reported a procedure code describing the insertion of a short-term external heart assist device are higher compared to the average costs for all cases in MS–DRG 163, we stated in the proposed rule that we could not ascertain from the claims data the additional resource use specifically attributable to the insertion of the short-term external heart assist device during the hospital stay as compared to the severity of illness of the patient and other circumstances of the admission. We stated that these data show that while cases that reported a procedure code describing the insertion of a short-term external heart assist device and a principal diagnosis of pulmonary embolism required greater resource utilization, there is a wide variance in average costs and average length of stay depending on the ICD–10–CM code reported as principal diagnosis. For example, the three cases that reported a principal diagnosis of I26.02 (Saddle embolus of pulmonary artery with acute cor pulmonale) had an average length of stay of 7.3 days and average costs of $61,956, while the two cases that reported a principal diagnosis of I26.92 (Saddle embolus of pulmonary artery without acute cor pulmonale) had an average length of stay of 11.5 days and average costs of $111,452. When reviewing consumption of hospital resources for this subset of cases, it is unclear to what degree the higher average costs for these cases are attributable to the severity of illness of the patient and other circumstances of the admission as opposed to the insertion of a short-term external heart assist device. There may have been other factors contributing to the higher costs.

As discussed in the proposed rule, during our review of this issue and the examination of the cases reporting procedure codes describing the insertion of a short-term external heart assist device found in MS–DRG 163, as noted previously, we found these cases all reported a principal diagnosis of pulmonary embolism. The ICD–10–codes that describe pulmonary embolism are currently assigned to MDC 04 (Diseases and Disorders of the Respiratory System). The diagnoses assigned to MDC 04 reflect conditions associated with the respiratory system. In ICD–10, the body or organ system is the axis of the classification, and diagnosis codes are classified by the body or organ system affected. The concept of clinical coherence generally requires that the patient characteristics included in the definition of each MS–DRG relate to a common organ system or etiology and that a specific medical specialty should typically provide care to the patients in the DRG. These diagnosis codes would require reassignment to MDC 05 (Diseases and Disorders of the Circulatory System) to group to MDC 05 MS–DRG 215.

Although MDC 04 diagnoses such as pulmonary embolism can lead to RV failure and cardiogenic shock, which might be reasonable indications for the insertion of a short-term external heart assist device, we stated it would not be appropriate to move these diagnoses into MDC 05 because it could inadvertently cause cases reporting these same MDC 04 diagnoses with a respiratory system procedure to be assigned to an ''unrelated'' MS–DRG because whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in a MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

To further examine the impact of moving the diagnosis codes describing pulmonary embolism into MDC 05, we stated we analyzed claims data for cases reporting a respiratory system O.R. procedure and a principal diagnosis of pulmonary embolism. Our findings are reflected in the following table.

CASES REPORTING A RESPIRATORY SYSTEM O.R. PROCEDURE WITH A PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM				
MS-DRG	Description	Number of Cases	Average Length of Stay	Average Costs
163	Major Chest Procedures with MCC	5,470	5.2	$36,565
164	Major Chest Procedures with CC	1,750	3.2	$28,565
165	Major Chest Procedures without CC/MCC	186	2.3	$24,097
166	Other Respiratory System O.R. Procedures with MCC	223	10.6	$33,791
167	Other Respiratory System O.R. Procedures with CC	50	6.1	$20,171
168	Other Respiratory System O.R. Procedures without CC/MCC	2	2.5	$9,592
173	Ultrasound Accelerated and Other Thrombolysis with Principal Diagnosis Pulmonary Embolism	971	4.5	$27,571
	Total Cases	**8,652**	**4.8**	**$33,497**

As shown in the table, we identified 8,652 cases reporting a respiratory system O.R. procedure and a principal diagnosis of pulmonary embolism. We reviewed this issue and noted in the proposed rule if we were to move the diagnosis codes describing pulmonary embolism to MDC 05, these cases would be assigned to the surgical class referred to as ''unrelated operating room procedures'' as an unintended consequence because the surgical procedure reported on the claim would be considered unrelated to the MDC to which the case was assigned based on the principal diagnosis. We noted the data also indicates that there were more cases that reported an O.R. procedure assigned to MDC 04 with a principal diagnosis describing pulmonary embolism than there were cases that reported a procedure code describing the insertion of a short-term external heart assist device, and a principal diagnosis of pulmonary embolism in MDC 04 (8,652 cases versus 17 cases) demonstrating that inpatient admissions for pulmonary embolism more typically have an O.R. procedure assigned to MDC 04 performed and do not report a procedure code describing the insertion of a short-term external heart assist device.

In the proposed rule, we stated we also reviewed the cases reporting an O.R. procedure assigned to MDC 04 and a principal diagnosis describing pulmonary embolism to identify the top ten O.R. procedures assigned to MDC 04 that were reported within the claims data for these cases. Our findings are shown in the following table:

TOP 10 PROCEDURES ASSIGNED TO MDC 04 REPORTED WITH A PRINCIPAL DIAGNOSIS DESCRIBING PULMONARY EMBOLISM

ICD-10-PCS Code	Description	Number of Times Reported	Average Length of Stay	Average Costs
02CQ3ZZ	Extirpation of matter from right pulmonary artery, percutaneous approach	3,887	4.7	$ 34,738
02CR3ZZ	Extirpation of matter from left pulmonary artery, percutaneous approach	2,314	4.3	$ 32,792
X2CY3T7	Extirpation of matter from great vessel using computer-aided mechanical aspiration, percutaneous approach, new technology group 7	519	4.4	$ 33,033
02FQ3Z0	Fragmentation of right pulmonary artery, percutaneous approach, ultrasonic	509	4.7	$ 28,313
02CP3ZZ	Extirpation of matter from pulmonary trunk, percutaneous approach	492	4.6	$ 35,816
02FR3Z0	Fragmentation of left pulmonary artery, percutaneous approach, ultrasonic	378	4.2	$ 27,023
0JH60WZ	Insertion of totally implantable vascular access device into chest subcutaneous tissue and fascia, open approach	77	7.5	$ 24,055
02FP3Z0	Fragmentation of pulmonary trunk, percutaneous approach, ultrasonic	31	5.1	$ 21,186
02FQ3ZZ	Fragmentation of right pulmonary artery, percutaneous approach	27	5.2	$ 30,877
02CQ0ZZ	Extirpation of matter from right pulmonary artery, open approach	21	9.5	$ 60,650

As noted previously, if we were to move the diagnosis codes describing pulmonary embolism to MDC 05, cases reporting one of the O.R. procedures assigned to MDC 04 shown in the table would be assigned to the surgical class referred to as ''unrelated operating room procedures'' as an unintended consequence. Based on the results of our analysis, we stated we believe that the diagnosis codes describing pulmonary embolism are most clinically aligned with the other diagnosis codes assigned to MDC 04 (where they are currently assigned). Considering the impact that moving the diagnoses describing pulmonary embolism to MDC 05 from MDC 04 would have, we stated we also believe it would not be appropriate to move these diagnoses into MDC 05 because it would inadvertently cause cases reporting pulmonary embolism with O.R. procedures assigned to MDC 04 to be assigned to an unrelated MS–DRG.

We then explored alternative options, as was requested, as discussed in the proposed rule. We noted that the 17 cases reporting a procedure code describing the insertion of a short-term external heart assist device had an average length of stay of 8.4 days and average costs of $81,960, as compared to the 13,396 cases in MS–DRG 163 that had an average length of stay of 8.2 days and average costs of $40,641. While these cases reporting a procedure code describing the insertion of a short-term external heart assist device had average costs that were $41,319 higher than the average costs of all cases in MS–DRG 163 (the highest severity level ''with MCC'' MS–DRG), there were only a total of 17 cases. We stated that the results of the claims analysis demonstrate that there are not sufficient claims data in the MedPAR file on which to assess the resource use of cases reporting a procedure code describing the insertion of a short-term external heart assist device with a principal diagnosis from MDC 04 to consider the creation of a new MS–DRG. As noted previously, we could not ascertain from the claims data the resource use specifically attributable to the insertion of a short-term external heart assist device during the hospital stay. Accordingly, we stated we do not believe that the small subset of cases reporting a procedure code describing the insertion of a short-term external heart assist device with a principal diagnosis from MDC 04 warrants the creation of a new MS–DRG for these cases at this time.

Lastly, we explored reassigning cases reporting a procedure code describing the insertion of a short-term external heart assist device with an O.R. procedure assigned to MDC 04 and a principal diagnosis from MDC 04 to other MS–DRGs within MDC 04. However, we stated in the proposed rule our review did not support reassignment of these cases to any other surgical MS–DRGs in MDC 04, as MS–DRGs 163, 164 and 165, where the cases are currently assigned, represent the highest surgical class in the surgical hierarchy of MDC 04. The surgical hierarchy is an ordering of surgical classes from most resource-intensive to least resource-intensive. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class. We note that discussion of the surgical hierarchy is in section II.C.14. of the preamble of this final rule.

As discussed in the proposed rule, while the data analysis reflects that cases that report a procedure code describing the insertion of a short-term external heart assist device with an O.R. procedure assigned to MDC 04 and a principal diagnosis from MDC 04 demonstrate higher average costs in their respective MS–DRGs, as discussed in prior rulemaking (86 FR 44878), the MS–DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may

demonstrate lower than average costs. We further note that section 1886(d)(5)(A) of the Act provides for Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for cases incurring extraordinarily high costs. We stated we will continue to evaluate the clinical coherence and resource consumption costs that impact this subset of cases and their current MS–DRG assignment.

Therefore, for the reasons stated previously, we did not propose to reassign cases reporting procedure codes describing the insertion of a short-term external heart assist device from MDC 04 MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) to MDC 05 MS–DRG 215 (Other Heart Assist System Implant) for FY 2027.

Comment: Many commenters expressed support for CMS' proposal to not reassign cases reporting procedure codes describing the insertion of a short-term external heart assist device from MDC 04 MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) to MDC 05 MS–DRG 215 (Other Heart Assist System Implant) for FY 2027. These commenters stated they support CMS' decision not to proceed with reassignment of these cases.

Response: We thank the commenters for their support.

Comment: Another commenter stated they recognize that CMS appropriately relies on diagnosis and procedure coding, as well as average costs, lengths of stay, and case counts in determining whether a cohort is sufficiently distinct to warrant a different MS–DRG assignment or subgrouping but stated, for the rare subset of pulmonary embolism cases requiring short-term external heart assist devices, high early mortality may materially distort the data by shortening length of stay and lowering total costs for some of the sickest patients. This commenter requested that, in addition to its standard analysis of average costs, lengths of stay (LOS), variance, and volume, CMS evaluate cases by taking into account patient discharge status in order to consider mortality-stratified cost analyses (for example, survivors versus non-survivors) before concluding that cases are not sufficiently distinct to justify further MS–DRG refinement or other payment adjustments.

Response: We thank the commenter for sharing their view and recommendation. As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on clinical factors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases. We will take the commenters' feedback into consideration in future policy development.

Comment: Another commenter recommended that CMS move the assignment of the procedure codes describing the insertion of a short-term external heart assist device from MDC 04 MS–DRGs 163, 164, 165 to MDC 05 (Diseases and Disorders of the Circulatory System) MS–DRG 215 (Other Heart Assist System Implant) to reflect the severity of the patient's condition and the complexity of care provided as well as the incremental resources consumed.

Response: We thank the commenter for its recommendation.

As discussed in the proposed rule, in reviewing this request, we identified six ICD–10–PCS procedure codes that describe the insertion of a short-term external heart assist device. In response to the recommendation that CMS move the assignment of the procedures codes describing the insertion of a short-term external heart assist device from MDC 04 MS–DRGs 163, 164, 165 to MDC 05 MS–DRG 215, we note that these procedure codes are not assigned to MDC 04 in the ICD–10 MS–DRG Definitions Manual Version 43.1. The six ICD–10–CM procedure codes reviewed, as well as their current MDC assignments, are found in the table:

ICD-10-PCS Code	Description	MDC
02HA0RS	Insertion of biventricular short-term external heart assist system into heart, open approach	05
02HA0RZ	Insertion of short-term external heart assist system into heart, open approach	PRE
02HA3RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous approach	05
02HA3RZ	Insertion of short-term external heart assist system into the heart, percutaneous approach	05
02HA4RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach	05
02HA4RZ	Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach	05

As reflected in the ICD–10 MS–DRG Definitions Manual, we note that for the subset of cases reporting a procedure code describing the insertion of a short-term external heart assist device with a principal diagnosis from MDC 04, the logic for case assignment to MDC 04 MS–DRGs 163, 164, 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) is driven by also reporting a procedure code assigned to these MS–DRGs. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 43.1, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software* for complete documentation of the GROUPER logic for MS–DRGs 163, 164, and 165.

We appreciate the commenters' concern regarding ensuring that these cases are assigned to an MS–DRG that reflects the severity of the patient's condition, the complexity of care provided, as well as the incremental resources consumed. We acknowledge the results of the claims analysis as summarized in the proposed rule and this final rule indicate that the average costs of cases that reported a procedure

code describing the insertion of a short-term external heart assist device and a principal diagnosis of pulmonary embolism are higher compared to the average costs for all cases in their assigned MS–DRG. However, considering the impact that moving the diagnoses describing pulmonary embolism to MDC 05 from MDC 04 would have, we continue to believe it would not be appropriate to move these diagnoses into MDC 05 because it would inadvertently cause cases reporting pulmonary embolism with O.R. procedures assigned to MDC 04 to be assigned to an unrelated MS–DRG.

Additionally, as discussed in the proposed rule, we examined the MS–DRGs within MDC 04 and noted that MS–DRGs 163, 164, and 165 represent the highest surgical class in the surgical hierarchy of MDC 04. Therefore, the cases reporting procedure codes describing the insertion of a short-term external heart assist device and a principal diagnosis of pulmonary embolism are most suitably assigned to MS–DRGs 163, 164, and 165, where the cases are currently assigned. There is no other alternative assignment for these procedures in MDC 04. While the data do not support creating a new MS–DRG for cases reporting a procedure code describing the insertion of a short-term external heart assist device and a principal diagnosis of pulmonary embolism, we will continue to monitor the claims data to determine if refinements may be warranted in the future. We note that we will address any proposed modifications in future rulemaking.

Therefore, after consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to not reassign cases reporting procedure codes describing the insertion of a short-term external heart assist device from MDC 04 MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) to MDC 05 MS–DRG 215 (Other Heart Assist System Implant), without modification, for FY 2027.

b. Fluorescence Guided Procedures of the Trunk Region Using Pafolacianine

CYTALUX® (pafolacianine) is a folate receptor–targeted fluorescent optical imaging agent used as an adjunct for the identification of malignant and non-malignant pulmonary lesions in adult patients with known or suspected lung cancer. CYTALUX® binds to the folate receptors on these cancer cells and is endocytosed into folate receptor positive cancer cells. CYTALUX® is administered intravenously prior to thoracic resection procedures and requires use of a near-infrared imaging (NIR) system to illuminate, thereby making cancer visible within the surgical field. CYTALUX® received FDA approval and is indicated as an adjunct for intraoperative identification of malignant and non-malignant pulmonary lesions in adult patients with known or suspected cancer in the lung. In the FY 2027 IPPS/LTCH PPS proposed rule, we noted that CYTALUX® for the lung indication was approved for new technology add-on payments for FY 2024 (88 FR 58810 through 58818), FY 2025 (89 FR 69120 through 69126), and FY 2026 (90 FR 36668). We refer readers to section II.E.5 of the preamble of this final rule for a discussion regarding the FY 2027 status of technologies approved for FY 2026 new technology add-on payments, including CYTALUX® for the lung indication.

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19328 through 19330, we received a request from the manufacturer of CYTALUX® to modify the GROUPER logic of MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) by reassigning cases with an ICD–10–PCS code that describes fluorescence guided surgery using CYTALUX® (pafolacianine) for the lung indication that currently map to the lower severity level MS–DRG 165 (without CC/MCC) to the higher severity level MS–DRG 163 (with MCC) or MS–DRG 164 (with CC). According to the requestor, the utilization of CYTALUX® does not change the surgical procedure but adds significant value and cost to the procedure by improving the surgeon's ability to identify and completely resect malignant tissue. The requestor performed their own analysis of Medicare claims data from October 1, 2023, through March, 31, 2025, and stated they found approximately 135 cases that used CYTALUX® in thoracic resections and that they expect adoption to accelerate as NIR systems become more widely available. Additionally, the requestor stated they found 35 percent of the cases using CYTALUX® within MS–DRG 165, and the average costs of these cases exceeded the average costs of cases that did not report the usage of CYTALUX®. When controlling for procedural and facility variation, the requestor stated they found that CYTALUX cases in MS–DRG 165 were $1,515 (8 percent) higher in cost and that 60 percent of the cases using CYTALUX® in MS–DRG DRG 165 received new technology add-on payments averaging approximately $2,300. The requestor further asserted that their review of the inpatient Standard Analytical Files (SAF) indicated underreporting of CYTALUX® costs due to unclear inpatient drug billing guidance. The requestor stated they found that 64 percent of cases reporting an ICD–10–PCS code that describes fluorescence guided surgery using CYTALUX® (pafolacianine) for the lung indication fall into MS–DRGs 163 or 164. Additionally, the requestor stated while they found that the average length of stay for cases reporting CYTALUX® in MS–DRG 165 is lower (1.9 vs. 2.3 days), the cost profile of these cases aligns more closely with the higher-severity MS–DRGs 164 and 163. According to the requestor, this misalignment leads to underpayment when CYTALUX® cases are grouped into MS–DRG 165, therefore CMS should reassign cases with an ICD–10–PCS code that describes fluorescence guided surgery using CYTALUX® (pafolacianine) for the lung indication from MS–DRG 165 to MS–DRGs 163 or 164 to prevent barriers to hospital adoption of CYTALUX® as NIR system availability expands nationwide.

As discussed in the proposed rule, the following ICD–10–PCS procedure codes describe fluorescence guided surgery using CYTALUX® (pafolacianine) for the lung indication.

ICD-10-PCS Code	Description
8E0W0EN	Fluorescence guided procedure of trunk region using pafolacianine, open approach
8E0W3EN	Fluorescence guided procedure of trunk region using pafolacianine, percutaneous approach
8E0W4EN	Fluorescence guided procedure of trunk region using pafolacianine, percutaneous endoscopic approach
8E0W7EN	Fluorescence guided procedure of trunk region using pafolacianine, via natural or artificial opening
8E0W8EN	Fluorescence guided procedure of trunk region using pafolacianine, via natural or artificial opening endoscopic

In the ICD–10 MS–DRGs Definitions Manual Version 43.1, procedure codes 8E0W0EN, 8E0W3EN, 8E0W4EN, 8E0W7EN and 8E0W8EN are designated as non-O.R. procedures for purposes of MS–DRG assignment, therefore when CYTALUX® is utilized during a procedure for the lung indication, the ICD–10–PCS code describing the surgical procedure will determine the surgical MS–DRG assignment based on the principal diagnosis reported.

In the proposed rule, we stated we examined claims data from the September 2025 update of the FY 2025 MedPAR file for MS–DRGs 163, 164, and 165 to identify cases reporting one of the five procedure codes listed previously that describe fluorescence guided surgery using CYTALUX® (pafolacianine). Our findings are shown in the following table:

MS-DRGS 163 – 165: ALL CASES AND CASES REPORTING PROCEDURE CODES THAT DESCRIBE FLUORESCENCE GUIDED SURGERY USING CYTALUX® (PAFOLACIANINE)				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
163	All cases	13,396	8.2	$40,641
	Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine)	14	4.6	$30,818
164	All cases	14,384	4	$23,393
	Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine)	87	2.7	$22,426
165	All Cases	6,431	2.3	$17,981
	Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine)	58	1.9	$20,854

As shown in the table, in MS–DRG 163, we identified a total of 13,396 cases with an average length of stay of 8.2 days and average costs of $40,641. Of those 13,396 cases, there were 14 cases reporting one of five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), with average costs lower than the average costs in the FY 2025 MedPAR file for MS–DRG 163 ($30,818 compared to $40,641) and a shorter average length of stay (4.6 days compared to 8.2 days). In MS–DRG 164, we identified a total of 14,384 cases with an average length of stay of 4 days and average costs of $23,393. Of those 14,384 cases, there were 87 cases reporting one of five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), with average costs lower than the average costs in the FY 2025 MedPAR file for MS–DRG 164 ($22,426 compared to $23,393) and a shorter average length of stay (2.7 days compared to 4 days). In MS–DRG 165, we identified a total of 6,431 cases with an average length of stay of 2.3 days and average costs of $17,981. Of those 6,431 cases, there were 58 cases reporting one of five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), with average costs higher than the average costs in the FY 2025 MedPAR file for MS–DRG 165 ($20,854 compared to $17,981), and a shorter average length of stay (1.9 days compared to 2.3 days).

In the proposed rule we noted that the 58 cases in MS–DRG 165 reporting one of five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), without a secondary diagnosis code designated as a CC or MCC, have a shorter average length of stay (1.9 days versus 4 days) and lower average costs ($20,854 versus $23,393) when compared to all the cases in MS–DRG 164. Similarly, the 58 cases in MS–DRG 165 reporting one of five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) have a shorter average length of stay (1.9 days versus 8.2 days) and lower average costs ($20,854 versus $40,641) when compared to all the cases in MS–DRG 163. While the data analysis reflects that cases that report one of five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), without a secondary diagnosis code designated as a CC or MCC, demonstrate slightly higher average costs compared to all the cases in MS–DRG 165, we stated in the proposed rule we believe these cases are more suitably grouped to MS–DRG 165, where they are currently assigned, based on the closer similarities in resource utilization compared to all the cases in their respective MS–DRG. As discussed in prior rulemaking (86 FR 44878), the MS–DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. We further noted that section 1886(d)(5)(A) of the Act provides for Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for cases incurring extraordinarily high costs. Moreover, we stated the data do not indicate cases reporting procedure codes that describe fluorescence guided surgery using CYTALUX®

(pafolacianine), without a secondary diagnosis code designated as a CC or MCC, utilize similar resources when compared to the cases assigned to MS–DRGs 163 and 164. We stated that we believe it would be advantageous to allow for more claims data to be analyzed in consideration of any future modifications to the MS–DRGs for which fluorescence guided surgeries using CYTALUX® (pafolacianine) are assigned. We stated we will continue to evaluate the clinical coherence and resource consumption costs that impact this subset of cases and their MS–DRG assignment.

Therefore, for the reasons stated, for FY 2027, we proposed to maintain the current structure of MS–DRGs 163, 164, and 165.

Comment: Several commenters agreed with the proposal to maintain the current structure of MS–DRGs 163, 164, and 165 for FY 2027. Another commenter (the manufacturer) disagreed with the proposal and urged CMS to reassign cases reporting procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) that currently group to MS–DRG 165 to MS–DRG 164 based on demonstrated differences in resource utilization for FY 2027. The commenter noted that 64 percent of the cases that report an ICD–10–PCS code that describes fluorescence guided surgery using CYTALUX® (pafolacianine) for the lung indication already group to MS–DRGs 163 or 164. The commenter asserted that this demonstrates that CYTALUX® (pafolacianine) is predominantly utilized in more complex thoracic oncology procedures and that the remaining cases assigned to MS–DRG 165 represent a subset of cases that continue to incur materially higher costs when compared to all the cases in MS–DRG 165. In their own analysis, the commenter stated they found that 70 percent of the cases reporting procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) that do currently group to MS–DRG 165 trigger new technology add-on payments, which the commenter states indicate hospitals routinely incur costs above beyond the standard payment for that MS–DRG. This commenter also stated that current Medicare claims data likely understate the true resource utilization associated with CYTALUX® (pafolacianine). The commenter stated they reviewed inpatient billing practices and found that 42 percent of hospitals do not consistently report the full acquisition cost of CYTALUX® (pafolacianine) because of uncertainty regarding billing and reporting requirements regarding the appropriate treatment of discarded products under the IPPS and whether Medicare Part B discarded drug billing policies apply in the inpatient setting under Medicare Part A, and frequently fail to capture the full cost associated with utilization of CYTALUX® (pafolacianine), which could materially affect the assessment of resource consumption within MS–DRGs 163, 164, and 165. The commenter further stated that maintaining cases reporting procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) within MS–DRG 165 following new technology add-on payment expiration on September 30, 2026, risks creating a financial disincentive to adoption and will limit beneficiary access to a technology that can improve intraoperative visualization and facilitate more complete resections.

Response: We thank the commenters for their feedback.

As discussed in the proposed rule, based on our review and analysis of the claims data, the findings appear to indicate that cases reporting one of five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) for the lung indication, without a secondary diagnosis code designated as a CC or MCC, have a shorter average length of stay and lower average costs when compared to all the cases in MS–DRGs 163 and 164. While the data analysis reflects that the cases that report one of five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), without a secondary diagnosis code designated as a CC or MCC, demonstrate slightly higher average costs compared to all the cases in MS–DRG 165, we continue to believe these cases are more suitably grouped to MS–DRG 165, where they are currently assigned, based on the closer similarities in resource utilization compared to all the cases in their respective MS–DRG.

In response to the commenter's assertion that maintaining cases reporting procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) within MS–DRG 165 risks creating a financial disincentive to adoption and will limit beneficiary access to this technology, as we have stated in prior rulemaking, we rely on providers to assess the needs of their patients and provide the most appropriate treatment. It is not appropriate for facilities to deny treatment to beneficiaries needing a specific type of therapy or treatment that potentially involves increased costs (86 FR 44847). It would also not be appropriate to consider modifications to the MS–DRG assignment of cases reporting the performance of a procedure that identifies and describes a specific technology solely as an incentive for providers to purchase and utilize one technology over another.

Additionally, in consideration of the concerns expressed by the manufacturer with respect to suspected facility billing and reporting inaccuracies and therefore, the reliability of the claims data, we believe it would be premature to finalize any MS–DRG modifications cases that report an ICD–10–PCS code that describes fluorescence guided surgery using CYTALUX® (pafolacianine) for the lung indication at this time. We will continue to examine the claims data for cases reporting the ICD–10–PCS code that describes fluorescence guided surgery using CYTALUX® (pafolacianine) for the lung indication to determine if refinements may be warranted in the future.

Therefore, after consideration of the public comments received, and for the reasons previously described, we are finalizing our proposal to maintain the current structure of MS–DRGs 163, 164, and 165 for FY 2027, without modification.

3. MDC 05 (Diseases and Disorders of the Circulatory System): WiSE® CRT System

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19330 through 19334), the WiSE® CRT System is an implantable cardiac pacing system that delivers left ventricular endocardial pacing (LVEP) specifically for cardiac resynchronization therapy (CRT) without the use of wires or leads going into the heart. The WiSE® CRT System was designed to stimulate the endocardial surface of the left ventricle (LV) without a transvenous LV lead. Working in conjunction with previously implanted standard commercially available pacemakers or defibrillators, the WiSE® CRT System utilizes a wireless ultrasound-based energy transmission to a small, implanted electrode in the LV endocardium, which converts the ultrasound signal into pacing energy. According to the manufacturer, the WiSE® CRT System is engineered to benefit patients with heart failure who were previously untreatable with conventional CRT or who are considered at high risk for placement of a coronary sinus (CS) lead for CRT upgrades. The WiSE® CRT system consists of four components: the receiver, also known as the receiver electrode or electrode (implanted via catheter), delivery sheath, battery and transmitter. An external programmer is used to adjust parameters of the battery.

The WiSE® CRT System was approved for new technology add-on payments for FY 2026 (90 FR 36821 through 36823). We refer readers to section II.E.4.a of the preamble of this final rule for a discussion regarding the FY 2027 status of technologies approved for FY 2026 new technology add-on payments, including the WiSE® CRT System.

In support of the new technology add-on payment application that was submitted for FY 2026 consideration, we discussed in the proposed rule that we received a request to create new ICD–10–PCS codes to differentiate cardiac procedures that involve the insertion of an implantable endocardial pacing system, such as the WiSE® CRT System, and a code proposal was displayed in association with the Spring 2025 ICD–10 Coordination and Maintenance Committee Update. As a result, effective October 1, 2025 (FY 2026), we implemented the following ICD–10–PCS procedure codes to identify the insertion of the WiSE® CRT System: X2HN37B (Insertion of endocardiac pacing electrode into left ventricle, percutaneous approach, new technology group 11) in combination with XHH80HB (Insertion of ultrasound transmitter and battery for endocardiac pacing electrode into chest subcutaneous tissue and fascia, open approach, new technology group 11). In the ICD–10 MS–DRGs Version 43.1, this procedure code combination is assigned to MS–DRGs 242, 243, and 244 (Permanent Cardiac Pacemaker Implant with MCC, with CC, without MCC respectively) in a logic list referred to as ''CARDIAC PACEMAKER DEVICE'' that includes 720 other ICD–10–PCS procedure code combinations that identify the insertion of cardiac pacemakers. When reported as standalone procedures, ICD–10–PCS code X2HN37B is assigned to MDC 05 MS–DRGs 264 (Other Circulatory System O.R. Procedures) and ICD–10–PCS code XHH80HB is assigned to MDC 05 MS–DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with and without MCC, respectively). We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 43.1, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software* for complete documentation of the GROUPER logic for MS–DRGs 242, 243, 244, 258, 259 and 264.

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule, we received a request to reassign the ICD–10–PCS procedure codes that describe the insertion of the WiSE® CRT System from MS–DRGs 242, 243, and 244 to MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively). The requestor stated that insertion of the WiSE® CRT System electrode, which is described by ICD–10–PCS code X2HN37B, is similar both clinically and in terms of resource utilization, to the procedure codes that describe the insertion of leadless pacemakers that are currently assigned to MS–DRGs 228 and 229. The requestor further stated that the cases assigned to MS–DRGs 242, 243, and 244 involve traditional pacemaker devices with leads and are dissimilar to the WiSE® CRT System. According to the requestor, based on clinical function, implant methodology, and patient profile, the WiSE® CRT System more closely aligns with leadless pacemaker technology than with traditional pacemaker procedures as the use of multi-modality imaging, arterial navigation, and ultrasound-guided transmitter placement adds to both time and resource utilization, paralleling the procedural profile of leadless pacemaker implantation rather than traditional pacemaker surgery. Therefore, the requestor suggested that CMS reassign ICD–10–PCS code X2HN37B that describes the insertion of the electrode of the WiSE® CRT System to MS–DRGs 228 and 229 to appropriately group the procedure with the leadless pacemaker cases.

To begin our analysis, we reviewed the procedure codes as discussed in the proposed rule. As noted previously, a code proposal was displayed as part of the ICD–10 Coordination and Maintenance Committee Spring 2025 update process to create unique ICD–10–PCS codes to describe the insertion of an implantable endocardial pacing system such as the WiSE® CRT System. As discussed in prior rulemaking (86 FR 44805), we used our established process to examine the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment of new procedure codes X2HN37B and XHH80HB for FY 2026. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We have noted in prior rulemaking that this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code.

Because the codes that describe the insertion of the WiSE® CRT System were effective October 1, 2025 (FY 2026), in the FY 2027 IPPS/LTCH PPS proposed rule, we stated we would not expect the codes to be reported in the FY 2025 claims data used for the proposed rule. We stated we examined claims data from the September 2025 update of the FY 2025 MedPAR file for MS–DRGs 242, 243, and 244 and confirmed that there were zero cases reporting the procedure codes describing the insertion of the WiSE® CRT System across MS–DRGs 242, 243, and 244.

We reviewed this issue and noted the requestor is correct that the ICD–10–PCS codes that describe the insertion of intracardiac pacemakers, also known as ''leadless'' pacemakers, are currently assigned to MS–DRGs 228 and 229. In leadless pacemakers, the components are combined into a single device implanted within a heart chamber. As discussed in the proposed rule, they do not require a chest incision, a subcutaneous pocket or a tunneled lead. These devices are implanted via a femoral vein transcatheter approach and then advanced into the heart chamber, fixed to the chamber wall, and released. Conventional pacemakers are comprised of a metal generator (battery + electronics) placed under the skin in the upper chest, connected by one or more insulated wires (leads) threaded into the heart. We stated we agree that leadless pacemakers and the WiSE® CRT System electrode are clinically coherent in that both eliminate the need for traditional, wire-based leads that run from the device to the heart muscle to transmit electrical impulses to the heart. We further stated we believe that the electrode of the WiSE® CRT System is more closely aligned with the leadless pacemakers assigned to MS–DRGs 228 and 229 as compared to the insertion of conventional pacemakers assigned to MS–DRGs 242, 243, and 244. While our analysis did not identify any cases reporting the procedure code that describes the insertion of the electrode of the WiSE® CRT System, based on our review of the clinical issues, and recognizing that it is expected that some Medicare patients will receive the WiSE® CRT System on an inpatient basis, we stated we believe reassigning ICD–10–PCS code X2HN37B that describes the insertion of the endocardiac pacing electrode into the left ventricle from MS–DRG 264 to MDC 05 MS–DRGs 228 and 229 would improve clinical coherence in these MS–DRGs.

For these reasons, for FY 2027, we proposed to reassign procedure code X2HN37B (Insertion of endocardiac pacing electrode into left ventricle, percutaneous approach, new technology group 11) from MS–DRG 264 to MS–DRGs 228 and 229 for clinical coherence and to better account for the anticipated resources required. We also proposed to delete the procedure code combination of X2HN37B and XHH80HB from the GROUPER logic of MS–DRGs 242, 243, and 244. Under this proposal, procedure code X2HN37B will not need to be reported as part of a procedure code combination or procedure code ''cluster'' to satisfy the logic for assignment to MS–DRGs 228 and 229. When reported as a standalone procedure, ICD–10–PCS code XHH80HB (Insertion of ultrasound transmitter and battery for endocardiac pacing electrode into chest subcutaneous tissue and fascia, open approach, new technology group 11) will be assigned to new MDC 05 MS–DRG 210 (Cardiac Pacemaker Revision or Device Replacement with MCC) and new MS–DRG 211 (Cardiac Pacemaker Revision or Device Replacement without MCC), which are discussed later in this section.

Comment: Commenters supported the proposal to reassign procedure code X2HN37B from MS–DRG 264 to MS–DRGs 228 and 229 and the proposal to delete the procedure code combination of X2HN37B and XHH80HB from the GROUPER logic of MS–DRGs 242, 243, and 244 for FY 2027. Several commenters specifically stated that they strongly support the proposed changes and stated that they believe CMS has developed a reasonable approach for ensuring that the MS–DRGs maintain clinical coherence and reflect the resource intensity of procedures when performed in the inpatient setting.

Response: We appreciate the commenters' support.

Comment: Another commenter disagreed with the proposal to reassign procedure code X2HN37B from MS–DRG 264. The commenter noted that in the FY 2027 IPPS/LTCH PPS proposed rule, CMS stated it found zero cases reporting the procedure codes describing the insertion of the WiSE® CRT System in the examination of claims data from the September 2025 update of the FY 2025 MedPAR file, yet proposed to reassign procedure code X2HN37B to MS–DRGs 228 and 229 without any underlying claims data to validate if the proposed reassignment to these MS–DRGs would be appropriate. The commenter further stated that it is unclear whether CMS' assumption about the clinical use of this technology will align with actual practice patterns. Therefore, the commenter recommended that CMS defer the proposed reassignment of procedure code X2HN37B from MS–DRG 264 to MS–DRGs 228 and 229 for FY 2027 until MedPAR claims data are available to support an evidence-based reassignment determination and preserve clinical and resource cohesion among these MS–DRGs. The commenter also recommended that CMS specify that the assignment of ICD–10–PCS code XHH80HB (Insertion of ultrasound transmitter and battery for endocardiac pacing electrode into chest subcutaneous tissue and fascia, open approach, new technology group 11) to new MS–DRGs 210 and 211 is a provisional assignment should the proposal for FY 2027 be finalized, and encouraged CMS to revisit this assignment in future rulemaking once more robust claims data are available.

Response: We thank the commenter for their feedback and for sharing their concerns.

In response to the suggestion that CMS defer the proposed reassignment of procedure code X2HN37B from MS–DRG 264 to MS–DRGs 228 and 229, while we recognize that our analysis did not identify any applicable cases, we continue to believe that the proposed reassignment would improve clinical coherence as compared to the current assignment and do not agree that a delay is necessary or appropriate. As stated earlier, the WiSE® CRT System is an implantable cardiac pacing system that delivers LVEP specifically for CRT without the use of wires or leads going into the heart. Both leadless pacemakers and the WiSE® CRT System share the goal of pacing the heart without traditional wires. We continue to believe that procedure code X2HN37B is more closely aligned with the procedure codes that describe the insertion of leadless pacemakers assigned to MS–DRGs 228 and 229 as compared to the procedure codes that describe the insertion of conventional pacemakers assigned to MS–DRGs 242, 243, and 244. CMS will continue to monitor and analyze the claims data with respect to procedure codes X2HN37B and XHH80HB to determine if future revisions are warranted.

Therefore, after consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to reassign procedure code X2HN37B (Insertion of endocardiac pacing electrode into left ventricle, percutaneous approach, new technology group 11) from MS–DRG 264 to MS–DRGs 228 and 229, without modification, effective October 1, 2026, for FY 2027. We are also finalizing our proposal to delete the procedure code combination of X2HN37B and XHH80HB from the GROUPER logic of MS–DRGs 242, 243, and 244, without modification, for FY 2027. Under this finalization, procedure code X2HN37B will not need to be reported as part of a procedure code combination or procedure code ''cluster'' to satisfy the logic for assignment to MS–DRGs 228 and 229. When reported as a standalone procedure, ICD–10–PCS code XHH80HB (Insertion of ultrasound transmitter and battery for endocardiac pacing electrode into chest subcutaneous tissue and fascia, open approach, new technology group 11) will be assigned to new MDC 05 MS–DRG 210 (Cardiac Pacemaker Revision or Device Replacement with MCC) and new MS–DRG 211 (Cardiac Pacemaker Revision or Device Replacement without MCC), which are discussed later in this section.

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule, consistent with our annual review of the MS–DRGs, we consider changes in resource consumption, treatment patterns, technology, and any other factors that may change the relative use of hospital resources. In our review of the claims data from the September 2025 update of the FY 2025 MedPAR file for this request, we stated we identified a low volume of cases for MS–DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with MCC and without MCC, respectively), where procedure code XHH80HB is assigned when reported as a standalone procedure in Version 43.1. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
258	35	7	$28,275
259	68	3.3	$16,833

In light of the initial findings of only 35 cases for MS–DRG 258 and 68 cases in MS–DRG 259, we further reviewed the MedPAR claims data for cases assigned to MS–DRGs 258 and 259 for the past 5 fiscal years. As reflected in the following tables, these data indicate that the number of cases grouping to MS–DRGs 258 and 259 has generally declined.

FY and MedPAR Data Reviewed for MS-DRG 258	Number of Cases	Average Length of Stay	Average Costs
FY 2023 (FY 2021 MedPAR)	579	6.3	$22,031
FY 2024 (FY 2022 MedPAR)	572	6.3	$23,522
FY 2025 (FY 2023 MedPAR)	557	6.6	$24,910
FY 2026 (FY 2024 MedPAR)	484	6.2	$24,662
FY 2027 (FY 2025 MedPAR)	35	7	$28,275

FY and MedPAR Data Reviewed for MS-DRG 259	Number of Cases	Average Length of Stay	Average Costs
FY 2023 (FY 2021 MedPAR)	652	3.1	$16,695
FY 2024 (FY 2022 MedPAR)	693	3	$16,520
FY 2025 (FY 2023 MedPAR)	696	3	$15,912
FY 2026 (FY 2024 MedPAR)	692	3	$16,546
FY 2027 (FY 2025 MedPAR)	68	3.3	$16,833

In the proposed rule we noted that, if, during our annual MS–DRG analysis we identify that there are only a few patients in a respective MS–DRG, consistent with our established process in deciding whether to propose to make further modifications, we consider if there have been potential changes in the clinical characteristics of the patients, treatment patterns, or resource utilization. A principle of the MS–DRGs and the characteristics of a meaningful DRG classification scheme is the ability to detect such changes and accordingly, propose clinically appropriate modifications that are also consistent with resource utilization. We have noted in prior rulemaking that we prefer to have a substantial number of cases in an MS–DRG because having larger clinically cohesive groups within an MS–DRG provides greater stability for annual updates to the relative payment weights. In light of these considerations, and the low volume of cases in MS–DRGs 258 and 259, we stated we believed it was appropriate to further analyze how to potentially reclassify these cases.

Accordingly, using the September 2025 update of the FY 2025 MedPAR file, we examined whether there were other MS–DRGs to which these cases could appropriately be reassigned. As discussed in the proposed rule, we noted that surgical MS–DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively) also include procedure codes related to cardiac pacemakers. A cardiac pacemaker device replacement (generator change) is a procedure to change an old battery (generator) for a new one. A cardiac pacemaker revision is a procedure that may involve replacing, moving or adding leads, or fixing the pocket of the generator. While the terms are distinct, both cardiac pacemaker revision and cardiac pacemaker replacement procedures are performed in order to improve the way the cardiac pacemaker system works.

As such, we reviewed the claims data from the September 2025 update of the FY 2025 MedPAR file for MS–DRGs 260, 261, and 262 to examine the resource utilization associated with cases assigned to these MS–DRGs. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
260	2,730	7.5	$29,313
261	2,847	3.5	$17,151
262	795	2.5	$15,119

As part of this analysis, we also reviewed the MS–DRGs for cases reporting ICD–10–PCS codes describing cardiac pacemaker device replacement procedures by severity claims data for MS–DRG 259 because this MS–DRG includes cases reporting a CC as well as cases reporting a NonCC. Therefore, we analyzed the claims data to determine the number of cases, the average length of stay, and average costs for the cases in MS–DRG 258 and 259 by severity level (1=MCC, 2=CC, and 3=NonCC). Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
258-1	35	7	$28,275
259-2	42	4	$18,246
259-3	26	2	$14,552

As shown in the data, the 35 cases reporting an MCC in MS–DRG 258 have an average length of stay of 7 days with average costs of $28,275, which is comparable to the cases in MS–DRG 260 reporting an MCC that have an average length of stay of 7.5 days with average costs of $29,313. The 42 cases reporting a CC in MS–DRG 259 have an average length of stay of 4 days with average costs of $18,246, which is comparable to the cases in MS–DRG 261 reporting a CC that have an average length of stay of 3.5 days with average costs of $17,151. The 26 cases not reporting a CC or an MCC in MS–DRG 259 have an average length of stay of 2 days with average costs of $14,552, which is comparable to the cases in MS–DRG 262 not reporting a CC or an MCC that have an average length of stay of 2.5 days with average costs of $15,119.

As discussed in the proposed rule, we reviewed these findings and stated we believe that it may no longer be necessary to subdivide these MS–DRGs based on the cardiac pacemaker revision or device replacement procedure codes reported. We noted that DRGs that differentiate cases reporting procedure codes describing cardiac pacemaker device replacement from cases reporting procedure codes describing cardiac pacemaker revisions have existed since the enactment of The Social Security Amendments of 1983 (Pub. L. 98–21), which established a national DRG-based hospital prospective payment system for all Medicare patients (48 FR 39878).

We stated in the proposed rule that our analysis of claims data from the September 2025 update of the FY 2025 MedPAR file showed that in the 43 years since the DRGs for cases reporting cardiac pacemaker revision procedures and cases reporting cardiac pacemaker device replacement procedures were created, the resource utilization appears to now be aligned, and the cases are clinically coherent, and therefore we stated we believe it is appropriate to now restructure these MS–DRGs accordingly. Specifically, we stated we believe it would be appropriate to delete MS–DRGs 258, 259, 260, 261, and 262, and to create new MS–DRGs for cases reporting ICD–10–PCS codes describing cardiac pacemaker revision or device replacement procedures, based on our analysis and review of the cases grouping to these MS–DRGs.

The following table illustrates our simulation of the proposal.

Proposed New MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX Cardiac Pacemaker Revision or Device Replacement	6,475	5.1	$22,086

Consistent with our established process as discussed in section II.C.1.b. of the preamble of the proposed rule and this final rule, once the decision has been made to propose to make further modifications to the MS–DRGs, such as creating a new base MS–DRG, all five criteria to create subgroups must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of the preamble of the proposed rule and this final rule. As shown, a three-way split of the proposed new MS–DRG failed to meet the criterion that there be at least a 20 percent difference in average costs between the CC and NonCC subgroup.

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	2,765	7.5	$29,300
With CC	2,889	3.5	$17,167
Without CC/MCC	821	2.5	$15,101

As discussed in section II.C.1.b. of the preamble of the proposed rule and this final rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the ''with MCC'' and ''without MCC'' subgroups and found that all five criteria were met. The following table illustrates our findings.

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	2,765	7.5	$29,300
Without MCC	3,710	3.3	$16,710

For the proposed new MS–DRGs for cases reporting procedure codes describing cardiac pacemaker revision or device replacement, there is at least (1) 500 cases in the MCC group and 500 cases in the without MCC group; (2) 5 percent of the cases in the MCC group and 5 percent in the without MCC group; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

Therefore, for FY 2027, we proposed to delete MS–DRGs 258, 259, 260, 261, and 262 and to create two new MS–DRGs with a two-way severity level split for cases reporting procedure codes describing cardiac pacemaker revision or device replacement in MDC 05. These proposed new MS–DRGs are proposed new MS–DRG 210 (Cardiac Pacemaker Revision or Device Replacement with MCC) and proposed new MS–DRG 211 (Cardiac Pacemaker Revision or Device Replacement without MCC). We refer the reader to Table 6P.2a associated with the FY 2027 IPPS/LTCH PPS proposed rule (which is available on the CMS website at: *https://www.cms.gov/*

Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index) for the list of procedure codes we proposed to define in the logic for the proposed new MS–DRGs. We note that discussion of the surgical hierarchy for the proposed modification is discussed in section II.C.14. of the preamble of the proposed rule.

Comment: Commenters supported the proposal to delete MS–DRGs 258, 259, 260, 261, and 262 and to create two new MS–DRGs with a two-way severity level split for cases reporting procedure codes describing cardiac pacemaker revision or device replacement in MDC 05 for FY 2027.

Response: We appreciate the commenters' support.

Comment: Other commenters expressed concern related to the proposed two-way severity level split in the new MS–DRGs for cases reporting procedure codes describing cardiac pacemaker revision or device replacement. The commenters noted the proposed consolidation collapses the existing three-way severity split in MS–DRGs 260, 261, and 262 (that is a ''with MCC'', ''with CC'', and ''without CC/MCC'' split) into a two-way split (that is a ''with MCC'' and ''without MCC'' split). These commenters stated that the review of the claims data from the September 2025 update of the FY 2025 MedPAR file showed that cases reporting procedure codes describing cardiac pacemaker revision or device replacement with a secondary diagnosis designated as a CC have average costs of $17,167, while cases reporting procedure codes describing cardiac pacemaker revision or device replacement without a secondary diagnosis designated as a CC or an MCC have average costs of $15,101, which represents a difference of approximately 13.7 percent. The commenters acknowledged that this differential is below the 20 percent threshold required for a three-way split under CMS' established methodology; however, they stated that this differential is meaningful enough that hospitals that disproportionately treat Medicare beneficiaries with secondary diagnoses designated as CCs, such as academic medical centers and safety-net hospitals, could have to absorb a structural payment shortfall under the proposed two-way structure. These commenters requested that CMS commit in the final rule to monitoring the claims data for new MS–DRGs 210 and 211 to reassess whether a three-way severity split should be reintroduced in future rulemaking.

Response: We appreciate the commenters' feedback and thank the commenters for sharing their concerns.

As discussed in the FY 2008 IPPS final rule (72 FR 47169), the objective in establishing criteria to create subgroups was to create homogeneous subgroups that are significantly different from one another in terms of resource use, that have enough volume to be meaningful, and that improve our ability to explain variance in resource use. As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19333), we applied the criteria for the proposed new base MS–DRG and found that the criteria for a three-way split failed. Specifically, a three-way split of the proposed new MS–DRG failed to meet the criterion that there be at least a 20 percent difference in average costs between the CC and NonCC subgroup. We then applied the criteria for a two-way split for the ''with MCC'' and ''without MCC'' subgroups and found that all five criteria were met. Therefore, we proposed to create two new MS–DRGs with a two-way severity level split for cases reporting procedure codes describing cardiac pacemaker revision or device replacement in MDC 05.

As discussed in prior rulemaking (86 FR 44878), the MS–DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. It is generally expected that as a result of the annual MS–DRG reclassifications that are finalized, the experience of different categories of hospitals may differ based on the population of patients they treat and the services offered by the facility. We also provide outlier payments to mitigate extreme loss on individual cases.

In response to the recommendation that CMS continue to closely monitor claims to determine whether a three-way split should be restored in future rulemaking, we note that, as stated in the preamble of the annual IPPS rulemakings, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. We include these changes as part of our annual IPPS rulemaking, which provides the public, including any interested parties, the opportunity to review and comment on these proposals.

Therefore, after consideration of the public comments we received, we are finalizing our proposal to delete MS–DRGs 258, 259, 260, 261, and 262, effective October 1, 2026, without modification, for FY 2027. We are also finalizing our proposal to create new MS–DRG 210 (Cardiac Pacemaker Revision or Device Replacement with MCC) and new MS–DRG 211 (Cardiac Pacemaker Revision or Device Replacement without MCC) for cases reporting procedure codes describing cardiac pacemaker revision or device replacement effective October 1, 2026, without modification, for FY 2027. We refer the reader to Table 6P.2a associated with the FY 2027 IPPS/LTCH PPS proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) for the list of procedure codes we are finalizing to define in the logic for each of the new MS–DRGs. We note that discussion of the surgical hierarchy for the finalized modification is discussed in section II.C.14. of the preamble of this final rule.

Comment: Other commenters stated they reviewed table 6P.2a associated with the FY 2027 IPPS/LTCH PPS proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) that includes the list of procedure codes CMS proposed to define in the logic for proposed new MS–DRGs 210 and 211 and stated they encountered inconsistencies when grouping cases using the Version 44 test GROUPER that was made publicly available in association with the FY 2027 IPPS/LTCH PPS proposed rule on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.* A commenter stated that although Table 6P.2a lists the ICD–10–PCS codes proposed for assignment to MS–DRGs 210 and 211, the relationship between those codes and actual Version 44 GROUPER results could not be fully validated without additional detail on the logic interactions, including surgical hierarchy rules and the effects of removing cluster requirements.

The commenters stated they identified six procedure codes that should map to new MS–DRGs 210 or 211 based on their inclusion in Table 6P.2a, but when assessed with the Version 44 test GROUPER, instead mapped to MS–DRGs 242, 243, and 244 (Permanent Cardiac Pacemaker Implant with MCC, with CC, without MCC respectively). Specifically, the

commenters stated they entered ICD–10–PCS procedure codes 02PA3MZ (Removal of cardiac lead from heart, percutaneous approach), 0JPT0PZ (Removal of cardiac rhythm related device from trunk subcutaneous tissue and fascia, open approach), 02H63JZ (Insertion of pacemaker lead into right atrium, percutaneous approach), 02HK32Z (Insertion of monitoring device into right ventricle, percutaneous approach), 02HK3MZ (Insertion of cardiac lead into right ventricle, percutaneous approach) and 0JH605Z (Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach) and said MS–DRG 244 was assigned instead of the anticipated MS–DRG 211, which appears to be inconsistent with both the clinical scenario and the intended MS–DRG definitions.

Lastly, these commenters stated that they performed their own analysis of the supplemental After Outliers Removed (AOR)/Before Outliers Removed (BOR) file available in association with the FY 2027 IPPS/LTCH PPS proposed rule on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps* and stated it was unclear why over 40 MS–DRGs within MDC 05 demonstrate variances in volume between the Version 43 and Version 44. The commenters stated the magnitude and distribution of these shifts make it difficult for hospitals to reliably model financial and operational impacts using standard tools and the case-by-case test GROUPER. Another commenter noted CMS indicated in its discussion that cases involving WiSE® CRT procedures would shift into MS–DRGs 228 and 229. However, their review of the AOR file suggested a decline in case volumes within MS–DRGs 228 and 229.

Response: We thank the commenters for their feedback.

In table 6P.2a associated with the FY 2027 IPPS/LTCH proposed rule, the list of procedure codes we proposed to define the logic for the proposed new MS–DRGs 210 and 211 included 27 ICD–10–PCS codes designated as ''operating room procedures'' and 60 ICD–10–PCS codes designated as ''non-operating room procedures.'' Consistent with our proposal to delete MS–DRGs 258, 259, 260, 261, and 262, and to create new MS–DRGs 210 and 211 for cases reporting ICD–10–PCS codes describing cardiac pacemaker revision or device replacement procedures, this list was developed by combining the 21 ICD–10–PCS procedure codes designated as ''non-operating room procedures'' currently in the logic for MS–DRGs 258 and 259, with the 27 ICD–10–PCS codes designated as ''operating room procedures'' and 39 ICD–10–PCS codes designated as ''non-operating room procedures'' currently in the logic for MS–DRGs 260, 261, and 262. We further note that the proposal to create new MS–DRGs 210 and 211 did not involve proposing to create procedure code combinations in the GROUPER logic of the proposed new MS–DRGs. We refer the reader to the ICD–10 MS–DRG Version 43.1 Definitions Manual (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*) for complete documentation of the GROUPER logic for MS–DRGs 258, 259, 260, 261 and 262.

As discussed in the proposed rule and earlier in this section, existing MS–DRGs 242, 243, and 244 are defined by a logic list referred to as ''CARDIAC PACEMAKER DEVICE'' that includes 721 ICD–10–PCS procedure code combinations that identify the insertion of cardiac pacemakers. The code combinations are represented by two ICD–10–PCS procedure codes; one ICD–10–PCS code for the insertion of a lead by site along with one ICD–10–PCS code for the insertion of a generator by site. As discussed in prior rulemaking (90 FR 36608 through 36610), it is correct that under the GROUPER software program some collections of ICD–10–PCS procedure codes have a different set of attributes, independent of those of the codes that make them up (that is, their ''components''). These collections of ICD–10–PCS procedure codes are called clusters. A routine program in the GROUPER, upstream of the MS–DRG assignment logic, searches the claim for clusters. When a cluster is found, it is added to the list of procedures found on the claim. Clusters may be ''restricted'' by Major Diagnostic Category (MDC), and a restricted cluster inhibits the use of its procedure code component attributes for the MDC's MS–DRG assignment logic. For purposes of our analysis, and consequently our proposal, for new MS–DRGs 210 and 211, we did not remove the restriction logic under MDC 05 for the procedure code combinations within MS–DRGs 242, 243, and 244 to maintain the differentiation in MS–DRG assignment between cases that report an ICD–10–PCS code for the insertion of a lead along with an ICD–10–PCS code for the insertion of a generator as opposed to cases that report ICD–10–PCS codes that describe performance of standalone procedures.

Similar to case assignment for any other MS–DRG, assignment to MS–DRGs 210 and 211 would also be dependent on the absence of other procedure codes that could affect MS–DRG assignment on the claim. If other procedure codes that could affect MS–DRG assignment are also reported on the claim along with procedure codes describing cardiac pacemaker revision or device replacement, the MS–DRG assignment can vary depending on the procedure codes reported. We reviewed the ICD–10–PCS codes identified by commenters and agree that MS–DRG 244 is assigned when ICD–10–PCS procedure codes 02PA3MZ, 0JPT0PZ, 02H63JZ, 02HK32Z, 02HK3MZ and 0JH605Z are reported with a principal diagnosis from MDC 05, without reporting a secondary diagnosis designated as a CC or an MCC. This is an expected outcome as the procedure code combination of ICD–10–PCS code 02H63JZ (Insertion of pacemaker lead into right atrium, percutaneous approach) with 0JH605Z (Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach) is listed in the logic list referred to as ''CARDIAC PACEMAKER DEVICE'' in MS–DRGs 242, 243, and 244. We further note that this assignment is consistent using both the Versions 43.1 GROUPER software and the Version 44 test GROUPER software.

We disagree that the resulting MS–DRG assignment to MS–DRG 244 in the scenario provided by the commenters is inconsistent with the intended MS–DRG definitions. As discussed in the FY 2027 IPPS/LTCH proposed rule, a cardiac pacemaker device replacement (generator change) is a procedure to change an old battery (generator) for a new one, while a cardiac pacemaker revision is a procedure that may involve replacing, moving, or adding leads, or fixing the pocket of the generator. We believe that cases that involve changing an old battery, replacing, moving or adding leads, or fixing the pocket of the generator as standalone procedures are clinically distinct from cases that involve the insertion of both a lead and a generator that would be assigned to MS–DRGs 242, 243, or 244.

With respect to concerns related to the apparent MS–DRG shifts in the Version 44 AOR/BOR file for MS–DRGs in MDC 05, we appreciate the commenters' feedback. We note that, as stated in the proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2025 update of the FY 2025 MedPAR file, which contains hospital bills received from October 1, 2024, through

September 30, 2025. In comparison, as also stated in the proposed rule, the AOR/BOR file, which contains data used to develop the proposed MS–DRG relative weights for FY 2027, includes discharges occurring on and after October 1, 2024, through September 30, 2025, based on bills received by CMS through December 31, 2025.

We also note, that as discussed in section II.C.12.c.1 of the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19370 through 19371) and this final rule, we proposed to change the severity level designation of diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), Z59.02 (Unsheltered homelessness), Z59.10 (Inadequate housing, unspecified), Z59.11 (Inadequate housing environmental temperature), Z59.12 (Inadequate housing utilities), Z59.19 (Other inadequate housing), Z59.811 (Housing instability, housed, with risk of homelessness), Z59.812 (Housing instability, housed, homelessness in past 12 months) and Z59.819 (Housing instability, housed unspecified) from CC to NonCC for FY 2027. Additionally, based on the changes that we proposed to make for FY 2027, we proposed to modify the existing surgical hierarchy of MDC 05 as illustrated in the tables available in section II.C.14 of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule. As discussed in section II.C.14, some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. Therefore, although we note the AOR/BOR file is used for a distinct but related aspect of IPPS/LTCH PPS rulemaking, it is expected that shifts in the assignment of cases would be reflected in the AOR/BOR file when we propose a change in the severity level designation of any ICD–10–CM diagnosis code or to modify the existing surgical hierarchy for an MDC.

We intend to continue to explore alternative options and additional reports that could be made available to further facilitate modeling of the financial and operational impacts of the MS–DRG classification proposed changes.

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule, in our evaluation of this MS–DRG classification request, we also noted that we identified 7,772 cases in base MS–DRG 264 (Other Circulatory System O.R. Procedures) with an average length of stay of 9.4 days and average costs of $29,545. Accordingly, in connection with our analysis we stated we applied the five criteria as described in section II.C.1.b. of the preamble of the proposed rule and this final rule to determine if it would be appropriate to subdivide cases currently assigned to base MS–DRG 264 into severity levels. This analysis includes two years of MedPAR claims data to compare the data results from one year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also to validate that the established severity levels within a base MS–DRG are supported. Therefore, we reviewed the claims data for base MS–DRG 264 using the September 2024 update of the FY 2024 MedPAR file and the September 2025 update of the FY 2025 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2026 and FY 2027, respectively. Our findings are shown in the following table:

FY Data	Number of Cases	Number of Cases MCC	Number of Cases CC	Number of Cases Non CC	Average Costs No Split	Average Costs MCC	Average Costs CC	Average Costs Non CC	Average Costs MCC/CC combo	Average Costs CC/NonCC combo
2024	7,762	5,276	2,332	154	$29,236	$33,846	$19,720	$15,393	$29,516	$19,452
2025	7,772	5,255	2,372	145	$29,545	$34,100	$20,251	$16,501	$29,793	$20,035

First, we applied the criteria to create subgroups for the three-way severity level split. We found that the criterion that there be at least 5 percent of the patients are in each of the MCC, CC, and NonCC subgroups failed based on the data in both the FY 2024 and FY 2025 MedPAR files. The criterion that there be at least 500 cases for each subgroup also was not met, as shown in the table for both years. Specifically, for the ''with MCC'', ''with CC'', and ''without CC/MCC'' split, there were only 154 cases in the ''without CC/MCC'' subgroup based on the data in the FY 2024 MedPAR file and only 145 cases in the ''without CC/MCC'' subgroup based on the data in the FY 2025 MedPAR file.

As discussed in section II.C.1.b. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the ''with MCC'' and ''without MCC'' subgroups and found that all five criteria were met for both years. For both years, there are at least (1) 500 cases in the MCC group and 500 cases in the without MCC group; (2) 5 percent of the cases in the MCC group and 5 percent in the without MCC group; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that a ''with MCC'' and ''without MCC'' severity level split increases the explanatory power of the base MS–DRG in capturing differences in expected cost between the MS–DRG severity level splits by at least 3 percent and thus improves the overall accuracy of the IPPS payment system.

As discussed in the proposed rule, as the claims data support a two-way severity level split for cases reporting other circulatory system O.R. Procedures, for FY 2027, we proposed to delete base MS–DRG 264 and proposed to create two new MS–DRGs with a two-way severity level split for cases reporting other circulatory system O.R. Procedures in MDC 05. The proposed new MS–DRGs are proposed new MS–DRG 361 (Other Circulatory System O.R. Procedures with MCC) and proposed new MS–DRG 362 (Other Circulatory System O.R. Procedures without MCC). We stated under this proposal, we would reassign the 1,447 listed procedure codes in the GROUPER logic of MS–DRG 264 to new MS–DRGs 361 and 362. We refer the reader to the ICD–10 MS–DRG Version 43.1 Definitions Manual (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*) for complete documentation of the

GROUPER logic for MS–DRG 264. We note that the surgical hierarchy for the proposed modification is discussed in section II.C.14. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule.

Comment: Commenters supported the proposal to delete base MS–DRG 264 and to create two new MS–DRGs with a two-way severity level split for cases reporting other circulatory system O.R. Procedures in MDC 05 for FY 2027.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to delete base MS–DRG 264, effective October 1, 2026, without modification, for FY 2027. We are also finalizing our proposal to create new MS–DRG 361 (Other Circulatory System O.R. Procedures with MCC) and new MS–DRG 362 (Other Circulatory System O.R. Procedures without MCC) in MDC 05, effective October 1, 2026, without modification, for FY 2027. Under this finalization, we are reassigning the 1,447 listed procedure codes in the GROUPER logic of MS–DRG 264 to new MS–DRGs 361 and 362. We note that the surgical hierarchy for the finalized modification is discussed in section II.C.14. of the preamble of this final rule.

4. MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Spinal Fusion and Pelvic Fixation Procedures

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19334 through 19342), we summarized a request we received from a manufacturer that was also previously discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18012 through 108013) and final rule (90 FR 36550 through 36552). Specifically, in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36552), we stated that we would continue to consider the request to modify the GROUPER logic of MS–DRG 426 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device), MS–DRG 427 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC), and MS–DRG 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC); MS–DRG 447 (Multiple Level Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device) and MS–DRG 448 (Multiple Level Spinal Fusion Except Cervical without MCC); and MS–DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively) by reassigning cases reporting the use of the iFuse Bedrock™ Granite Implant System with an ICD–10–PCS code that describes fusion of a sacroiliac joint using an internal fixation device with tulip connector or insertion of an internal fixation device with tulip connector into a pelvic bone with another spinal fusion procedure code that currently map to the lower severity level (without CC/MCC) MS–DRG to the highest severity level (with MCC) MS–DRG in connection with future rulemaking. We noted that the logic for MS–DRGs 456, 457, and 458 is defined by extensive fusions, in addition to specific diagnosis code logic, and MS–DRGs 426, 427, 428, 447, and 448 had recently become effective October 1, 2024, which we were continuing to monitor. We also stated that the data analysis necessary to examine the intricate logic within the spinal fusion MS–DRGs outlined in the request is complex and would require additional time for careful consideration of case redistribution and potential relative weight impacts, in connection with other related spinal fusion procedure requests that may be discussed in future rulemaking.

The requestor stated that historically, the junction between the lumbar spine and the sacrum (the L5–S1 spinal level), has been the most challenging level in which to achieve fusion. One of the primary reasons is because of our upright posture and normal spinal curvature that causes the L5–S1 intervertebral disc to become significantly inclined (tilted forward). The requester indicated that this results in significant shear load at this level, making this the level most likely to break down, and the level most challenging to stabilize during a fusion procedure. Per the requestor, the L5–S1 level is the junction between the mobile spine above and the much more rigid sacrum/pelvis below, leading to stress concentration at this level. The L5–S1 level experiences the most axial load as it is the base of the spine supporting the weight of the entire torso. Finally, the L5–S1 level experiences progressively more stress/load with more levels of the spine that are fused. The requestor stated that including additional levels in the fusion construct results in additional lengthening of the lever arm and increasing the loads acting at the L5–S1 level.

The requestor stated that anchorage of spinal instrumentation into the sacrum is also challenging. The sacrum is narrow in the posterior to anterior dimension, resulting in the need to place shorter screws. The pedicles are larger diameter which results in diminished cortical engagement of the screws. According to the requestor, the bone structure of the sacrum is also suboptimal for screw anchorage as the density of the sacrum is frequently diminished, particularly in older adults, and especially in those with osteoporosis. The requestor stated that the problem also exists for older adults without osteoporosis.

The requestor indicated that historically, surgeons added additional spinal instrumentation fixation anchor points into the pelvis (ilium and sacrum) to try and help solve the biomechanical and anatomic challenges previously described. These anchors (typically longer, larger diameter pedicle-type screws) are placed into the ilium or placed crossing through the sacrum and then into the ilium. These screws are then connected to the spinal instrumentation and improve the biomechanical stability of the spinal instrumentation construct. The requestor stated that clinical practice has evolved to include pelvic fixation as an integral part of spinal instrumentation with multi-level fusions ending at the sacrum. The requestor stated that the current standard is to include pelvic fixation in fusions of four levels or more.[2] The requestor added that recently, recommendations have been suggested to include pelvic fixation in some instances if the fusion includes three or more levels.[3] The requestor stated that pelvic fixation is also considered in shorter level fusion procedures in clinical scenarios when there is increased risk of fusion failure, including patients with high pelvic incidence (PI), high body mass index (BMI), and conditions with sagittal plane deformity such as spondylolisthesis. The requestor stated that surgeons performing revision lumbar surgery to treat an existing pseudarthosis (that is, nonunion or failed fusion) commonly include pelvic

[2] Lee CS, Chung SS, Choi SW, Yu JW, Sohn MS. Critical length of fusion requiring additional fixation to prevent nonunion of the lumbosacral junction. Spine (Phila Pa 1976). 2010 Mar 15;35(6):E206–11. doi: 10.1097/BRS.0b013e3181bfa518. PMID: 20195201.

[3] Jankowski PP, Hashmi SZ, Lord EL, Heller JE, Essig DA, Passias PG, Tahmasebpour P, Capobianco RA, Kleck CJ, Polly DW, Zuckerman SL; Spinopelvic Study Group. Trends in Lumbosacral-Pelvic Fixation Strategies. Int J Spine Surg. 2025 Sep 2;19(4):402–408. doi: 10.14444/8765. PMID: 40514223.

fixation to provide additional stability in these challenging clinical situations.

According to the requestor, although pelvic fixation strategies and implants have evolved since they were first introduced in the 1970s, including the development of sacro-alar-iliac (SAI) screws in 2007,[4] challenges with pelvic fixation persist. Studies indicate a 17 percent–23 percent complication rate, including screw or rod breakages, loose screws, L5–S1 pseudoarthrosis, and high revision rates.[5] [6] Many patients also experience sacroiliac (SI) joint pain and degeneration after multilevel fusions to the sacrum.[7] The SI joint often exhibits pathological increased motion in spinal deformity patients [8] and continues to move even after single-implant pelvic fixation [9] [10] leading to suboptimal outcomes and loss of correction.

The requestor stated that currently, greater biomechanical loads are being placed on spinopelvic constructs and surgeons are performing an increasing number of multilevel fusions. Evolving surgical techniques and instrumentation now allow for treatment of more severe deformities, as well as the performance of surgery on patients with a higher BMI and poor bone quality. According to the requestor, the iFuse Bedrock™ Granite Implant System represents a next-generation solution that allows for both pelvic fixation and sacroiliac joint fusion. The requestor stated this implant is the first Food and Drug Administration (FDA) cleared device designed for both purposes,[11] featuring a composite construction that includes a strong inner threaded screw component and a 3D-printed porous fusion sleeve to promote osseointegration. The requestor reported that there have been no reported breakages of the implant in over 8,500 cases.[12]

The requestor asserted the iFuse Bedrock™ Granite Implant System provides clinical advantages such as immediate and durable stability of the spinal instrumentation construct, reducing the likelihood of implant breakage due to its larger diameter and stronger construction. The requestor stated the porous fusion sleeve facilitates osseous integration, enhancing stability over time as it is designed for permanent fusion of the SI joint. Per the requestor, multiple implants can be placed on each side, either connected to a single rod or to separate rods, providing multiple points of fixation across the SI joints which increases construct stability and decreases SI joint motion. According to the requestor, the iFuse Bedrock™ Granite Implant System requires no changes to physician workflow, requires no additional surgical dissection, does not increase surgical time, or alter the length of hospital stay. The requestor stated that the iFuse Bedrock™ Granite Implant System is cleared for use with two navigation systems most frequently used in surgical facilities across the country.

The ICD–10–PCS codes that may be reported to describe the iFuse Bedrock™ Granite tulip connector device are:

ICD-10-PCS Code	Description
XNH6058	Insertion of internal fixation device with tulip connector into right pelvic bone, open approach, new technology group 8
XNH6358	Insertion of internal fixation device with tulip connector into right pelvic bone, percutaneous approach, new technology group 8
XNH7058	Insertion of internal fixation device with tulip connector into left pelvic bone, open approach, new technology group 8
XNH7358	Insertion of internal fixation device with tulip connector into left pelvic bone, percutaneous approach, new technology group 8
XRGE058	Fusion of right sacroiliac joint using internal fixation device with tulip connector, open approach, new technology group 8
XRGE358	Fusion of right sacroiliac joint using internal fixation device with tulip connector, percutaneous approach, new technology group 8
XRGF058	Fusion of left sacroiliac joint using internal fixation device with tulip connector, open approach, new technology group 8
XRGF358	Fusion of left sacroiliac joint using internal fixation device with tulip connector, percutaneous approach, new technology group 8

The previously listed procedure codes describing ''Insertion'' (ICD–10–PCS codes XNH6058, XNH6358, XNH7058, and XNH7358) are assigned to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) and the procedure codes describing ''Fusion'' (ICD–10–PCS codes XRGE058, XRGE358, XRGF058, and XRGF358) are assigned to MS–DRGs 028 (Spinal Procedures with MCC), MS–DRG 029 (Spinal Procedures with CC or Spinal Neurostimulators), and MS–DRG 030 (Spinal Procedures without CC/MCC) under MDC 01 (Diseases and Disorders of the Nervous System) and MS–DRGs 402, 426, 427, 428, 447, 448, 450, 451, 456, 457, and 458 under MDC 08. In the proposed rule we noted that because the ICD–10–PCS codes describing ''Insertion'' of internal fixation device with tulip connector are not assigned to one of the spinal fusion MS–DRGs as a standalone procedure, another ICD–10–PCS code describing a spinal fusion procedure would need to be reported on the same claim to group to one of the previously listed spinal fusion MS–DRGs. We refer the reader to the ICD–10 MS–DRG Definitions Manual, Version 43.1, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/*

[4] Kebaish, Khaled M. MD (Johns Hopkins Hospital); Gunne, Albert Pull ter MD; Mohamed, Ahmed S. MD; Zimmerman, Ryan; Ko, Phebe S. BS; Skolasky, Richard L. ScD; O'Brien, Joseph R. MD, MPH; Sponseller, Paul D. MD. A New Low Profile Sacro-Pelvic Fixation Using S2 Alar Iliac (S2AI) Screws in Adult Deformity Fusion to the Sacrum: A Prospective Study with Minimum Two-Year Follow-Up: E-Poster #21. Spine: Affiliated Society Meeting Abstracts 10():p 170, September 2009.

[5] Eastlack RK, Soroceanu A, Mundis GM Jr, et al. Rates of Loosening, Failure, and Revision of Iliac Fixation in Adult Deformity Surgery. *Spine (Phila Pa 1976).* 2022;47(14):986–994. doi:10.1097/BRS.0000000000004356.

[6] Odland K, Chanbour H, Zuckerman SL, Polly DW Jr. Spinopelvic fixation failure in the adult spinal deformity population: systematic review and meta-analysis. Eur Spine J. 2024 Jul;33(7):2751–2762. doi: 10.1007/s00586–024–08241–6. Epub 2024 Apr 15. Erratum in: Eur Spine J. 2025 Sep 18. doi: 10.1007/s00586–025–09232–x. PMID: 38619634.

[7] Manzetti M, Ruffilli A, Barile F, et al. Sacroiliac Joint Degeneration and Pain After Spinal Arthrodesis: A Systematic Review. *Clin Spine Surg.* 2023;36(4):169–182. doi:10.1097/BSD.0000000000001341.

[8] Mikula AL, Fogelson JL, Oushy S, Pinter ZW, Peters PA, Abode-Iyamah K, Sebastian AS, Freedman B, Currier BL, Polly DW, Elder BD. Change in pelvic incidence between the supine and standing positions in patients with bilateral sacroiliac joint vacuum signs. J Neurosurg Spine. 2021 Jan 15;34(4):617–622. doi: 10.3171/2020.8.SPINE20742. PMID: 33450735.

[9] Wei C, Zuckerman SL, Cerpa M, Ma H, Yang M, Yuan S, Lenke LG. Can pelvic incidence change after spinal deformity correction to the pelvis with S2-alar-iliac screws? Eur Spine J. 2021 Sep;30(9):2486–2494. doi: 10.1007/s00586–020–06658–3. Epub 2020 Nov 11. PMID: 33179128.

[10] Cunningham BW, Sponseller PD, Murgatroyd AA, Kikkawa J, Tortolani PJ. A comprehensive biomechanical analysis of sacral alar iliac fixation: an in vitro human cadaveric model. J Neurosurg Spine. 2019 Jan 4;30(3):367–375. doi: 10.3171/2018.8.SPINE18328. PMID: 30611149.

[11] U.S. Food and Drug Administration. 510(k) Premarket Notification: iFuse Bedrock Granite™ Implant System. Published May 26, 2022. Accessed October 15, 2024. *www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K220195.*

[12] Eastlack RK, Menger RP, Turner JD, Ashcraft KR, Carlton Recking W, Kleck C.J. Spinopelvic Fixation Using an Osseointegrative Implant: Analysis of Postmarket Surveillance to Determine the Failure Rate. Int J Spine Surg. 2025 Jun 12;19(3):273–278. doi: 10.14444/8720. PMID: 39890424; PMCID: PMC12268591.

ms-drg-classifications-and-software for complete documentation of the GROUPER logic for the previously listed MS–DRGs.

As also discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19336), we received a separate, but related request, from another manufacturer of devices used in the performance of a spinal fusion procedure. Specifically, we received a request to reassign cases reporting the use of the aprevo® Intervertebral Body Fusion Device (hereafter referred to as aprevo®) from MS–DRG 402 (Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical) to MS–DRG 450 (Single Level Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device) or alternatively, to reassign cases reporting the use of aprevo® from MS–DRG 402 to MS–DRG 428, and separately, to reassign cases reporting the use of aprevo® from MS–DRG 428 to the higher severity level (with MCC) MS–DRG 426. We noted that we have previously discussed the reassignment of cases reporting the use of the aprevo® technology in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26726 through 26729) and final rule (88 FR 58731through 58735, as corrected in the FY 2024 final rule correction notice at 88 FR 77211), and in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 35971 through 39585) and final rule (89 FR 69034 through 69061). We also noted that the aprevo® technology was approved for new technology add-on payments for FY 2022 (86 FR 45127 through 45133), FY 2023 (87 FR 49468 through 49469) and FY 2024 (88 FR 58802). We refer the reader to those rulemaking discussions for additional detailed information regarding the aprevo® technology.

The ICD–10–PCS codes that may be reported to describe lumbar fusion procedures that use the aprevo® device are:

ICD-10-PCS Code	Description
XRGA0R7	Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7
XRGA3R7	Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7
XRGA4R7	Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGB0R7	Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7
XRGB3R7	Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7
XRGB4R7	Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGC0R7	Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, open approach, new technology group 7
XRGC3R7	Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7
XRGC4R7	Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGD0R7	Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7
XRGD3R7	Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7
XRGD4R7	Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7

In the proposed rule we noted that for the Spring 2026 ICD–10–PCS code update, the manufacturer of the aprevo® custom-made anatomically designed interbody fusion device submitted a request to revise the descriptions for the procedure codes that describe use of the aprevo® device. The manufacturer requested that the description of the previously listed codes (and nine other procedure codes that describe a cervical fusion using a custom-made anatomically designed interbody fusion device) be revised to specifically identify that the technology is designed from a virtual anatomic model. The agenda and related meeting materials for these specific topics are available on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials.* We also noted that the deadline for receipt of public comments for the proposals included in the Spring 2026 procedure code update was April 17, 2026; therefore, the final code decisions on these proposals were not yet available for inclusion in Table 6B.—New Procedure Codes associated with the FY 2027 IPPS/LTCH PPS proposed rule. Under our established process, if the new and revised procedure code proposals are finalized after review and consideration of public comments following the Spring procedure code update, the codes are specifically identified with a footnote in Table 6B.—New Procedure Codes and Table 6F.—Revised Procedure Code Titles along with the MDC, MS–DRG assignment(s), and operating room (O.R.) or non-operating room (non-O.R.) designation that is made publicly available in association with the final rule on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.* This established process includes initially reviewing the predecessor codes' MS–DRG assignment and designation, while considering other relevant factors (for example, severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition). We noted that the public may provide feedback on these finalized assignments, which is then taken into consideration for the following fiscal year.

Each of the previously listed procedure codes is currently assigned to MDC 01 in MS–DRGs 028, 029, and 030, and to MDC 08 in MS–DRGs 402, 426, 427, 428, 447, 448, 450, 451, 456, 457, and 458.

As stated in the proposed rule and previously discussed in the preamble of this final rule, in the FY 2026 IPPS/

LTCH PPS final rule (90 FR 36552), we noted that we would continue to consider the request to modify the GROUPER logic of MS–DRGs 426, 427, and 428 (with regard to the reassignment of cases with an ICD–10–PCS code that describes fusion of a sacroiliac joint using an internal fixation device with tulip connector or insertion of an internal fixation device with tulip connector into a pelvic bone with another spinal fusion procedure code that currently map to the lower severity level MS–DRG to the highest severity level (with MCC) MS–DRG) in connection with future rulemaking and stated that the logic for MS–DRGs 456, 457, and 458 is defined by extensive fusions. Under ICD–10–PCS, an extensive fusion procedure is defined as a spinal fusion procedure involving 8 or more thoracic vertebral joint levels. For example, ICD–10–PCS code 0RG8070 (Fusion of 8 or more thoracic vertebral joints with autologous tissue substitute, anterior approach, anterior column, open approach) describes an extensive fusion procedure. An extensive fusion procedure may also be reported with a combination of codes (cluster) that includes at least one code describing fusion at the thoracic vertebral joint levels and at least one code describing fusion at the lumbar vertebral joint levels, such as ICD–10–PCS code 0RG7070 (Fusion of 2 to 7 thoracic vertebral joints with autologous tissue substitute, anterior approach, anterior column, open approach) and ICD–10–PCS code 0SG1070 (Fusion of 2 or more lumbar vertebral joints with autologous tissue substitute, anterior approach, anterior column, open approach). We refer the reader to Table 6P. 3a that is publicly available in association with the FY 2027 IPPS/LTCH PPS proposed rule on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps* for the list of procedure codes we analyzed to identify an extensive fusion that is also reflected in the ICD–10 MS–DRG Definitions Manual, Version 43.1 under MS–DRGs 456, 457, and 458.

As stated in the proposed rule, in review of these requests, we first analyzed claims data from the September 2025 update of the FY 2025 MedPAR file for MS–DRGs 028, 029, and 030 and for cases reporting a spinal fusion procedure with a custom-made anatomically designed interbody fusion device, cases reporting an SI joint fusion or spinal fusion procedure with insertion of an internal fixation device with tulip connector, and cases reporting an extensive fusion. We found zero cases reporting either technology across MS–DRGs 028, 029, and 030. We found 4 cases reporting an extensive fusion in MS–DRG 028, 4 cases reporting an extensive fusion in MS–DRG 029, and zero cases reporting an extensive fusion in MS–DRG 030. Findings from our analysis are shown in the following table.

MS-DRG	Description	Number of cases	Average Length of Stay	Average costs
028	All cases	2,067	12.2	$54,697
	Cases with extensive fusion	4	16.8	$122,802
	All other cases	2,063	12.2	$54,565
029	All cases	3,070	6.1	$32,288
	Cases with extensive fusion	4	6.8	$31,250
	All other cases	3,066	6.1	$32,289
030	All cases	861	3.1	$20,965

As shown in the table, for MS–DRG 028, the four cases reporting an extensive fusion had a longer average length of stay (16.8 days versus 12.2 days) and higher average costs ($122,802 versus $54,697) compared to the average length of stay and average costs of all the cases in MS–DRG 028. After further review of the data we considered three of the four cases to be outlier cases (that is, unusually expensive cases) because the costs for each of the three cases exceeded $100,000 and the length of stay for each of the three cases was twice as long or longer than the average length of stay of all the cases in MS–DRG 028. For MS–DRG 029, the four cases reporting an extensive fusion had a comparable average length of stay (6.8 days versus 6.1 days) and lower average costs ($31,250 versus $32,288) compared to the average length of stay and average costs of all the cases in MS–DRG 029.

In the proposed rule we noted that although the logic for case assignment to MS–DRGs 028, 029, and 030 includes procedure codes that describe a spinal fusion procedure with a custom-made anatomically designed interbody fusion device and procedure codes that describe an SI joint fusion with insertion of an internal fixation device with tulip connector, as well as procedure codes that describe an extensive fusion procedure, the MS–DRG assigned is based on an MDC 01 principal diagnosis code that describes a disease or disorder of the nervous system, therefore, we would not expect to see a significant volume of cases reporting the procedure codes that describe a spinal fusion procedure with a custom-made anatomically designed interbody fusion device, an SI joint fusion with insertion of an internal fixation device with tulip connector, or an extensive fusion procedure in the data. Additionally, we noted that the indications for the aprevo® custom-made anatomically designed interbody fusion device include adults with spinal deformities and degenerative conditions and the indications for the iFuse Bedrock™ Granite Implant System include patients with sacroiliac joint dysfunction that is a direct result of SI joint disruption and degenerative sacroiliitis as well as patients with acute, non-acute, and non-traumatic fractures involving the SI joint. The diagnosis codes describing these conditions are assigned to MDC 08, therefore, it is expected that the majority of cases reporting the procedure codes that describe a spinal fusion procedure with a custom-made anatomically designed interbody fusion device, an SI joint fusion with insertion of an internal fixation device with tulip connector, or an extensive fusion procedure would group to the MDC 08 MS–DRGs instead of to MDC 01 MS–DRGs 028, 029, and 030. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 43.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for complete documentation of the GROUPER logic for MDC 01 and MDC 08.

We then analyzed claims data for MS–DRGs 402, 426, 427, 428, 447, 448, 450, 451, 456, 457, and 458 and for: (1) cases reporting a spinal fusion procedure with

a custom-made anatomically designed interbody fusion device, (2) cases reporting an SI joint fusion or spinal fusion procedure with insertion of an internal fixation device with tulip connector, (3) cases reporting a fusion procedure with both technologies (that is, a single case reporting a procedure code describing a spinal fusion procedure with a custom-made anatomically designed interbody fusion device and another procedure code(s) describing an SI joint fusion or a spinal fusion procedure with insertion of an internal fixation device with tulip connector, (4) cases reporting an extensive fusion without either technology (that is, aprevo® or iFuse Bedrock™ Granite Implant System), (5) cases reporting an extensive fusion with a custom-made anatomically designed interbody fusion device, (6) cases reporting an extensive fusion with an SI joint fusion or spinal fusion procedure with insertion of an internal fixation device with tulip connector, and 7) cases reporting an extensive fusion with both technologies.

In the proposed rule we noted that the logic for case assignment to MS–DRGs 402, 447, 448, 450 and 451 does not include the procedure codes or the procedure code clusters that describe an extensive fusion; therefore, no data for extensive fusion cases are reflected in the table that follows for those MS–DRGs. There were also zero cases found reporting both technologies in MS–DRG 402. In addition, because the logic for case assignment to MS–DRGs 426, 447, and 450 includes the reporting of a custom-made anatomically designed interbody fusion device to group to the respective MCC severity level MS–DRG, no data for cases reporting a custom-made anatomically designed interbody fusion device are reflected in the table that follows for MS–DRGs 427, 448, and 451. Findings from our analysis are shown in the following table.

BILLING CODE 4169–69–P

MS-DRG	Description	Number of cases	Average Length of Stay	Average costs
402	All cases	15,344	2.9	$38,483
	Cases with custom-made anatomically designed interbody fusion device	85	3.3	$59,906
	Cases with internal fixation device with tulip connector	11	4.2	$46,207
	All other cases	15,248	2.9	$38,358
426	All cases	3,123	8.9	$99,235
	Cases with custom-made anatomically designed interbody fusion device	142	5.6	$103,797
	Cases with internal fixation device with tulip connector	154	9.3	$134,327
	Cases with both technologies	22	7.8	$112,683
	Cases with extensive fusion without either technology	532	10.5	$128,537
	Cases with extensive fusion with custom-made anatomically designed interbody fusion device	65	9.7	$118,927
	Cases with extensive fusion with internal fixation device with tulip connector	151	10.8	$165,523
	Cases with extensive fusion with both technologies	13	7.8	$179,522
	All other cases	2,044	8.5	$82,469
427	All cases	13,359	4.7	$68,506
	Cases with internal fixation device with tulip connector	502	5.7	$93,993
	Cases with both technologies	0	0	$0
	Cases with extensive fusion without either technology	1,251	7.1	$103,226
	Cases with extensive fusion with custom-made anatomically designed interbody fusion device	0	0	$0
	Cases with extensive fusion with internal fixation device with tulip connector	247	7.0	$129,777
	Cases with extensive fusion with both technologies	0	0	$0
	All other cases	11,359	4.4	$62,224
428	All cases	7,847	3.0	$56,192
	Cases with custom-made anatomically designed interbody fusion device	51	3.2	$75,595
	Cases with internal fixation device with tulip connector	134	3.5	$71,458
	Cases with both technologies	0	0	$0
	Cases with extensive fusion without either technology	138	4.8	$81,054
	Cases with extensive fusion with custom-made anatomically designed interbody fusion device	2	10.5	$119,007
	Cases with extensive fusion with internal fixation device with tulip connector	22	5.5	$83,447
	Cases with extensive fusion with both technologies	2	8.0	$149,474
	All other cases	7,498	2.9	$55,208
447	All cases	2,428	10.2	$62,858
	Cases with custom-made anatomically designed interbody fusion device	19	3.8	$74,184
	Cases with internal fixation device with tulip connector	47	10.4	$78,810
	Cases with both technologies	0	0	$0

	All other cases	2,362	10.3	$62,450
448	All cases	13,835	4.1	$40,716
	Cases with internal fixation device with tulip connector	258	4.8	$62,513
	Cases with both technologies	0	0	$0
	All other cases	13,577	4.1	$40,301
450	All cases	1,141	7.9	$48,325
	Cases with custom-made anatomically designed interbody fusion device	37	2.5	$55,985
	Cases with internal fixation device with tulip connector	3	5.7	$21,440
	Cases with both technologies	0	0	$0
	All other cases	1,101	8.1	$48,141
451	All cases	12,475	3.0	$30,366
	Cases with internal fixation device with tulip connector	56	2.1	$27,438
	Cases with both technologies	0	0	$0
	All other cases	12,419	3.1	$30,379
456	All cases	1,571	12.2	$79,972
	Cases with custom-made anatomically designed interbody fusion device	1	15.0	$66,999
	Cases with internal fixation device with tulip connector	26	14.5	$106,983
	Cases with both technologies	0	0	$0
	Cases with extensive fusion without either technology	584	11.8	$92,132
	Cases with extensive fusion with custom-made anatomically designed interbody fusion device	0	0	$0
	Cases with extensive fusion with internal fixation device with tulip connector	60	12.7	$136,660
	Cases with extensive fusion with both technologies	0	0	$0
	All other cases	900	12.3	$67,537
457	All cases	3,706	6.0	$56,069
	Cases with custom-made anatomically designed interbody fusion device	5	3.4	$67,984
	Cases with internal fixation device with tulip connector	39	5.5	$57,500
	Cases with both technologies	0	0	$0
	Cases with extensive fusion without either technology	1,354	6.3	$66,745
	Cases with extensive fusion with custom-made anatomically designed interbody fusion device	0	0	$0
	Cases with extensive fusion with internal fixation device with tulip connector	121	6.6	$91,823
	Cases with extensive fusion with both technologies	0	0	$0
	All other cases	2,187	5.7	$47,428
458	All cases	1,265	2.7	$40,771
	Cases with custom-made anatomically designed interbody fusion device	7	2.9	$64,086
	Cases with internal fixation device with tulip connector	8	3.1	$60,041
	Cases with both technologies	0	0	$0
	Cases with extensive fusion without either technology	143	4.3	$57,964
	Cases with extensive fusion with custom-made anatomically designed interbody fusion device	0	0	$0
	Cases with extensive fusion with internal fixation device with tulip connector	10	4.2	$62,304
	Cases with extensive fusion with both technologies	0	0	$0
	All other cases	1,097	2.5	$38,044

BILLING CODE 4169–69–C

The findings show that the cases reporting a spinal fusion procedure with the custom-made anatomically designed interbody fusion device, cases reporting

an SI joint fusion or spinal fusion procedure with an internal fixation device with tulip connector, and cases reporting both technologies generally had higher average costs with variation in the average length of stay in comparison to the average costs and average length of stay of all the cases in their respective MS–DRG. The findings also show that cases reporting an extensive spinal fusion procedure with or without either of the technologies had average costs that are higher in comparison to the average costs of all the cases in their respective MS–DRG and generally had a comparable or longer average length of stay in comparison to the average length of stay of all the cases in their respective MS–DRG.

As discussed in the proposed rule, with regard to the request to reassign cases reporting a spinal fusion procedure with the custom-made anatomically designed interbody fusion device from MS–DRG 402 to MS–DRG 450 and the alternative request to reassign cases reporting a spinal fusion procedure with the custom-made anatomically designed interbody fusion device from MS–DRG 402 to MS–DRG 428, we noted that MS–DRG 402 is a base MS–DRG and therefore is not subdivided into severity level subgroups. Additionally, the logic for MS–DRG 402 is defined by single level combined anterior and posterior spinal fusion procedures (except cervical) and the logic for MS–DRG 428 is defined by multiple level combined anterior and posterior spinal fusion procedures. Therefore, we stated that the reassignment of cases reporting the use of a custom-made anatomically designed interbody fusion device from MS–DRG 402 to MS–DRG 428 would not be feasible and would not be consistent with the logic of these recently formed MS–DRGs which is intended to differentiate a single level combined anterior and posterior fusion from a multiple level combined anterior and posterior spinal fusion. As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69058 through 69059), in response to public comments, we previously reviewed a request to reassign cases from the then proposed MS–DRG 402 to the then proposed MS–DRG 428 (both subsequently finalized) from this same manufacturer.

We stated in the proposed rule that although the findings from our analysis show that the average costs of the cases reporting the use of a custom-made anatomically designed interbody fusion device in MS–DRG 402 are higher compared to all the cases in MS–DRG 402 ($59,906 versus $38,483) with a longer average length of stay (3.3 days versus 2.9 days), and are more similar to the average costs of all the cases in MS–DRG 450 which are $48,325 with an average length of stay of 7.9 days, we disagreed with the requested reassignment of cases reporting a spinal fusion procedure with the custom-made anatomically designed interbody fusion device from MS–DRG 402 to MS–DRG 450 because MS–DRG 450 is subdivided into two severity level subgroups and defined by single level spinal fusions (except cervical), meaning either the anterior column of the spine or the posterior column of the spine is fused in a single operative episode. As previously discussed, the logic for case assignment to MS–DRG 402 reflects single level combined anterior and posterior spinal fusion procedures, meaning both the anterior column of the spine and the posterior column of the spine are fused in a single operative episode. MS–DRG 402 is also not subdivided into severity levels. As such, the logic for case assignment to MS–DRGs 402 and 450 reflects two different types of spinal fusions that are clinically distinct procedures with different resources.

As discussed in the proposed rule, in our review of the requested reassignment of cases reporting the use of a custom-made anatomically designed interbody fusion device from MS–DRG 428 to MS–DRG 426, the average costs of the 51 cases in MS–DRG 428 are higher compared to all the cases in MS–DRG 428 ($75,595 versus $56,192) with a comparable average length of stay (3.2 days versus 3.0 days), and the average costs of all the cases in MS–DRG 426 are $99,235 with an average length of stay of 8.9 days. However, we also noted that there are 142 cases reporting the use of a custom-made anatomically designed interbody fusion device in MS–DRG 426 with average costs of $103,797 and an average length of stay of 5.6 days. We stated that because the logic for MS–DRG 426 includes cases that are reassigned from MS–DRG 427 reporting the use of a custom-made anatomically designed interbody fusion device with a CC, we expanded our analysis to identify how many of the 142 cases would otherwise have grouped to MS–DRG 427 in the absence of the current logic. Of the 142 cases reporting the use of a custom-made anatomically designed interbody fusion device in MS–DRG 426, we found 22 cases were reported with an MCC secondary diagnosis with average costs of $143,062 and an average length of stay of 8.8 days and 120 cases were reported with a CC secondary diagnosis with average costs of $96,598 and an average length of stay of 5.1 days. We noted that, as reflected in the previously displayed table, the average costs of all the cases in MS–DRG 427 is $68,506.

As shown in our review of MS–DRG 426, the 154 cases reporting a fusion procedure with an internal fixation device with tulip connector had average costs of $134,327 with an average length of stay of 9.3 days in comparison to the average costs of all the cases in MS–DRG 426 of $99,235 with an average length of stay of 8.9 days. We also recognized a similar pattern in MS–DRGs 427, 428, 447, 448, 456, 457, and 458 where the average costs for cases reporting a fusion procedure with an internal fixation device with tulip connector had higher average costs and a longer or comparable average length of stay compared to the average costs and average length of stay of all the cases in their respective MS–DRG.

Relatedly, our findings for cases reporting an extensive fusion without either technology and our findings for cases reporting an extensive fusion with either or both technologies for MS–DRGs 426, 427, and 428 and MS–DRGs 456, 457, and 458 demonstrate higher average costs in comparison to the average costs of all the cases in their respective MS–DRG, including at the MCC level. Specifically, our data analysis shows that cases reporting an extensive fusion without either technology currently grouping to MS–DRGs 426, 427, and 428 have higher average costs ($128,537, $103,226, and $81,054, respectively) compared to the average costs of all the cases in their respective MS–DRG ($99,235, $68,506, and $56,192, respectively). Similarly, cases reporting an extensive fusion without either technology currently grouping to MS–DRGs 456, 457, and 458 have higher average costs ($92,132, $66,745, and $57,964, respectively) compared to the average costs of all the cases in their respective MS–DRG ($79,972, $56,069, and $40,771, respectively). Our data analysis also shows that cases reporting an extensive fusion with either or both technologies currently grouping to MS–DRGs 426, 427, and 428 have higher average costs compared to the average costs of all the cases in their respective MS–DRG. Overall, the 229 cases (65+151+13=229) in MS–DRG 426 reporting an extensive fusion with either or both technologies have average costs of $153,092 and an average length of stay of 10.3 days compared to the average cost and average length of stay of all the cases in MS–DRG 426 ($99,235 and 8.9 days, respectively). The 247 cases in MS–DRG

427 reporting an extensive fusion with either or both technologies have costs of $129,777 and a length of stay of 7.0 days compared to the average cost and average length of stay of all the cases in MS–DRG 427 ($68,506 and 4.7 days, respectively). The 26 cases (2+22+2=26) in MS–DRG 428 reporting an extensive fusion with either or both technologies have average costs of $91,261 and an average length of stay of 6.1 days compared to the average cost and average length of stay of all the cases in MS–DRG 428 ($56,192 and 3.0 days, respectively). Additionally, cases reporting an extensive fusion with either or both technologies currently grouping to MS–DRGs 456, 457, and 458 have higher costs and a longer length of stay compared to the average costs and average length of stay of all the cases in their respective MS–DRG. The 60 cases in MS–DRG 456 reporting an extensive fusion with either or both technologies have a cost of $136,660 and a length of stay of 12.7 days, the 121 cases in MS–DRG 457 reporting an extensive fusion with either or both technologies have a cost of $91,823 and a length of stay of 6.6 days, and the 10 cases in MS–DRG 458 reporting an extensive fusion with either or both technologies have a cost of $62,304 and a length of stay of 4.2 days.

We stated in the proposed rule that, based on our review and analysis, we disagreed with the requested reassignment of cases from the lower severity level to the higher severity level MS–DRG for cases reporting use of the aprevo® custom-made anatomically designed interbody fusion device, as well as for cases reporting use of the iFuse Bedrock™ Granite Implant System. We stated we believed that each technology is indicated for use in complex spinal fusion procedures and requires increased resource utilization. We also stated that if we were to reassign cases from the lower severity level to the higher severity level, that would not account for the cases at the MCC level that are unable to be reassigned. Specifically, the cases reporting use of the aprevo® custom-made anatomically designed interbody fusion device and cases reporting use of the iFuse Bedrock™ Granite Implant System at the MCC level would continue to have higher average costs and a longer average length of stay compared to all the other cases at the MCC level.

In the proposed rule, we stated our belief that extensive spinal fusion procedures, with or without the use of either or both technologies, also demonstrate increased resource utilization because extensive spinal fusion procedures address various spinal deformities across multiple spinal vertebral joint levels.

As such, to address the differences in resource utilization and additional treatment options for the patients whose spinal condition requires an extensive fusion procedure or a complex spinal fusion procedure that uses either the aprevo® custom-made anatomically designed interbody fusion device or the iFuse Bedrock™ Granite Implant System, we proposed a new base MS–DRG.

Consistent with our established process as discussed in section II.C.1.b. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule, once the decision has been made to propose to make further modifications to the MS–DRGs, such as creating a new base MS–DRG, all five criteria to create subgroups must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS–DRG. We noted that, as shown in the table that follows, a three-way split of this proposed new base MS–DRG was met.

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	1,613	11.1	$117,743
With CC	3,997	6.4	$87,683
Without CC/MCC	692	3.8	$65,891

For the proposed new MS–DRGs for cases reporting an extensive fusion or a complex spinal fusion procedure with either the aprevo® custom-made anatomically designed interbody fusion device or the iFuse Bedrock™ Granite Implant System, there is at least (1) 500 cases in the MCC group, 500 cases in the with CC group, and 500 cases in the without CC/MCC group; (2) 5 percent of the cases in the MCC group, 5 percent of the cases in the CC group, and 5 percent of the cases in the without CC/MCC group; (3) a 20 percent difference in average costs between the MCC group, the CC group, and the without CC/MCC group; (4) a $2,000 difference in average costs between the MCC group, the CC group, and the without CC/MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

Therefore, for FY 2027, we proposed to create new MS–DRGs 523, 524, and 525 (Extensive or Complex Spinal Fusion Procedures Except Cervical with MCC, with CC, and without CC/MCC, respectively). Specifically, we proposed to reassign cases reporting an extensive spinal fusion procedure from MS–DRGs 426, 427, 428, 456, 457 and 458 and to reassign cases reporting a spinal fusion procedure with use of the aprevo® custom-made anatomically designed interbody fusion device or the iFuse Bedrock™ Granite Implant System from MS–DRGs 402, 426, 427, 428, 447, 448, 450, 451, 456, 457 and 458 to proposed new MS–DRGs 523, 524, and 525. We also proposed to revise the titles for MS–DRGs 426, 447, and 450 to remove the reference to ''Custom-made Anatomically Designed Interbody Fusion Device'' and to revise the titles for MS–DRGs 456, 457, and 458 to remove the reference to ''Extensive Fusions''. We noted that discussion of the surgical hierarchy for the proposed modification is discussed in section II.C.14. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule.

Comment: Several commenters (practicing spine surgeons, neurosurgeons, and hospitals) expressed support for proposed new MS–DRGs 523, 524, and 525 and the proposed revisions to the titles for MS–DRGs 426, 447, and 450. The commenters stated that these cases often involve medically complex patients in need of extensive, multi-segment constructs and advanced pelvic fixation techniques. The commenters stated the proposed new MS–DRGs better reflect the clinical complexity and resource intensity of these cases. The commenters also stated the proposed new MS–DRGs support hospitals' and surgeons' ability to appropriately treat more complex patients. The commenters stated these cases are clinically distinct from less extensive spinal fusion and often require greater operative time, specialized implants, advanced

planning, and increased hospital resource utilization.

Response: We thank the commenters for their support.

Comment: A commenter who supported proposed MS–DRGs 523, 524, and 525 stated their belief that CMS omitted the eight Section X ICD–10–PCS procedure codes identifying the use of the iFuse Bedrock Granite® Implant System in the performance of spinal fusion procedures in Table 6P.3a that was made available in association with the proposed rule on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.* The commenter requested that a correction be provided for Table 6P.3a in association with the final rule. Specifically, the commenter indicated that ICD–10–PCS procedure codes XNH6058, XNH6358, XNH7058, XNH7358, XRGE058, XRGE358, XRGF058, and XRGF358 were omitted and should be included in the logic for proposed MS–DRGs 523, 524, and 525 for FY 2027.

Response: We thank the commenter for their feedback. We note that the ICD–10–PCS procedure codes listed in Table 6P.3a in association with the FY 2027 IPPS/LTCH PPS proposed rule and made available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps* describe extensive fusion procedures only. As stated in the proposed rule (91 FR 19337), we referred the reader to Table 6P. 3a for the list of procedure codes we analyzed to identify an extensive fusion and noted that extensive fusions are also reflected in the ICD–10 MS–DRG Definitions Manual, Version 43.1 under MS–DRGs 456, 457, and 458. We further noted that under ICD–10–PCS, an extensive fusion procedure is defined as a spinal fusion procedure involving 8 or more thoracic vertebral joint levels and provided specific examples of the procedure codes describing an extensive spinal fusion procedure. We note that because the procedure codes that may be reported to describe the iFuse Bedrock™ Granite tulip connector device were listed separately in the preamble of the proposed rule (91 FR 19336) and the procedure codes that may be reported to describe lumbar fusion procedures that use the aprevo® device were also listed separately in the preamble of the proposed rule (91 FR 19337), the purpose of Table 6P.3a was to list the procedure codes that describe an extensive fusion procedure.

As also discussed in the proposed rule (91 FR 19336), the listed procedure codes describing ''Insertion'' (ICD–10–PCS codes XNH6058, XNH6358, XNH7058, and XNH7358) are assigned to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) and the procedure codes describing ''Fusion'' (ICD–10–PCS codes XRGE058, XRGE358, XRGF058, and XRGF358) are assigned to MS–DRGs 028 (Spinal Procedures with MCC), MS–DRG 029 (Spinal Procedures with CC or Spinal Neurostimulators), and MS–DRG 030 (Spinal Procedures without CC/MCC) under MDC 01 (Diseases and Disorders of the Nervous System) and MS–DRGs 402, 426, 427, 428, 447, 448, 450, 451, 456, 457, and 458 under MDC 08. We noted that because the ICD–10–PCS codes describing ''Insertion'' of internal fixation device with tulip connector are not assigned to one of the spinal fusion MS–DRGs as a standalone procedure, another ICD–10–PCS code describing a spinal fusion procedure would need to be reported on the same claim to group to one of the previously listed spinal fusion MS–DRGs. We referred the reader to the ICD–10 MS–DRG Definitions Manual, Version 43.1, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software* for complete documentation of the GROUPER logic for the previously listed MS–DRGs. As such, the four ICD–10–PCS codes describing ''Insertion'' (ICD–10–PCS codes XNH6058, XNH6358, XNH7058, and XNH7358), were not included in the logic for proposed new MS–DRGs 523, 524, and 525 in association with the proposed rule, rather, only the four procedure codes describing ''Fusion'' (ICD–10–PCS codes XRGE058, XRGE358, XRGF058, and XRGF358) were included, as reflected in the test version of the ICD–10 MS–DRG GROUPER Software, Version 44, and the draft version of the ICD–10 MS–DRG Definitions Manual, Version 44, that was made available in association with the proposed rule on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.*

Comment: A commenter representing an association of device manufacturers who supported the proposal stated that the creation of these MS–DRGs represents a meaningful refinement to the IPPS, aligning payment with the hospital reported costs of the most resource intensive spinal fusion procedures furnished to Medicare beneficiaries. Another commenter representing a specialty society stated they supported CMS' broader efforts to modernize the spinal fusion DRG hierarchy so that Medicare payment policy more accurately reflects the substantial clinical, operational, and resource differences between routine degenerative fusion procedures and highly complex spinal deformity and reconstruction surgery; however, this commenter expressed concern that the proposed MS–DRG descriptions may inadvertently exclude numerous clinically comparable, high-complexity spinal reconstruction procedures that do not involve the named devices or do not meet the current definition of ''extensive'' or ''complex''. The commenter urged CMS to collaborate with neurosurgical and orthopedic specialty societies to develop clinically grounded procedure based definitions of ''extensive'' and ''complex'' spinal fusion, regardless of the specific implant technology used or the number of vertebral levels fused. Another commenter who also supported the proposed new spinal fusion MS–DRGs requested that CMS monitor the claims data for impacts.

Response: We appreciate the commenters' support and feedback. In response to the concerns expressed for the proposed MS–DRG descriptions, we note that the definition of an ''extensive'' spinal fusion has existed since the implementation of ICD–10–PCS in October 2015. As discussed in the preamble of the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19337 through 19338) and this final rule, under ICD–10–PCS, an extensive fusion is defined as a spinal fusion procedure involving 8 or more thoracic vertebral joint levels. An extensive fusion procedure may also be reported with a combination of codes (cluster) that includes at least one code describing fusion of 2–7 thoracic vertebral joint levels and at least one code describing fusion of 2 or more lumbar vertebral joint levels. We note that the proposed logic for case assignment to proposed MS–DRGs 523, 524, and 525, as reflected in the ICD–10 MS–DRG Definitions Manual, Version 43.1, that was made available in association with the proposed rule includes the lists of procedure codes that describe an extensive fusion and separately lists the procedure codes describing complex spinal fusion procedures performed with the use of the aprevo® custom-made anatomically designed interbody fusion device or the iFuse Bedrock Granite® Implant System. Based on our clinical review and the findings from our analysis as discussed in the proposed rule, the majority of spinal

fusion procedures that were reported to use either technology were those performed on a subset of clinically complex patients with adult spinal deformities and other conditions requiring specialized instrumentation and treatment plans. In response to the request that we should monitor the claims data for impacts, we note that we will continue to monitor the claims data in consideration of any potential modifications that may be warranted. Any discussion regarding proposed changes will be discussed in future rulemaking.

Comment: A commenter who supported the proposal to create proposed new MS–DRGs 523, 524, and 525 expressed appreciation for the thoughtful analysis that was performed and urged CMS to finalize the proposal. The commenter also stated that they supported the proposal to revise the descriptions and create new procedure codes that describe use of the aprevo® device as proposed in the Spring 2026 procedure code update and discussed in the preamble of the proposed rule. The commenter requested that CMS follow its established process to identify any finalized procedure changes with a footnote in Table 6B.—New Procedure Codes, and that the final ICD–10 MS–DRG GROUPER, Version 44, also reflect the appropriate procedure code logic finalized for case assignment.

Response: We thank the commenter for their support and feedback. As discussed in the preamble of the proposed rule, we noted that for the Spring 2026 ICD–10–PCS code update, the manufacturer of the aprevo® custom-made anatomically designed interbody fusion device submitted a request to revise the descriptions for the procedure codes that may be reported to describe use of the aprevo® device. The agenda and related meeting materials for this specific topics are available on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials.* As reflected in the FY 2027 ICD–10–PCS Code Update files that were made publicly available on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codeshttps://www.cms.gov/medicare/coding-billing/icd-10-codes* on June 5, 2026, and in Table 6B.—New Procedure Codes associated with this FY 2027 IPPS/LTCH PPS final rule (and available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*), consistent with our established processes, new procedure codes have been finalized that may be reported to describe use of the aprevo® custom-made anatomically and virtually designed interbody fusion device that are designated with a footnote and display the finalized operating room designation, MDC, and MS–DRG assignments effective with discharges on and after October 1, 2026. In addition, the FY 2027 ICD–10 MS–DRG GROUPER and Medicare Code Editor (MCE) Software Version 44, and the ICD–10 MS–DRG Definitions Manual files Version 44 available to the public on our CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps* also reflect the finalized logic for case assignment. We also note that the current codes that may be reported to describe use of the aprevo® custom-made anatomically designed interbody fusion device are invalid effective with discharges on and after October 1, 2026, as reflected in Table 6D.—Invalid Procedure Codes, associated with this FY 2027 IPPS/LTCH PPS final rule (and available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*).

Comment: A couple of commenters who supported the proposed new spinal fusion MS–DRGs 523, 524, and 525, stated that there have been revisions to the spinal fusion MS–DRGs for the last three fiscal years. Using MS–DRG 426 as an example, a commenter stated that cases grouping to this MS–DRG for FY 2025, FY 2026, and proposed FY 2027 are all unique and require recalibration to compare the MS–DRG with a batch GROUPER for accurate comparison. The commenters also stated there is a proposed relative weight difference for MS–DRG 426 in FY 2027 showing a decrease from approximately 11.0212 to 9.9191, making it difficult to compare current spinal fusion MS–DRGs with the V43 GROUPER due to cases shifting out of MS–DRG 426 as a result of changes made over the last three years. Another commenter stated that the observed shifts in MS–DRG 426 across the two years may reflect classification dynamics rather than true changes in patient acuity or resource use. The commenter requested that CMS publish supplemental files to enable hospitals to evaluate impacts using their own claims under the applicable GROUPER logic which may help inform and clarify the logic changes affecting the redistribution of cases among the MS–DRGs.

Response: We thank the commenters for their support of the proposed new MS–DRGs and acknowledge there have been revisions to the logic for case assignment to MS–DRG 426 for FY 2025 and FY 2026, with proposed changes for FY 2027. As shown in the data analyses that have been discussed in prior rulemakings, and more recently in the preamble of the FY 2027 proposed rule, cases reporting use of the aprevo® technology generally have higher average costs and either a comparable or a longer average length of stay when compared to all the cases in the respective MS–DRG. When higher volume and higher average cost cases shift in and out of an MS–DRG, the relative weight of that MS–DRG will fluctuate. It is expected that changes to the relative weight will occur when logic changes are finalized resulting in a redistribution of cases. As discussed elsewhere in the preamble of this final rule, we may consider making available additional resources such as a batch GROUPER for future rulemaking. With regard to the request that CMS publish supplemental files to assist hospitals in their evaluation of the potential impacts as a result of the proposed MS–DRG changes, we intend to make available a redistribution report in association with future proposed rulemakings to further assist stakeholders in evaluating how proposed logic changes may affect the redistribution of cases among the MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to create new MS–DRGs 523, 524, and 525, for FY 2027. We are also finalizing our proposal to reassign cases reporting an extensive spinal fusion procedure from MS–DRGs 426, 427, 428, 456, 457 and 458 and to reassign cases reporting a spinal fusion procedure with use of the aprevo® device or the iFuse Bedrock™ Granite Implant System from MS–DRGs 402, 426, 427, 428, 447, 448, 450, 451, 456, 457 and 458 to new MS–DRGs 523, 524, and 525. Lastly, we are finalizing our proposal to revise the titles for MS–DRGs 426, 447, and 450 to remove the reference to ''Custom-made Anatomically Designed Interbody Fusion Device'' and to revise the titles for MS–DRGs 456, 457, and 458 to remove the reference to ''Extensive Fusions''. We refer the reader to the ICD–10 MS–DRG Definitions Manual files, Version 44 made available in association with this final rule at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software* for complete documentation of the GROUPER logic.

We note that the surgical hierarchy for the finalized modification is discussed

in section II.C.14. of the preamble of this final rule.

b. Hip or Knee Procedures With Periprosthetic Joint Infection

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18049 through 18052) and final rule (90 FR 36606 through 36610), we discussed a request we received to reassign cases reporting a hip or knee procedure with a principal diagnosis of periprosthetic joint infection (PJI) from the lower severity level ''without CC/MCC'' MS–DRG to the higher severity level ''with CC'' MS–DRG when there is no major complication or comorbidity (MCC) or complication or comorbidity (CC) reported for the following MS–DRGs; MS–DRGs 463, 464, and 465 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC, with CC, and without CC/MCC, respectively), MS–DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively), MS–DRGs 474, 475, and 476 (Amputation for Musculoskeletal System and Connective Tissue Disorders with MCC, with CC, and without CC/MCC, respectively), MS–DRGs 480, 481, and 482 (Hip and Femur Procedures Except Major Joint with MCC, with CC, and without CC/MCC, respectively) and MS–DRG 485, 486, and 487 (Knee Procedures with Principal Diagnosis of Infection with MCC, with CC, and without CC/MCC, respectively). We stated that, based on our review and analysis of the data, we disagreed with the request to reassign PJI cases from the lower severity ''without CC/MCC'' level MS–DRG to the higher severity ''with CC'' level MS–DRG suggested by the requestor as the average costs of the PJI cases in the ''without CC/MCC'' level were not comparable and did not align with the average costs of all the cases at the ''with CC'' level. We stated we believed that MS–DRGs 466, 467, and 468 appeared to group appropriately in their respective MS–DRG assignments and noted that the logic for case assignment to MS–DRGs 485, 486, and 487 includes a principal diagnosis of infection and the difference in average costs for the cases reporting a PJI with a hip or knee procedure compared to the average costs of all the cases in their respective MS–DRG was minimal. We stated we believed the data support proposing a new base MS–DRG for the cases reporting a PJI with a hip or knee procedure in MS–DRGs 463, 464, 465, 474, 475, 476, 480, 481, and 482 to better reflect the complexity of services, resource utilization, and severity of illness of these patients. We applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of the preamble of the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18014 through 18015) and final rule (90 FR 36553 through 36554) and noted that the criteria for a two-way split was met. Therefore, for FY 2026 we proposed to create new MS–DRGs 403 and 404 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC and without MCC, respectively).

As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36608 through 36610), several commenters expressed support for the proposal to create proposed new MS–DRGs 403 and 404; however, a commenter stated they encountered inconsistencies when grouping cases using the Version 43 test GROUPER that was made publicly available in association with the FY 2026 IPPS/LTCH PPS proposed rule on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.* The commenter also stated they found an overlap of approximately 52 procedure codes among the list of procedure codes analyzed by CMS made publicly available in Table 6P.6a in connection with the proposed rule analysis and also listed in the logic for MS–DRGs 466, 467, and 468 included in the Draft Version 43 ICD–10 MS–DRG Definitions Manual. The commenter stated it was unable to reconcile some of the shifts in case volume from the MS–DRGs that were analyzed and those that shifted into the proposed new MS–DRGs because it was not clear if the cases shifted because of the procedure code overlap or because of programming within the Version 43 test GROUPER.

We acknowledged the commenter's findings and noted that under the GROUPER software program, some collections of ICD–10–PCS procedure codes have a different set of attributes, independent of those of the codes that make them up (that is, their ''components''). We stated that these collections of ICD–10–PCS procedure codes are called clusters and that a routine program in the GROUPER, upstream of the MS–DRG assignment logic, searches the claim for clusters. We noted that when a cluster is found, it is added to the list of procedures found on the claim. We stated that clusters may be ''restricted'' by Major Diagnostic Category (MDC) and a restricted cluster inhibits the use of its procedure code component attributes for the MDC's MS–DRG assignment logic. We provided the example that procedure code cluster 0SPC0JZ (Removal of synthetic substitute from right knee joint, open approach) and 0SRT0JZ (Replacement of right knee joint, femoral surface with synthetic substitute, open approach) may be recognized on a claim if both codes appear (in any order) and the reporting of these codes creates a new procedure code cluster ''@0045''. We stated that the cluster @0045 has a different set of attributes than either code 0SPC0JZ or 0SRT0JZ by itself and is further ''restricted'' for MDC 08. We noted that when the GROUPER logic determines that the MDC is 08, it ignores the attributes of procedure codes 0SPC0JZ and 0SRT0JZ individually, only using those of @0045. We indicated in that example how the logic results in assignment of the claim to MS–DRGs 466, 467, and 468 rather than MS–DRGs 463, 464, and 465. We stated that if the principal diagnosis reported is not assigned under MDC 08, the cluster would not restrict the interpretation of the component codes and their individual attributes could be relevant as well as those of @0045.

As also discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36610), following publication of the FY 2026 IPPS/LTCH PPS proposed rule, we identified that the intended grouping of cases to the proposed new MS–DRGs 403 and 404 was impacted because of these cluster restrictions under MDC 08; therefore, we removed the restrictions and performed additional analysis. As a result of removing the restrictions, and due to the existing overlapping procedure code logic among a subset of the MDC 08 MS–DRGs, our analysis showed that further redistribution of the cases under MDC 08 occurred, impacting the remaining number of cases in MS–DRGs 466, 467, and 468 and MS–DRGs 485, 486, and 487, such that, those MS–DRGs no longer satisfied the criteria for a 3-way split. We noted that under our established process for applying the criteria to create subgroups within a base MS–DRG, existing MS–DRGs 466, 467, and 468 would be deleted and a new base MS–DRG for Revision of Hip or Knee Replacement would be established. Additionally, we noted that under this established process, existing MS–DRGs 485, 486, and 487 would be deleted and new MS–DRGs (2-way split) for Knee Procedures with Principal Diagnosis of Infection with and without MCC, respectively, would be established. Because these findings associated with removal of the MDC 08 restrictions on the procedure code clusters for existing MS–DRGs 466, 467, and 468 and MS–DRGs 485, 486,

and 487 were not identified until after publication of the proposed rule, in addition to having an updated test Grouper that reflected these potential changes, we did not finalize the creation of proposed new MS–DRGs 403 and 404 for FY 2026. We stated that we may further consider these potential MS–DRG changes for future rulemaking. We refer the reader to the FY 2026 IPPS/LTCH PPS proposed and final rulemaking discussions for additional detailed information.

As also discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18012 through 18013) and final rule (90 FR 36550 through 36552), we received a request to modify the GROUPER logic of MS–DRGs 463, 464, and 465; MS–DRGs 466, 467, and 468; and MS–DRGs 492, 493, and 494 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with MCC, with CC, and without CC/MCC, respectively) by reassigning cases with ICD–10–PCS code XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7) that currently map to the lower severity level MS–DRG to the highest severity level (with MCC) MS–DRG. We noted that the procedure to insert a bone void filler is designated as a non-operating room (Non-O.R.) procedure and stated our belief that the key factor that would contribute to resource utilization in these cases is the fact that the patients have an infection(s) which require additional resources. We further noted that, as discussed in section II.C.5.a. of the preamble of the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18049 through 18052), we received an MS–DRG request related to cases reporting a hip or knee procedure with a diagnosis of PJI in MS–DRGs 463, 464, and 465 (the same set of MS–DRGs that were submitted to analyze ICD–10–PCS code XW0V0P7). We stated that in our review of the claims data to address that specific request, we noted that a subset of the cases also reported procedure code XW0V0P7 and for these reasons and those previously described, we believed additional time was needed to review and evaluate potential extensive modifications to the structure of these MS–DRGs.

As discussed in the preamble of the proposed rule, based on our analysis of the September 2025 update of the FY 2025 MedPAR file for the FY 2027 IPPS/LTCH PPS proposed rule, we continued to believe it is appropriate to propose new MS–DRGs 403 and 404 to better differentiate and reflect the complexity of services, resource utilization, and severity of illness for patients diagnosed with a PJI. We stated in the FY 2027 IPPS/LTCH PPS proposed rule that for purposes of our analysis, in connection with the FY 2026 IPPS/LTCH PPS final rule discussion related to the findings about the restriction logic and overlap of procedure codes, for proposed new MS–DRGs 403 and 404 for FY 2027, we removed the restriction logic under MDC 08 for the procedure code clusters within MS–DRGs 466, 467, and 468, and within MS–DRGs 485, 486, and 487. These changes were reflected in the test version of the ICD–10 MS–DRG GROUPER Software, Version 44, and the draft version of the ICD–10 MS–DRG Definitions Manual, Version 44, available in association with the FY 2027 IPPS/LTCH PPS proposed rule (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) so that the public could better analyze and understand the impact of the proposals as summarized in the discussion that follows.

We stated in the FY 2027 IPPS/LTCH PPS proposed rule that, in connection with the FY 2026 IPPS/LTCH PPS final rule discussion related to the request for reassignment of cases with ICD–10–PCS code XW0V0P7 that currently map to the lower severity level MS–DRG to the highest severity level (with MCC) MS–DRG, the requestor submitted a revised request. Specifically, in addition to the previously listed MS–DRGs identified for CMS' consideration for FY 2026, the requestor added MDC 08 MS–DRGs 474, 475, and 476 and MS–DRGs 480, 481, and 482, that are also the subject of the request to reassign cases reporting a hip or knee procedure with a principal diagnosis of PJI from the lower severity level ''without CC/MCC'' MS–DRG to the higher severity level ''with CC'' MS–DRG, and further added MDC 08 MS–DRGs 477, 478, and 479 (Biopsies of Musculoskeletal System and Connective Tissue with MCC, with CC, and without CC/MCC, respectively). We also noted that separately, this same requestor submitted a request for the reassignment of cases reporting ICD–10–PCS code XW0V0P7 that currently map to the lower severity level MS–DRG to the highest severity level (with MCC) MS–DRG within MDC 10 for MS–DRGs 616, 617, and 618 (Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC, with CC, without CC/MCC, respectively) and MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, without CC/MCC, respectively) that is discussed separately in section II.C.5 of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule.

Effective October 1, 2021, ICD–10–PCS code XW0V0P7 was created in association with a new technology add-on payment application for CERAMENT® G, a combination device-drug product intended to treat bone infections (for example, osteomyelitis). It is an implantable bone void filler that consists of hydroxyapatite and calcium sulfate, as well as gentamicin sulfate, which is an antibacterial agent. We refer the reader to the September 8, 2020, ICD–10 Coordination and Maintenance Committee meeting materials available on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials* for information regarding the procedure code request, including a transcript of the discussion and the related meeting materials. We also note that CERAMENT® G was approved for a new technology add-on payment beginning October 1, 2022 for the indication of infection which expired on September 30, 2025. For FY 2026, CERAMENT® G was approved for a new technology add-on payment for the indication of an open fracture. We refer the reader to section II.E.4. of the preamble of the FY 2026 IPPS/LTCH PPS proposed and final rules for additional discussion regarding CERAMENT® G in association with the new technology add-on payment indication.

As discussed in the proposed rule, for the Spring 2026 ICD–10–PCS code update, the manufacturer of CERAMENT® G submitted a request for a new code to describe another antibiotic-eluting bone void filler product, CERAMENT® V, in association with a new technology add-on payment application for FY 2027. We refer the reader to section II.E.6. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule for additional discussion regarding CERAMENT® V in association with the new technology add-on payment policy. The manufacturer also requested a revision to the existing code, ICD–10–PCS code XW0V0P7, that is reported to identify the administration of CERAMENT® G. CERAMENT® V is an injectable synthetic bone void filler that consists of hydroxyapatite, calcium sulfate, and the antibiotic vancomycin hydrochloride. The manufacturer requested that the description of existing ICD–10–PCS code XW0V0P7 be revised to specifically identify gentamicin and that a new code be created to specifically identify vancomycin in association with the new technology add-on payment application.

The agenda and related materials for these specific topics are available on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials.* We note that the deadline for receipt of public comments for the proposals included in the Spring 2026 procedure code update was April 17, 2026; therefore, the final code decisions on these proposals were not yet available for inclusion in Table 6B.—New Procedure Codes associated with the FY 2027 IPPS/LTCH PPS proposed rule. Under our established process, if the new and revised procedure code proposals are finalized after review and consideration of public comments following the Spring update, the codes are specifically identified with a footnote in Table 6B.—New Procedure Codes and Table 6F.—Revised Procedure Code Titles along with the MDC, MS–DRG assignment(s), and operating room (O.R.) or non-operating room (non-O.R.) designation that is made publicly available in association with the final rule on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.* This established process includes initially reviewing the predecessor codes' MS–DRG assignment and designation, while considering other relevant factors (for example, severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition). The public may provide feedback on these finalized assignments, which is then taken into consideration for the following fiscal year.

We note that, after review and consideration of the public comments from the Spring 2026 ICD–10–PCS code update, we finalized the proposal to create a new ICD–10–PCS code to describe the administration of the antibiotic-eluting bone void filler product, CERAMENT® V, and we finalized the proposal to revise the existing ICD–10–PCS code XW0V0P7, to identify the administration of CERAMENT® G, as reflected in the FY 2027 ICD–10–PCS Code Update files that were made publicly available on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes* on June 5, 2026. The new procedure code, XW0V0BC (Introduction of vancomycin-eluting bone void filler into bones, open approach, new technology group 12), is reflected in Table 6B.—New Procedure Codes, and the revised procedure code title for procedure code XW0V0P7 (Introduction of gentamicin-eluting bone void filler into bones, open approach, new technology group 7) is reflected in Table 6F.—Revised Procedure Code Titles, in association with this final rule and available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps,* including the MS–DRG assignments for the new code for FY 2027.

Accordingly, to continue our analysis of cases reporting a hip or knee procedure with a principal diagnosis of PJI as discussed in the FY 2026 IPPS/LTCH PPS final rule with removal of the restriction logic and to address the request to modify the GROUPER logic by reassigning cases with ICD–10–PCS code XW0V0P7 that currently map to the lower severity level MS–DRG to the highest severity level (with MCC) MS–DRG, we reviewed claims data from the September 2025 update of the FY 2025 MedPAR file for MS–DRGs 463, 464, 465, 466, 467, 468, 474, 475, 476, 477, 478, 479, 480, 481, 482, 485, 486, 487, 492, 493, and 494 and for: (1) cases reporting a principal diagnosis of PJI with a hip or knee procedure based on the proposed logic as reflected in Table 6P.3b, (2) cases reporting the insertion of antibiotic-eluting bone void filler (code XW0V0P7) without a principal diagnosis of PJI among all the cases in the respective MS–DRG (that is, not limited to the proposed logic reflected in Table 6P.3b), and (3) cases reporting both a principal diagnosis of PJI with a hip or knee procedure and ICD–10–PCS code XW0V0P7 based on the proposed logic as reflected in Table 6P.3b. We refer the reader to Table 6P. 3b that is publicly available in association with the FY 2027 IPPS/LTCH PPS proposed rule on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps* for the list of diagnosis codes we analyzed to identify a PJI, for the procedure code we analyzed to identify the insertion of antibiotic-eluting bone void filler, and for the list of procedure codes we analyzed from the previously listed MS–DRGs (excluding MS–DRGs 477, 478, and 479 that were not the subject of the request) to identify a hip or knee procedure. Findings from our analysis with removal of the restriction logic are shown in the following table.

BILLING CODE 4169–69–P

MS-DRG	Description	Number of cases	Average Length of Stay	Average costs
463	All cases	9,360	11.0	$44,308
	Cases with principal diagnosis of PJI with hip or knee procedure	3,262	11.0	$44,259
	Cases with code XW0V0P7 without a principal diagnosis of PJI	37	11.6	$58,390
	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	37	12.8	$66,398
	All other cases	6,024	11.1	$44,112
464	All cases	25,312	4.8	$29,451
	Cases with principal diagnosis of PJI with hip or knee procedure	7,107	6.0	$30,776
	Cases with code XW0V0P7 without a principal diagnosis of PJI	62	7.9	$42,191
	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	55	7.7	$53,840
	All other cases	18,088	4.3	$28,813
465	All cases	15,298	1.9	$23,216
	Cases with principal diagnosis of PJI with hip or knee procedure	1,539	3.7	$26,422
	Cases with code XW0V0P7 without a principal diagnosis of PJI	13	3.4	$37,878
	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	6	4.7	$37,250
	All other cases	13,740	1.7	$22,837
466	All cases	233	7.8	$45,156
	Cases with principal diagnosis of PJI with hip or knee procedure	0	0.0	$0
	Cases with code XW0V0P7 without a principal diagnosis of PJI	1	7.0	$65,185
	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	0	0.0	$0
	All other cases	232	7.8	$45,070
467	All cases	1,191	3.9	$34,165
	Cases with principal diagnosis of PJI with hip or knee procedure	0	0.0	$0
	Cases with code XW0V0P7 without a principal diagnosis of PJI	6	3.7	$56,375

	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	0	0.0	$0
	All other cases	1,185	3.9	$34,053
468	All cases	703	2.0	$30,588
	Cases with principal diagnosis of PJI with hip or knee procedure	0	0.0	$0
	Cases with code XW0V0P7 without a principal diagnosis of PJI	0	0.0	$0
	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	0	0.0	$0
	All other cases	703	2.0	$30,588
474	All cases	2,333	12.2	$36,126
	Cases with principal diagnosis of PJI with hip or knee procedure	95	13.8	$37,558
	Cases with code XW0V0P7 without a principal diagnosis of PJI	15	11.6	$44,350
	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	3	18.0	$55,079
	All other cases	2,220	12.1	$35,984
475	All cases	2,751	7.5	$20,485
	Cases with principal diagnosis of PJI with hip or knee procedure	207	7.9	$27,205
	Cases with code XW0V0P7 without a principal diagnosis of PJI	17	9.6	$38,015
	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	2	8.5	$31,397
	All other cases	2,525	7.5	$19,807
476	All cases	329	3.3	$10,428
	Cases with principal diagnosis of PJI with hip or knee procedure	21	3.8	$14,176
	Cases with code XW0V0P7 without a principal diagnosis of PJI	0	0.0	$0
	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	0	0.0	$0
	All other cases	308	3.3	$10,172
477	All cases	3,142	10.2	$31,429
	Cases with code XW0V0P7 without a principal diagnosis of PJI	9	11.4	$35,531
	All other cases	3,133	10.2	$31,417
478	All cases	5,332	6.5	$22,446
	Cases with code XW0V0P7 without a principal diagnosis of PJI	41	6.6	$28,786
	All other cases	5,291	6.5	$22,397
479	All cases	887	4.1	$17,157
	Cases with code XW0V0P7 without a principal diagnosis of PJI	7	2.9	$11,760
	All other cases	880	4.1	$17,200
480	All cases	25,136	7.1	$26,366
	Cases with principal diagnosis of PJI with hip or knee procedure	115	10.6	$34,940
	Cases with code XW0V0P7 without a principal diagnosis of PJI	14	7.4	$46,859
	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	0	0.0	$0
	All other cases	25,007	7.1	$26,341
481	All cases	61,471	4.8	$19,579
	Cases with principal diagnosis of PJI with hip or knee procedure	181	7.1	$23,982
	Cases with code XW0V0P7 without a principal diagnosis of PJI	12	5.3	$36,464

	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	0	0.0	$0
	All other cases	61,278	4.8	$19,563
482	All cases	13,347	3.4	$15,230
	Cases with principal diagnosis of PJI with hip or knee procedure	29	4.4	$17,640
	Cases with code XW0V0P7 without a principal diagnosis of PJI	3	3.7	$27,391
	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	0	0.0	$0
	All other cases	13,315	3.4	$15,222
485	All cases	646	10.0	$29,585
	Cases with principal diagnosis of PJI with knee procedure	218	9.8	$32,871
	Cases with code XW0V0P7 without a principal diagnosis of PJI	0	0.0	$0
	Cases with principal diagnosis of PJI with knee procedure and code XW0V0P7	2	16.0	$84,670
	All other cases	426	10.1	$27,645
486	All cases	1,332	6.4	$18,960
	Cases with principal diagnosis of PJI with knee procedure	394	6.4	$23,058
	Cases with code XW0V0P7 without a principal diagnosis of PJI	2	7.6	$20,822
	Cases with principal diagnosis of PJI with knee procedure and code XW0V0P7	2	8.0	$38,624
	All other cases	934	6.4	$17,185
487	All cases	312	4.5	$13,801
	Cases with principal diagnosis of PJI with knee procedure	62	4.0	$20,903
	Cases with code XW0V0P7 without a principal diagnosis of PJI	0	0.0	$0
	Cases with principal diagnosis of PJI with knee procedure and code XW0V0P7	0	0.0	$0
	All other cases	250	4.6	$12,040
492	All cases	5,806	8.1	$32,889
	Cases with principal diagnosis of PJI with hip or knee procedure	17	13.2	$58,792
	Cases with code XW0V0P7 without a principal diagnosis of PJI	26	9.5	$46,746
	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	0	0.0	$0
	All other cases	5,763	8.1	$32,750
493	All cases	17,072	5.1	$23,555
	Cases with principal diagnosis of PJI with hip or knee procedure	43	6.2	$29,352
	Cases with code XW0V0P7 without a principal diagnosis of PJI	58	5.7	$34,714
	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	0	0.0	$0
	All other cases	16,971	5.1	$23,502
494	All cases	7,229	3.3	$18,846
	Cases with principal diagnosis of PJI with hip or knee procedure	5	2.6	$15,251
	Cases with code XW0V0P7 without a principal diagnosis of PJI	12	2.5	$20,387
	Cases with principal diagnosis of PJI with hip or knee procedure and code XW0V0P7	0	0.0	$0
	All other cases	7,212	3.3	$18,846

BILLING CODE 4169–69–C

The findings show that with removal of the restriction logic from MS–DRGs 466, 467, and 468, there are zero cases reporting a principal diagnosis of PJI with a hip or knee procedure in MS–DRGs 466, 467, and 468. With removal

of the restriction logic, the cases that previously grouped to MS–DRGs 466, 467, and 468 are redistributed to MS–DRGs 463, 464, and 465 based on the proposed Version 44 GROUPER logic and the surgical hierarchy. Under the current ICD–10 MS–DRGs Version 43.1, procedure code 0SP90JZ (Removal of synthetic substitute from right hip joint, open approach) is listed in the logic for case assignment to MS–DRGs 463, 464, and 465 and is also listed as part of a code cluster with procedure code 0SR9019 (Replacement of right hip joint with metal synthetic substitute, cemented, open approach) in the logic for case assignment to MS–DRGs 466, 467, and 468. With removal of the cluster restriction logic in MS–DRGs 466, 467, and 468, cases reporting procedure code 0SP90JZ with a principal diagnosis assigned to MDC 08 will group to MS–DRGs 463, 464, and 465 under the proposed ICD–10 MS–DRGs, Version 44. The findings also show that with removal of the restriction logic from MS–DRGs 485, 486, and 487 further redistribution of the cases occurs. Specifically, cases that previously grouped to MS–DRGs 485, 486, and 487 now group or ''shift'' to other MS–DRGs. As a result, the remaining number of cases in MS–DRGs 466, 467, and 468 and MS–DRGs 485, 486, and 487 is reduced and those MS–DRGs no longer satisfy the criteria for a 3-way split under application of our established criteria for subgroups consistent with the discussion in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36610).

The findings show that for the cases reporting a principal diagnosis of PJI with a hip or knee procedure in MS–DRGs 463, 464, 465, 474, 475, 476, 480, 481, 482, 485, 486, 487, 492, and 493, the average length of stay is generally comparable or longer compared to the average length of stay of all the cases in their respective MS–DRG. Findings from our analysis also show that the average costs of the cases reporting a principal diagnosis of PJI with a hip or knee procedure in MS–DRGs 464, 465, 474, 475, 476, 480, 481, 482, 485, 486, 487, 492, and 493 are higher compared to the average costs of all the cases in their respective MS–DRG. We note that the average length of stay and the average costs of the 5 cases reporting a PJI with a hip or knee procedure in MS–DRG 494 are shorter than (2.6 days versus 3.3 days) the average length of stay and lower than ($15,251 versus $18,846) the average costs of all the cases in MS–DRG 494. We also note that the average costs of the 3,262 cases reporting a principal diagnosis of PJI with a hip or knee procedure in MS–DRG 463 are approximately $49 less than the average costs of all the cases in MS–DRG 463 ($44,259 versus $44,308). For the cases reporting procedure code XW0V0P7 without a principal diagnosis of PJI in MS–DRGs 463, 464, 465, 466, 467, 474, 475, 477, 478, 480, 481, 482, 486, 492, and 493, we found that the average length of stay is generally comparable or longer compared to the average length of stay of all the cases in their respective MS–DRG. We note that there were zero cases found reporting procedure code XW0V0P7 without a principal diagnosis of PJI in MS–DRGs 468 and 476. Findings from our analysis also show that the average costs of the cases reporting procedure code XW0V0P7 without a principal diagnosis of PJI in MS–DRGs 463, 464, 465, 466, 467, 474, 475, 477, 478, 480, 481, 482, 486, 492, 493, and 494 are higher compared to the average costs of all the cases in their respective MS–DRG. We also note that the 7 cases in MS–DRG 479 have a shorter average length of stay (2.9 days versus 4.1 days) and lower average costs ($11,760 versus $17,157) compared to the average length of stay and average costs of all the cases in MS–DRG 479. As shown in the table, the cases reporting procedure code XW0V0P7 without a principal diagnosis of PJI in the lower severity level MS–DRGs (that is, MS–DRGs 464, 465, 475, 478, 481, 482, 493, and 494) have average costs that overall, are more aligned with the average costs of all the cases at the respective higher severity level (with MCC) MS–DRG (that is MS–DRGs 463, 474, 477, 480, and 492). For example, the 62 cases in MS–DRG 464 and the 13 cases in MS–DRG 465 reporting procedure code XW0V0P7 without a principal diagnosis of PJI have average costs of $42,191 and $37,878 respectively, compared to the average costs of $44,308 for all the cases in MS–DRG 463.

Lastly, for the cases reporting both a principal diagnosis of PJI with a hip or knee procedure and ICD–10–PCS code XW0V0P7 in MS–DRGs 463, 464, 465, 474, 475, 485, and 486, we found that the average length of stay is longer and the average costs are comparable or higher compared to the average length of stay and average costs of the cases reporting a principal diagnosis of PJI with a hip or knee procedure without ICD–10–PCS code XW0V0P7, as well as compared to all the cases in their respective MS–DRG.

We stated in the proposed rule that based on our review and analysis of the data, we believed the data support proposing a new base MS–DRG for the cases reporting a PJI with a hip or knee procedure to better differentiate and reflect the complexity of services, resource utilization, and severity of illness of these patients. In connection with our review and analysis of the data, we noted that under the current ICD–10 MS–DRGs Version 43.1, diagnosis codes T84.53XA (Infection and inflammatory reaction due to internal right knee prosthesis, initial encounter) and T84.54XA (Infection and inflammatory reaction due to internal left knee prosthesis, initial encounter) are listed in the logic for case assignment to MS–DRGs 485, 486, and 487, and are also listed in Table 6P.3b in association with the FY 2027 IPPS/LTCH PPS proposed rule as they describe a PJI of the knee and were included in our analysis previously discussed. Therefore, we stated we believed it is appropriate to propose to remove these codes from the logic for case assignment to MS–DRGs 485, 486, and 487 in association with the removal of the restriction logic so that cases reporting a PJI with a knee procedure from those MS–DRGs appropriately group to the proposed new base MS–DRG.

As discussed in the proposed rule and this final rule, we also note that, as previously described, procedure code XW0V0P7 is currently designated as a non-O.R. procedure. Because our analysis of the data supports the reassignment of cases reporting procedure code XW0V0P7 without a principal diagnosis of PJI from the lower severity level (without CC/MCC or with CC) to the higher (with MCC) severity level, we proposed to redesignate procedure code XW0V0P7 from a non-O.R. procedure to a non-O.R. procedure affecting the MS–DRG assignment at the higher with MCC severity level for MS–DRGs 463, 474, 477, 480, and 492. We further noted that because the data show that the cases reporting both a principal diagnosis of PJI with a hip or knee procedure and ICD–10–PCS code XW0V0P7 in MS–DRGs 463, 464, 465, 474, 475, 485, and 486 have a longer average length of stay and higher average costs compared to the average length of stay and average costs of the cases reporting a principal diagnosis of PJI with a hip or knee procedure alone (without ICD–10–PCS code XW0V0P7), with the proposed redesignation of code XW0V0P7 from non-O.R. to non-O.R. affecting the MS–DRG, these cases reporting ICD–10–PCS code XW0V0P7 would also be reassigned at the highest severity level in connection with a new base MS–DRG proposal and consistent with the proposal for assignment to MS–DRGs 463, 474, 477, 480, and 492

previously discussed. As such, we stated that the data supported the proposal for a new base MS–DRG for cases reporting a principal diagnosis of PJI with a hip or knee procedure with or without procedure code XW0V0P7.

Consistent with our established process as discussed in section II.C.1.b. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule, once the decision has been made to propose to make further modifications to the MS–DRGs, such as creating a new base MS–DRG, all five criteria to create subgroups must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS–DRG. We note that, as shown in the table that follows, a three-way split of this proposed new base MS–DRG failed to meet the criterion that there is at least a 20 percent difference in average costs in the without CC/MCC group. The following table illustrates our findings.

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	3,653	11.1	$44,365
With CC	7,655	6.1	$30,755
Without CC/MCC	1,626	3.7	$26,142

As discussed in section II.C.1.b. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the ''with MCC and without MCC'' subgroups and found that all five criteria were met. The following table illustrates our findings and reflects a simulation of the proposed new MS–DRG 403 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC or Insertion of Antibiotic-eluting Bone Void Filler) and MS–DRG 404 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection without MCC).

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	3,653	11.1	$44,365
Without MCC	9,281	5.7	$29,947

For the proposed new MS–DRGs to identify cases reporting a PJI with a hip or knee procedure with or without procedure code XW0V0P7, there is at least (1) 500 cases in the MCC group and 500 cases in the without MCC group; (2) 5 percent of the cases in the MCC group and 5 percent in the without MCC group; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

As also discussed in the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule, in connection with the proposed removal of the restriction logic and findings from our analysis, existing MS–DRGs 466, 467, and 468 and MS–DRGs 485, 486, and 487 would no longer meet the criteria for a 3-way split under our established process for applying the criteria to create subgroups within a base MS–DRG. We noted that, as shown in the table that follows, a three-way split for MS–DRGs 466, 467, and 468 failed to meet the criterion that there be at least 500 cases in the MCC group and that there is at least a 20 percent difference in average cost between the CC and NonCC group. The following table illustrates our findings.

MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
466 - With MCC	232	7.8	$45,070
467 - With CC	1,185	3.9	$34,053
468 - Without CC/MCC	703	2.0	$30,588

As discussed in section II.C.1.b. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the ''with MCC and without MCC'' subgroups and found that a two-way split for these MS–DRGs failed to meet the criterion that there be at least 500 cases in the MCC group. The following table illustrates our findings.

MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
466 - With MCC	232	7.8	$45,070
467/468 - Without MCC	1,888	3.2	$32,763

We then applied the criteria for a two-way split for the ''with CC/MCC'' and ''without CC/MCC'' subgroups. As shown in the table that follows, a two-way split of this base MS–DRG failed to meet the criterion that there be at least

a 20 percent difference in average cost between the with CC/MCC and the without CC/MCC group.

MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
466/467 - With CC/MCC	1,417	4.5	$35,857
468 – Without CC/MCC	703	2.0	$30,588

We therefore proposed to delete MS–DRGs 466, 467, and 468 and proposed to create new base MS–DRG 449 (Revision of Hip or Knee Replacement). We also noted that following our analysis previously described that reflects removal of the restriction logic for MS–DRGs 466, 467, and 468, we identified 20 procedure codes that are listed individually in the logic for case assignment to MS–DRGs 466, 467, and 468 that are also listed separately in the logic with another procedure code as a code cluster. For example, procedure code 0SPE0JZ (Removal of synthetic substitute from left hip joint, acetabular surface, open approach) is listed individually and is also listed separately with procedure code 0SRB019 (Replacement of left hip joint with metal synthetic substitute, cemented, open approach) as a code cluster. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 43.1, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software* for complete documentation of the GROUPER logic for MS–DRGs 466, 467, and 468. To appropriately reflect the logic list for proposed new base MS–DRG 449 under the proposed ICD–10 MS–DRGs, Version 44, and to ensure cases group appropriately in connection with the proposed changes to the ICD–10 MS–DRGs for FY 2027, we proposed to remove the following 20 procedure codes from the logic list as individually listed codes.

ICD-10-PCS Code	Description
0SPA0JZ	Removal of synthetic substitute from right hip joint, acetabular surface, open approach
0SPA4JZ	Removal of synthetic substitute from right hip joint, acetabular surface, percutaneous endoscopic approach
0SPC0JC	Removal of synthetic substitute from right knee joint, patellar surface, open approach
0SPC4JC	Removal of synthetic substitute from right knee joint, patellar surface, percutaneous endoscopic approach
0SPD0JC	Removal of synthetic substitute from left knee joint, patellar surface, open approach
0SPD4JC	Removal of synthetic substitute from left knee joint, patellar surface, percutaneous endoscopic approach
0SPE0JZ	Removal of synthetic substitute from left hip joint, acetabular surface, open approach
0SPE4JZ	Removal of synthetic substitute from left hip joint, acetabular surface, percutaneous endoscopic approach
0SPR0JZ	Removal of synthetic substitute from right hip joint, femoral surface, open approach
0SPR4JZ	Removal of synthetic substitute from right hip joint, femoral surface, percutaneous endoscopic approach
0SPS0JZ	Removal of synthetic substitute from left hip joint, femoral surface, open approach
0SPS4JZ	Removal of synthetic substitute from left hip joint, femoral surface, percutaneous endoscopic approach
0SPT0JZ	Removal of synthetic substitute from right knee joint, femoral surface, open approach
0SPT4JZ	Removal of synthetic substitute from right knee joint, femoral surface, percutaneous endoscopic approach
0SPU0JZ	Removal of synthetic substitute from left knee joint, femoral surface, open approach
0SPU4JZ	Removal of synthetic substitute from left knee joint, femoral surface, percutaneous endoscopic approach
0SPV0JZ	Removal of synthetic substitute from right knee joint, tibial surface, open approach
0SPV4JZ	Removal of synthetic substitute from right knee joint, tibial surface, percutaneous endoscopic approach
0SPW0JZ	Removal of synthetic substitute from left knee joint, tibial surface, open approach
0SPW4JZ	Removal of synthetic substitute from left knee joint, tibial surface, percutaneous endoscopic approach

The following table illustrates our simulation of proposed new MS–DRG 449.

Proposed New MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 449	983	4.8	$30,657

We then applied the criteria to MS–DRGs 485, 486, and 487 in connection with the proposed removal of the restriction logic. We note that, as shown in the table that follows, a three-way split for MS–DRGs 485, 486, and 487 failed to meet the criterion that there be at least 500 cases in the MCC group. The following table illustrates our findings.

MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
485 - With MCC	426	10.1	$27,645
486 - With CC	934	6.4	$17,185
487 - Without CC/MCC	250	4.6	$12,040

As discussed in section II.C.1.b. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the ''with MCC and without MCC'' groups. We note that, as shown in the table that follows, a two-way split for these MS–DRGs failed to meet the criterion that there be at least 500 cases in the MCC group. The following table illustrates our findings.

MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
485 - With MCC	426	10.1	$27,645
486/487 - Without MCC	1,184	6.0	$16,099

We therefore proposed to delete MS–DRGs 485, 486, and 487 and proposed to create new base MS–DRG 400 (Knee Procedures with Principal Diagnosis of Infection). The following table illustrates our simulation of the proposal.

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 400	1,555	6.9	$18,142

In summary, for FY 2027, we proposed to (1) remove the restriction logic for MS–DRGs 466, 467, and 468 and MS–DRGs 485, 486, and 487, (2) remove ICD–10–CM diagnosis codes T84.53XA and T84.54XA from the logic for case assignment to MS–DRGs 485, 486, and 487, (3) delete MS–DRGs 466, 467, and 468 and MS–DRGs 485, 486, and 487, (4) create new base MS–DRG 449 and new base MS–DRG 400 with the logic lists as reflected in Tables 6P.3c and 6P.3d, respectively, that is available in association with the FY 2027 IPPS/LTCH PPS proposed rule, (5) redesignate procedure code XW0V0P7 from non-O.R. to non-O.R. affecting specified MS–DRGs as discussed in this section of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule, (6) create new MS–DRG 403 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC or Insertion of Antibiotic-eluting Bone Void Filler) to reflect cases reporting a hip or knee procedure with a principal diagnosis of PJI and the reassignment of cases reporting ICD–10–PCS code XW0V0P7 from the lower severity level to the higher (with MCC) severity level and create new MS–DRG 404 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection without MCC) with the logic lists as reflected in Table 6P.3b in association with the proposed rule, and (7) reassign cases reporting ICD–10–PCS code XW0V0P7 from the lower severity level (without CC/MCC or with CC) to the higher (with MCC) severity level and revise the titles to the following MS–DRGs to reflect the proposed reassignment.

Current Description	Proposed Description
MS-DRG 463 Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC	MS-DRG 463 Wound Debridement or Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler
MS-DRG 474 Amputation for Musculoskeletal System and Connective Tissue Disorders with MCC	MS-DRG 474 Amputation for Musculoskeletal System and Connective Tissue Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler
MS-DRG 477 Biopsies of Musculoskeletal System and Connective Tissue with MCC	MS-DRG 477 Biopsies of Musculoskeletal System and Connective Tissue with MCC or Insertion of Antibiotic-eluting Bone Void Filler
MS-DRG 480 Hip and Femur Procedures Except Major Joint with MCC	MS-DRG 480 Hip and Femur Procedures Except Major Joint with MCC or Insertion of Antibiotic-eluting Bone Void Filler
MS-DRG 492 Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with MCC	MS-DRG 492 Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with MCC or Insertion of Antibiotic-eluting Bone Void Filler

We noted that the surgical hierarchy for the proposed modification is discussed in section II.C.14. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule.

In the proposed rule, we also noted that the titles for MS–DRGs 463, 464, and 465 reflect ''Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC, with CC, and without CC/MCC'', respectively. We stated we believe the term ''and'' in these MS–DRG titles may be misleading as it implies that both a wound debridement and skin graft need to be reported to satisfy the logic for case assignment to these MS–DRGs. However, the logic for case assignment to MS–DRGs 463, 464, and 465 is satisfied when either a procedure code describing a wound debridement or a procedure code describing a skin graft (except hand) from the logic list is reported. Therefore, we proposed to revise the term ''and'' to ''or'' for the titles for MS–DRGs 463, 464, and 465. These proposed title changes were reflected in the test version of the ICD–10 MS–DRG GROUPER Software, Version 44, and the draft version of the ICD–10 MS–DRG Definitions Manual, Version 44, available in association with the FY 2027 IPPS/LTCH PPS proposed rule (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*).

Comment: Several commenters expressed support for the seven proposals outlined in response to the request discussed for cases reporting a principal diagnosis of a PJI with a hip or knee procedure. A commenter stated accurately capturing infection severity and treatment complexity in the MS–DRG groupings and relative weights is vital. The commenter agreed with CMS' proposal for MS–DRGs 403 and 404. However, a couple of commenters expressed concern that the proposed removal of the restriction logic inappropriately shifts cases currently reported with both a ''removal'' procedure code and a ''replacement'' procedure code from existing MS–DRGs 466, 467, and 468 to MS–DRGs 463, 464, and 465. The commenters stated that the ICD–10–PCS Official Guidelines for Coding and Reporting state that if a device that is intended to remain after the procedure is completed requires removal before the end of the operative episode in which it was inserted, both the insertion and removal of the device should be coded. According to the commenters, the current restriction logic recognizes when a removal and replacement procedure are performed together. The commenters stated that MS–DRGs 463, 464, and 465 are not similar clinically or from a resource perspective. The commenters requested that MS–DRGs 466, 467, and 468 be retained.

Response: We thank the commenters for their support and feedback. With respect to the concerns expressed about clinical coherence, we note that under the proposal, the removal of the restriction logic and the redistribution of a subset of the cases from MS–DRGs 466, 467, and 468 to MS–DRGs 463, 464, and 465 aligns with the existing GROUPER logic that currently exists under Version 43.1 for MS–DRGs 463, 464, and 465. Specifically, the ICD–10–PCS procedure codes describing removal of synthetic substitute or removal of liner from the right or left hip or knee joint are currently reflected in the logic for cases assignment to MS–DRGs 463, 464, and 465 in the ICD–10 MS–DRG Definitions Manual, Version 43.1, available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.* We note that the procedure codes describing these removal procedures have been in the logic for MS–DRGs 463, 464, and 465 since the implementation of ICD–10–PCS. With regard to the ICD–10–PCS Official Guidelines for Coding and Reporting that was referenced, we note that the guideline is not applicable for this subset of cases. This guideline is referring to operative episodes where the intent is that an implanted device remain in the patient but due to reasons such as an ill-fitting implant or a broken implant, the implanted device must be removed, and no replacement device is subsequently implanted. In addition, as the commenters noted in their comments, the guideline is describing insertion and removal procedures, not removal and replacement procedures. As discussed previously, we intend to make available a redistribution report in association with future proposed rulemakings to further assist stakeholders in evaluating how proposed logic changes may affect the redistribution of cases among the MS–DRGs.

Comment: A commenter who agreed with the proposed changes for revision procedures stated that they did not agree with the grouping methodology to MS–DRGs 463, 464, and 465 when a removal procedure was assigned and that these procedures are not reflected in the description of the MS–DRGs. The commenter also requested that the logic for MS–DRGs 463, 464, and 465 be further evaluated to determine a more appropriate MS–DRG assignment for the hip and knee joint removal procedures which are orthopedic in nature.

Response: We appreciate the commenter's support and feedback. We acknowledge that the descriptions for MS–DRGs 463, 464, and 465 do not currently reflect orthopedic procedures. We also note that not every MS–DRG title reflects every type of procedure listed in the definition of the logic for

case assignment. Based on the findings from our analyses and clinical review, we believe that the proposed assignment for orthopedic procedures resulting from removal of the restriction logic is appropriate. We also note that, as previously discussed, the removal of the restriction logic and the redistribution of a subset of the cases from MS–DRGs 466, 467, and 468 to MS–DRGs 463, 464, and 465 aligns with the existing GROUPER logic that currently exists under Version 43.1 for MS–DRGs 463, 464, and 465; procedure codes describing removal of a synthetic substitute or removal of a liner from the hip or knee joint procedures are presently reflected in the logic for MS–DRGs 463, 464, and 465. As such, we do not believe that there is a clinical coherence issue to address. With regard to the commenter's request that the logic for MS–DRGs 463, 464, and 465 be further evaluated to determine a more appropriate MS–DRG assignment for the joint procedures which are orthopedic in nature, we note that, consistent with our established process, we will continue to analyze the data and any proposed modifications will be discussed in future rulemaking.

For additional clarification in response to the public comments received, we note that with removal of the restriction logic in MS–DRGs 466, 467, and 468, the resulting proposed logic for proposed new MS–DRG 449 more accurately reflects the ICD–10–PCS definition of Revision. Under ICD–10–PCS, the root operation Revision is defined as: Correcting, to the extent possible, a portion of a malfunctioning device or the position of a displaced device. Revision can include correcting a malfunctioning or displaced device by taking out or putting in components of the device such as a screw or pin. Therefore, we believe that the proposed new MS–DRG more accurately aligns with the ICD–10–PCS definition of Revision. However, in response to some of the confusion expressed by commenters, we also believe it is appropriate to further clarify the intent of the proposed new MS–DRG by further revising the title for proposed MS–DRG 449 (Revision of Hip or Knee Replacement) to reflect ''Revision of Hip or Knee Prosthesis''. We believe that this modification will better describe the types of cases that are expected to group there.

After consideration of the public comments we received, we are finalizing our proposals to (1) remove the restriction logic for MS–DRGs 466, 467, and 468 and MS–DRGs 485, 486, and 487, (2) remove ICD–10–CM diagnosis codes T84.53XA and T84.54XA from the logic for case assignment to MS–DRGs 485, 486, and 487, (3) delete MS–DRGs 466, 467, and 468 and MS–DRGs 485, 486, and 487, (4) create new base MS–DRG 449, with modification of the MS–DRG title to reflect ''Revision of Hip or Knee Prosthesis'' and new base MS–DRG 400, (5) redesignate procedure code XW0V0P7 from non-O.R. to non-O.R. affecting specified MS–DRGs as discussed in this section of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule, (6) create new MS–DRG 403 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC or Insertion of Antibiotic-eluting Bone Void Filler) to reflect cases reporting a hip or knee procedure with a principal diagnosis of PJI and the reassignment of cases reporting ICD–10–PCS code XW0V0P7 from the lower severity level to the higher (with MCC) severity level and create new MS–DRG 404 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection without MCC), and (7) reassign cases reporting ICD–10–PCS code XW0V0P7 from the lower severity level (without CC/MCC or with CC) to the higher (with MCC) severity level and revise the titles to the previously listed MS–DRGs 463, 474, 477, 480, and 492 to reflect the reassignment.

We are also finalizing our proposal to remove the 20 procedure codes previously listed to appropriately reflect the logic list for new base MS–DRG 449 and to ensure cases group correctly. Lastly, we are finalizing our proposal to revise the term ''and'' to ''or'' for the titles for MS–DRGs 463, 464, and 465.

These finalized changes, including the finalized logic lists for case assignment, are also reflected in the ICD–10 MS–DRG GROUPER Software, Version 44, and the ICD–10 MS–DRG Definitions Manual, Version 44, available in association with this final rule (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*).

We note that a few commenters suggested that if a new procedure code to describe CERAMENT® V was finalized, that the new procedure code also be assigned to the highest severity level MS–DRG, consistent with the proposals for cases reporting procedure code XW0V0P7, to identify the administration of CERAMENT® G. As previously discussed in this section of the preamble of this final rule, and as reflected in Table 6B.—New Procedure Codes in association with this final rule, we finalized new procedure code, XW0V0BC (Introduction of vancomycin-eluting bone void filler into bones, open approach, new technology group 12), and we finalized a revision to the procedure code title for procedure code XW0V0P7 (Introduction of gentamicin-eluting bone void filler into bones, open approach, new technology group 7) as reflected in Table 6F.—Revised Procedure Code Titles, in association with this final rule. As also previously discussed in this section of the preamble of this final rule, we finalized the proposal to redesignate procedure code XW0V0P7 from non-O.R. to non-O.R. affecting specified MS–DRGs and we finalized the proposal to reassign cases reporting ICD–10–PCS code XW0V0P7 from the lower severity level (without CC/MCC or with CC) to the higher (with MCC) severity level. Under our established process, we have finalized the O.R. status designation and the MS–DRG assignments for new procedure code XW0V0BC consistent with the finalized policies for procedure code XW0V0P7, as reflected in Tables 6B and 6F associated with this final rule (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*). These finalized changes, including the finalized logic lists for case assignment, are also reflected in the ICD–10 MS–DRG GROUPER Software, Version 44, and the ICD–10 MS–DRG Definitions Manual, Version 44, available in association with this final rule (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*).

5. MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders): CERAMENT® G Antibiotic-Eluting Bone Void Filler

As discussed in the preamble of section II.C.4. of the FY 2027 IPPS/LTCH PPS proposed rule, we received a request to reassign cases reporting ICD–10–PCS code XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7) from the lower severity level MS–DRG to the highest severity level (with MCC) MS–DRG within MDC 10 for MS–DRGs 616, 617, and 618 (Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC, with CC, without CC/MCC, respectively) and MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, without CC/MCC, respectively).

As also discussed in the preamble of section II.C.4 of the FY 2027 IPPS/LTCH

PPS proposed rule, ICD–10–PCS code XW0V0P7 was created effective October 1, 2021, in association with a new technology add-on payment application for CERAMENT® G, a combination device-drug product intended to treat bone infections (for example, osteomyelitis). It is an implantable bone void filler that consists of hydroxyapatite and calcium sulfate, as well as gentamicin sulfate, which is an antibacterial agent. We refer the reader to the September 8, 2020, ICD–10 Coordination and Maintenance Committee meeting materials available on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials* for information regarding the procedure code request, including a transcript of the discussion and the related meeting materials. In the proposed rule, we also noted that CERAMENT® G was approved for a new technology add-on payment beginning October 1, 2022 for the indication of infection which expired on September 30, 2025. For FY 2026, CERAMENT® G was approved for a new technology add-on payment for the indication of an open fracture. We refer the reader to section II.E.4. of the preamble of the FY 2026 IPPS/LTCH PPS proposed and final rules for additional discussion regarding CERAMENT® G in association with the new technology add-on payment indication.

In the preamble of section II.C.4 of the FY 2027 IPPS/LTCH PPS proposed rule we also noted that for the Spring 2026 ICD–10–PCS code update, the manufacturer of CERAMENT® G submitted a request for a new code to describe another antibiotic-eluting bone void filler product, CERAMENT® V, in association with a new technology add-on payment application for FY 2027. We refer the reader to section II.E.6. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule for additional discussion regarding CERAMENT® V in association with the new technology add-on payment policy. The manufacturer also requested a revision to the existing code, ICD–10–PCS code XW0V0P7, that is reported to identify the administration of CERAMENT® G. CERAMENT® V is an injectable synthetic bone void filler that consists of hydroxyapatite, calcium sulfate, and the antibiotic vancomycin hydrochloride. The manufacturer requested that the description of existing ICD–10–PCS code XW0V0P7 be revised to specifically identify gentamicin and that a new code be created to specifically identify vancomycin in association with the new technology add-on payment application. The agenda and related meeting materials for these specific topics are available on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials.* We noted in the proposed rule that the deadline for receipt of public comments for the proposals included in the Spring 2026 procedure code update was April 17, 2026; therefore, the final code decisions on these proposals were not yet available for inclusion in Table 6B.—New Procedure Codes associated with the FY 2027 IPPS/LTCH PPS proposed rule. Under our established process, if the new and revised procedure code proposals are finalized after review and consideration of public comments following the Spring update, the codes are specifically identified with a footnote in Table 6B.—New Procedure Codes and Table 6F.—Revised Procedure Code Titles along with the MDC, MS–DRG assignment(s), and operating room (O.R.) or non-operating room (non-O.R.) designation that is made publicly available in association with the final rule on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.* This established process includes initially reviewing the predecessor codes MS–DRG assignment and designation, while considering other relevant factors (for example, severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition). The public may provide feedback on these finalized assignments, which is then taken into consideration for the following fiscal year.

As previously discussed in section II.C.4.b of the preamble of this final rule, we finalized new ICD–10–PCS code XW0V0BC (Introduction of vancomycin-eluting bone void filler into bones, open approach, new technology group 12) to describe the administration of the antibiotic-eluting bone void filler product, CERAMENT® V, as reflected in Table 6B.-New Procedure Codes, and we finalized a revision to the title for existing ICD–10–PCS code XW0V0P7 (Introduction of gentamicin-eluting bone void filler into bones, open approach, new technology group 7) to identify the administration of CERAMENT® G, as reflected in Table 6F.—Revised Procedure Code Titles, in association with this final rule and available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.* Tables 6B and 6F also include the finalized O.R. designations and MS–DRG assignments for these new and revised procedure codes for FY 2027.

The requestor (the manufacturer) stated that the occurrence and economic burden of osteomyelitis is significant and diabetes has been driving the increase in osteomyelitis incidence over time, with the incidence of diabetes-related osteomyelitis rising from 2.3 to 10.5 cases per 100,000 person-years from the 1970s to the 1990s as reported by the Mayo Clinic. The requestor reported that the incidence of foot osteomyelitis among patients with diabetes mellitus is estimated to be approximately 0.3 percent per year, with a lifetime risk of 4 percent, and 68 percent of patients with diabetes-related foot osteomyelitis needing an amputation. Studies indicate many individuals are readmitted to the hospital within 1 year of the amputation due to complications of the affected limb.

In addition to diabetic foot ulcers, the requestor stated that the incidence of fracture-associated osteomyelitis varies from 1.8 percent to 27 percent depending on the bone involved and the grade/type of fracture. According to the requestor, clinical trials demonstrate that the overall incidence of osteomyelitis may continue to rise due to multiple factors including improved diagnosis, increasing patient risk factors such as diabetes, and increased needs for arthroplasties. Per the requestor, re-hospitalization and treatment for osteomyelitis has significant costs to both the individual and healthcare systems, impacting quality of life and the ability to work.

The requestor stated that the antimicrobial properties of CERAMENT® G combat antimicrobial resistance, thereby effectively reducing the recurrence of infection. The requestor also stated that these antimicrobial properties have been shown to achieve good infection prevention with a shortened course of systemic antibiotics that does not extend beyond seven days.

As discussed in the proposed rule, the requestor performed its own analysis using Medicare claims data across a subset of MS–DRGs for cases reporting the use of CERAMENT® G with ICD–10–PCS code XW0V0P7 and acknowledged that the volume of cases is small, however, it also stated that its findings reflected that claims reporting the use of CERAMENT® G have higher resource utilization compared to claims that did not report the use of CERAMENT® G. Of the MS–DRGs analyzed, the requestor

stated the cases reporting ICD–10–PCS code XW0V0P7 in the lower severity level MS–DRG had standardized costs that were more aligned with the costs of the higher severity level MS–DRG sequenced above it. The requestor stated its belief that the data demonstrate cases reporting ICD–10–PCS code XW0V0P7 should be reassigned to the higher MCC level MS–DRG within the MS–DRG groupings requested.

We reviewed claims data from the September 2025 update of the FY 2025 MedPAR file for MS–DRGs 616, 617, 618, 628, 629, and 630 and for cases reporting ICD–10–PCS code XW0V0P7. Findings from our analysis are shown in the following table.

MS-DRG	Description	Number of cases	Average Length of Stay	Average costs
616	All cases	3,568	10.9	$30,212
	Cases with code XW0V0P7	33	12.8	$47,082
	All other cases	3,535	10.9	$30,055
617	All cases	9,868	6.5	$16,621
	Cases with code XW0V0P7	68	9.9	$28,916
	All other cases	9,800	6.5	$16,536
618	All cases	42	3.9	$11,028
	Cases with code XW0V0P7	0	0	$0
	All other cases	42	3.9	$11,028
628	All cases	2,904	10.6	$32,481
	Cases with code XW0V0P7	29	14.3	$43,839
	All other cases	2,875	10.6	$32,366
629	All cases	3,435	6.9	$19,605
	Cases with code XW0V0P7	73	7.6	$28,764
	All other cases	3,362	6.9	$19,406
630	All cases	122	2.6	$12,383
	Cases with code XW0V0P7	0	0	$0
	All other cases	122	2.6	$12,383

The findings show that the cases reporting ICD–10–PCS code XW0V0P7 in MS–DRGs 616, 617, 628, and 629 have a longer average length of stay and higher average costs compared to all the cases in their respective MS–DRGs. We note there were zero cases reporting ICD–10–PCS code XW0V0P7 in MS–DRGs 618 and 630.

We stated in the proposed rule that based on our review and analysis of the data, we agreed with the requestor that the average costs of the cases reporting ICD–10–PCS code XW0V0P7 at the lower severity level are more aligned with the average costs of the cases at the higher MCC severity level. To better reflect the resource utilization and severity of illness of patients with diabetic osteomyelitis, we proposed to reassign cases reporting ICD–10–PCS code XW0V0P7 from the lower severity (without CC/MCC and with CC) MS–DRGs to the higher severity (MCC) level MS–DRG.

As previously discussed, there were no cases found in our analysis reporting ICD–10–PCS code XW0V0P7 in MS–DRGs 618 and 630 at the ''without CC/MCC'' level, however, if any cases reporting ICD–10–PCS code XW0V0P7 potentially grouped to MS–DRGs 618 or 630 in the future, we stated we would anticipate those cases also demonstrating higher average costs compared to all the cases in their respective MS–DRG.

Therefore, for FY 2027, we proposed to reassign cases reporting procedure code XW0V0P7 from the lower severity level MS–DRGs 617 and 618 to the higher severity (MCC) level MS–DRG 616 and from the lower severity level MS–DRGs 629 and 630 to the higher severity (MCC) level MS–DRG 628. We also proposed to revise the title of MS–DRG 616 from ''Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC'' to ''Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler'' and to revise the title of MS–DRG 628 from ''Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC'' to ''Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC or Insertion of Antibiotic-eluting Bone Void Filler'' to reflect the reassignment of cases reporting procedure code XW0V0P7.

Comment: Commenters agreed with the proposal to reassign cases reporting procedure code XW0V0P7 from the lower severity level MS–DRGs 617 and 618 to the higher severity (MCC) level MS–DRG 616 and from the lower severity level MS–DRGs 629 and 630 to the higher severity level MS–DRG 628. Commenters also agreed with the proposed revision to the title of MS–DRG 616 and MS–DRG 628 to reflect the ''Insertion of Antibiotic-eluting Bone Void Filler'' component with the reassignment of cases reporting procedure code XW0V0P7.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to reassign cases reporting procedure code XW0V0P7 from the lower severity level MS–DRGs 617 and 618 to the higher severity (MCC) level MS–DRG 616 and from the lower severity level MS–DRGs 629 and 630 to the higher (MCC) level MS–DRG 628. We are also finalizing our proposal to revise the titles of MS–DRG 616 and MS–DRG 628 to reflect the reassignment of cases reporting procedure code XW0V0P7 by adding the phrase ''Insertion of Antibiotic-eluting Bone Void Filler'' as also reflected in the ICD–10 MS–DRG Definitions Manual Version 44, available in association with this final rule on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.*

6. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)

a. Prostatectomy

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19354 through 19355), consistent with our annual review of the MS–DRGs, we stated we identified that the current GROUPER logic for MDC 11 MS–DRGs 665, 666, and 667 (Prostatectomy with MCC, with CC, and without CC/MCC, respectively) contains a logic list referred to as ''OPERATING ROOM PROCEDURES'' that includes 14 ICD–10–PCS procedure codes describing the destruction, excision, and resection of the prostate and also includes eight ICD–10–PCS procedure code combinations or procedure code ''clusters'' that, when reported together, satisfy the logic for assignment to MS–DRGs 665, 666, and 667. The code combinations are represented by two ICD–10–PCS procedure codes and include one ICD–10–PCS code for the resection of the prostate with one ICD–10–PCS code for the resection of bilateral seminal vesicles. In this final rule, we would like to correct the statement in the proposed rule and note that in the ICD–10 MS–DRG Definitions Manual Version 43.1, the logic list referred to as ''OPERATING ROOM PROCEDURES'' includes 18 ICD–10–PCS procedure codes describing the destruction, excision, and resection of the prostate and also includes eight ICD–10–PCS procedure code combinations or procedure code ''clusters'' that, when reported together, satisfy the logic for assignment to MS–DRGs 665, 666, and 667. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 43.1, which is available on the CMS website at*: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software,* for complete documentation of the GROUPER logic for MDC 11 MS–DRGs 665, 666, and 667.

The eight ICD–10–PCS procedure code combinations currently assigned to MDC 11 MS–DRGs 665, 666, and 667 that identify the resection of the prostate with the resection of bilateral seminal vesicles are shown in the following table:

ICD-10-PCS Code	Description
0VT00ZZ and 0VT30ZZ	Resection of prostate, open approach
	Resection of bilateral seminal vesicles, open approach
0VT00ZZ and 0VT34ZZ	Resection of prostate, open approach
	Resection of bilateral seminal vesicles, percutaneous endoscopic approach
0VT04ZZ and 0VT30ZZ	Resection of prostate, percutaneous endoscopic approach
	Resection of bilateral seminal vesicles, open approach
0VT04ZZ and 0VT34ZZ	Resection of prostate, percutaneous endoscopic approach
	Resection of bilateral seminal vesicles, percutaneous endoscopic approach
0VT07ZZ and 0VT30ZZ	Resection of prostate, via natural or artificial opening
	Resection of bilateral seminal vesicles, open approach
0VT07ZZ and 0VT34ZZ	Resection of prostate, via natural or artificial opening
	Resection of bilateral seminal vesicles, percutaneous endoscopic approach
0VT08ZZ and 0VT30ZZ	Resection of prostate, via natural or artificial opening endoscopic
	Resection of bilateral seminal vesicles, open approach
0VT08ZZ and 0VT34ZZ	Resection of prostate, via natural or artificial opening endoscopic
	Resection of bilateral seminal vesicles, percutaneous endoscopic approach

In the proposed rule we stated as we examined the GROUPER logic that would determine the assignment of a case to MDC 11 MS–DRGs 665, 666, and 667, we noted that ICD–10–PCS codes 0VT00ZZ, 0VT04ZZ, 0VT07ZZ and 0VT08ZZ that describe the resection of the prostate, differing only in approach, are assigned to MS–DRGs 665, 666, and 667 as standalone procedures, as well as being included in the eight procedure code combinations listed previously in these same MS–DRGs. We noted that the GROUPER software program will recognize codes 0VT00ZZ, 0VT04ZZ, 0VT07ZZ and 0VT08ZZ and assign MS–DRGs 665, 666, and 667 even when a procedure code describing the resection of the bilateral seminal vesicles is not also reported, when the other parameters of the GROUPER logic are met. As procedure codes 0VT00ZZ, 0VT04ZZ, 0VT07ZZ and 0VT08ZZ are assigned to MS–DRGs 665, 666, and 667 as standalone procedures, specific assignment of these procedure codes in procedure code combinations in MS–DRGs 665, 666, and 667 is not required.

Therefore, for FY 2027, we proposed to remove the eight ICD–10–PCS procedure code combinations listed previously from the GROUPER logic of MDC 11 MS–DRGs 665, 666, and 667 (Prostatectomy with MCC, with CC, and without CC/MCC, respectively).

Comment: Commenters supported the proposal to remove the eight ICD–10–PCS procedure code combinations from the GROUPER logic of MDC 11 MS–DRGs 665, 666, and 667 (Prostatectomy with MCC, with CC, and without CC/MCC, respectively), effective October 1, 2026, for FY 2027.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove the eight ICD–10–PCS procedure code combinations listed previously from the GROUPER logic of MDC 11 MS–DRGs 665, 666, and 667 (Prostatectomy with MCC, with CC, and without CC/MCC, respectively), without modification, effective October 1, 2026, for FY 2027.

b. Islet Cell Transplantation

As discussed in section II.C.11.b.1 of the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19366 through 19367) and this final rule, we received a request to change the designation of ICD–10–PCS code XW033DA (Introduction of donislecel-jujn allogeneic pancreatic islet cellular suspension into peripheral vein, percutaneous approach, new technology group 10) from a non-O.R. procedure to an O.R. procedure. In the ICD–10 MS–DRGs Definitions Manual Version 43.1, procedure code XW033DA is currently designated as a non-O.R. procedure affecting assignment to MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively).

As discussed in the proposed rule (91 FR 19355 through 19358), in our review of the GROUPER logic of MS–DRGs 673, 674, and 675, we noted that the logic for case assignment to MS–DRGs 673, 674, and 675 as displayed in the ICD–10 MS–DRG Version 43.1 Definitions Manual (which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) is comprised of seven logic lists. We stated in the proposed rule that the first logic list is entitled ''Operating Room Procedures'' and is defined by a list of 1,754 ICD–10–PCS procedure codes describing surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in MDC 11. In this final rule, we would like to correct the statement in the proposed rule and note that in the ICD–10 MS–DRG Definitions Manual Version 43.1, the first logic list entitled ''Operating Room Procedures'' is defined by a list of 1,765 ICD–10–PCS procedure codes describing surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in MDC 11. The second and third logic lists are entitled ''or Principal Diagnosis'' and are defined by the 25 ICD–10–CM diagnosis codes. The fourth logic list is entitled ''with Secondary Diagnosis'' and is defined by ICD–10–CM diagnosis codes N18.5 (Chronic kidney disease, stage 5) and N18.6 (End stage renal disease). The fifth logic list is entitled ''and Non-Operating Room Procedures'' and is defined by a list of 30 ICD–10–PCS procedure codes describing the insertion of totally implantable vascular access devices (TIVADs) and tunneled vascular access devices. The second, third, and fourth logic lists are the components of the special logic in MS–DRGs 673, 674, and 675 for certain MDC 11 diagnoses reported with procedure codes for the insertion of tunneled or totally implantable vascular access devices.

The sixth logic list entitled ''or Principal Diagnosis'' is defined by ICD–10–CM diagnosis codes E10.21 (Type 1 diabetes mellitus with diabetic nephropathy), E10.22 (Type 1 diabetes mellitus with diabetic chronic kidney disease) and E10.29 (Type 1 diabetes mellitus with other diabetic kidney complication) and the seventh logic list entitled ''and Non-Operating Room Procedures'' is defined by the 11 ICD–10–PCS procedure codes describing the introduction of pancreatic islet cells listed in the following table. As discussed in the FY 2027 IPPS/LTCH PPS proposed rule, these 11 procedure codes are all designated as non-O.R. procedures affecting assignment to MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively).

ICD-10-PCS Code	Description
3E030U0	Introduction of autologous pancreatic islet cells into peripheral vein, open approach
3E030U1	Introduction of nonautologous pancreatic islet cells into peripheral vein, open approach
3E033U0	Introduction of autologous pancreatic islet cells into peripheral vein, percutaneous approach
3E033U1	Introduction of nonautologous pancreatic islet cells into peripheral vein, percutaneous approach
3E0J3U0	Introduction of autologous pancreatic islet cells into biliary and pancreatic tract, percutaneous approach
3E0J3U1	Introduction of nonautologous pancreatic islet cells into biliary and pancreatic tract, percutaneous approach
3E0J7U0	Introduction of autologous pancreatic islet cells into biliary and pancreatic tract, via natural or artificial opening
3E0J7U1	Introduction of nonautologous pancreatic islet cells into biliary and pancreatic tract, via natural or artificial opening
3E0J8U0	Introduction of autologous pancreatic islet cells into biliary and pancreatic tract, via natural or artificial opening endoscopic
3E0J8U1	Introduction of nonautologous pancreatic islet cells into biliary and pancreatic tract, via natural or artificial opening endoscopic
XW033DA	Introduction of donislecel-jujn allogeneic pancreatic islet cellular suspension into peripheral vein, percutaneous approach, new technology group 10

The sixth and seventh logic lists are the components of the special logic in MS–DRGs 673, 674, and 675 for pancreatic islet cell transplantation. As discussed in the FY 2005 IPPS/LTCH PPS final rule (69 FR 48950 through 48953), the procedure codes describing islet cell transplantation were added to the GROUPER logic of DRG 315 (Other Kidney and Urinary Tract O.R. Procedures), the predecessor DRG of MS–DRGs 673, 674, and 675, to recognize the resource utilization associated with islet cell transplantation, performed to decrease or eliminate the need for insulin in patients with type 1 diabetes, in the absence of any other surgical procedure.

In the FY 2005 IPPS/LTCH PPS final rule, we acknowledged that islet cell transplants do not involve either the kidney or the urinary tract directly. Rather, the islet cells are transplanted into the patient's liver. We also acknowledged that the diagnoses are the same for islet cell and pancreas transplants, and that the patient

populations involved in these two procedures are virtually identical in terms of comorbidities and the nature of their primary disease. However, we stated islet cell transplants are not exactly the same as solid organ transplants. We stated that while the patient populations requiring intervention are similar, we did not believe that one can equate an operation of the magnitude of a pancreas transplant with a less intensive islet cell transplantation in which the portal vein is accessed and islet cells infused through a catheter. It is only because the technical aspects of islet transplants are of a surgical nature that we modified surgical DRG 315 to reflect the transfusion of islet cells.

To understand the resource use for the subset of cases reporting procedure codes describing the introduction of pancreatic islet cells for the FY 2027 IPPS/LTCH PPS proposed rule, we stated we began our analysis by examining claims data from the September 2025 update of the FY 2025 MedPAR file for cases assigned to MS–DRGs 673, 674, and 675. We found zero cases reporting procedure codes describing the introduction of pancreatic islet cells in MS–DRGs 673, 674, and 675.

Then, to evaluate the frequency with which the procedure codes describing the introduction of pancreatic islet cells are reported for different clinical scenarios, we stated we examined claims data from the September 2025 update of the FY 2025 MedPAR file to determine the MS–DRGs reporting one of the 11 procedure codes listed previously that describe the introduction of pancreatic islet cells. Our findings are shown in the following table.

CASES REPORTING ICD-10-PCS PROCEDURE CODES DESCRIBING THE INTRODUCTION OF PANCREATIC ISLET CELLS

MS-DRG	Description	Number of Cases	Average Length of Stay	Average Costs
003	ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures	1	36	$188,359
326	Stomach, Esophageal and Duodenal Procedures with MCC	1	35	$226,176
405	Pancreas, Liver and Shunt Procedures with MCC	3	30.3	$107,637
406	Pancreas, Liver and Shunt Procedures with CC	4	6.3	$28,268
650	Kidney Transplant with Hemodialysis with MCC	1	15	$160,401
	Total	**10**	**20.2**	**$101,092**

The data analysis shows a procedure code describing the introduction of pancreatic islet cells was reported in a total of ten cases across five MS–DRGs with an average length of stay of 20.2 days and average costs of $101,092. We reviewed these assignments and noted that the special logic in MS–DRGs 673, 674, and 675 for pancreatic islet cell transplantation is defined by ICD–10–CM diagnosis codes E10.21 (Type 1 diabetes mellitus with diabetic nephropathy), E10.22 (Type 1 diabetes mellitus with diabetic chronic kidney disease) and E10.29 (Type 1 diabetes mellitus with other diabetic kidney complication). As noted previously, the ICD–10–PCS procedure codes describing the introduction of pancreatic islet cells are all designated as non-O.R. procedures affecting assignment only to MS–DRGs 673, 674, and 675. Therefore, when diagnosis codes E10.21, E10.22, or E10.29 are not reported as principal diagnosis, the MS–DRG assignment is determined by the principal diagnosis and other procedures reported on the claim when the ICD–10–PCS procedure codes describing the introduction of pancreatic islet cells are assigned.

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule, pancreatic islet cell transplantation is indicated for patients with type 1 diabetes who have attempted to control their hypoglycemic episodes medically but continue to have hypoglycemic episodes without recognizing them.[13] As the indication for pancreatic islet cell transplantation is not limited to patients with type 1 diabetes mellitus with kidney complications, we stated we believe the special logic in MS–DRGs 673, 674, and 675 for pancreatic islet cell transplantation does not fully reflect the indications for pancreatic islet cell transplantation.

In the proposed rule, we further noted in type 1 diabetes, the body's immune system attacks and destroys the beta cells. Patients with type 1 diabetes must take insulin because their bodies no longer make this hormone. In patients for whom the primary indication for transplantation is unstable glycemic control, particularly hypoglycemic unawareness, the choice is between solid-organ pancreas transplantation alone or islet transplantation.[14] Islet cell transplantation offers a less invasive established alternative to pancreas transplant, and the procedures are regulated similarly.[15] The goal of both pancreas whole organ transplant and islet cell transplantation is to enable effective, stable glycemic management (often with insulin independence), to improve quality of life, and to reduce secondary complications. Both pancreas and islet cell transplantation require lifelong immunosuppression to prevent rejection of the graft. Islet transplantation may be performed at the same time as or after a kidney transplant. Kidney transplant recipients will already be taking immunosuppressants to prevent rejection of the transplanted kidney. Therefore, the islet transplant does not add much more risk.

As discussed in prior rulemaking, the MS–DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. We generally seek to identify sufficient sets of claims data with demonstrated clinical similarity in developing diagnosis related groups. After reviewing the indications for both

[13] Spence KT, Ladie DE. Islets Transplantation. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK562272/*.

[14] Mittal S, Johnson P, Friend P. Pancreas transplantation: solid organ and islet. Cold Spring Harb Perspect Med. 2014 Apr 1;4(4):a015610. doi: 10.1101/cshperspect.a015610. PMID: 24616200; PMCID: PMC3968790.

[15] Rickels MR, Robertson RP. Pancreatic Islet Transplantation in Humans: Recent Progress and Future Directions. Endocr Rev. 2019 Apr 1;40(2):631–668. doi: 10.1210/er.2018–00154. PMID: 30541144; PMCID: PMC6424003.

whole organ pancreas transplant and pancreatic islet cell transplantation, and consideration of the intent of the MS–DRGs, we stated in the FY 2027 IPPS/LTCH PPS proposed rule we believe that for clinical coherence, the cases reporting procedure codes that describe the introduction of pancreatic islet cells should be grouped with the subset of cases that report pancreas transplant procedures. We stated that while we continue to acknowledge that islet cell transplants are not exactly the same as solid organ pancreas transplants, we believe the procedures are coherent given the similarity in clinical indication. For these reasons, we stated we believe reassigning the 11 ICD–10–PCS procedure codes that describe the introduction of pancreatic islet cells from MS–DRGs 673, 674, and 675 to Pre-MDC MS–DRG 008 (Simultaneous Pancreas and Kidney Transplant), MS–DRG 010 (Pancreas Transplant) and MS–DRG 019 (Simultaneous Pancreas and Kidney Transplant with Hemodialysis) would improve clinical coherence in these MS–DRGs.

The following table reflects the simulation of our proposed changes in MS–DRGs 008, 010, and 019.

MS-DRG		Number of Cases	Average Length of Stay	Average Cost
008	All Cases	168	9.3	$51,760
	-- add cases reporting procedure codes describing the introduction of pancreatic islet cells	0	0	$0
	Simultaneous Pancreas, Islet Cell and Kidney Transplant	**168**	**9.3**	**$51,760**
010	All Cases	20	15.8	$66,872
	-- add cases reporting procedure codes describing the introduction of pancreatic islet cells	8	18.9	$82,770
	Pancreas or Islet Cell Transplant	**28**	**16.7**	**$71,414**
019	All Cases	56	14.5	$69,841
	-- add cases reporting procedure codes describing the introduction of pancreatic islet cells	1	15	$160,401
	Simultaneous Pancreas, Islet Cell and Kidney Transplant with Hemodialysis	**57**	**14.5**	**$71,430**

We stated we believe that this simulation supports that the resulting MS–DRG assignments would be more clinically homogeneous, coherent and better reflect hospital resource use. As the table shows, for MS–DRG 008, there were a total of 168 cases with an average length of stay of 9.3 days and average costs of $51,760. For MS–DRG 010, there were a total of 20 cases with an average length of stay of 15.8 days and average costs of $66,872. For MS–DRG 019, there were a total of 56 cases with an average length of stay of 14.5 days and average costs of $69,841. We stated a review of this simulation shows that adding a new ''Islet Cell Transplant Procedures'' logic list, to the GROUPER logic in MS–DRGs 008, 010, and 019 has a limited effect on the average costs of these MS–DRGs, while leading to a grouping that is more coherent and better reflects the clinical severity and resource use involved in these cases.

In summary, for FY 2027, for clinical coherence, we proposed to add the 11 ICD–10–PCS procedure codes that describe the introduction of pancreatic islet cells to a new ''Islet Cell Transplant Procedures'' logic list in MS–DRGs 008, 010, and 019. Additionally, we also proposed to delete the sixth logic list entitled ''or Principal Diagnosis'' that is defined by ICD–10–CM diagnosis codes E10.21 (Type 1 diabetes mellitus with diabetic nephropathy), E10.22 (Type 1 diabetes mellitus with diabetic chronic kidney disease) and E10.29 (Type 1 diabetes mellitus with other diabetic kidney complication) and the seventh logic list entitled ''and Non-Operating Room Procedures'' from MS–DRGs 673, 674, and 675. Lastly, for consistency, we proposed to change the title of MS–DRG 008 from ''Simultaneous Pancreas and Kidney Transplant'' to ''Simultaneous Pancreas, Islet Cell and Kidney Transplant,'' proposed to change the title of MS–DRG 010 from ''Pancreas Transplant'' to ''Pancreas or Islet Cell Transplant'' and proposed to change the title of MS–DRG 019 from ''Simultaneous Pancreas and Kidney Transplant with Hemodialysis'' to ''Simultaneous Pancreas, Islet Cell and Kidney Transplant with Hemodialysis'' to better reflect the assigned procedures effective October 1, 2026, for FY 2027. Under this proposal, the current ''principal or secondary diagnosis'' logic in MS–DRGs 008, 010, and 019 would be maintained. Additionally, to maintain stability, we proposed to add logic to MS–DRG 010 to exclude cases also reporting kidney transplant procedures to ensure cases will continue to group accordingly to MS–DRGs 008 and 019.

We refer the reader to Table 6P.4a, Table 6P.4b, and Table 6P.4c associated with the FY 2027 IPPS/LTCH PPS proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) for the list of procedure codes we proposed to define in the ''Islet Cell Transplant Procedures'' logic list in Pre-MDC MS–DRGs 008, 010, and 019. We note that the surgical hierarchy for the proposed modification is discussed in section II.C.14. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule.

Comment: Many commenters expressed support for the proposal to add the 11 ICD–10–PCS procedure codes that describe the introduction of pancreatic islet cells to a new ''Islet Cell Transplant Procedures'' logic list in MS–DRGs 008, 010, and 019. Commenters stated they appreciate CMS' acknowledgement of the benefits of islet cell transplantation and stated they commend CMS for conducting an analysis and proposing to reassign the procedure codes to MS–DRGs that better reflect the clinical severity and resource use involved. Several commenters stated they agreed that the special logic in MS–DRGs 673, 674, and 675 did not fully reflect the indications for pancreatic islet cell transplantation and noted that deceased donor islet cell transplantation has been a proven and effective treatment indicated for adults with type 1 diabetes who are unable to approach target glycated hemoglobin levels because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. A commenter specifically

stated that they value CMS' rigorous assessment of islet cell transplantation to improve clinical alignment. Another commenter stated that the proposed addition of a new ''Islet Cell Transplant Procedures'' logic list in MS–DRGs 008, 010, and 019 leads to groupings that are more coherent with diagnoses and procedures with similar clinical characteristics and utilization of resources. This commenter stated they agreed with CMS' approach in acknowledging the unique nature of islet cell transplant procedures and appreciate CMS' efforts to find a more suitable payment methodology for cases that report procedure codes that describe the introduction of pancreatic islet cells.

Response: We appreciate the commenters' support.

Comment: While expressing support for CMS' proposal to reassign the 11 ICD–10–PCS procedure codes that describe the introduction of pancreatic islet cells from MS–DRGs 673, 674, and 675 to improve clinical coherence, a commenter stated that they believe that assigning these procedure codes into MS–DRG 010 (Pancreas Transplant) is structurally unsuitable due to the fundamental clinical, operational, and cost distinctions between a manufactured cellular biologic and a standard whole-organ product because unlike a standard solid-organ pancreas transplant, donislecel-jujn (Lantidra™) has a distinct commercial product acquisition cost as a manufactured allogeneic cellular biologic. This commenter recommended CMS create a new, dedicated Pre-MDC MS–DRG specifically for ''Allogeneic Islet Cellular Therapies'' that captures the commercial acquisition costs of this FDA approved cellular biologic to align hospital payment with the resource-intensive nature of the therapy, and ensure patients have equitable access to a reasonable and necessary treatment that addresses a critical unmet clinical need.

Another commenter stated they continue to believe that MS–DRG 018 (Chimeric Antigen Receptor (CAR) T–Cell and Other Immunotherapies) is a more appropriate assignment for ICD–10–PCS code XW033DA (Introduction of donislecel-jujn allogeneic pancreatic islet cellular suspension into peripheral vein, percutaneous approach, new technology group 10) to ensure strong clinical and hospital adoption. This commenter recommended that CMS consider the totality of other relevant clinical circumstances that differentiate (or tie together) the procedure from other procedures assigned to the applicable MS–DRG so as not to chill development in the still nascent but growing field of cell and gene therapy to the detriment of patients.

Commenters recommended that CMS conduct a full and individualized evaluation of clinical and resource coherence when evaluating other future technologies, including future cell and gene therapies involving islet cells. Several commenters stated that there are noteworthy islet cell therapies under investigation that are substantially different from both traditional donor-derived transplantation and more recent allogeneic (deceased donor) islet cell therapies. A commenter stated that donor-derived islet therapies such as donislecel-jujn (Lantidra™) have limited manufacturing capacity as they use cells isolated from deceased human organs, and act like an organ transplant by requiring lifelong immunosuppression, while manufactured, or stem cell-derived, islet cell therapies use lab-grown cells engineered from pluripotent cells to provide an unlimited supply. In light of the islet cell therapies currently in clinical trial, several commenters recommended that CMS consider the clinical and resource related distinctions, unique administrative requirements, clinical outcomes, and manufacturing requirements that warrant differentiation from currently approved islet cell therapies when these investigational islet cell replacement technologies move to approval.

Response: We thank commenters for sharing their views and recommendations. We will take the commenters' feedback into consideration in future policy development. As discussed in the FY 2027 proposed rule, and in prior rulemaking (90 FR 36554 through 36560), we are in the process of carefully considering the feedback we have previously received about ways in which we can continue to appropriately reflect resource utilization associated with cell and gene therapies while maintaining clinical coherence and stability in the relative weights under the IPPS MS–DRGs.

As we examine these complex issues in consideration for future rulemaking, we continue to believe that for clinical coherence, the cases reporting procedure codes that describe the introduction of pancreatic islet cells should be grouped with the subset of cases that report pancreas transplant procedures for FY 2027, after reviewing the indications for both whole organ pancreas transplant and pancreatic islet cell transplantation, and consideration of the intent of the MS–DRGs. Accordingly, we continue to believe that reassigning the 11 ICD–10–PCS procedure codes that describe the introduction of pancreatic islet cells from MS–DRGs 673, 674, and 675 to Pre-MDC MS–DRG 008 (Simultaneous Pancreas and Kidney Transplant), MS–DRG 010 (Pancreas Transplant) and MS–DRG 019 (Simultaneous Pancreas and Kidney Transplant with Hemodialysis) will improve clinical coherence in these MS–DRGs.

Comment: A commenter noted that we proposed to change of title of MS–DRG 008 from ''Simultaneous Pancreas and Kidney Transplant'' to ''Simultaneous Pancreas, Islet Cell and Kidney Transplant,'' and that we proposed to change the title of MS–DRG 019 from ''Simultaneous Pancreas and Kidney Transplant with Hemodialysis'' to ''Simultaneous Pancreas, Islet Cell and Kidney Transplant with Hemodialysis'' to better reflect the assigned procedures. This commenter stated that they believe that the use of the word ''and'' instead of ''or'' in the titles for these MS–DRGs is concerning and recommended the title of MS–DRG 008 be changed to ''Simultaneous Kidney, Pancreas and/or Islet Cell Transplant'' and the title for MS–DRG 019 be changed to ''Simultaneous Pancreas, Islet Cell and/or Kidney Transplant with Hemodialysis.''

Response: We thank the commenter for their feedback.

With respect to the titles of MS–DRGs 008 and 019, we will consider this suggestion for future rulemaking. While we disagree with using the conjunction ''and/or'' in the title of these new MS–DRGs, as we have found the conjunction can lead to ambiguity, we acknowledge that we did consider other alternatives to the revision of the titles of MS–DRG 008 and MS–DRG 019. After review, we found that ''Simultaneous Pancreas, Islet Cell and Kidney Transplant,'' and ''Simultaneous Pancreas, Islet Cell and Kidney Transplant with Hemodialysis,'' respectively, were the most appropriate options to better reflect the assigned procedures after our proposed modifications, given the conventions of the classification.

To assist interested parties in understanding what conditions must be met to satisfy the GROUPER logic for MS–DRG 008, we note that we provided a logic table in the draft version of the ICD–10 MS–DRG Definitions Manual, Version 44, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.* The logic table is reflected as follows:

Pancreas Transplant	*Islet Cell Transplant*	*Kidney Transplant*	*Renal Failure PDX/SDX*	*Diabetes SDX/PDX*	*DRG*
Yes	n/a	Yes	Yes	Yes	008
n/a	Yes	Yes	Yes	Yes	008

Similarly, we provided a logic table for MS–DRG 019 in the draft version of the ICD–10 MS–DRG Definitions Manual, Version 44. The logic table is reflected as follows:

Pancreas Transplant	*Islet Cell Transplant*	*Kidney Transplant*	*Hemodialysis*	*Renal Failure PDX/SDX*	*Diabetes PDX/SDX*	*DRG*
Yes	n/a	Yes	Yes	Yes	Yes	019
n/a	Yes	Yes	Yes	Yes	Yes	019

These logic tables will also be reflected in the final ICD–10 MS–DRG Definitions Manual, Version 44. We will continue to review these MS–DRGs to determine if additional refinements to their titles may be warranted in the future.

After consideration of the public comments received, we are finalizing our proposal to add the 11 ICD–10–PCS procedure codes that describe the introduction of pancreatic islet cells to a new ''Islet Cell Transplant Procedures'' logic list in MS–DRGs 008, 010, and 019, effective October 1, 2026, without modification, for FY 2027. Additionally, we are also finalizing our proposal to delete the sixth logic list entitled ''or Principal Diagnosis'' that is defined by ICD–10–CM diagnosis codes E10.21 (Type 1 diabetes mellitus with diabetic nephropathy), E10.22 (Type 1 diabetes mellitus with diabetic chronic kidney disease) and E10.29 (Type 1 diabetes mellitus with other diabetic kidney complication) and the seventh logic list entitled ''and Non-Operating Room Procedures'' from MS–DRGs 673, 674, and 675. Lastly, for consistency, we are finalizing our proposals to change the title of MS–DRG 008 from ''Simultaneous Pancreas and Kidney Transplant'' to ''Simultaneous Pancreas, Islet Cell and Kidney Transplant,'' to change the title of MS–DRG 010 from ''Pancreas Transplant'' to ''Pancreas or Islet Cell Transplant'' and to change the title of MS–DRG 019 from ''Simultaneous Pancreas and Kidney Transplant with Hemodialysis'' to ''Simultaneous Pancreas, Islet Cell and Kidney Transplant with Hemodialysis'' to better reflect the assigned procedures, effective October 1, 2026, without modification, for FY 2027. Under this finalization, the current ''principal or secondary diagnosis'' logic in MS–DRGs 008, 010, and 019 will be maintained. Additionally, to maintain stability, we are finalizing our proposal to add logic to MS–DRG 010 to exclude cases also reporting kidney transplant procedures to ensure cases will continue to group accordingly to MS–DRGs 008 and 019.

7. MDC 12 (Diseases and Disorders of the Male Reproductive System): Prostatectomy

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19358 through 19360), we stated consistent with our annual review of the MS–DRGs, we identified that the current GROUPER logic for MDC 12 MS–DRGs 707 and 708 (Major Male Pelvic Procedures with MCC and without CC/MCC, respectively) contains a logic list referred to as ''OPERATING ROOM PROCEDURES'' that includes 51 procedure codes describing various male pelvic procedures, including procedure codes describing the destruction, or resection of the prostate, and also includes eight procedure code combinations or procedure code ''clusters'' that, when reported together, satisfy the logic for assignment to MS–DRGs 707 and 708. In this final rule, we would like to correct the statement in the proposed rule and note that in the ICD–10 MS–DRG Definitions Manual Version 43.1, the logic list referred to as ''OPERATING ROOM PROCEDURES'' includes 53 procedure codes describing various male pelvic procedures, including procedure codes describing the destruction, or resection of the prostate, and also includes eight procedure code combinations or procedure code ''clusters'' that, when reported together, satisfy the logic for assignment to MS–DRGs 707 and 708. The code combinations are represented by two procedure codes and include one code for the resection of the prostate with one code for the resection of bilateral seminal vesicles.

We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 43.1, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software,* for complete documentation of the GROUPER logic for MDC 12 MS–DRGs 707 and 708.

The eight ICD–10–PCS procedure code combinations currently assigned to MS–DRGs 707 and 708 that identify the resection of the prostate with the resection of bilateral seminal vesicles are shown in the following table:

ICD-10-PCS Code	Description
0VT00ZZ and 0VT30ZZ	Resection of prostate, open approach Resection of bilateral seminal vesicles, open approach
0VT00ZZ and 0VT34ZZ	Resection of prostate, open approach Resection of bilateral seminal vesicles, percutaneous endoscopic approach
0VT04ZZ and 0VT30ZZ	Resection of prostate, percutaneous endoscopic approach Resection of bilateral seminal vesicles, open approach
0VT04ZZ and 0VT34ZZ	Resection of prostate, percutaneous endoscopic approach Resection of bilateral seminal vesicles, percutaneous endoscopic approach
0VT07ZZ and 0VT30ZZ	Resection of prostate, via natural or artificial opening Resection of bilateral seminal vesicles, open approach
0VT07ZZ and 0VT34ZZ	Resection of prostate, via natural or artificial opening Resection of bilateral seminal vesicles, percutaneous endoscopic approach
0VT08ZZ and 0VT30ZZ	Resection of prostate, via natural or artificial opening endoscopic Resection of bilateral seminal vesicles, open approach
0VT08ZZ and 0VT34ZZ	Resection of prostate, via natural or artificial opening endoscopic Resection of bilateral seminal vesicles, percutaneous endoscopic approach

As we examined the GROUPER logic that would determine an assignment of a case to MDC 12 MS–DRGs 707 and 708 as discussed in the proposed rule, we noted that ICD–10–PCS codes 0VT00ZZ (Resection of prostate, open approach) and 0VT04ZZ (Resection of prostate, percutaneous endoscopic approach) that describe the resection of the prostate, differing only in approach, are assigned to MS–DRGs 707 and 708 as standalone procedures, as well as being included in one of the eight procedure code combinations, or code clusters, listed previously in these same MS–DRGs. We noted that the GROUPER software program will recognize codes 0VT00ZZ and 0VT04ZZ and assign MS–DRGs 707 and 708 even when a procedure code describing the resection of the bilateral seminal vesicles is not also reported when the other parameters of the GROUPER logic are met. As procedure codes 0VT00ZZ and 0VT04ZZ are assigned to MS–DRGs 707 and 708 as standalone procedures, specific assignment of these procedure codes in procedure code combinations in MS–DRGs 707 and 708 is not required.

During our review of this issue, as discussed in the proposed rule, we noted that that ICD–10–PCS codes 0VT07ZZ (Resection of prostate, via natural or artificial opening) and 0VT08ZZ (Resection of prostate, via natural or artificial opening endoscopic) that describe the transurethral resection of the prostate, or removal of the prostate using an instrument inserted through the urethra, are also represented in the eight procedure code combinations in MS–DRGs 707 and 708. These codes are assigned to MDC 12 MS–DRGs 713 and 714 (Transurethral Prostatectomy with CC/MCC and without CC/MCC) when reported as standalone procedures. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 43.1, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software,* for complete documentation of the GROUPER logic for MDC 12 MS–DRGs 713 and 714.

We stated we then analyzed claims data from the September 2025 update of the September 2025 MedPAR file for all cases in MS–DRGs 707 and 708 and compared the results to cases reporting procedure codes describing transurethral prostatectomy and resection of bilateral seminal vesicles in these MS–DRGs. Our findings are shown in the following table.

MS-DRGS 707-708: ALL CASES AND CASES REPORTING PROCEDURE CODES DESCRIBING TRANSURETHRAL PROSTATECTOMY AND RESECTION OF BILATERAL SEMINAL VESICLES			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 707--All cases	1,697	3.1	$19,942
MS-DRG 707--Cases reporting procedure codes describing transurethral prostatectomy and resection of bilateral seminal vesicles	3	4	$14,896
MS-DRG 708--All cases	1,685	1.5	$14,075
MS-DRG 708--Cases reporting procedure codes describing transurethral prostatectomy and resection of bilateral seminal vesicles	1	1	$6,726

As shown in the table, for MS–DRG 707, we identified a total of 1,697 cases, with an average length of stay of 3.1 days and average costs of $19,942. Of the 1,697 cases in MS–DRG 707, there were three cases reporting transurethral prostatectomy and resection of bilateral seminal vesicles with an average length of stay of 4 days and average costs of $14,896. For MS–DRG 708, we identified a total of 1,685 cases, with an average length of stay of 1.5 days and average costs of $14,075. Of the 1,685 cases in MS–DRG 708, there was one case reporting transurethral prostatectomy and resection of bilateral seminal vesicles with a length of stay of 1 day and costs of $6,726.

We also examined claims data from the September 2025 update of the September 2025 MedPAR file for MS–DRGs 713 and 714. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
713	3,746	3.4	$14,670
714	860	1.7	$10,869

In MS–DRG 713, we found a total of 3,746 cases with an average length of stay of 3.4 days and average costs of $14,670. In MS–DRG 714, we found a total of 860 cases with an average length of stay of 1.7 days and average costs of $10,869.

Overall, the data analysis shows that the average costs for the cases reporting transurethral prostatectomy and resection of bilateral seminal vesicles in MS–DRGs 707 and 708 are more aligned with the average costs for all the cases in MS–DRGs 713 ($14,896 versus $14,670) and 714 ($6,726 versus $10,869), respectively.

We reviewed this issue and in the proposed rule noted that ICD–10–PCS procedure codes 0VT07ZZ or 0VT08ZZ describe transurethral resection of the prostate, and therefore, are most clinically aligned with the procedure codes assigned to MDC 12 MS–DRGs 713 and 714, where they are currently assigned when reported as standalone procedures.

Therefore, for FY 2027, we proposed to delete the eight ICD–10–PCS procedure code combinations listed previously from the GROUPER logic of MDC 12 MS–DRGs 707 and 708 (Major Male Pelvic Procedures with CC/MCC and without CC/MCC, respectively). Under this proposal, when the other parameters of the GROUPER logic are met, cases reporting procedure codes 0VT00ZZ (Resection of prostate, open approach) and 0VT04ZZ (Resection of prostate, percutaneous endoscopic approach) would group to MS–DRGs 707 and 708, even when a procedure code describing the resection of the bilateral seminal vesicles is not also reported. Additionally, under this proposal, when the other parameters of the GROUPER logic are met, cases reporting procedure codes 0VT07ZZ (Resection of prostate, via natural or artificial opening) or 0VT08ZZ (Resection of prostate, via natural or artificial opening endoscopic) would group to MS–DRGs 713 and 714 (Transurethral Prostatectomy with CC/MCC and without CC/MCC), even when a procedure code describing the resection of the bilateral seminal vesicles is not also reported.

Comment: Commenters supported the proposal to delete the eight ICD–10–PCS procedure code combinations listed previously from the GROUPER logic of MDC 12 MS–DRGs 707 and 708 (Major Male Pelvic Procedures with CC/MCC and without CC/MCC, respectively), effective October 1, 2026, for FY 2027.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to delete the eight ICD–10–PCS procedure code combinations listed previously from the GROUPER logic of MDC 12 MS–DRGs 707 and 708 (Major Male Pelvic Procedures with CC/MCC and without CC/MCC, respectively), without modification, effective October 1, 2026, for FY 2027.

As discussed in the proposed rule, during our review of this issue and the examination of the MS–DRGs within MDC 12, we noted that the title of MS–DRGs 715 and 716 is ''Other Male Reproductive System O.R. Procedures for Malignancy with and without CC/MCC, respectively'' and the title of MS–DRGs 717 and 718 is ''Other Male Reproductive System O.R. Procedures Except Malignancy with and without CC/MCC, respectively.'' In examining the GROUPER logic for these MS–DRGs and reviewing the diagnoses listed under the heading of ''Principal Diagnosis'' in the ICD–10 MS–DRG Definitions Manual, we stated we believe the titles for these MS–DRGs no longer accurately reflect the assigned diagnoses. The titles of DRGs 715, 716, 717, and 718 were established prior to the transition to the Medicare Severity DRGs (MS–DRGs) from the CMS DRGs (48 FR 39883). In the development of the DRGs, generally, in each MDC, a medical and a surgical class was formed and referred to as ''other medical diseases'' and ''other surgical procedures,'' respectively. The ''other'' medical and surgical classes are not as precisely defined from a clinical perspective and include diagnoses or procedures which are infrequently encountered. The ''other'' surgical class contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC. Assignment to the ''other'' surgical class should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate. As the cases in MS–DRGs 715 and 716 are further defined based on the precise principal diagnosis for which the patients were admitted to the hospital, we stated we believe it is appropriate to propose to revise the titles of these MS–DRGs for consistency. Therefore, we also proposed to change the title of MS–DRGs 715 and 716 from ''Other Male Reproductive System O.R. Procedures for Malignancy with and without CC/MCC, respectively'' to ''Male Reproductive System and Other O.R. Procedures for Malignancy with and without CC/MCC, respectively'' and to change the title of MS–DRGs 717 and 718 from ''Other Male Reproductive System O.R. Procedures Except Malignancy with and without CC/MCC, respectively'' to ''Other Male Reproductive System O.R. Procedures with and without CC/MCC, respectively'' to better reflect the assigned diagnoses.

As discussed in section II.C.1.b of the preamble of the proposed rule, we provided a test version of the ICD–10 MS–DRG GROUPER Software, Version 44, so that the public can better analyze and understand the impact of the proposals included in the proposed rule. In the proposed rule, we noted that at the time of the development of the test software, this issue was unable to be addressed and therefore, the test software did not reflect the proposed change to the title of MS–DRGs 715 and 716 from ''Other Male Reproductive System O.R. Procedures for Malignancy with and without CC/MCC, respectively'' to ''Male Reproductive System and Other O.R. Procedures for Malignancy with and without CC/MCC, respectively'' and the proposed change to the title of MS–DRGs 717 and 718 from ''Other Male Reproductive System O.R. Procedures Except Malignancy with and without CC/MCC, respectively'' to ''Other Male Reproductive System O.R. Procedures with and without CC/MCC, respectively'' in MDC 12 for Version 44.

Comment: Commenters supported the proposal to change the title of MS–DRGs 715 and 716 from ''Other Male Reproductive System O.R. Procedures for Malignancy with and without CC/MCC, respectively'' to ''Male Reproductive System and Other O.R. Procedures for Malignancy with and without CC/MCC, respectively'' and to change the title of MS–DRGs 717 and 718 from ''Other Male Reproductive System O.R. Procedures Except Malignancy with and without CC/MCC, respectively'' to ''Other Male Reproductive System O.R. Procedures with and without CC/MCC,

respectively'' effective October 1, 2026, for FY 2027.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the title of MS–DRGs 715 and 716 from ''Other Male Reproductive System O.R. Procedures for Malignancy with and without CC/MCC, respectively'' to ''Male Reproductive System and Other O.R. Procedures for Malignancy with and without CC/MCC, respectively'' and to change the title of MS–DRGs 717 and 718 from ''Other Male Reproductive System O.R. Procedures Except Malignancy with and without CC/MCC, respectively'' to ''Other Male Reproductive System O.R. Procedures with and without CC/MCC, respectively'', effective October 1, 2026, for FY 2027.

8. MDC 13 (Diseases and Disorders of the Female Reproductive System): Fluorescence Guided Procedures of the Female Reproductive System Using Pafolacianine

CYTALUX® (pafolacianine) is a folate receptor-targeted fluorescent optical imaging agent used as an adjunct for intraoperative identification of ovarian cancer. CYTALUX® binds to the folate receptors on these cancer cells and is endocytosed into folate receptor positive cancer cells. CYTALUX® is administered intravenously prior to gynecologic oncology procedures, including ovarian cytoreduction and debulking surgeries, and requires use of a near-infrared imaging system (NIR) to illuminate, thereby making cancer visible within the surgical field. CYTALUX® received FDA approval and is indicated as an adjunct for intraoperative identification of malignant lesions in adult patients with ovarian cancer. We note that CYTALUX® for the ovarian indication was approved for new technology add-on payments for FY 2024 (88 FR 58804 through 58810) and FY 2025 (89 FR 69120 through 69126).

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19360 through 19364), we received a request from the manufacturer of CYTALUX® to modify the GROUPER logic of MS–DRGs 736, 737, and 738 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with MCC, with CC, and without CC/MCC, respectively) by reassigning cases with an ICD–10–PCS code that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) to the higher severity level MS–DRG 736 (with MCC) or MS–DRG 737 (with CC). According to the requestor, the utilization of CYTALUX® does not change the surgical procedure but adds significant cost. The requestor performed their own analysis of Medicare claims data from October 1, 2023, through March, 31, 2025, and stated they found approximately 13 cases that used CYTALUX® in ovarian surgery and that they expect adoption to accelerate as NIR systems become more widely available. The requestor stated they found that over 50 percent of cases using CYTALUX® in ovarian procedures triggered new technology add-on payments averaging $2,285. The requestor also stated they found cases reporting an ICD–10–PCS code that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) within MS–DRG 737 exhibit higher average costs than baseline and align more closely with cases in MS–DRG 736. Additionally, the requestor stated their analysis also found cases that reported the use of CYTALUX® in MS–DRGs 739, 740, and 741 (Uterine and Adnexa Procedures for Non-Ovarian and Non-Adnexal Malignancy with MCC, with CC, and without CC/MCC, respectively) due to the reporting of diagnosis codes describing metastatic malignancies. The requestor stated their analysis found that cases reporting an ICD–10–PCS code that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) cases in MS–DRG 737 exhibited higher average costs than baseline ($34,735 vs. $23,538) and aligned more closely with cases in MS–DRG 736 ($39,682).

The requestor further asserted that their review of the Inpatient SAF indicated there were some accounts underreporting the full cost of the vial of CYTALUX® due to inconsistent guidance for single-use inpatient drugs and that, where applicable, pharmacy costs were adjusted to account for missing costs of the single-use vial. The requestor stated they found that cases reporting an ICD–10–PCS code that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) in MS–DRG 737 were approximately $11,000 more expensive than non-CYTALUX cases when controlled for the underreporting of costs. Therefore, the requestor suggested that CMS reassign cases with an ICD–10–PCS code that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) to MS–DRGs 736 or 737 to ensure accurate payment, clinical integrity, and to prevent barriers to hospital adoption of CYTALUX® as NIR system availability expands nationwide.

To begin our analysis, as discussed in the proposed rule, we reviewed the GROUPER logic for MS–DRGs 736, 737, 738, 739, 740, and 741. MS–DRGs 736, 737, 738, 739, 740 and 741 contains a logic list referred to as ''OPERATING ROOM PROCEDURES'' that includes 689 ICD–10–PCS procedure codes that describe uterine and adnexa procedures, a logic list referred to as ''Ovarian or Adnexal Malignancy PRINCIPAL DIAGNOSIS'' that includes 22 ICD–10–CM diagnosis codes that describe ovarian or adnexal malignancies and a logic list referred to as ''Non-Ovarian and Non-Adnexal Malignancy PRINCIPAL DIAGNOSIS'' that includes 36 ICD–10–CM diagnosis codes that describe non-ovarian and non-adnexal malignancies. We refer the reader to the ICD–10 MS–DRG Definitions Manual, Version 43.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for complete documentation of the GROUPER logic for MS–DRGs 736, 737, 738, 739, 740, and 741.

The following five ICD–10–PCS procedure codes describe fluorescence guided procedures of the female reproductive system using pafolacianine for the ovarian indication.

ICD-10-PCS Code	Description
8E0U0EN	Fluorescence guided procedure of female reproductive system using pafolacianine, open approach
8E0U3EN	Fluorescence guided procedure of female reproductive system using pafolacianine, percutaneous approach
8E0U4EN	Fluorescence guided procedure of female reproductive system using pafolacianine, percutaneous endoscopic approach
8E0U7EN	Fluorescence guided procedure of female reproductive system using pafolacianine, via natural or artificial opening
8E0U8EN	Fluorescence guided procedure of female reproductive system using pafolacianine, via natural or artificial opening endoscopic

In the ICD–10 MS–DRGs Definitions Manual Version 43.1, procedure codes 8E0U0EN, 8E0U3EN, 8E0U4EN, 8E0U7EN, and 8E0U8EN are designated as non-O.R. procedures for purposes of MS–DRG assignment, therefore when CYTALUX® is utilized during a uterine and adnexa procedure described by one of the 689 ICD–10–PCS procedure codes in the GROUPER logic for MS–DRGs 736, 737, 738, 739, 740, and 741, the ICD–10–PCS code describing the uterine and adnexa procedure will determine the surgical MS–DRG assignment to one of the previously listed surgical MS–DRGs based on the principal diagnosis reported.

We then examined claims data from the September 2025 update of the FY 2025 MedPAR file for MS–DRGs 736, 737, 738, 739, 740, and 741 to identify cases reporting one of the five procedure codes listed previously that describe fluorescence guided surgery using CYTALUX® (pafolacianine). Our findings are shown in the following table:

MS-DRGS 736, 737, 738, 739, 740 AND 741: ALL CASES AND CASES REPORTING PROCEDURE CODES THAT DESCRIBE FLUORESCENCE GUIDED SURGERY USING CYTALUX® (PAFOLACIANINE)

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
736	All cases	647	8.5	$33,196
	Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine)	2	7	$28,068
737	All cases	1,803	4.3	$18,702
	Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine)	0	0	$0
738	All Cases	317	2.5	$13,519
	Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine)	0	0	$0
739	All cases	481	8.4	$33,235
	Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine)	2	1.5	$11,565
740	All cases	1,327	3.2	$16,784
	Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine)	1	5	$39,154
741	All Cases	740	1.7	$13,365
	Cases with procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine)	1	1	$14,036

As shown in the table, in MS–DRG 736, we identified a total of 647 cases with an average length of stay of 8.5 days and average costs of $33,196. Of those 647 cases, there were two cases reporting one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), with average costs lower than the average costs in the FY 2025 MedPAR file for MS–DRG 736 ($28,068 compared to $33,196) and a shorter average length of stay (7 days compared to 8.5 days). There were zero cases reporting one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) in MS–DRGs 737 and 738.

In MS–DRG 739, we identified a total of 481 cases with an average length of stay of 8.4 days and average costs of $33,235. Of those 481 cases, there were two cases reporting one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), with average costs lower than the average costs in the FY 2025 MedPAR file for MS–DRG 739 ($11,565 compared to $33,235) and a shorter average length of stay (1.5 days compared to 8.4 days). In MS–DRG 740, we identified a total of 1,327 cases with an average length of stay of 3.2 days and average costs of $16,784. Of those 1,327 cases, there was

one case reporting one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), with costs higher than the average costs in the FY 2025 MedPAR file for MS–DRG 740 ($39,154 compared to $16,784), and a longer length of stay (5 days compared to 3.2 days). In MS–DRG 741, we identified a total of 740 cases with an average length of stay of 1.7 days and average costs of $13,365. Of those 1,327 cases, there was one case reporting one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine), with costs higher than the average costs in the FY 2025 MedPAR file for MS–DRG 741 ($14,036 compared to $13,365), and a shorter length of stay (1 day compared to 1.7 days).

As discussed in the proposed rule, the data reflect the six cases reporting one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) found across MS–DRGs 736, 737, 738, 739, 740, and 741 have an average length of stay of 3.8 days and average costs of $22,076. These six cases have a shorter average length of stay (3.8 days versus 8.5 days) and lower average costs ($22,076 versus $33,196) when compared to all the cases in MS–DRG 736. The six cases reporting one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) found across MS–DRGs 736, 737, 738, 739, 740, and 741 have a shorter average length of stay (3.8 days versus 4.3 days) and higher average costs ($22,076 versus $18,702) when compared to all the cases in MS–DRG 737.

After reviewing the claims data, in the proposed rule we stated we believe it is premature to consider a proposal for cases with an ICD–10–PCS code that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) for FY 2027. While the data analysis reflects that six cases that report one of the five procedure codes that describe fluorescence guided surgery using CYTALUX® (pafolacianine) across MS–DRGs 736, 737, 738, 739, 740, and 741 demonstrate slightly higher average costs compared to all the cases in MS–DRG 737, the number of cases is small across the MS–DRGs. The claims data also reflect a wide variance with regard to the average costs for these cases reporting fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine). We noted the one case that reported a fluorescence guided procedure of the female reproductive system using CYTALUX® (pafolacianine) in MS–DRG 740 had a length of stay of 5 days and costs of $39,154, while the two cases that reported a procedure code describing a fluorescence guided procedure of the female reproductive system using CYTALUX® (pafolacianine) in MS–DRG 739 had an average length of stay of 1.5 days and average costs of $11,565.

In the proposed rule, we stated we could not ascertain from the claims data the resource use specifically attributable to the utilization of fluorescence guidance using CYTALUX® (pafolacianine) in procedures of the female reproductive system during inpatient admissions. We stated we recognize the average costs of the small numbers of cases reporting an ICD–10–PCS code that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) can be greater when compared to the average costs of all cases in their respective MS–DRG; however, the MS–DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. We further noted that section 1886(d)(5)(A) of the Act provides for Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for cases incurring extraordinarily high costs. We stated we believe it would be advantageous to allow for more claims data to be analyzed in consideration of any future modifications to the MS–DRGs for which fluorescence guided surgeries using CYTALUX® (pafolacianine) are assigned. We stated we will continue to evaluate the clinical coherence and resource consumption costs that impact this subset of cases and their MS–DRG assignment.

Therefore, for the reasons stated, for FY 2027, we did not propose to modify the GROUPER logic of MS–DRGs 736, 737, and 738 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with MCC, with CC, and without CC/MCC, respectively) by reassigning cases reporting ICD–10–PCS codes that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) to the higher severity level MS–DRG 736 (with MCC) or MS–DRG 737 (with CC).

Comment: Commenters expressed support for the decision to not modify the GROUPER logic of MS–DRGs 736, 737, and 738 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with MCC, with CC, and without CC/MCC, respectively) by reassigning cases reporting ICD–10–PCS codes that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine) to the higher severity level MS–DRG 736 (with MCC) or MS–DRG 737 (with CC) for FY 2027. A commenter stated that they understand the concerns regarding the current volume of cases available for analysis and acknowledge that additional claims data is needed before evaluating any potential MS–DRG reassignment of cases reporting ICD–10–PCS codes that describes fluorescence guided procedures of the female reproductive system using CYTALUX® (pafolacianine).

Response: We appreciate the commenters' support.

During our review of this issue, as discussed in the proposed rule, we noted that the data analysis reflects that in cases reporting uterine and adnexa procedures in MS–DRGs 736, 737, 738, 739, 740, and 741, the average costs and length of stay are generally similar without regard to the presence of diagnosis codes describing ''ovarian or adnexal'' malignancies or ''non-ovarian or non-adnexal'' malignancies. In MS–DRG 736, there were 647 cases reporting an uterine and adnexa procedure with a principal diagnosis describing an ''ovarian or adnexal'' malignancy and a MCC with average costs of $33,196 and an average length of stay of 8.5 days compared to 481 cases reporting an uterine and adnexa procedure with a principal diagnosis describing a ''non-ovarian or non-adnexal'' malignancy and a MCC with average costs of $33,235 and an average length of stay of 8.4 days in MS–DRG 739. In MS–DRG 737, there were 1,803 cases reporting an uterine and adnexa procedure with a principal diagnosis describing an ''ovarian or adnexal'' malignancy and a CC with average costs of $18,702 and an average length of stay of 4.3 days compared to 1,327 cases reporting an uterine and adnexa procedure with a principal diagnosis describing a ''non-ovarian or non-adnexal'' malignancy and a CC with average costs of $16,784 and an average length of stay of 3.2 days in MS–DRG 740. In MS–DRG 738, there were 317 cases reporting an uterine and adnexa procedure with a principal diagnosis describing an ''ovarian or adnexal'' malignancy without a CC or an MCC with average costs of $13,519 and an average length of stay of 2.5 days compared to 740 cases reporting an uterine and adnexa procedure with a principal diagnosis describing a ''non-ovarian or non-adnexal'' malignancy

without a CC or an MCC with average costs of $13,365 and an average length of stay of 1.7 days in MS–DRG 741.

We reviewed these findings and stated in the proposed rule we believe that it may no longer be necessary to subdivide these MS–DRGs based on the diagnosis codes reported. In the FY 1987 proposed notice titled ''Medicare Program; Changes to the DRG Classification System'' (51 FR 8770 through 8771), we stated that our analysis of cases with a principal diagnosis of malignancy where both a hysterectomy and uterine or adnexa procedures were performed suggested that malignancies and non-malignancies should be classified in different DRGs, and that ovarian and adnexa cancers were the most resource intensive of the malignancies in the DRGs reviewed. We further stated that, among the cases examined in the DRGs, the diagnosis had consistently greater explanatory power with respect to resource intensity than did the procedure performed; therefore, we stated that cases with a principal diagnosis of malignancy would be further subdivided. Therefore, for FY 1987, DRG 357 (Non-Radical Hysterectomy, Uterus and Adnexa Procedures, for Ovarian and Adnexal Malignancy) and DRGs 354 and 355 (Non-Radical Hysterectomy, Uterus and Adnexa Procedures for Malignancy Except Ovarian/Adnexal Malignancy; Age over 69 and/or C.C., and Age under 70 without C.C., respectively) were created to ''increase homogeneity and thus more accurately reflect resource intensity of cases assigned to these DRGs'' (51 FR 31571).

As discussed in the proposed rule our analysis of claims data from the September 2025 update of the FY 2025 MedPAR file shows that in the 39 years since the DRGs for cases reporting uterine and adnexa procedures split based on the presence of diagnosis codes describing ''ovarian or adnexal'' malignancies or ''non-ovarian or non-adnexal'' malignancies were created, the resource utilization appears to now be more related to the procedures performed rather than the diagnoses describing malignancies reported on the claim, and therefore we stated we believe it is appropriate to restructure these MS–DRGs accordingly. In our direct comparison of the cases reporting diagnosis codes describing ''ovarian or adnexal'' malignancies or ''non-ovarian or non-adnexal'' malignancies in these MS–DRGs, we believe the distinction is no longer meaningful with regard to resource consumption. Clinically, a principal diagnosis of an ''ovarian or adnexal'' or a ''non-ovarian or non-adnexal'' malignancy in association with a uterine and adnexa procedure requires a commensurate level of patient care, including managing pain, monitoring for complications, ensuring proper wound and drain care, preventing blood clots, managing bowel function, and facilitating recovery through gradual activity, diet, and mobility. Decisions on potential further treatment like chemotherapy or radiation therapy for these diagnoses are based on the cancer's stage.

In the proposed rule we noted that, as discussed in prior rulemaking, the MS–DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. We generally seek to identify sufficient sets of claims data with demonstrated clinical similarity in developing diagnosis related groups. As a result of our analysis and review of this issue, and consideration of the intent of the MS–DRGs, we stated we believe the findings support restructuring the six MS–DRGs by proposing to create new MS–DRGs for uterine and adnexa procedures for female reproductive system malignancies and eliminating the logic that differentiates cases by reporting principal diagnoses describing ''ovarian or adnexal'' and ''non-ovarian or non-adnexal'' malignancies.

For these reasons, we proposed the deletion of MS–DRGs 736, 737, 738, 739, 740, and 741, and the creation of a base MS–DRG for cases reporting uterine and adnexa procedures and a principal diagnosis describing a female reproductive system malignancy, split by a three-way severity level subgroup. The following table illustrates our simulation of the proposal.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX Uterine and Adnexa Procedures for Malignancy	5,315	4.4	$20,251

Consistent with our established process as discussed in section II.C.1.b. of the preamble of the proposed rule and this final rule, once the decision has been made to propose to make further modifications to the MS–DRGs, all five criteria to create subgroups must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule. We note that, as shown in the table that follows, a three-way split of this proposed new base MS–DRG was met. The following table illustrates our findings.

Proposed new MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	1,128	8.5	$33,213
With CC	3,130	3.8	$17,889
Without CC/MCC	1,057	1.9	$13,411

For the proposed new MS–DRGs, there is (1) at least 500 cases in the MCC subgroup, the CC subgroup, and in the without CC/MCC subgroup; (2) at least 5 percent of the cases are in the MCC subgroup, the CC subgroup, and in the without CC/MCC subgroup; (3) at least a 20 percent difference in average costs between the MCC subgroup and the CC subgroup and between the CC group and NonCC subgroup; (4) at least a $2,000 difference in average costs between the MCC subgroup and the with CC subgroup and between the CC subgroup and NonCC subgroup; and (5) at least a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory

power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

Therefore, for FY 2027, we proposed to delete MS–DRGs 736, 737, 738, 739, 740, and 741 and proposed to create new MS–DRG 731 (Uterine and Adnexa Procedures for Malignancy with MCC), MS–DRG 732 (Uterine and Adnexa Procedures for Malignancy with CC), and MS–DRG 733 (Uterine and Adnexa Procedures for Malignancy without CC/MCC). We proposed to include the current list of 689 ICD–10–PCS procedure codes in the logic for MS–DRGs 736, 737, 738, 739, 740, and 741 for case assignment of uterine and adnexa procedures for the proposed new MS–DRGs. We refer the reader to Table 6P.5a and Table 6P.5b associated with the FY 2027 IPPS/LTCH PPS proposed rule (which are available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*) for the lists of the 58 diagnosis codes and 689 procedure codes we proposed to define in the logic for the proposed new MS–DRGs. We note that the surgical hierarchy for the proposed modification is discussed in section II.C.14. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule.

Comment: Commenters expressed support for the proposal to delete MS–DRGs 736, 737, 738, 739, 740, and 741 and to create new MS–DRGs 731, 732 and 733 in MDC 13 for FY 2027. Commenters also stated they agreed with the proposal to include the list of 689 ICD–10–PCS procedure codes currently in the logic for MS–DRGs 736, 737, 738, 739, 740, and 741 in the logic for the proposed new MS–DRGs. A commenter specifically stated they support the proposal to eliminate the current logic that differentiates cases based on principal diagnoses describing ''ovarian or adnexal'' versus ''non-ovarian or non-adnexal'' malignancies, as this change will improve clinical coherence and better align MS–DRG assignment with contemporary surgical practice patterns. This commenter thanked CMS for its thoughtful consideration of these issues and its ongoing efforts to ensure that MS–DRG classifications accurately reflect resource utilization and patient care.

Response: We thank the commenters for their support.

Comment: Another commenter stated that they seek clarification on how CMS will handle concomitant procedures in the proposed new MS–DRGs. The commenter noted that hysterectomy procedures are commonly performed concomitantly with procedures such as salpingectomies and oophorectomies. The commenter stated that while concomitant MS–DRGs exist in the classification, there are none that are representative of common gynecologic procedures and recommended that CMS explore avenues in which creating MS–DRGs for concomitant gynecologic procedures makes sense to better represent the actualized resource use for these procedures. This commenter stated that in reviewing the GROUPER logic of the proposed new MS–DRGs, a gynecologic oncology patient having a simple laparoscopic hysterectomy, and another gynecologic oncology patient having a total abdominal hysterectomy, bilateral salpingo-oophorectomy, and pelvic lymph node dissection would be assigned to the same MS–DRG despite the cases having a large gap in complexity. The commenter further stated that this structure could lead to many facilities only taking lower complexity gynecologic cases and fewer facilities taking higher complexity cases.

Response: We thank the commenter for the feedback.

In response to the request that CMS provide clarification on how combination procedures will be handled in the proposed new MS–DRGs, we note that we provided a test version of the ICD–10 MS–DRG GROUPER Software, Version 44, as discussed in the FY 2027 IPPS/LTCH PPS proposed rule and this final rule, so that the public can better analyze and understand the impact of the proposals included in the FY 2027 IPPS/LTCH PPS proposed rule, including testing how the reporting of multiple uterine and adnexa procedures in a single inpatient encounter would be handled in the proposed new MS–DRGs.

We further note that the proposal to create new MS–DRGs 731, 732, and 733 did not involve modifying the list of ICD–10–PCS procedure codes that describe uterine and adnexa procedures or proposing to create procedure code combinations in the GROUPER logic of the proposed new MS–DRGs. As discussed in the proposed rule, in the ICD–10 MS–DRG Definitions Manual, Version 43.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) the GROUPER logic for MS–DRGs 736, 737, 738, 739, 740, and 741 contains a logic list referred to as ''OPERATING ROOM PROCEDURES'' that includes 689 ICD–10–PCS procedure codes that describe uterine and adnexa procedures, a logic list referred to as ''Ovarian or Adnexal Malignancy PRINCIPAL DIAGNOSIS'' that includes 22 ICD–10–CM diagnosis codes that describe ovarian or adnexal malignancies and a logic list referred to as ''Non-Ovarian and Non-Adnexal Malignancy PRINCIPAL DIAGNOSIS'' that includes 36 ICD–10–CM diagnosis codes that describe non-ovarian and non-adnexal malignancies. We stated we proposed to include the list of 689 ICD–10–PCS procedure codes currently in the logic for MS–DRGs 736, 737, 738, 739, 740, and 741 in the logic for case assignment of uterine and adnexa procedures for the proposed new MS–DRGs 731, 732, and 733. Therefore, when multiple surgical uterine and adnexa procedures are performed, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned, application of the surgical hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class as discussed in section II.C.14. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule.

In response to the recommendation that CMS create MS–DRGs for procedures performed concomitantly for diseases and disorders of the female reproductive system, while we consider this recommendation to be outside the scope of the proposal included in the FY 2027 IPPS/LTCH PPS proposed rule, we encourage individuals with MS–DRG classification change requests to submit these requests no later than October 20, 2026, via MEARIS™ at: *https://mearis.cms.gov/public/home,* so that they can be considered for possible inclusion in an annual proposed rule.

In response to the suggestion that facilities may decide which cases to take on due to their potential MS–DRG assignment, we note that the choice of which or how many uterine and adnexa procedures to perform should not be based on potential facility payment. As we have stated in prior rulemaking (83 FR 41201), it is not appropriate for facilities to deny treatment to beneficiaries needing a specific type of therapy or treatment that involves increased costs.

Comment: A commenter stated that in reviewing the simulation of the proposal to create a base MS–DRG for cases reporting uterine and adnexa procedures and a principal diagnosis describing a female reproductive system malignancy, split by a three-way severity level subgroup, they were concerned that a non-equitable spread of cases across the three new MS–DRGs

could potentially result in lower average costs and lengths of stay for more complex cases. This commenter stated that CMS is proposing a fixed payment rate for the MCC cases to be $33,213, for CC cases to be $17,889, and for NonCC cases to be $13,411, and asserted that with the majority of cases being found at the CC level, it is imperative to ensure that the average cost is set as close to actualized resource use as possible. This commenter further recommended an ongoing review of usage and actualized costs of these new MS–DRGs to better understand where the average costs should land when usage stabilizes and recommended that CMS increase the average costs of the MCC cases to be closer to the outlier fixed-loss cost threshold in order to maintain financial stability within facilities working these cases and ensure access to these services does not continue to decrease due to potentially inadequate payment.

Response: We thank the commenter for expressing their concerns.

In response to the suggestion that CMS set the average costs of the cases at the CC level, and increase the average costs for MCC cases, we wish to clarify for the commenter that the average costs displayed in the table reflecting the simulation of the proposal do not reflect fixed payment rates for the proposed new MS–DRGs and furthermore, we wish to note that CMS does not set or establish the average costs of the cases in any MS–DRG.

The simulation of the proposal as described in the FY 2027 IPPS/LTCH PPS proposed rule was based on analysis of claims data from the September 2025 update of the FY 2025 MedPAR file. As discussed in section II.C.1.b of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2025 update of the FY 2025 MedPAR file, which contains fully coded diagnostic and procedure data for all Medicare inpatient hospital bills received from October 1, 2024, through September 30, 2025. Consequently, the values reflected in the ''number of cases'', ''average length of stay'', and ''average costs'' columns of the tables in the preamble of the proposed rule and this final rule are driven by the underlying claims data for cases reporting uterine and adnexa procedures and a principal diagnosis describing a female reproductive system malignancy from the September 2025 update of the FY 2025 MedPAR file.

Therefore, after consideration of the public comments we received, we are finalizing our proposal to delete MS–DRGs 736, 737, 738, 739, 740, and 741 and finalizing our proposal to create new MS–DRG 731 (Uterine and Adnexa Procedures for Malignancy with MCC), new MS–DRG 732 (Uterine and Adnexa Procedures for Malignancy with CC), and new MS–DRG 733 (Uterine and Adnexa Procedures for Malignancy without CC/MCC), effective October 1, 2026, without modification, for FY 2027. Under this finalization, the current list of 689 ICD–10–PCS procedure codes in the logic for MS–DRGs 736, 737, 738, 739, 740, and 741 will be included for case assignment of uterine and adnexa procedures for the new MS–DRGs 731, 732, and 733. We refer the reader to Table 6P.5a and Table 6P.5b associated with the FY 2027 IPPS/LTCH PPS proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) for the list of diagnosis codes and the list of procedure codes, respectively, that we are finalizing to define in the logic for each of the new MS–DRGs. We note that the surgical hierarchy for the finalized modification is discussed in section II.C.14. of the preamble of this final rule.

9. MDC 25 (Human Immunodeficiency Virus Infections): Significant HIV Related Conditions

As discussed in the proposed rule, under the ICD–10 IPPS MS–DRGs, each of the 25 MDCs generally reflect a major organ system or etiology. Within each MDC, there is a list of all the possible ICD–10–CM diagnoses or conditions that correspond to the specific organ system(s) or etiology reflected by the respective MDC title to ensure clinical coherence. When one of the listed conditions for a designated MDC is reported as a principal or secondary diagnosis, the ICD–10–CM diagnosis code informs the resulting MS–DRG assignment from within that MDC.

The logic for case assignment under MDC 25 (Human Immunodeficiency Virus Infections) is comprised of ICD–10–CM diagnosis code B20 (Human immunodeficiency virus [HIV] disease) when reported as a principal diagnosis or when reported as a secondary diagnosis with a principal diagnosis of a significant HIV related condition and the logic for case assignment specifically to MS–DRGs 974, 975, and 976 (HIV with Major Related Condition with MCC, with CC, without CC/MCC, respectively) under MDC 25 is comprised of ICD–10–CM diagnosis code B20 when reported as a principal or secondary diagnosis with a principal or secondary diagnosis of a major related condition as displayed in the ICD–10 MS–DRG Definitions Manual, Version 43.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*). We noted in the proposed rule that in reviewing the listed diagnoses that fall under the MDC 25 header ''AND PRINCIPAL DIAGNOSIS OF SIGNIFICANT HIV RELATED CONDITION'' as reflected in the ICD–10 MS–DRG Definitions Manual, Version 43.1, we identified that a number of the listed diagnoses under this specific header overlap with the listed diagnoses in the logic list for case assignment to MS–DRGs 974, 975, and 976 as a major related condition of HIV, as displayed in the ICD–10 MS–DRG Definitions Manual, Version 43.1. To improve clarity of the listed diagnoses between the header that reflects ''SIGNIFICANT'' and the diagnoses listed in the logic for case assignment to MS–DRGs 974, 975, and 976 described as ''Major'', we stated we believe the term ''SIGNIFICANT'' should be removed from the header under MDC 25.

As also discussed in the proposed rule, we identified a subset of diagnoses listed under the header ''AND PRINCIPAL DIAGNOSIS OF SIGNIFICANT HIV RELATED CONDITION'' that do not appear to describe a significant HIV related condition. For example, ICD–10–CM diagnosis code A09 Infectious gastroenteritis and colitis, unspecified, and ICD–10–CM diagnosis code A74.9 Chlamydial infection, unspecified, are listed under the current significant HIV header list of diagnoses; however, these same diagnoses are not listed as a major condition under MS–DRGs 974, 975, and 976. We stated we do not believe these conditions are clinically appropriate to be included as a significant HIV related condition. We further stated that we intend to perform additional review and analysis of the diagnoses listed in the logic for case assignment to MDC 25 as well as specifically, the logic for case assignment to MS–DRGs 974, 975, and 976 in consideration of any potential modifications that may be warranted. We noted that any discussion regarding proposed changes will be discussed in future rulemaking.

Therefore, for FY 2027, we proposed to remove the term ''SIGNIFICANT'' under the header for MDC 25 and revise it to reflect, ''AND PRINCIPAL DIAGNOSIS OF HIV RELATED CONDITION''.

Comment: Commenters supported the proposal to remove the term ''SIGNIFICANT'' under the header for MDC 25 and revise it to reflect, ''AND

PRINCIPAL DIAGNOSIS OF HIV RELATED CONDITION''. A commenter who expressed support for the proposal stated that the proposed change maintains the underlying logic for case assignment under the MDC 25 MS–DRGs while reducing confusion between the terms ''significant'' and ''major'' HIV-related conditions. The commenter stated that because the proposal improves consistency and transparency in MS–DRG descriptions they considered this proposed change to be an appropriate and noncontroversial technical update.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to remove the term ''SIGNIFICANT'' under the header for MDC 25 and revise it to reflect, ''AND PRINCIPAL DIAGNOSIS OF HIV RELATED CONDITION''.

10. Review of Procedure Codes in MS–DRGs 981 Through 983 and 987 Through 989

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move cases reporting these procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC. We use this information to determine which procedure codes and diagnosis codes to examine.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. We also consider whether it would be more appropriate to move the principal diagnosis codes into the MDC to which the procedure is currently assigned.

Based on the results of our review of the claims data from the September 2025 update of the FY 2025 MedPAR file of cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we did not identify any cases for reassignment and did not propose to move any cases from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into a surgical MS–DRG for the MDC into which the principal diagnosis or procedure is assigned.

In addition to the internal review of procedures producing assignment to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate to add procedure codes to one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls or to move the principal diagnosis to the surgical MS–DRGs to which the procedure codes are assigned. We stated we did not receive any requests suggesting reassignment.

We also review the list of ICD–10–PCS procedure codes that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, or 987 through 989, to ascertain whether any of those procedure codes should be reassigned from one of those two groups of MS–DRGs to the other group of MS–DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedure codes for which we have an adequate number of discharges to analyze the data.

Additionally, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate for the cases to be reassigned from one of the MS–DRG groups to the other. We stated that based on the results of our review of the claims data from the September 2025 update of the FY 2025 MedPAR file we did not identify any cases for reassignment. We also stated we did not receive any requests suggesting reassignment. Therefore, for FY 2027 we did not propose to move any cases reporting procedure codes from MS–DRGs 981 through 983 to MS–DRGs 987 through 989 or vice versa.

Comment: Commenters expressed support for CMS' proposal to not move any cases reporting procedure codes from MS–DRGs 981 through 983 to MS–DRGs 987 through 989 or vice versa.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to not move any cases reporting procedure codes from MS–DRGs 981 through 983 to MS–DRGs 987 through 989 or vice versa.

11. Operating Room (O.R.) and Non-O.R. Procedures

a. Background

Under the IPPS MS–DRGs (and former CMS MS–DRGs), we have a list of procedure codes that are considered operating room (O.R.) procedures. Historically, we developed this list using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. For example, generally the presence of a surgical procedure which required the use of the operating room would be expected to have a significant effect on the type of hospital resources (for example, operating room, recovery room, and anesthesia) used by a patient, and therefore, these patients were considered surgical. Because the claims data generally available do not precisely indicate whether a patient was taken to the operating room, surgical patients were identified based on the procedures that were performed.

Generally, if the procedure was not expected to require the use of the operating room, the patient would be considered medical (non-O.R.). Currently, each ICD–10–PCS procedure code has designations that determine whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment. First, each ICD–10–PCS procedure code is either designated as an O.R. procedure for purposes of MS–DRG assignment (''O.R. procedures'') or is not designated as an O.R. procedure for purposes of MS–DRG assignment (''non-O.R. procedures''). Second, for each procedure that is designated as an O.R. procedure, that O.R. procedure is further classified as either extensive or non-extensive. Third, for each procedure that is designated as a non-O.R. procedure, that non-O.R. procedure is further classified as either affecting the MS–DRG assignment or not affecting the MS–DRG assignment. We refer to these designations that do affect MS–DRG assignment as ''non-O.R. affecting the MS–DRG.'' For new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee code update process and are proposed to be classified as O.R.

procedures or non-O.R. procedures affecting the MS–DRG, we recommend the MS–DRG assignment which is then made available in association with the proposed rule (Table 6B.—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. For example, we generally examine the MS–DRG assignment for similar procedures, such as the other approaches for that procedure, to determine the most appropriate MS–DRG assignment for procedures proposed to be newly designated as O.R. procedures. As discussed in section II.C.15 of the preamble of this final rule, we are making Table 6B.—New Procedure Codes—FY 2027 available on the CMS website at*: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.html.* We also refer readers to the ICD–10 MS–DRG Version 43.1 Definitions Manual at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.html* for detailed information regarding the designation of procedures as O.R. or non-O.R. (affecting the MS–DRG) in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index.

In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19230), we stated that, given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, the incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. This will be a multiyear project during which we will also review the process for determining when a procedure is considered an operating room procedure. For example, we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data. We refer readers to the discussion regarding the designation of procedure codes in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38066) where we stated that the determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD–10–PCS classification, as well as changes in medical practice. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10.

We discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19230) that, as a result of this planned review and potential restructuring, procedures that are currently designated as O.R. procedures may no longer warrant that designation, and conversely, procedures that are currently designated as non-O.R. procedures may warrant an O.R. designation. We intend to consider the resources used and how a procedure should affect the MS–DRG assignment. We may also consider the effect of certain surgical approaches to evaluate whether to subdivide a subset of MS–DRGs based on a specific surgical approach. We stated we plan to utilize our available MedPAR claims data as a basis for this review and the input of our clinical advisors. As part of this comprehensive review of the procedure codes, we also intend to evaluate the MS–DRG assignment of the procedures and the current surgical hierarchy because both of these factor into the process of refining the ICD–10 MS–DRGs to better recognize complexity of service and resource utilization.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58540 through 58541), we provided a summary of the comments we had received in response to our request for feedback on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system for future consideration. We also stated that in consideration of the PHE, we believe it may be appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review. As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19366), we continue to believe additional time is necessary as we continue to develop our process and methodology.

Comment: Commenters supported CMS' plan to continue to conduct a comprehensive, systematic review of the ICD–10–PCS codes and to evaluate their current O.R. and non-O.R. designations. These commenters expressed that they were supportive of CMS' decision to continue to develop our process and methodology. Commenters stated they share CMS' interest in appropriately identifying the service complexity and resource utilization of inpatient procedures as these distinctions can materially affect the MS–DRG assignment and payment by determining whether the resource demands of a procedure are appropriately recognized. A commenter stated they appreciate CMS providing an update on its consideration of changes to the O.R. versus non-O.R. designation framework. Another commenter stated they agreed that the performance of a procedure in an operating room may no longer be the most critical differentiator between resource-intensive procedures for MS–DRG purposes. A commenter stated they agreed that the revolution in medical procedures in recent years may render the performance of a procedure in an O.R. a less critical distinction in driving payment policy and stated that because of technological advances, sophisticated, resource-intensive procedures are no longer confined to the O.R. setting and noted that in their observation, bi-plane radiology interventional suites and cardiac catheterization labs used for procedures such as mechanical thrombectomy or endovascular coiling for aneurysms can utilize more advanced equipment and supplies than a basic operating room with minimal installed equipment. Commenters recommended that CMS provide opportunities for public comment regarding its methodology and provide detailed impact files prior to the adoption of changes to MS–DRG structures or procedure code designations in the future.

Response: We appreciate the commenters' support and thank the commenters for sharing their views. We agree with commenters and believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10. Consistent with our established process, once we are in a position to provide more detail on this analysis and the methodology for conducting this comprehensive review, we will do so in future rulemaking, which will provide the public, including any interested parties, the opportunity to review and comment. We will also explore additional means of eliciting feedback and will notify the public of any other opportunities for communication and comment in the future.

Comment: As part of the broader and continuing conversation about the designations of procedures in the ICD–10–PCS classification system, a few commenters recommended that CMS work closely with physician specialty societies and industry stakeholders to identify the most important drivers of complexity and resource use in the hospital setting to incorporate into the

MS–DRG hierarchy. Several commenters specifically recommended that CMS include registered nurses when reviewing methodologies for determining the designation of procedure codes in the ICD–10–PCS classification system and noted that nurses are an integral part of the healthcare team, work closely with physicians in the operating room, and have firsthand knowledge and experience to know what hospital resources are needed for procedures. Other commenters further stated that omitting nurses only serves to discount their perspectives and could result in decision making that does not fully capture the hospital resources needed. Some commenters noted in the proposed rule we stated that historically we developed the list of procedure codes that are considered O.R. procedures using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. These commenters noted in the CY 2024 Physician Fee Schedule, CMS began using the term practitioner instead of physician to explicitly include all practitioners involved in the delivery of health care services, including nurses and recommended CMS change the name of the panels to ''practitioner panels'' to be consistent in its use of the term practitioner.

Response: We appreciate the commenters' feedback and will take the suggestions into consideration. We note that, as discussed in the CY 2024 Physician Fee Schedule (PFS) final rule (88 FR 78820), unless otherwise noted, the term ''practitioner'' is used throughout that final rule to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries. In regard to O.R. and non-O.R. designations, we note that while historically we may have developed the list of procedure codes that are considered O.R. procedures using physician panels, as we continue to develop our process and methodology to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes, CMS has already convened an internal team comprised of clinicians, consultants, coding specialists and other policy analysts. We have also provided the opportunity for interested parties to provide feedback as to what factors to consider in evaluating O.R. versus non-O.R. designations, and we welcome further input and feedback from interested parties, including nurses. While we do not agree that the term ''practitioner panel'' would be fully representative of the comprehensive expertise and varying viewpoints that will be provided by the internal team, we will consider a utilizing a term that better reflects the perspectives offered when referring to the team in future rulemaking.

Comment: Other commenters noted that for several years, CMS has expressed its intention to undertake a multi-year, comprehensive review of its system for designating ICD–10–PCS procedure codes as either O.R. or non-O.R. procedures to account for hospital resources. While expressing support for CMS' continued solicitation of stakeholder feedback, a commenter stated that they were concerned that CMS has again deferred meaningful progress on the comprehensive, multiyear review it has discussed in prior rulemaking and instead states that additional time is needed to develop its process and methodology. This commenter expressed that they believe the absence of further methodological development in the FY 2027 IPPS/LTCH PPS proposed rule prolongs uncertainty for hospitals and clinicians whose services may be affected by outdated procedure code designations and encouraged CMS to move from general statements of intent to a more transparent and actionable framework in future rulemaking, including a clear timeline for review, opportunities for specialty society input and explicit criteria for evaluating procedures whose resource intensity may not be well captured by legacy O.R. and non-O.R. designations.

Response: We thank the commenters for their feedback. We acknowledge that CMS has indicated we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes since the FY 2018 IPPS/LTCH PPS final rule. We wish to emphasize we have consistently indicated in prior rulemaking that this will be a multiyear project as extensive analyses are required to identify and evaluate all of the data relevant to assessing any potential modifications. Recognizing sufficient time is needed to provide feedback on what factors or criteria to consider in determining whether a procedure should be designated as an O.R. procedure in the ICD–10–PCS classification system, we also have provided opportunity for the public to provide feedback and we continue to solicit input.

As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58749), we have signaled in prior rulemaking that the designation of an O.R. procedure encompasses more than the physical location of the hospital room in which the procedure may be performed; in other words, the performance of a procedure in an operating room is not the sole determining factor we will consider as we examine the designation of a procedure in the ICD–10–PCS classification system. We stated we are exploring alternatives on how we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is available in the ICD–10 claims data. As part of this comprehensive review of the procedure codes, we are considering renaming the designations that determine whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment (that is, ''O.R. procedures'', ''non-O.R. procedures'', or ''non O.R. affecting the MS–DRG'') for consistency, as discussed in prior rulemaking (90 FR 36620). As part of this evaluation, we will also analyze the ICD–10 coded claims data to determine if the patients' diagnoses, the objective of the procedure performed, the specific anatomical site where the procedure is performed or the surgical approach used (for example, open, percutaneous, percutaneous endoscopic, among others) factor into the resources used and how a procedure should affect the MS–DRG assignment. We also intend to evaluate the MS–DRG assignment of the procedures and the current surgical hierarchy because both of these factor into the process of refining the ICD–10 MS–DRGs to better recognize complexity of service and resource utilization. We are considering the feedback received on what factors and/or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system as we continue to develop our process and methodology. Once we are in a position to provide more detail on this analysis and the methodology for conducting this comprehensive review, we will do so in future rulemaking.

We continue to encourage the public to continue to submit comments and feedback on any other factors to consider in our refinement efforts to recognize and differentiate consumption of resources for procedures within the ICD–10 MS–DRGs under the IPPS. We will also explore additional means of eliciting feedback and will notify the public of any other opportunities for communication and comment in the future. We also refer readers to Appendix E of the ICD–10 MS–DRG Version 43.1 Definitions Manual (which is available on the CMS website at: *https://www.cms.gov/Medicare/*

Medicare-Feefor-Service-Payment/AcuteInpatientPPS/MS-DRGClassifications-and-Software) for a list of all the ICD–10–PCS procedure codes that affect MS–DRG assignment (that is, procedure codes designated as O.R. procedures or as non-O.R. procedures affecting the MS–DRG), the MDCs and MS–DRGs to which they are assigned, and a description of the surgical categories. We encourage individuals with comments about the appropriate MDC, MS–DRG, and operating room designation of ICD–10–PCS procedure codes to submit these comments no later than October 20th of each year, via the Medicare Electronic Application Request Information System™ (MEARIS™) at: *https://mearis.cms.gov/public/home,* so that they can be considered for possible inclusion in an annual proposed rule.

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule, we received requests regarding changing the designation of specific ICD–10–PCS procedure codes from non-O.R. to O.R. procedures. In this section of the preamble of this final rule, as we did in the proposed rule, we summarize and respond to those requests. In this section of the preamble of this final rule, we also discuss the proposals we made based on our internal review and analysis and the process that was utilized for evaluating each procedure code. For each procedure, we considered—

- Whether the procedure would typically require the resources of an operating room;
- Whether it is an extensive or a non-extensive procedure; and
- To which MS–DRGs the procedure should be assigned.

We note that many MS–DRGs require the presence of any O.R. procedure. As a result, cases with a principal diagnosis associated with a particular MS–DRG would, by default, be grouped to that MS–DRG. Therefore, we do not list these MS–DRGs in our discussion in this section of the preamble of this final rule. Instead, we only discuss MS–DRGs that require explicitly adding the relevant procedure codes to the GROUPER logic in order for those procedure codes to affect the MS–DRG assignment as intended.

For procedures that would not typically require the resources of an operating room, we determined if the procedure should affect the MS–DRG assignment. In cases where we proposed to change the designation of procedure codes from non-O.R. procedures to O.R. procedures, we also proposed one or more MS–DRGs with which these procedures are clinically aligned and to which the procedure code would be assigned.

In addition, cases that contain O.R. procedures will map to MS–DRGs 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987, 988, or 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. These procedures need not be assigned to MS–DRGs 981 through 989 in order for this to occur. Therefore, we did not specifically address that aspect in summarizing the request and our response to that request or the proposals we made based on our internal review and analysis in the proposed rule and this section of the preamble of this final rule.

b. Non-O.R. Procedures to O.R. Procedures

(1) Introduction of Allogeneic Pancreatic Islet Cellular Suspension

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19366 through 19367), we received a request to change the designation of ICD–10–PCS code XW033DA (Introduction of donislecel-jujn allogeneic pancreatic islet cellular suspension into peripheral vein, percutaneous approach, new technology group 10) from a non-O.R. procedure to a O.R. procedure.

Donislecel-jujn (Lantidra™) is Food & Drug Administration (FDA) approved as an allogeneic pancreatic islet cellular therapy indicated for the treatment of adults with type 1 diabetes (T1D) who are unable to approach target HbA1c because of current, repeated episodes of severe hypoglycemia despite intensive diabetes management and education. Donislecel-jujn (Lantidra™) consists of a suspension of allogeneic pancreatic islets of Langerhans derived from a donor pancreas in buffered transplant medium containing sodium chloride, dextrose, minerals, amino acids, vitamins, and other compounds supplemented with HEPES (2-[4-(2-hydroxyethyl) piperazin-1-yl] ethanesulfonic acid; 10 mM final concentration) and human serum albumin (0.5 percent final concentration).

In the ICD–10 MS–DRGs Definitions Manual Version 43.1, procedure code XW033DA is currently designated as a non-O.R. procedure affecting assignment to MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively). We refer the reader to the ICD–10 MS–DRG Version 43.1 Definitions Manual (which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software* for complete documentation of the GROUPER logic for the MS–DRGs 673, 674, and 675.

According to the requestor, the clinical characteristics and costs of cases assigned to MS–DRGs 673 through 675 are significantly different from those associated with the administration of donislecel-jujn (Lantidra™). The requestor states that the cost of donislecel-jujn (Lantidra™) is high due to complex and highly regulated manufacturing processes for biologic cell products. According to the requestor, code XW033DA should be assigned to Pre MDC MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies) because donislecel-jujn (Lantidra™) is similar to other CAR–T technologies that map to DRG 018 as a cellular product, and in regard to procedure complexity, high cost, and is indicated for a rare patient population.

We reviewed this issue as discussed in the proposed rule and noted a proposal to create a procedure code that describes the administration of donislecel-jujn was presented and discussed at the March 19–20, 2024 ICD–10 Coordination and Maintenance Committee meeting and subsequently finalized. For new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee code update process, we recommend the O.R. designation, which is generally based on the assignment of predecessor codes or the assignment of similar codes. Consistent with our annual process of assigning new procedure codes to MDCs and MS–DRGs and designating a procedure as an O.R. or non-O.R. procedure, we reviewed the predecessor procedure code assignment. The predecessor code for procedure code XW033DA is procedure code 3E033U1 (Introduction of nonautologous pancreatic islet cells into peripheral vein, percutaneous approach) which is designated as a non-O.R. procedure affecting assignment to MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively).

We analyzed claims data from the September 2025 update of the FY 2025 MedPAR file for MS–DRGs 673, 674, and 675 for cases reporting procedure code XW033DA and did not find any

cases. We then extended our analysis to all MS–DRGs and again did not find any cases. We noted that these procedures do not typically require the resources of an operating room and are not surgical in nature. As such, we stated we disagree with designating procedure code XW033DA, which describes the intravenous portal vein administration of donislecel-jujn, as an O.R. procedure.

As discussed in the proposed rule, in reviewing this request, we noted the underlying intent of this request was to change the MS–DRG assignment of procedure code XW033DA from MS–DRGs 673, 674, and 675 to MS–DRG 018. In regard to the reassignment of procedure code XW033DA to MS–DRG 018, we noted that the category of cell and gene therapies continues to evolve. As discussed in prior rulemaking (90 FR 36554 through 36560), we are in the process of carefully considering the feedback we have previously received about ways in which we can continue to appropriately reflect resource utilization associated with cell and gene therapies while maintaining clinical coherence and stability in the relative weights under the IPPS MS–DRGs. We continue to examine these complex issues in consideration for future rulemaking. We acknowledge that there may be distinctions to account for as we continue to gain more experience in the use of these therapies and have additional claims data to analyze. We stated we believe this topic, relating to the administration of donislecel-jujn (Lantidra™), an allogeneic (donor) pancreatic islet cellular therapy, is appropriately aligned with and should be considered as part of that broader effort.

Therefore, for the reason discussed, we proposed to maintain the current designation of procedure code XW033DA as ''non-O.R. affecting the MS–DRG'' for FY 2027.

Comment: Commenters supported CMS' proposal to maintain the designation of procedure code XW033DA as ''non-O.R. affecting the MS–DRG'' for FY 2027.

Response: We appreciate the commenters' support.

Comment: While not taking a position on the O.R. or non-O.R. designation of ICD–10–PCS code XW033DA, several commenters stated that this proposal provided an opportunity to raise an ongoing, structural concern as they believe that CMS lacks a transparent, predictable, and clinically coherent framework for determining which cell and gene therapies map to MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies) versus other MS–DRGs, which makes it difficult for manufacturers and academic medical centers to anticipate MS–DRG mapping, complicates economic modeling, and creates payment volatility that ultimately affects patient access. These commenters urged CMS to develop and publish, through notice-and-comment rulemaking, prospective criteria for assignment to MS–DRG 018 as the cell and gene therapy product landscape continues to expand and recommended that CMS solicit public input on the broader assignment of cell and gene therapies into the MS–DRG system to improve Medicare inpatient payment for other existing and future cell and gene therapies as the field evolves.

Response: We thank commenters for sharing their views and recommendations. We will take the commenters' feedback into consideration in future policy development. As discussed in the FY 2027 proposed rule, and in prior rulemaking (90 FR 36554 through 36560), we are in the process of carefully considering the feedback we have previously received about ways in which we can continue to appropriately reflect resource utilization associated with cell and gene therapies while maintaining clinical coherence and stability in the relative weights under the IPPS MS–DRGs. We continue to examine these complex issues in consideration for future rulemaking.

After consideration of the public comments received, we are finalizing our proposal to maintain the designation of procedure code XW033DA (Introduction of donislecel-jujn allogeneic pancreatic islet cellular suspension into peripheral vein, percutaneous approach, new technology group 10) as ''non-O.R. affecting the MS–DRG'', for FY 2027. We refer the reader to the discussion in section II.C.6.b. of this final rule, regarding the finalized modifications for cases currently mapping to MS–DRGs 673, 674, and 675, effective October 1, 2026, for FY 2027.

(2) Percutaneous Introduction of AGN1 Bone Void Filler Into Bones

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19367 through 19368), one requestor identified ICD 10–PCS procedure code XW0V3WA (Introduction of AGN1 bone void filler into bones, percutaneous approach, new technology group 10) that the requestor stated is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor noted that the Local Osteo-Enhancement Procedure (LOEP) is an investigational surgical procedure designed to mechanically strengthen the proximal femur to reduce the risk of hip fractures in patients who are known to have weakened bones or other factors leading to a high risk of hip fracture. According to the requestor, the AGN1 LOEP Kit is expected to be indicated to reduce the risk of hip fracture in patients at risk of fragility fracture and require access to specialized equipment only available in the operating room (including anesthesia, C-arm, operating table, etc.). The requestor stated that FDA approval of the AGN1 LOEP Kit is anticipated in late 2027. According to the requestor, there may be situations where the procedure could be performed as a standalone procedure. The requestor noted the procedure may be performed under any one of the following three clinical scenarios (1) unilateral, standalone cases: a patient has one hip treated in a scheduled procedure, (2) bilateral, standalone cases: a patient has both hips treated in a scheduled procedure, or (3) concomitant to an index hip fragility fracture in the unfractured, contralateral hip: a patient has their index hip fracture repaired and then the procedure utilizing the LOEP kit is performed to treat the unfractured, contralateral hip during the same operative session. Therefore, the requestor stated that this procedure should be recognized as an O.R. procedure for purposes of MS–DRG assignment.

In the proposed rule we stated we agree with the requestor that in the ICD–10 MS–DRGs Definitions Manual Version 43.1, procedure code XW0V3WA is designated as a non-O.R. procedure for purposes of MS–DRG assignment; therefore, when the introduction of AGN1 bone void filler is reported with a procedure code that describes a surgical procedure, the ICD–10–PCS code describing the surgical procedure will determine the surgical MS–DRG assignment based on the principal diagnosis reported.

We reviewed this issue and note a proposal to create a procedure code that describes the percutaneous introduction of AGN1 bone void filler into bones was presented and discussed at the September 12–13, 2023 ICD–10 Coordination and Maintenance Committee meeting and subsequently finalized. For new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee code update process, we recommend the O.R. designation, which is generally based on the assignment of predecessor codes or the assignment of similar codes. Consistent with our annual process of assigning new procedure codes to MDCs and MS–

DRGs and designating a procedure as an O.R. or non-O.R. procedure, we reviewed the predecessor procedure code assignment. The predecessor code for procedure code XW0V3WA is procedure code 3E0V3GC (Introduction of other therapeutic substance into bones, percutaneous approach) which is designated as a non-O.R. procedure.

To evaluate the frequency with which procedure code XW0V3WA is reported for different clinical scenarios, as discussed in the proposed rule, we examined claims data from the September 2025 update of the FY 2025 MedPAR file to determine the MS–DRGs reporting procedure code XW0V3WA. Our findings are shown in the following table.

CASES REPORTING ICD-10-PCS CODE XW0V3WA				
MS-DRG	**Description**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
466	Revision of Hip or Knee Replacement with MCC	1	20	$29,229
482	Hip and Femur Procedures Except Major Joint without CC/MCC	1	3	$19,276
486	Knee Procedures with Principal Diagnosis of Infection with CC	1	7	$24,361
494	Lower Extremity and Humerus Procedures Except Hip, Foot and Femur without CC/MCC	1	1	$6,941
	Total	**4**	**7.8**	**$19,952**

There were four cases reporting the percutaneous introduction of AGN1 bone void filler into bones with procedure code XW0V3WA. Overall, the data indicate that the percutaneous introduction of AGN1 bone void filler into bones was not the underlying reason for, or main driver of, resource utilization for those cases. As shown in the table, when the procedure code XW0V3WA is reported, the MS–DRGs assigned are classified as surgical MS–DRGs which indicates that at least one procedure code designated as an O.R. procedure was also reported in these cases. We refer the reader to the ICD–10 MS–DRG Version 43.1 Definitions Manual (which is available on the CMS website at*: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for complete documentation of the GROUPER logic for the listed MS–DRGs.

After reviewing the claims data, in the proposed rule we stated we believe it is premature to consider a proposal to change the designation of the procedure code that describes the percutaneous introduction of AGN1 bone void filler into bones. While the September 2025 update of the FY 2025 MedPAR file does contain claims reporting the percutaneous introduction of AGN1 bone void filler into bones, the number of cases is small across the MS–DRGs. Additionally, as stated previously, when the procedure code XW0V3WA is reported, the MS–DRGs assigned are classified as surgical MS–DRGs, which indicates that at least one procedure code designated as an O.R. procedure was also reported in these cases. We stated we did not have claims data to further examine the impact of the percutaneous introduction of AGN1 bone void filler into bones when performed as a standalone procedure. The claims data also reflect a wide variance with regard to the average costs and average lengths of stay for the cases reporting the percutaneous introduction of AGN1 bone void filler into bones. As such, we stated we disagree with designating the procedure code that describes the percutaneous introduction of AGN1 bone void filler into bones as an O.R. procedure for FY 2027.

As noted previously, the Local Osteo-Enhancement Procedure (LOEP) is an investigational surgical procedure. In the absence of additional data, we stated in the proposed rule that we believe that more time is needed to consider the clinical characteristics and resource utilization associated with this procedure before considering changing the designation of the procedure code to an O.R. procedure. We stated that in future years, we expect we will have additional data that could be used to evaluate the O.R. designation of procedure code XW0V3WA.

Therefore, for the reasons discussed, we proposed to maintain the designation of procedure code XW0V3WA as non-O.R. for FY 2027.

Comment: Commenters supported CMS' proposal to maintain the designation of procedure code XW0V3WA as a non-O.R. procedure for FY 2027.

Response: We appreciate the commenters' support.

Comment: While thanking CMS for reviewing their request to classify ICD–10–PCS code XW0V3WA as an O.R. procedure for MS–DRG assignment, a commenter (the requestor) stated they continue to believe that the complexity of service, the associated resource utilization, and the need to be performed in the operating room as a standalone surgical procedure, supports designation of XW0V3WA as an O.R. procedure. The commenter noted that LOEP, an investigational surgical procedure designed to percutaneously implant AGN1 to treat diseased osteoporotic bone to reduce the risk of fragility fractures of the hip, may be performed as an independent standalone procedure on the unfractured hip opposite to the site of a hip fracture repair during the same operative session. The commenter stated when performed as a standalone procedure in the inpatient setting, the LOEP is clinically similar to hip fracture repair and requires similar resource utilization in the O.R. (for example, specialized equipment and instrumentation). Further, this commenter stated that in the four cases reporting the percutaneous introduction of AGN1 bone void filler into bones identified by CMS, procedure code XW0V3WA may have been inaccurately reported, given that the AGN1 LOEP is not yet on the market and is undergoing clinical trials.

Response: We thank the commenter for their feedback.

As we have signaled in prior rulemaking (88 FR 58750), the designation of an O.R. procedure encompasses more than the physical location of the hospital room in which the procedure may be performed; in other words, the performance of a procedure in an operating room is not the sole determining factor we consider as we examine the designation of a procedure in the ICD–10–PCS classification system. As discussed in the FY 2027 IPPS/LTCH PPS proposed rule, the examination of claims data from the September 2025 update of the FY 2025 MedPAR file indicates that the percutaneous introduction of AGN1 bone void filler into bones was not the underlying reason for, or main driver of, resource utilization in the cases identified. We note that in admissions where LOEP is performed in conjunction with surgical repair of the contralateral hip, the MS–DRG assignment will be dependent on the surgical repair procedure performed. Accordingly, in the cases identified

where procedure code XW0V3WA was reported, the MS–DRGs assigned are classified as surgical MS–DRGs, which indicates that at least one procedure code designated as an O.R. procedure was also reported in these cases. We do not have claims data to further examine the impact of the percutaneous introduction of AGN1 bone void filler into bones when performed in the absence of another surgical procedure to assess whether and in what way the presence of the procedure on a claim impacts the MS–DRG assignment.

As such we continue to believe it is premature to consider a change in the designation of the procedure code XW0V3WA that describes the percutaneous introduction of AGN1 bone void filler into bones. After reviewing the commenter's feedback and appreciating the concerns expressed by the commenter regarding the potential inaccurate reporting of the investigational local osteo-enhancement procedure, we believe that additional time is needed to allow for further analysis of the claims data to determine to what extent the percutaneous introduction of AGN1 bone void filler into bones has an effect on the hospital resources used by a patient in an inpatient admission.

Therefore, after consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to maintain the designation of ICD–10–PCS procedure code XW0V3WA (Introduction of AGN1 bone void filler into bones, percutaneous approach, new technology group 10) as a non-O.R. procedure, without modification, for FY 2027.

12. Changes to the MS–DRG Diagnosis Codes for FY 2027

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length-of-stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (NonCC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Overview of Comprehensive CC/MCC Analysis

In the FY 2008 IPPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization of diagnoses as an MCC, a CC, or a NonCC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We refer readers to the FY 2008 IPPS final rule (72 FR 47159) for a complete discussion of our approach. Since the comprehensive analysis was completed for FY 2008, we have evaluated diagnosis codes individually when assigning severity levels to new codes and when receiving requests to change the severity level of specific diagnosis codes.

We noted in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235 through 19246) that with the transition to ICD–10–CM and the significant changes that have occurred to diagnosis codes since the FY 2008 review, we believed it was necessary to conduct a comprehensive analysis once again. Based on this analysis, we proposed changes to the severity level designations for 1,492 ICD–10–CM diagnosis codes and invited public comments on those proposals. As summarized in the FY 2020 IPPS/LTCH PPS final rule, many commenters expressed concern with the proposed severity level designation changes overall and recommended that CMS conduct further analysis prior to finalizing any proposals. After careful consideration of the public comments we received, as discussed further in the FY 2020 IPPS/LTCH PPS final rule, we generally did not finalize our proposed changes to the severity designations for the ICD–10–CM diagnosis codes, other than the changes to the severity level designations for the diagnosis codes in category Z16 (Resistance to antimicrobial drugs) from a NonCC to a CC. We stated that postponing adoption of the proposed comprehensive changes in the severity level designations would allow further opportunity to provide additional background to the public on the methodology utilized and clinical rationale applied across diagnostic categories to assist the public in its review. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42150 through 42152) for a complete discussion of our response to public comments regarding the proposed severity level designation changes for FY 2020.

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550), to provide the public with more information on the CC/MCC comprehensive analysis discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules, CMS hosted a listening session on October 8, 2019. The listening session included a review of this methodology utilized to mathematically measure the impact on resource use. We refer readers to *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/Downloads/10082019ListingSessionTrasncriptandQandAsandAudioFile.zip* for the transcript and audio file of the listening session. We also refer readers to *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for the supplementary file containing the mathematical data generated using claims from the FY 2018 MedPAR file describing the impact on resource use of specific ICD–10–CM diagnosis codes when reported as a secondary diagnosis that was made available for the listening session.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58550 through 58554), we discussed our plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of nine guiding principles and plan to present the findings and proposals in future rulemaking. The nine guiding principles are as follows:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions.

- Reflects systemic impact.
- Post-operative/post-procedure condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation or management of care or both.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

We refer readers to the FY 2021 IPPS/LTCH PPS final rule for a complete summation of the comments we received for each of the nine guiding principles and our responses to those comments.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25175 through 25180), as another interval step in our comprehensive review of the severity designations of ICD–10–CM diagnosis codes, we requested public comments on a potential change to the severity level designations for ''unspecified'' ICD–10–CM diagnosis codes that we were considering adopting for FY 2022. Specifically, we noted we were considering changing the severity level designation of ''unspecified'' diagnosis codes to a NonCC where there are other codes available in that code subcategory that further specify the anatomic site. As summarized in the FY 2022 IPPS/LTCH PPS final rule, many commenters expressed concern with the potential severity level designation changes overall and recommended that CMS delay any possible change to the designation of these codes to give hospitals and their physicians time to prepare. After careful consideration of the public comments we received, we maintained the severity level designation of the ''unspecified'' diagnosis codes currently designated as a CC or MCC where there are other codes available in that code subcategory that further specify the anatomic site for FY 2022. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44916 through 44926) for a complete discussion of our response to public comments regarding the potential severity level designation changes. Instead, for FY 2022, we finalized a new MCE code edit for ''unspecified'' codes, effective with discharges on and after April 1, 2022. We stated we believe finalizing this new edit would provide additional time for providers to be educated while not affecting the payment the provider is eligible to receive. We refer the reader to section II.D.14.e. of the preamble of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44940 through 44943) for the complete discussion.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48866), we stated that as the new unspecified edit became effective beginning with discharges on and after April 1, 2022, we believed it was appropriate to not propose to change the designation of any ICD–10–CM diagnosis codes, including the unspecified codes that are subject to the ''Unspecified Code'' edit, as we continue our comprehensive CC/MCC analysis to allow interested parties the time needed to become acclimated to the new edit.

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28177 through 28181), we also requested public comments on how the reporting of diagnosis codes in categories Z55–Z65 might improve our ability to recognize severity of illness, complexity of illness, and/or utilization of resources under the MS–DRGs. We stated we were also interested in receiving feedback on how we might otherwise foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data.

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 58755 through 58759), based on our analysis of the impact on resource use for the ICD–10–CM Z codes that describe homelessness and after consideration of public comments, we finalized changes to the severity levels for diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and Z59.02 (Unsheltered homelessness), from NonCC to CC. In the FY 2025 proposed rule (89 FR 35995), we noted that since the FY 2021 IPPS/LTCH PPS final rule we have continued to solicit feedback regarding the nine guiding principles, as well as other possible ways we can incorporate meaningful indicators of clinical severity. We stated we had encouraged the public to provide a detailed explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code when providing feedback or comments. We also noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26748 through 26750) we illustrated how the nine guiding principles might be applied in evaluating changes to the severity designations of diagnosis codes in our discussion of our proposed changes to the severity level designation for certain diagnosis codes that describe homelessness. After consideration of the ongoing feedback and comments we had received, we proposed to finalize the nine guiding principles. After consideration of the public comments received, and for the reasons discussed, we finalized the nine guiding principles as listed previously in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69076 through 69078). Accordingly, we stated that our evaluations to determine the extent to which the presence of a diagnosis code as a secondary diagnosis results in increased hospital resource use will include a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of the nine guiding principles.

Additionally, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69079 through 69084), based on our analysis of the impact on resource use for the ICD–10–CM diagnosis codes that describe inadequate housing and housing instability, and after consideration of public comments, we finalized changes to the severity levels for seven diagnosis codes for FY 2025. We refer the reader to the following section of this final rule for our finalized changes to the severity level designation for the diagnosis codes that describe homelessness, inadequate housing and housing instability for FY 2027.

We have updated the Impact on Resource Use Files on the CMS website so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2019 through the FY 2025 MedPAR files. These files are posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.*

We encourage individuals with comments about the severity level designations of ICD–10–CM diagnosis codes to submit these comments no later than October 20th of each year, via the Medicare Electronic Application Request Information System™ (MEARIS™) at: *https://mearis.cms.gov/public/home,* so that they can be considered for possible inclusion in the annual proposed rule. When submitting requests to change the severity level designation of an ICD–10–CM diagnosis code when reported as a secondary diagnosis, we encourage the public to review the mathematical data for the impact on resource use generated using claims from the FY 2019 through the FY 2025 MedPAR files as well as to provide a detailed explanation of how applying

a suggested guiding principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code.

For new diagnosis codes approved for FY 2027, consistent with our annual process for designating a severity level (MCC, CC, or NonCC) for new diagnosis codes, we first review the predecessor code designation, followed by review and consideration of other factors that may be relevant to the severity level designation, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis or treatment of the condition. We note that this process does not automatically result in the new diagnosis code having the same designation as the predecessor code. We refer the reader to section II.C.13 of the preamble of this final rule for the discussion of the finalized changes to the ICD–10–CM and ICD–10–PCS coding systems for FY 2027.

c. Changes to Severity Levels

1. SDOH—Homelessness, Inadequate Housing, and Housing Instability

As discussed earlier in this section, in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58755 through 58759), we finalized changes to the severity levels for diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and Z59.02 (Unsheltered homelessness), from NonCC to CC. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69079 through 69084), we finalized changes to the severity levels for seven diagnosis codes that describe inadequate housing and housing instability from NonCC to CC. We stated CMS would further examine the claims data and consider future changes to the designation of the SDOH Z codes when reported as a secondary diagnosis. We further stated CMS would continue to monitor and evaluate the reporting of the diagnosis codes describing social and economic circumstances.

In continuation of our examination of the SDOH Z codes, as discussed in FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19370 through 19371), we reviewed the mathematical data on the impact on resource use for the ICD–10–CM Z codes that describe homelessness, inadequate housing, and housing instability. The following table reflects the impact on resource use data generated using claims from the September 2025 update of the FY 2025 MedPAR file. We refer readers to the FY 2008 IPPS final rule (72 FR 47159) for a complete discussion of our historical approach to mathematically evaluate the extent to which the presence of an ICD–10–CM code as a secondary diagnosis resulted in increased hospital resource use, and a more detailed explanation of the columns in the table.

ICD-10-CM Code[a]	Description[b]	Tota1 Count[c]	Cnt1[d]	C1[e]	Cnt2[f]	C2[g]	Cnt3[h]	C3[i]
Z59.00	Homelessness unspecified	30,603	3,308	1.67	13,544	2.24	13,751	3.24
Z59.01	Sheltered homelessness	14,271	1,538	1.81	6,236	2.28	6,497	3.23
Z59.02	Unsheltered homelessness	8,023	712	2.03	3,528	2.35	3,783	3.32
Z59.10	Inadequate housing, unspecified	2,019	74	1.97	853	2.16	1,092	3.03
Z59.11	Inadequate housing environmental temperature	753	32	1.96	281	1.76	440	3.10
Z59.12	Inadequate housing utilities	3,541	196	1.61	1,497	2.20	1,848	3.07
Z59.19	Other inadequate housing	2,277	145	1.62	904	2.63	1,228	3.27
Z59.811	Housing instability, housed, with risk of homelessness	14,069	720	1.02	5,215	2.13	8,134	3.07
Z59.812	Housing instability, housed, homelessness in past 12 months	593	37	1.83	268	2.42	288	3.04
Z59.819	Housing instability, housed unspecified	10,565	643	1.35	4,295	2.08	5,627	3.09

[a] This column is the secondary diagnosis code (SDX).
[b] This column is the title of the SDX.
[c] The total count of discharge claims with the SDX.
[d] Count of discharge claims with the SDX but with no other SDX or with all other SDX a NonCC.
[e] "C1" impact on resource use of the SDX for discharge claims in "Cnt1".
[f] Count of discharge claims with the SDX and with at least one other SDX that is a CC but none that is an MCC.
[g] "C2" impact on resource use of the SDX for discharge claims in "Cnt2".
[h] Count of discharge claims with the SDX and with at least one other SDX that is a MCC.
[i] "C3" impact on resource use of the SDX for discharge claims in "Cnt3".

We reviewed the findings from these data as discussed in the proposed rule. As reflected in the table, the C1 findings ranged from a low of 1.02 to a high of 2.03. A value close to 2.0 in the C1 field suggests that the condition is more like a CC than a NonCC but not as significant in resource usage as an MCC. Because the C1 values in the table are generally close to 2, the mathematical data suggest that when these SDOH Z codes are reported as a secondary diagnosis increased resources are involved in caring for patients experiencing these circumstances, however in the proposed rule we noted that these SDOH Z codes describe social circumstances and not medical conditions or illnesses.

As previously noted, in the FY 2008 IPPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization of diagnoses as an MCC, a CC, or a NonCC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We noted in the FY 2008 IPPS final rule that as a result of the changes that had occurred during the years since the implementation of the IPPS, the CC list as defined at the time had lost much of its capacity to discriminate hospital resource use. The need for a revised CC list prompted a reexamination of the secondary diagnoses that qualify as a CC. Therefore, our efforts to better recognize severity of illness began with a comprehensive review of the CC list. Our intent was to better distinguish cases that are likely to result in

increased hospital resource use based on secondary diagnoses.

We stated in the FY 2008 IPPS final rule (72 FR 47153) that certain diagnoses, such as chronic illness diagnoses, do not cause a significant increase in hospital resource use unless there is an acute exacerbation present or there is a significant deterioration in the underlying chronic condition. Therefore, in the revised CC list, we removed chronic diseases without a significant acute manifestation. We stated that recognition of the impact of the chronic disease is accomplished by separately coding the acute manifestation.

In our further examination of the claims data and the current designation of the ICD–10–CM Z codes that describe homelessness, inadequate housing, and housing instability when reported as a secondary diagnosis, in the proposed rule we stated we now believe that similar to our analysis of the chronic illness diagnoses, change of designation from NonCC to CC should be based on the expected resource use associated with the treatment of an underlying medical condition or illness rather than social circumstances. Specifically, we stated we believe that recognition of the contribution that patient social and economic circumstances, such as homelessness, inadequate housing, and housing instability, add to the complexity of acute hospital care should be accomplished by separately coding those diagnoses that describe an acute exacerbation or deterioration of an underlying medical condition or illness, similar to the approach we undertook in categorizing chronic illness diagnoses as stated in the FY 2008 IPPS final rule. While we continue to include a mathematical analysis of claims data in evaluating the extent to which the presence of a diagnosis code as a secondary diagnosis results in increased hospital resource use, as previously described, we stated we believe that in the context of the ICD–10–CM Z codes that describe social circumstances, it is more appropriate to align our analysis with our intent as stated in the FY 2008 IPPS final rule with respect to chronic illness diagnoses (that is, recognition of the contribution to the complexity of hospital care would be accomplished by separately coding those diseases on the CC list that are associated with an acute exacerbation or deterioration of the underlying medical condition or illness (72 FR 47154)). Accordingly, we stated we believe that categorization of a diagnosis code as an MCC, a CC, or a NonCC should recognize the clinical complexity and expected resource consumption for the treatment of an underlying medical condition or illness, and not social circumstances. Therefore, we proposed to change the severity level designation of diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), Z59.02 (Unsheltered homelessness), Z59.10 (Inadequate housing, unspecified), Z59.11 (Inadequate housing environmental temperature), Z59.12 (Inadequate housing utilities), Z59.19 (Other inadequate housing), Z59.811 (Housing instability, housed, with risk of homelessness), Z59.812 (Housing instability, housed, homelessness in past 12 months) and Z59.819 (Housing instability, housed unspecified) from CC to NonCC for FY 2027.

Comment: Commenters expressed support for our proposal to change the severity level designation of the ten ICD–10–CM Z codes that describe homelessness, inadequate housing, and housing instability from CC to NonCC. A commenter stated that they believed that designating these codes as CCs is an imperfect proxy for an associated increase in acuity and resource use and further stated they believe it would be better to address social determinants as part of other adjustments, such as value-based purchasing, to ensure that only actions taken to alleviate health-related social needs are rewarded with higher payments rather than simply the presence of the need. Another commenter stated that they agreed with CMS's rationale and stated treatment-disrupting conditions that reliably increase hospital resource use by interrupting or impeding the delivery of medically necessary care by delaying treatment initiation, increasing procedural complexity, prolonging staff time, and requiring escalation to specialized services should instead be identified to support a more accurate measurement of inpatient complexity, improve care planning, and inform future policy development.

Response: We thank the commenters for their support.

Comment: Some commenters urged CMS to maintain the current SDOH quality measures and to not lower their severity levels. Several commenters stated that rather than lowering the severity of the SDOH-related measures, CMS should consider incentivizing hospitals and health systems to fully implement them to transform data into actionable care interventions and catalyze healthcare innovations that integrate social service partners. Other commenters stated that lowering the severity level of the SDOH quality measures will disincentivize providers from fully implementing the measures and using them to improve patient care.

Response: We thank the commenters for their feedback.

In response to the suggestion that CMS maintain the severity of SDOH-related measures, we note that our proposal specifically relates to the severity level designation of the ICD–10–CM Z codes that describe homelessness, inadequate housing, and housing instability when reported as a secondary diagnosis. Our proposal does not relate to measures in the Hospital Inpatient Quality Reporting (IQR) Program, nor does it relate to measures in the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs. Further, we note that in the FY 2026 IPPS/LTCH PPS final rule (90 FR 37014), we finalized our proposal to remove the Screening for Social Drivers of Health (SDOH–1) measure and Screen Positive Rate for Social Drivers of Health (SDOH–2) measure from the Hospital IQR Program beginning with the FY 2026 payment determination. Additionally, we note that in the final rule for the Medicare Hospital Outpatient Prospective Payment System (OPPS) and the Medicare Ambulatory Surgical Center (ASC) payment system for calendar year (CY) 2026 (90 FR 53923), we finalized our proposal to remove the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure from the Hospital OQR, REHQR, and ASCQR Programs beginning with the CY 2025 reporting period.

Comment: Many other commenters opposed the proposal to change the severity level designation of the ten ICD–10–CM Z codes that describe homelessness, inadequate housing, and housing instability from CC to NonCC. Commenters stated that maintaining the severity designation of these codes as CCs is critical to ensure that hospital payment reflects the real-world resource demands associated with caring for unhoused individuals and reflects the realities faced by providers and community organizations serving some of the nation's most vulnerable populations. Some commenters stated this proposal shifts financial burden of caring for these patients onto hospitals and ignores the stark reality of delivering care to patients experiencing these circumstances, as providers and care coordination teams expend significantly more resources, time, care management, and cross-continuum planning to safely treat, manage, and discharge these patients compared to stably housed individuals. A commenter

asserted that finalizing this proposal will send a concerning message that housing instability does not complicate clinical care and diminish the importance of addressing SDOH in modern healthcare delivery, while in practice, housing instability is one of the most critical factors influencing treatment adherence, recovery, and readmission risk resulting from lack of follow-up. Other commenters stated that this change will disproportionately affect hospitals serving medically underserved populations and safety net hospitals that treat patients impacted by health-related social risk factors and stated that these providers will face more resource and infrastructure constraints while working to address the complex problems raised by housing homelessness, inadequate housing, and housing instability. These commenters stated this proposal risks widening existing disparities and will limit the ability of hospitals to invest in the very services that improve outcomes and reduce long-term costs.

A few commenters stated that incentives to ensure accurate coding of these social drivers of health are needed to better understand and address patient overall health and well-being. A commenter stated that in their own research, they found that the finalized changes to the severity levels of the diagnosis codes that describe homelessness to CCs in FY 2024 was associated with an immediate increase in inpatient documentation of homelessness and accelerated growth in documentation of other social determinants of health over the subsequent year. This commenter stated that these findings suggest that payment policy can meaningfully influence whether social risk factors are recognized and documented during hospitalization. Another commenter expressed concern that removing the CC designation might reduce the visibility of important social determinants of health data used for care planning, population health initiatives, and community resource allocation.

Some commenters noted that designation of an ICD–10–CM diagnosis code as a CC when reported as a secondary diagnosis is intended to reflect higher expected resource consumption, and stated that the Z codes that describe homelessness, inadequate housing, and housing instability clearly meet this criterion, based on the analysis of the mathematical data on the impact on resource use generated using claims from the September 2025 update of the FY 2025 MedPAR file. Several commenters noted that CMS used its own data-driven methodology in prior rulemaking to conclude that these conditions warranted CC designation because they are associated with greater hospital resource use, including longer lengths of stay driven by discharge barriers, higher care coordination needs, and greater clinical severity at presentation. These commenters stated that downgrading the severity designation of these SDOH Z-codes would represent a departure from the agency's longstanding data-driven methodology without a clearly articulated justification. A commenter specifically stated changing the severity level designation of the codes that describe homelessness, inadequate housing, and housing instability without new clinical evidence undermines hospital investment in integrating health-related social needs (HRSN) screening and intervention into hospital workflows. Other commenters recommended that CMS establish an alternative payment methodology before finalizing the proposal if CMS determines that the severity level designation is not the appropriate mechanism for recognizing social circumstances.

Response: We appreciate the commenters sharing their concerns.

As stated in prior rulemaking (90 FR 53923), we acknowledge that some patients may face challenges following discharge that may be related to SDOH and recognize that some clinicians may find value in obtaining SDOH information as part of clinical decision making, such as discharge planning and patient care. We also agree that healthcare outcomes may be different for those experiencing homelessness, inadequate housing, and housing instability. We further acknowledge that, as noted by the commenters and discussed in the proposed rule, CMS previously finalized changes to the severity levels for ICD–10–CM Z codes that describe homelessness, inadequate housing, and housing instability when reported as a secondary diagnosis based on our analysis of the impact on resource use for these codes and after consideration of public comments. However, as we also explained in the FY 2027 IPPS/LTCH PPS proposed rule, these SDOH Z codes describe social circumstances and not medical conditions or illnesses. After further consideration of the claims data and the current designation of the ICD–10–CM Z codes that describe homelessness, inadequate housing, and housing instability when reported as a secondary diagnosis, we believe that recognition of the contribution that patient social and economic circumstances, such as homelessness, inadequate housing, and housing instability, add to the complexity of acute hospital care should instead be accomplished by separately coding those diagnoses that describe an acute exacerbation or deterioration of an underlying medical condition or illness that is being treated in that inpatient admission. We note that the purpose of the DRGs is to relate a hospital's case mix to the resource demands and associated costs experienced by the hospital. As such we believe that any measurable increase in inpatient resource consumption associated with caring for patients experiencing homelessness, inadequate housing, and housing instability should be recognized by assigning ICD–10–CM diagnosis codes that describe the medical conditions that were more clinically severe at presentation, the conditions that required extended active treatment time and higher nursing intensity, and the conditions that were managed while the facilities navigated delays in securing clinically appropriate discharge due to the patients' social and economic circumstances, as documented in the medical record.

Comment: Some commenters stated that CMS did not identify any other diagnosis codes that would be appropriate to assign to capture the impact of homelessness, inadequate housing, and housing instability have on hospital resource utilization. These commenters suggested that if CMS finalizes the proposal to change the severity level designation of the ten ICD–10–CM Z codes that describe homelessness, inadequate housing, and housing instability, the agency should offer guidance to providers on evaluating and separately coding diagnoses that show an acute exacerbation or deterioration of an underlying medical condition or illness due to additional complexity added by homelessness and housing instability or inadequacy. Another commenter stated that recognition of the contribution that treatment of an underlying medical condition or illness adds to the complexity of acute hospital care can only be accomplished as long as there are codes available in the ICD–10–CM diagnosis code classification that allow for the acute exacerbation or deterioration of an underlying medical condition or illness to be coded separately.

Response: We appreciate the commenters' feedback.

In response to the assertion that CMS did not identify any other codes that would be appropriate to assign to capture the impact of homelessness, inadequate housing, and housing

instability have on hospital resource utilization, we note that assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. Therefore, the assignment of diagnosis codes that describe an underlying medical condition or illness that a patient experiencing homelessness, inadequate housing, and housing instability may have will depend on the specific terms used in the medical record documentation for each inpatient admission.

In response to the suggestion that CMS offer guidance to providers on evaluating and separately coding diagnoses that show an acute exacerbation or deterioration of an underlying medical condition or illness, we note that the ICD–10–CM Official Guidelines for Coding and Reporting, which can be found on the CDC website at: *https://www.cdc.gov/nchs/icd/icd-10-cm/files.html,* are available and regularly revised to provide guidance as it relates to assigning the diagnosis codes. Additionally, the American Hospital Association (AHA)'s *Coding Clinic for ICD–10–CM/PCS* publication provides further clarification on the appropriate coding and reporting of ICD–10–CM diagnosis codes. If providers have inpatient cases for which they need ICD–10 coding assistance, we encourage them to submit their questions to the American Hospital Association's Central Office on ICD–10 at *https://www.codingclinic advisor.com/.*

In response to the statement that recognition of the contribution that treatment of an underlying medical condition or illness adds to the complexity of acute hospital care can only be accomplished as long as there are codes available in the ICD–10–CM diagnosis code classification that allow for the reporting of that underlying medical condition or illness, we note that if an interested party believes that diagnosis codes do not currently exist to describe an underlying medical condition or illness that a patient experiencing homelessness, inadequate housing, and housing instability may have, there is an established process to request that diagnosis codes be added to the classification. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems, as discussed in section II.C.15 of the preamble of this final rule. The ICD–10 Coordination and Maintenance Committee presents proposals for ICD–10–CM diagnosis code changes each spring and fall to update the codes and the applicable payment and reporting systems by October 1 or April 1 of each year. As also discussed in section II.C.15 of the preamble of this final rule, the CDC/NCHS has lead responsibility for the diagnosis code classification. Proposals for updates to the diagnosis code classification should be directed to *nchsicd10CM@cdc.gov* for consideration at a future ICD–10 Coordination and Maintenance Committee meeting.

Therefore, after consideration of the public comments received, and for the reasons discussed, we are finalizing the changes to the severity level designations for diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), Z59.02 (Unsheltered homelessness), Z59.10 (Inadequate housing, unspecified), Z59.11 (Inadequate housing environmental temperature), Z59.12 (Inadequate housing utilities), Z59.19 (Other inadequate housing), Z59.811 (Housing instability, housed, with risk of homelessness), Z59.812 (Housing instability, housed, homelessness in past 12 months) and Z59.819 (Housing instability, housed unspecified) from CC to NonCC for FY 2027, without modification. In addition, these diagnosis codes are reflected in Table 6J.2—Deletions to the CC List—FY 2027 associated with this final rule and available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* We refer the reader to section II.C.12.d of the preamble of the proposed rule and this final rule for further information regarding Table 6J.2.

2. Newborn Affected by Malpresentation Before Labor

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19371 through 19372), we received a request to change the severity level designations of the ICD–10–CM diagnosis codes P01.7 (Newborn affected by malpresentation before labor) and P03.0 (Newborn affected by breech delivery and extraction) from NonCC to CC. The requestor did not provide additional rationale for this request.

To evaluate this request, we analyzed the claims data in the September 2025 update of the FY 2025 MedPAR file. The following table shows the analysis for each of the diagnosis codes identified by the requestor.

ICD-10-CM Code[a]	Description[b]	Tota1 Count[c]	Cnt1[d]	C1[e]	Cnt2[f]	C2[g]	Cnt3[h]	C3[i]
P01.7	Newborn affected by malpresentation before labor	-	-	-	-	-	-	-
P03.0	Newborn affected by breech delivery and extraction	-	-	-	-	-	-	-

[a] This column is the secondary diagnosis code (SDX).
[b] This column is the title of the SDX.
[c] The total count of discharge claims with the SDX.
[d] Count of discharge claims with the SDX but with no other SDX or with all other SDX a NonCC.
[e] "C1" impact on resource use of the SDX for discharge claims in "Cnt1".
[f] Count of discharge claims with the SDX and with at least one other SDX that is a CC but none that is an MCC.
[g] "C2" impact on resource use of the SDX for discharge claims in "Cnt2".
[h] Count of discharge claims with the SDX and with at least one other SDX that is a MCC.
[i] "C3" impact on resource use of the SDX for discharge claims in "Cnt3".

As reflected in the table, we found zero instances where diagnosis codes P01.7 or P03.0 were reported as secondary diagnoses. As discussed in the proposed rule, in considering the nine guiding principles, as summarized previously, we note that fetal malpresentation is any position of the fetus at birth where the head is not the presenting part. Common types include breech (bottom/feet first), transverse (sideways), or oblique lie. While normal in early pregnancy, most babies turn; however, if still malpresenting at term, management often involves external cephalic version (ECV) to turn the baby or a planned C-section due to risks like cord prolapse during vaginal delivery. A

higher level of care for the mother (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay) may be warranted depending on the treatment or management of the fetal malpresentation pursued by the attending provider.

Based on the lack of claims data to evaluate to consider a severity level change, we stated we believe that the ICD–10–CM diagnosis codes P01.7 and P03.0 should remain designated as NonCCs. Therefore, we proposed to maintain the severity level designation of codes P01.7 and P03.0 as NonCCs for FY 2027.

Comment: Commenters supported the proposal to maintain the severity level designation of ICD–10–CM diagnosis codes P01.7 and P03.0 as NonCCs for FY 2027.

Response: We appreciate the commenters' support.

Comment: Another commenter disagreed with the proposal to maintain the severity level designation of ICD–10–CM diagnosis codes P01.7 and P03.0 as NonCCs. While acknowledging that obstetric patients and newborns would not be well represented in the MedPAR data as these populations are not typically covered by Medicare, this commenter stated that clinically, malpresentation before labor requires elevated medical management, and possible procedural interventions resulting in increased resources needed to manage this population.

Response: We thank the commenter for their feedback and for sharing their concerns. In reviewing this feedback, we continue to believe that the ICD–10–CM diagnosis codes P01.7 and P03.0 should remain designated as NonCCs for FY 2027, based on the lack of claims data to evaluate to consider a severity level change. We will continue to monitor the claims data in consideration of any future modifications to the severity level designation of diagnosis codes P01.7 and P03.0.

We acknowledge in the FY 2008 IPPS final rule (72 FR 47158), when describing our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes, we stated the exception to our approach was for diagnoses related to newborns, maternity, and congenital anomalies. We stated we used the All Patient Refined DRGs (APR–DRGs) to categorize these diagnoses. For newborn, obstetric, and congenital anomaly diagnoses, we designated the APR–DRG default severity level 3 (major) and 4 (extreme) diagnoses as an MCC, the APR–DRG default severity level 2 (moderate) diagnoses as a CC, and the APR–DRG default severity 1 (minor) diagnoses as a NonCC. Using a combination of mathematical analysis of claims data and the application of the nine guiding principles, we may consider reevaluating the use of the APR–DRGs to categorize diagnoses related to newborns, maternity, and congenital anomalies in future rulemaking.

After consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to maintain the severity level designation of ICD–10–CM diagnosis codes P01.7 (Newborn affected by malpresentation before labor) and P03.0 (Newborn affected by breech delivery and extraction) as NonCCs without modification for FY 2027.

3. Functional Quadriplegia

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19372), we received a request to change the severity level designation of ICD–10–CM diagnosis code R53.2 (Functional quadriplegia) from MCC to NonCC. According to the requestor, code R53.2 describes patients who are unable to move any of their extremities, not because of a spinal cord or focal brain dysfunction, but because of global dysfunction such as severe dementia or contractures. The requestor further stated that the definition of functional quadriplegia does not exist in medical literature; therefore, the vagueness of the condition described by code R53.2 leads to the code being overused. The requestor also questioned whether an immobile patient during an inpatient stay utilizes more resources than other patients with very limited mobility.

In the proposed rule, we stated we agree that diagnosis code R53.2 (Functional quadriplegia) is currently designated as an MCC. We refer the reader to Appendix H of the ICD–10 MS–DRG Version 43.1 Definitions Manual (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for the complete list of diagnoses designated as MCCs when reported as secondary diagnoses, except when used in conjunction with the principal diagnosis in the corresponding CC Exclusion List in Appendix C.

To evaluate this request, we analyzed the claims data in the September 2025 update of the FY 2025 MedPAR file. The following table shows the analysis for diagnosis code R53.2.

ICD-10-CM Code[a]	Description[b]	Tota1 Count[c]	Cnt1[d]	C1[e]	Cnt2[f]	C2[g]	Cnt3[h]	C3[i]
R53.2	Functional quadriplegia	40,455	782	2.05	8,287	2.58	31,386	3.38

[a] This column is the secondary diagnosis code (SDX).
[b] This column is the title of the SDX.
[c] The total count of discharge claims with the SDX.
[d] Count of discharge claims with the SDX but with no other SDX or with all other SDX a NonCC.
[e] "C1" impact on resource use of the SDX for discharge claims in "Cnt1".
[f] Count of discharge claims with the SDX and with at least one other SDX that is a CC but none that is an MCC.
[g] "C2" impact on resource use of the SDX for discharge claims in "Cnt2".
[h] Count of discharge claims with the SDX and with at least one other SDX that is a MCC.
[i] "C3" impact on resource use of the SDX for discharge claims in "Cnt3".

We analyzed these data as described in FY 2008 IPPS final rule (72 FR 47158 through 47161). The table shows that the C1 values of the diagnosis code that describes causally functional quadriplegia is 2.05. A C1 value close to 2.0 suggests the condition is more like a CC than a NonCC but not as significant in resource usage as an MCC. The C2 finding of diagnosis code R53.2 is 2.58. C2 values close to 3.0 suggests the condition is more similar to an MCC than a CC or NonCC. The C2 findings support maintaining the code R53.2 as an MCC. We stated that the data are clearly mixed between the C1 and C2 findings and does not consistently support a change in the severity level.

As discussed in the proposed rule, in considering the nine guiding principles, as summarized previously, we noted

that functional quadriplegia is the inability to move due to another condition (for example, dementia, severe contractures, arthritis, etc.). It is a diagnosis that can impede patient cooperation or management of care or both. Patients diagnosed with functional quadriplegia can require a higher level of care by needing intensive monitoring, and a greater number of caregivers as the patient does not have the ability to ambulate.

After considering the C1, and C2 values of ICD–10–CM diagnosis code R53.2, the lack of consistent claims data to support a severity level change, and consideration of the nine guiding principles, we stated we believe R53.2 should remain designated as an MCC. Therefore, we proposed to maintain the severity level designation of ICD–10–CM diagnosis code R53.2 as an MCC for FY 2027.

Comment: Commenters supported the proposal to maintain the severity level designation of ICD–10–CM diagnosis code R53.2 as an MCC for FY 2027.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the severity level designation of ICD–10–CM diagnosis code R53.2 (Functional quadriplegia) as an MCC without modification for FY 2027.

4. Malnutrition

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19372 through 19373), we received a request to change the severity level designation of the following diagnosis codes from MCC to NonCC:

- E40 (Kwashiorkor)
- E41 (Nutritional marasmus)
- E42 (Marasmic kwashiorkor)
- E43 (Unspecified severe protein-calorie malnutrition)

According to the requestor, the criteria for the ICD–10–CM diagnosis codes that describe malnutrition are vague. The requestor stated that nutritional assessment is the standard of care for all hospital admissions, and the short-term weight loss that often occurs in the hospital as a result of keeping patients with an empty stomach (that is, nothing by mouth) for other interventions does not signal real malnutrition requiring intensive treatment. In circumstances when treatment is initiated, for example increasing the intake of calories or protein, the treatment adds little or no additional costs to overall resource utilization for the encounter.

In the proposed rule, we stated we agree that diagnosis codes E40, E41, E42, and E43 are currently designated as MCCs. We refer the reader to Appendix H of the ICD–10 MS–DRG Version 43.1 Definitions Manual (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for the complete list of diagnoses designated as MCCs when reported as secondary diagnoses, except when used in conjunction with the principal diagnosis in the corresponding CC Exclusion List in Appendix C.

To evaluate this request, we analyzed the claims data in the September 2025 update of the FY 2025 MedPAR file. The following table shows the analysis for each of the diagnosis codes identified by the requestor.

ICD-10-CM Code[a]	Description[b]	Total Count[c]	Cnt1[d]	C1[e]	Cnt2[f]	C2[g]	Cnt3[h]	C3[i]
E40	Kwashiorkor	35	-	-	10	2.84	25	3.43
E41	Nutritional marasmus	74	-	-	15	2.38	59	3.59
E42	Marasmic kwashiorkor	15	1	0.73	6	3.21	8	3.16
E43	Unspecified severe protein-calorie malnutrition	383,399	5,821	2.07	131,245	2.52	246,333	3.38

[a] This column is the secondary diagnosis code (SDX).
[b] This column is the title of the SDX.
[c] The total count of discharge claims with the SDX.
[d] Count of discharge claims with the SDX but with no other SDX or with all other SDX a NonCC.
[e] "C1" impact on resource use of the SDX for discharge claims in "Cnt1".
[f] Count of discharge claims with the SDX and with at least one other SDX that is a CC but none that is an MCC.
[g] "C2" impact on resource use of the SDX for discharge claims in "Cnt2".
[h] Count of discharge claims with the SDX and with at least one other SDX that is a MCC.
[i] "C3" impact on resource use of the SDX for discharge claims in "Cnt3".

We analyzed these data as described in FY 2008 IPPS final rule (72 FR 47158 through 47161). The table above shows that the C1 findings ranged from a low of 0.73 to a high of 2.07. As stated earlier, a C1 value close to 2.0 suggests the condition is more like a CC than a NonCC but not as significant in resource usage as an MCC. The C1 findings suggest that these codes are more like a CC than an MCC. However, the C2 findings ranged from a low of 2.38 to a high of 3.21. Values close to 3.0 suggests the conditions are more similar to an MCC than a CC or NonCC. The C2 findings support maintaining the malnutrition codes identified by the requestor as MCCs. We stated that the data are clearly mixed between the C1 and C2 findings and does not consistently support a change in the severity level.

As discussed in the proposed rule, in considering the nine guiding principles, as summarized previously, we noted that the World Health Organization (WHO) defines malnutrition as ''deficiencies, excesses or imbalances in a person's intake of energy and/or nutrients.'' Protein-calorie malnutrition is observed most frequently in developing countries but has been described with increasing frequency in hospitalized and chronically ill children in the United States. The distinction between the two forms of protein-calorie malnutrition is based on the presence of edema (kwashiorkor) or absence of edema (marasmus). Marasmus involves inadequate intake of protein and calories, whereas kwashiorkor involves fair-to-normal calorie intake with inadequate protein intake. In developed countries such as the United States, inadequate food intake is a less common cause of malnutrition. Instead, diseases and, in particular, chronic illnesses play an important role in the etiology of malnutrition. As such, the conditions described by the ICD–10–CM diagnosis codes identified by the requestor reflect systemic impact and serve as a marker for advanced disease states across multiple different comorbid conditions.

After considering the C1, and C2 values of ICD–10–CM diagnosis codes E40, E41, E42, and E43, the lack of consistent claims data to support a severity level change, and consideration of the nine guiding principles, we stated we believe E40, E41, E42, and E43 should remain designated as MCCs. Therefore, we proposed to maintain the severity level designation of ICD–10–CM diagnosis codes E40, E41, E42, and E43 as MCCs for FY 2027.

Comment: Commenters expressed support for the proposal to maintain the severity level designation of ICD–10–CM diagnosis codes E40, E41, E42, and E43 as MCCs for FY 2027. Several commenters stated that a person's nutrition status can be a key part of their diagnosis and noted malnutrition is related to many other medical conditions including vitamin deficiencies, scurvy, and osteoporosis. A commenter specifically stated that they support CMS' decision and rationale for maintaining the severity level designation of ICD–10–CM diagnosis codes E40, E41, E42, and E43. This commenter stated that the conditions described in these ICD–10–CM codes reflect systemic impacts, serve as useful markers for advanced disease states across many different comorbid conditions and stated that maintaining the severity level designations retains adequate recognition of the significance of the etiology and impact of malnutrition. Another commenter stated nutritional status is a critical clinical indicator that informs diagnosis, treatment planning, and recovery and that maintaining the current designations supports comprehensive, high-quality patient care.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the severity level designation of ICD–10–CM diagnosis codes E40 (Kwashiorkor), E41 (Nutritional marasmus), E42 (Marasmic kwashiorkor), and E43 (Unspecified severe protein-calorie malnutrition) as MCCs without modification, for FY 2027.

5. Prolonged First Stage (of Labor)

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19373 through 19374), we received a request to change the severity level designation of ICD–10–CM diagnosis code O63.0 (Prolonged first stage (of labor)) from NonCC to CC. According to the requestor, prolonged labor increases length of stay by up to two days and significantly increases resources required to care for these patients. The requestor performed their own analysis of the Impact on Resource Use File on the CMS website generated using claims from the FY 2024 MedPAR file and found that when reported as a secondary diagnosis, O63.0 had a C1 value higher than 2, and C2 and C3 values of at least close to 2, which suggests the code should be designated as a CC. Additionally, in their own analysis of the Impact on Resource Use File on the CMS website generated using claims from the FY 2024 MedPAR file, the requestor found that, in comparison, when reported as a secondary diagnosis, ICD–10–CM diagnosis code O63.9 (Long labor, unspecified), which is designated as a CC, had a C1 value of only 0.88. The requestor also performed an analysis of claims at their healthcare facility to identify cases where prolonged labor in either the latent phase or second phase likely occurred and found that the C1 value was approximately 1.35 for diagnosis code O63.0. The requestor did not state if the analysis of cases at their facility was limited to Medicare cases.

In the proposed rule, we stated we agree that that diagnosis code O63.0 (Prolonged first stage (of labor)) is currently designated as a NonCC and diagnosis code O63.9 (Long labor, unspecified) is currently designated as a CC. We refer the reader to Appendix G of the ICD–10 MS–DRG Version 43.1 Definitions Manual (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for the complete list of diagnoses designated as CCs when reported as secondary diagnoses, except when used in conjunction with the principal diagnosis in the corresponding CC Exclusion List in Appendix C.

To evaluate this request, we analyzed the claims data in the September 2025 update of the FY 2025 MedPAR file. The following table shows the analysis for diagnosis codes O63.0 and O63.9.

ICD-10-CM Code[a]	Description[b]	Tota1 Count[c]	Cnt1[d]	C1[e]	Cnt2[f]	C2[g]	Cnt3[h]	C3[i]
O63.0	Prolonged first stage (of labor)	17	6	2.14	9	3.54	2	3.10
O63.9	Long labor, unspecified	6	-	-	3	1.54	3	2.78

[a] This column is the secondary diagnosis code (SDX).
[b] This column is the title of the SDX.
[c] The total count of discharge claims with the SDX.
[d] Count of discharge claims with the SDX but with no other SDX or with all other SDX a NonCC.
[e] "C1" impact on resource use of the SDX for discharge claims in "Cnt1".
[f] Count of discharge claims with the SDX and with at least one other SDX that is a CC but none that is an MCC.
[g] "C2" impact on resource use of the SDX for discharge claims in "Cnt2".
[h] Count of discharge claims with the SDX and with at least one other SDX that is a MCC.
[i] "C3" impact on resource use of the SDX for discharge claims in "Cnt3".

We analyzed these data as described in the FY 2008 IPPS final rule (72 FR 47158 through 47161). The table shows that the C1 value of the diagnosis code that describes prolonged first stage of labor is 2.14. As stated earlier, a C1 value close to 2.0 suggests the condition is more like a CC than a NonCC but not as significant in resource usage as an MCC. The C2 finding of diagnosis code O63.0 is 3.54. C2 values close to 3.0 suggests the condition is more similar to an MCC than a CC or NonCC. We stated the C1 and C2 findings reflect increased resource utilization when prolonged labor is reported as a secondary diagnosis however the data are clearly mixed between the C1 and C2 findings, and there was a low volume of cases (17) reporting this code as a secondary diagnosis.

The table also shows there were zero cases that reported diagnosis code O63.9 with no other secondary diagnosis or with all other secondary diagnoses that are NonCCs. The C2 finding of diagnosis code O63.9 is 1.54. C2 values close to 2.0 suggest the condition is more similar to a CC than a NonCC. The C2 findings support maintaining diagnosis code O63.9 as a CC. Similar to diagnosis code O63.0, there was a low volume of cases

(6) reporting this code as a secondary diagnosis.

As discussed in the proposed rule, in considering the nine guiding principles, as summarized previously, we noted that the first stage of labor is defined as the interval between the onset of labor and complete or 10 cm cervical dilation. Prolonged first stage of labor refers to a slow initial dilation (0–6 cm), or a stalled active phase, lasting over 16–20 hours, whereas ''long labor'' describes the entire birth process exceeding 20–25 hours. Long labor is monitored closely for risks like infection or fetal distress. While a prolonged first stage is rarely dangerous, a prolonged first stage of labor can sometimes require a higher level of care. Management of prolonged first stage of labor can sometimes involve amniotomy for patients undergoing augmentation or induction of labor to reduce the duration of labor, administration of oxytocin and/or the use intrauterine pressure catheters to determine adequacy of uterine contractions. If labor fails to progress or fetal distress occurs, a cesarean section or instrumental delivery (forceps/vacuum) may be necessary.

After considering the C1, and C2 values of ICD–10–CM diagnosis codes O63.0 and O63.9, the lack of sufficient claims data to support a severity level change, and consideration of the nine guiding principles, we stated we believe diagnosis code O63.0 should remain designated as a NonCC and diagnosis code O63.9 should remain designated as a CC. Therefore, we proposed to maintain the severity level designations of ICD–10–CM diagnosis codes O63.0 and O63.9 for FY 2027.

Comment: A commenter supported the proposal to maintain the severity level designation of ICD–10–CM diagnosis codes O63.0 and O63.9 for FY 2027.

Response: We appreciate the commenters' support.

Comment: Other commenters suggested that CMS reconsider the proposal to maintain the severity level designation of ICD–10–CM diagnosis code O63.0 (Prolonged first stage (of labor)) as a NonCC for FY 2027. A few commenters stated that clinically, a prolonged first stage labor frequently necessitates heightened medical management and procedural intervention, including labor augmentation with oxytocin, amniotomy, invasive uterine monitoring, prolonged nursing care, and escalation to operative vaginal delivery or cesarean section in cases of failed labor progression or fetal compromise.

Several commenters noted that code O63.9 (Long labor, unspecified) is the only code in category O63 (Long labor) that is currently designated as a CC. These commenters recommended that CMS evaluate all of the codes in category O63 to determine if the severity level designation of any of the more specific codes in the category should be changed to a CC. A commenter specifically noted that diagnosis code O63.1 (prolonged second stage (of labor)) is also designated as a NonCC and stated recommended that CMS change the severity level designation of both code O63.0 and code O63.1 from NonCC to CC as a prolonged second stage of labor is associated with increased chorioamnionitis, third-degree or fourth-degree perineal lacerations, and neonatal morbidity.

Some commenters noted that the low volume of cases reporting ICD–10–CM diagnosis codes O63.0 and O63.9 as secondary diagnoses is likely attributable to the nature of the MedPAR dataset itself rather than being a reflection of a lack of clinical or resource significance. These commenters noted the MedPAR file captures predominantly Medicare beneficiaries, whereas prolonged labor disproportionately affects a younger obstetric population that is more commonly covered by commercial insurance or Medicaid. Several commenters stated that it is unreasonable to expect more claims data for these types of cases than is already available for analysis and CMS should not rely on this rationale to maintain the severity level designation of ICD–10–CM diagnosis code O63.0.

Response: We thank the commenters for their feedback and for sharing their concerns. We will take the commenters' feedback into consideration in future policy development.

While we continue to believe that based on the lack of sufficient claims data to evaluate to consider a severity level change, the severity level designation of ICD–10–CM diagnosis codes O63.0 and O63.9 should be maintained for FY 2027, we acknowledge that in the FY 2008 IPPS final rule (72 FR 47158), when describing our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes, we stated the exception to our approach was for diagnoses related to newborns, maternity, and congenital anomalies, as discussed earlier in this section. We stated we used the APR–DRGs to categorize these diagnoses. For newborn, obstetric, and congenital anomaly diagnoses, we designated the APR–DRG default severity level 3 (major) and 4 (extreme) diagnoses as an MCC, the APR–DRG default severity level 2 (moderate) diagnoses as a CC, and the APR–DRG default severity 1 (minor) diagnoses as a NonCC. Using a combination of mathematical analysis of claims data and the application of the nine guiding principles, we may consider reevaluating the use of the APR–DRGs to categorize diagnoses related to newborns, maternity, and congenital anomalies in future rulemaking. We will also continue to monitor the claims data in consideration of any future modifications to the severity level designation of diagnosis codes O63.0 and O63.9.

After consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to maintain the severity level designation of ICD–10–CM diagnosis code O63.0 (Prolonged first stage (of labor)) as a NonCC and to maintain the severity level designation of ICD–10–CM diagnosis code O63.9 (Long labor, unspecified) as a CC without modification for FY 2027.

d. Additions and Deletions to the Diagnosis Code Severity Levels for FY 2027

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19374), we stated that the following tables identify the proposed additions to the diagnosis code MCC severity level list and the proposed additions and deletions to the diagnosis code CC severity levels list for FY 2027 and are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

Table 6I.1—Proposed Additions to the MCC List-FY 2027;
Table 6J.1—Proposed Additions to the CC List-FY 2027; and
Table 6J.2—Proposed Deletions to the CC List-FY 2027

Comment: Commenters agreed with the proposed additions to the MCC and CC lists as shown in tables 6I.1 and 6J.1 associated with the proposed rule. Commenters also generally agreed with the proposed deletions to the CC list as shown in table 6J.2 associated with the proposed rule.

Response: We appreciate the commenters' support. We refer the reader to section II.C.12.c.1 of the preamble of this final rule for a summary of the public comments and our responses in connection with the diagnosis codes describing homelessness, inadequate housing, and housing instability. As discussed, after consideration of the public comments received, we are finalizing the proposed changes to the severity level

designations for the diagnosis codes describing homelessness, inadequate housing, and housing instability from CC to NonCC.

The following tables associated with this final rule reflect the finalized severity levels under Version 44 of the ICD–10 MS–DRGs for FY 2027 and are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html;* Table 6I.—Complete MCC List-FY 2027; Table 6I.1—Additions to the MCC List-FY 2027; Table 6J.—Complete CC List-FY 2027; Table 6J.1—Additions to the CC List-FY 2027; and Table 6J.2—Deletions to the CC List-FY 2027.

e. CC Exclusions List for FY 2027

In the September 1, 1987, final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) to preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

In the May 19, 1987, proposed notice (52 FR 18886) and the September 1, 1987, final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50544) for detailed information regarding revisions that were made to the CC and CC Exclusion Lists under the ICD–9–CM MS–DRGs.

The ICD–10 MS–DRGs Version 43.1 CC Exclusion List is included as Appendix C in the ICD–10 MS–DRG Definitions Manual (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) and includes three lists identified as Part 1, Part 2 and Part 3. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link is provided to a collection of diagnosis codes which, when reported as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a NonCC. Part 2 is the list of diagnosis codes designated as an MCC only for patients discharged alive; otherwise, they are assigned as a NonCC. Part 3 is the list of diagnosis codes that are designated as a CC or MCC and included in the definition of the logic for the listed MS–DRGs. When reported as a secondary diagnosis and grouped to one of the listed MS–DRGs, the diagnosis is excluded from acting as a CC/MCC for severity in DRG assignment (that is, suppression logic).

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19375), we proposed changes to the ICD–10 MS–DRGs Version 44 CC Exclusion List based on the diagnosis code updates as discussed in section II.C.13. of the preamble of the proposed rule and set forth in Tables 6G.1, 6G.2, 6H.1, and 6H.2 associated with the proposed rule and available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

We did not receive any public comments opposing the proposed CC Exclusions List.

For this final rule, we have developed Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List-FY 2027; Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List-FY 2027; Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List-FY 2027; Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List-FY 2027 and Table 6K.—Complete List of CC Exclusions-FY 2027.

For Table 6G.1, each secondary diagnosis code finalized for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses that exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2, each of the principal diagnosis codes for which there is a CC exclusion is shown with an asterisk and the conditions finalized for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. For Table 6H.1, each secondary diagnosis code finalized for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that exclude it. For Table 6H.2, each of the principal diagnosis codes is shown with an asterisk and the finalized deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis. Table 6K contains a list of all of the codes that are defined as either a CC or MCC when assigned as a secondary diagnosis. Each CC or MCC secondary diagnosis code is assigned to a principal diagnosis number that reflects a collection of diagnosis codes which, when reported as the principal diagnosis, will cause the CC or MCC secondary diagnosis to be considered as only a NonCC secondary diagnosis.

The finalized CC Exclusions List as displayed in Tables 6G.1, 6G.2, 6H.1, 6H.2, and 6K associated with this final rule are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* and reflect the additions, deletions, and complete list of CC Exclusions under Version 44 of the ICD–10 MS–DRGs.

13. Changes to the ICD–10–CM and ICD–10–PCS Coding Systems

To identify new, revised, and deleted diagnosis and procedure codes, for FY 2027, we have developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure Code Titles for this final rule.

These tables are not published in the Addendum to the proposed or final rule, but are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this final rule. As discussed in section II.C.11. of the preamble of this final rule, the code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee meeting process. Therefore, although we publish the code titles in association with the IPPS proposed and

final rules, they are not subject to comment in the proposed or final rules.

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19375), we proposed the MDC and MS–DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. We also stated that the proposed severity level designations for the new diagnosis codes are set forth in Table 6A. and the proposed O.R. status for the new procedure codes are set forth in Table 6B. Consistent with our established process, we examined the MS–DRG assignment and the attributes (severity level and O.R. status) of the predecessor diagnosis or procedure code, as applicable, to inform our proposed assignments and designations.

Specifically, we reviewed the predecessor code and MS–DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we considered other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We noted that this process does not automatically result in the new diagnosis or procedure code being proposed for assignment to the same MS–DRG or to have the same designation as the predecessor code.

In this final rule, we present a summation of the comments we received in response to the proposed assignments, our responses to those comments, and our finalized policies.

Comment: Several commenters supported the proposed MDC and MS–DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. However, a few commenters suggested that CMS should evaluate the MS–DRG assignment for cases reporting newly established ICD–10–PCS code X28M3DC (Division of ventricular septum using transcatheter septal scoring technique, percutaneous approach) for the treatment of obstructive hypertrophic cardiomyopathy (HCM) once additional claims data becomes available to determine if MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively) are the most appropriate assignment from both a clinical and resource utilization perspective. The commenters stated that this procedure, Septal Scoring Along Mid-Line Endocardium (SESAME), is primarily performed in a unique subset of patients who exhibit severe structural heart disease and are frequently considered poor surgical candidates for conventional surgery. A commenter specified that in the largest published contemporary cohort, the average patient age was older than 75 years, more than half of the patients had chronic kidney disease, over half the patients had prior aortic valve replacement surgery, and the majority of patients had severe mitral valve pathology. This same commenter acknowledged that SESAME is typically not performed as a stand-alone procedure; however, they indicated that the published literature also describes substantial procedural complexity. The commenter stated that SESAME requires computed tomography based procedural planning, transesophageal echocardiographic guidance, advanced catheter-based electrosurgical techniques, and coordination among structural heart specialists, imaging physicians, anesthesiologists, and procedural staff. Another commenter stated that the clinical presentation and hospital course of patients undergoing SESAME can vary considerably. For example, the commenter indicated that while some patients may experience uncomplicated recovery, other patients may require extended monitoring and management due to underlying disease severity or coexisting medical conditions. The commenter stated that the treatment landscape for obstructive HCM continues to rapidly evolve where catheter-based septal reduction therapies now occupy an increasingly important role alongside medical therapy, alcohol septal ablation, and surgical myectomy. Another commenter stated that SESAME is a novel transcatheter electrosurgical procedure designed to replicate the effects of surgical septal myotomy without requiring open-heart surgery. According to the commenter, early peer-reviewed clinical experience has demonstrated successful application in patients with obstructive HCM, patients requiring septal modification before transcatheter mitral valve replacement, and patients with other forms of left ventricular outflow tract obstruction. The commenter also stated that SESAME represents a fundamentally different therapeutic approach than alcohol septal ablation. Specifically, the commenter stated that alcohol septal ablation depends on favorable septal coronary anatomy and achieves septal reduction through a controlled myocardial infarction. The commenter stated that the location and extent of myocardial injury may be variable and the procedure is associated with clinically meaningful rates of permanent pacemaker implantation. In contrast, the commenter reported that SESAME directly modifies the interventricular septum using a transcatheter electrosurgical technique intended to reproduce the anatomic effect of surgical myotomy while preserving future treatment options. The commenters stated that future claims data may provide additional insight into whether cases reporting the SESAME procedure are clinically distinct from other cases that group to MS–DRGs 228 and 229 and it is important for CMS to monitor.

Response: We appreciate the commenters' support and feedback. We note that, as reflected in Table 6B.—New Procedure Codes, procedure code X28M3DC will become effective with discharges on and after October 1, 2026, for FY 2027. As claims data becomes available we intend to monitor the reporting of ICD–10–PCS code X28M3DC consistent with our annual rulemaking analyses to determine if MS–DRGs 228 and 229 are the most appropriate MS–DRG assignment from both a clinical coherence and resource utilization perspective.

Comment: A commenter stated that active mechanical clearance represents an important clinical distinction in the postoperative management of cardiac surgery patients. Specifically, the commenter stated that active mechanical clearance is designed to proactively maintain chest tube patency through internal mechanical action. According to the commenter, the proposed ICD–10–PCS qualifier to describe active mechanical clearance would help distinguish this treatment from passive drainage in the claims data. The commenter also stated that cases involving active mechanical clearance should not be considered equivalent to passive drainage cases because it involves incremental technology, implementation, and postoperative workflow requirements beyond passive drainage, including staff education and care processes intended to maintain drainage function. According to the commenter, these additional resources may not be adequately accounted for under the MS–DRG assignment. Another commenter stated it is a core part of how patients are able to recover safely and deserves to be reflected accurately in the data and payment system. The commenter also stated that impaired drainage and retained blood can complicate recovery and often drive additional monitoring, escalation of care, or a return to the operating room. The commenter

suggested that CMS should consider whether current MS–DRG payment reflects the real differences these cases involve, the clinical management required, implementation and equipment they depend on, staff education, the protocolized use they demand, and overall resource utilization these cases generate. Another commenter stated that nursing engagement is clinically meaningful as the nursing team plays a more proactive role in supporting drainage function, rather than relying solely on passive observation of output. According to the commenter, nurses must understand the purpose of the technology, how it is used, and incorporate it appropriately into routine postoperative care. The commenter stated a distinct qualifier for active mechanical clearance would provide an important mechanism for identifying cases and will allow CMS to better evaluate the clinical, operational, and resource-use differences associated with this approach within the MS–DRG framework.

Response: We appreciate the commenters' feedback. As reflected in the FY 2027 ICD–10–PCS Code Update files that were made publicly available on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes* on June 5, 2026, and in Table 6B.—New Procedure Codes, associated with this final rule (and available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*), new procedure codes describing drainage using active mechanical clearance were finalized. As stated in section II.C.1.b. of the preamble of this final rule, we encourage individuals with comments about MS–DRG classifications to submit these comments no later than October 20, 2026, via MEARIS™ at: *https://mearis.cms.gov/public/home,* so that they can be considered for possible inclusion in the annual proposed rule. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

After consideration of the public comments received, we are finalizing the MDC and MS–DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes associated with this final rule. In addition, the finalized severity level designations for the new diagnosis codes are set forth in Table 6A. and the finalized O.R. status designations for the new procedure codes are set forth in Table 6B. associated with this final rule.

In association with this final rule, we are making the following tables available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html:*

- Table 6A.—New Diagnosis Codes-FY 2027;
- Table 6B.—New Procedure Codes-FY 2027;
- Table 6C.—Invalid Diagnosis Codes-FY 2027;
- Table 6D.—Invalid Procedure Codes-FY 2027;
- Table 6E.—Revised Diagnosis Code Titles-FY 2027;
- Table 6F.—Revised Procedure Code Titles-FY 2027;
- Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List-FY 2027;
- Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List-FY 2027;
- Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List-FY 2027;
- Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List-FY 2027;
- Table 6I.—Complete MCC List-FY 2027;
- Table 6I.1.—Additions to the MCC List-FY 2027;
- Table 6J.—Complete CC List-FY 2027;
- Table 6J.1.—Additions to the CC List-FY 2027;
- Table 6J.2.—Deletions to the CC List-FY 2027; and
- Table 6K.—Complete List of CC Exclusions-FY 2027.

14. Changes to the Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which cases with multiple surgical procedures are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655).

Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed in this FY 2027 IPPS/LTCH PPS final rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for

two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift, such that the higher-ordered surgical class has lower average costs than the class ordered below it.

Based on the changes that we proposed to make for FY 2027, as discussed in section II.C. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule, we proposed to modify the existing surgical hierarchy for FY 2027 as illustrated in the following tables. We noted in the proposed rule that because the current methodology involves weighing the average costs of each MS–DRG in the surgical class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class, that the surgical hierarchy of other MS–DRGs in the MDC may need to be adjusted based on the MS–DRG classification changes that are proposed to ensure that the average weighted cost for each base MS–DRG in each MDC are monotonically decreasing. We further noted that the proposed Version 44 surgical hierarchy as illustrated in the following tables may be subject to further modifications based on the finalized changes to the MS–DRG classifications for FY 2027.

BILLING CODE 4169–69–P

PRE-MDC			
		Current Version 43 Surgical Hierarchy	**Proposed Version 44 Surgical Hierarchy**
MS-DRG 018	Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies	1	1
MS-DRGs 001-002	Heart Transplant or Implant of Heart Assist System	2	2
MS-DRG 003	ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures	3	3
MS-DRG 004	Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R. Procedures	4	5
MS-DRG 007	Lung Transplant	5	4
MS-DRG 014	Allogeneic Bone Marrow Transplant	6	6
MS-DRGs 005-006	Liver Transplant or Intestinal Transplant	7	7
MS-DRG 019	Simultaneous Pancreas, Islet Cell and Kidney Transplant with Hemodialysis	8	9
MS-DRG 008	Simultaneous Pancreas, Islet Cell and Kidney Transplant	9	11
MS-DRGs 016-017	Autologous Bone Marrow Transplant	10	10
MS-DRG 010	Pancreas or Islet Cell Transplant	11	8
MS-DRGs 011-013	Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy	12	12

MDC 05 (DISEASES AND DISORDERS OF THE CIRCULATORY SYSTEM)			
		Current Version 43 Surgical Hierarchy	**Proposed Version 44 Surgical Hierarchy**
MS-DRG 209	Complex Aortic Arch Procedures	1	1
MS-DRG 212	Concomitant Aortic and Mitral Valve Procedures	2	2
MS-DRG 215	Other Heart Assist System Implant	3	3
MS-DRGs 216-218	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization	4	4
MS-DRGs 231-232	Coronary Bypass with PTCA	5	5
MS-DRG 275	Cardiac Defibrillator Implant with Cardiac Catheterization	6	6
MS-DRG 317	Concomitant Left Atrial Appendage Closure and Cardiac Ablation	7	7
MS-DRGs 219-221	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization	8	8
MS-DRGs 233-234	Coronary Bypass with Cardiac Catheterization or Open Ablation	9	9
MS-DRG 213	Endovascular Abdominal Aorta with Iliac Branch Procedures	10	10
MS-DRGs 266-267	Endovascular Cardiac Valve Replacement and Supplement Procedures	11	12
MS-DRGs 276-277	Cardiac Defibrillator Implant	12	11
MS-DRGs 268-269	Aortic and Heart Assist Procedures Except Pulsation Balloon	13	13
MS-DRGs 235-236	Coronary Bypass without Cardiac Catheterization	14	14
MS-DRG 245	AICD Generator Procedures	15	15
MS-DRGs 270-272	Other Major Cardiovascular Procedures	16	17
MS-DRGs 228-229	Other Cardiothoracic Procedures	17	18
MS-DRGs 319-320	Other Endovascular Cardiac Valve Procedures	18	20
MS-DRGs 278-279	Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures	19	16
MS-DRGs 323-324	Coronary Intravascular Lithotripsy with Intraluminal Device	20	19
MS-DRGs 239-241	Amputation for Circulatory System Disorders Except Upper Limb and Toe	21	21
MS-DRG 265	AICD Lead Procedures	22	25
MS-DRGs 273-274	Percutaneous and Other Intracardiac Procedures	23	22
MS-DRG 325	Coronary Intravascular Lithotripsy without Intraluminal Device	24	23
MS-DRG 263	Vein Ligation and Stripping	25	24
MS-DRGs 252-254	Other Vascular Procedures	26	26
MS-DRGs 359-360	Percutaneous Coronary Atherectomy with Intraluminal Device	27	27
MS-DRGs 242-244	Permanent Cardiac Pacemaker Implant	28	29
Proposed New MS-DRGs 210-211	Cardiac Pacemaker Revision or Device Replacement	N/A	30
MS-DRG 318	Percutaneous Coronary Atherectomy without Intraluminal Device	30	28
MS-DRGs 321-322	Percutaneous Cardiovascular Procedures with Intraluminal Device	31	31
MS-DRGs 255-257	Upper Limb and Toe Amputation for Circulatory System Disorders	32	32
MS-DRGs 250-251	Percutaneous Cardiovascular Procedures without Intraluminal Device	33	33
Proposed New MS-DRGs 361-362	Other Circulatory System O.R. Procedures	N/A	34

MDC 08 (DISEASES AND DISORDERS OF THE MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE)			
		Current Version 43 Surgical Hierarchy	**Proposed Version 44 Surgical Hierarchy**
Proposed New MS-DRGs 523-525	Extensive or Complex Spinal Fusion Procedures Except Cervical	N/A	1
MS-DRGs 426-428	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical	2	2
MS-DRGs 429-430	Combined Anterior and Posterior Cervical Spinal Fusion	3	3
MS-DRGs 456-458	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or Infection	4	4
MS-DRGs 447-448	Multiple Level Spinal Fusion Except Cervical	5	5
Proposed New MS-DRGs 403-404	Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection	N/A	8
MS-DRG 402	Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical	7	6
MS-DRGs 463-465	Wound Debridement or Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders	8	11
MS-DRGs 450-451	Single Level Spinal Fusion Except Cervical	9	9
Proposed New MS-DRG 449	Revision of Hip or Knee Replacement	N/A	7
MS-DRGs 461-462	Bilateral or Multiple Major Joint Procedures of Lower Extremity	11	12
MS-DRGs 471-473	Cervical Spinal Fusion	12	10
MS-DRGs 474-476	Amputation for Musculoskeletal System and Connective Tissue Disorders	13	15
MS-DRG 483	Major Joint or Limb Reattachment Procedures of Upper Extremities	14	14
MS-DRGs 477-479	Biopsies of Musculoskeletal System and Connective Tissue	15	16
MS-DRGs 492-494	Lower Extremity and Humerus Procedures Except Hip, Foot and Femur	16	17
MS-DRGs 498-499	Local Excision and Removal of Internal Fixation Devices of Hip and Femur	17	13
Proposed New MS-DRGs 400-401	Knee Procedures with Principal Diagnosis of Infection	N/A	24
MS-DRGs 521-522	Hip Replacement with Principal Diagnosis of Hip Fracture	19	18
MS-DRGs 480-482	Hip and Femur Procedures Except Major Joint	20	19
MS-DRGs 518-520	Back and Neck Procedures Except Spinal Fusion or Disc Device or Neurostimulator	21	20
MS-DRGs 469-470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity or Total Ankle Replacement	22	22
MS-DRGs 510-512	Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures	23	21
MS-DRGs 503-505	Foot Procedures	24	25
MS-DRGs 500-502	Soft Tissue Procedures	25	23
MS-DRGs 495-497	Local Excision and Removal of Internal Fixation Devices Except Hip and Femur	26	27
MS-DRGs 507-508	Major Shoulder or Elbow Joint Procedures	27	28
MS-DRGs 488-489	Knee Procedures without Principal Diagnosis of Infection	28	26
MS-DRGs 513-514	Hand or Wrist Procedures, Except Major Thumb or Joint Procedures	29	29
MS-DRG 506	Major Thumb or Joint Procedures	30	30
MS-DRGs 515-517	Other Musculoskeletal System and Connective Tissue O.R. Procedures	31	31

MDC 10 (ENDOCRINE, NUTRITIONAL AND METABOLIC DISEASES AND DISORDERS)			
		Current Version 43 Surgical Hierarchy	**Proposed Version 44 Surgical Hierarchy**
MS-DRGs 616-618	Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders	1	2
MS-DRGs 619-621	O.R. Procedures for Obesity	2	5
MS-DRGs 614-615	Adrenal and Pituitary Procedures	3	3
MS-DRGs 622-624	Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Disorders	4	1
MS-DRGs 625-627	Thyroid, Parathyroid and Thyroglossal Procedures	5	4
MS-DRGs 628-630	Other Endocrine, Nutritional and Metabolic O.R. Procedures	6	6

MDC 11 (DISEASES AND DISORDERS OF THE KIDNEY AND URINARY TRACT)			
		Current Version 43 Surgical Hierarchy	Proposed Version 44 Surgical Hierarchy
MS-DRGs 650-651	Kidney Transplant with Hemodialysis	1	1
MS-DRG 652	Kidney Transplant	2	3
MS-DRGs 653-655	Major Bladder Procedures	3	2
MS-DRGs 656-658	Kidney and Ureter Procedures for Neoplasm	4	5
MS-DRGs 659-661	Kidney and Ureter Procedures for Non-Neoplasm	5	9
MS-DRGs 662-664	Minor Bladder Procedures	6	6
MS-DRGs 665-667	Prostatectomy	7	4
MS-DRGs 668-670	Transurethral Procedures	8	7
MS-DRGs 671-672	Urethral Procedures	9	8
MS-DRGs 673-675	Other Kidney and Urinary Tract Procedures	10	10

MDC 12 (DISEASES AND DISORDERS OF THE MALE REPRODUCTIVE SYSTEM)			
		Current Version 43 Surgical Hierarchy	Proposed Version 44 Surgical Hierarchy
MS-DRGs 707-708	Major Male Pelvic Procedures	1	4
MS-DRGs 709-710	Penis Procedures	2	2
MS-DRGs 711-712	Testes Procedures	3	3
MS-DRGs 713-714	Transurethral Prostatectomy	4	5
MS-DRGs 715-716	Male Reproductive System and Other O.R. Procedures for Malignancy	5	1
MS-DRGs 717-718	Other Male Reproductive System O.R. Procedures	6	6

MDC 13 (DISEASES AND DISORDERS OF THE FEMALE REPRODUCTIVE SYSTEM)			
		Current Version 43 Surgical Hierarchy	Proposed Version 44 Surgical Hierarchy
MS-DRGs 734-735	Pelvic Evisceration, Radical Hysterectomy and Radical Vulvectomy	1	2
Proposed New MS-DRGs 731-733	Uterine and Adnexa Procedures for Malignancy	N/A	1
MS-DRGs 742-743	Uterine and Adnexa Procedures for Non-Malignancy	3	4
MS-DRGs 744-745	D&C, Conization, Laparoscopy and Tubal Interruption	4	3
MS-DRGs 746-747	Vagina, Cervix and Vulva Procedures	5	6
MS-DRG 748	Female Reproductive System Reconstructive Procedures	6	5
MS-DRGs 749-750	Other Female Reproductive System O.R. Procedures	7	7

BILLING CODE 4169–69–C

Comment: Several commenters supported the proposed surgical hierarchy, however, a commenter expressed disagreement with the proposed sequencing for MDC 10 MS–DRGs 616, 617, and 618 from number one to number two, and also disagreed with the proposed surgical hierarchy sequencing for MDC 10 MS–DRGs 622, 623, and 624 from number four to number one. The commenter stated that ICD–10–PCS code 0JBQ0ZZ (Excision of right foot subcutaneous tissue and fascia, open approach) appears to drive the MS–DRG assignment when ICD–10–PCS code 0Y6M0ZF (Detachment at right foot, partial 5th ray, open approach) is also reported. According to the commenter, a partial foot amputation should not be sequenced lower in the surgical hierarchy because it is clinically more complex than a soft tissue excision.

Response: We appreciate the commenters' support and feedback. We note that, as discussed in the preamble of the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19375 through 19376) and this final rule, the surgical hierarchy is based on a methodology for determining the most resource-intensive surgical class that involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. As such, the sequencing of the surgical hierarchy is not based on the individual procedure codes listed in the logic for case assignment to an MS–DRG based on the clinical complexity of a procedure, rather, using the established methodology, each MS–DRG within the surgical class is assessed to calculate the weighted average resources for that surgical class. We note that because the weighted average resources for the surgical class comprised of MS–DRGs 622, 623, and 624 are greater than the

weighted average resources for the surgical class comprised of MS–DRGs 616, 617, and 618, the sequencing of the proposed surgical hierarchy reflects that analysis.

Therefore, after consideration of the public comments we received, and based on the changes that we are finalizing for FY 2027, as discussed in section II.C. of the preamble of this final rule, we are finalizing our proposals to modify the existing surgical hierarchy, effective with the ICD–10 MS–DRGs Version 44, without modification. The finalized changes are also reflected in Appendix D MS–DRG Surgical Hierarchy by MDC and MS–DRG of the ICD–10 MS–DRG Definitions Manual, Version 44 available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.*

For issues pertaining to the surgical hierarchy, as with other MS–DRG related requests, we encourage interested parties to submit comments no later than October 20, 2026, via MEARIS™ at *https://mearis.cms.gov/public/home,* so that they can be considered for possible inclusion in the annual proposed rule.

15. Maintenance of the ICD–10–CM and ICD–10–PCS Coding Systems

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly identified diseases and newly developed procedures and technologies. The Committee is also responsible for encouraging the use of Federal and non-Federal educational programs and employing other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-9-cm-diagnosis-procedure-codes-abbreviated-and-full-code-titles.*

The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html.*

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages health-related organizations to participate in the previously mentioned process. In this regard, the Committee makes code request materials and proposed coding changes publicly available. These materials provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. Members of the public may submit comments on the proposed procedure code topics to CMS at: *ICDProcedureCodeRequest@cms.hhs.gov* and may submit comments on the proposed diagnosis code topics to the CDC/NCHS at: *nchsICD-10-CM@cdc.gov.* After considering the public comments submitted, the Committee formulates recommendations, which then must be approved by CDC/NCHS and CMS.

The Committee presented proposals for ICD–10–CM diagnosis code changes for implementation in FY 2027 at the virtual public meetings held on September 9–10, 2025 and finalized the coding changes after consideration of comments received during the meetings and in writing by November 14, 2025.

In lieu of CMS holding its Fall 2025 meeting, the Committee solicited comments on the Fall 2025 ICD–10–PCS procedure code topics. The deadline to submit comments on the procedure code proposals considered for an April 1, 2026, implementation was October 10, 2025, and the deadline to submit comments on the procedure code proposals being considered for an October 1, 2026, implementation was November 14, 2025.

The Committee presented proposals for ICD–10–CM diagnosis code changes for implementation in FY 2027 and FY 2028 at the virtual public meetings held on March 17–18, 2026 and will finalize the coding changes after consideration of comments received during the meetings and in writing by May 15, 2026.

In lieu of CMS holding its Spring 2026 meeting, the Committee solicited comments on the Spring 2026 ICD–10–PCS procedure code topics. The deadline for submitting public comments on these code proposals was April 17, 2026. Any new diagnosis and procedure codes for which there was a consensus of public support, and for which complete tabular and indexing changes would be made by June 2026 are included in the October 1, 2026, update to the ICD–10–CM diagnosis and ICD–10–PCS procedure code sets. As discussed in earlier sections of the preamble of this final rule, there are new, revised, and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure Code Titles for this final rule, which are available on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps.*

The code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee process. As previously noted, although we make the code titles available in association with the IPPS proposed and final rules, they are not subject to comment in the proposed or final rule. Because of the length of these tables, they are not published in the Addendum to the proposed or final rule. Rather, they are available on the CMS website as discussed in section VI. of the Addendum to the proposed rule.

Recordings and materials for the virtual meeting discussions of the diagnosis codes at the Committee's September 9–10, 2025 and March 17–18, 2026 meeting can be found at: *https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html.* Materials for the Fall 2025 and Spring 2026 ICD–10–PCS procedure code topics can be obtained from the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.* These websites also provide detailed information about the Committee, including information on requesting a new code, participating in a Committee meeting, timeline requirements,

submitting comments, and meeting dates.

We encourage commenters to submit questions and comments on coding issues involving diagnosis codes to CDC/NCHS via Email to: *nchsICD-10-CM@cdc.gov.*

Questions and comments concerning the procedure codes should be submitted to CMS via Email to: *ICDProcedureCodeRequest@cms.hhs.gov.*

As discussed in the proposed rule (91 FR 19382), CMS implemented 80 new procedure codes including codes to describe the insertion of cardiac devices, (that is, leads) into the ventricular septum, codes to enable the differentiation between the endoscopic techniques utilized to drain hepatobiliary and pancreatic fluid collections, and codes to capture the utilization of adjunctive therapies such as microcurrent electrical neuromuscular stimulation (MENS) and frequency-specific microcurrent (FSM) into the ICD–10–PCS classification effective with discharges on and after April 1, 2026. The procedure codes are as follows:

BILLING CODE 4169–69–P

Procedure Code	Description	O.R.	MDC	MS-DRG
02HM3JZ**	Insertion of pacemaker lead into ventricular septum, percutaneous approach	N	01	040-042
			05	260-262
			21	907-909
			24	957-959
02HM3KZ	Insertion of defibrillator lead into ventricular septum, percutaneous approach	Y	05	265
			14	768-769
				817-819
			17	823-825
				829-830
				850
			18	853-855
				856-858
			19	876
			23	939-941
			25	969-970
02HM3MZ**	Insertion of cardiac lead into ventricular septum, percutaneous approach	N	05	260-262
02HM3NZ	Insertion of intracardiac pacemaker into ventricular septum, percutaneous approach	Y	05	228-229
			14	768-769
				817-819
			17	823-825
				829-830
				850
			18	853-855
				856-858
			19	876
			23	939-941
			25	969-970
02HM3YZ	Insertion of other device into ventricular septum, percutaneous approach	Y	05	260-262
			14	768-769
				817-819
			17	823-825
				829-830
				850
			18	853-855
				856-858
			19	876
			23	939-941
			25	969-970
0DDU0ZZ	Extraction of omentum, open approach	Y	06	356-358
			07	423-425
			10	628-630
			13	749-750
			14	768-769
				817-819
			17	820-822
				826-828
			18	853-855
			18	856-858
			19	876
			23	939-941
0DDU4ZZ	Extraction of omentum, percutaneous endoscopic approach	Y	06	356-358
			07	423-425
			10	628-630
			13	749-750
			14	768-769
				817-819
			17	820-822
				826-828
			18	853-855
			18	856-858
			19	876
			23	939-941

0DDV0ZZ	Extraction of mesentery, open approach	Y	06 07 10 13 14 17 18 18 19 23	356-358 423-425 628-630 749-750 768-769 817-819 820-822 826-828 853-855 856-858 876 939-941
0DDV4ZZ	Extraction of mesentery, percutaneous endoscopic approach	Y	06 07 10 13 14 17 18 18 19 23	356-358 423-425 628-630 749-750 768-769 817-819 820-822 826-828 853-855 856-858 876 939-941
0F9480D*	Drainage of gallbladder with drainage device, via natural or artificial opening endoscopic, transmural	N		
0F9480E*	Drainage of gallbladder with drainage device, via natural or artificial opening endoscopic, transpapillary	N		
0F9580D*	Drainage of right hepatic duct with drainage device, via natural or artificial opening endoscopic, transmural	N		
0F9580E*	Drainage of right hepatic duct with drainage device, via natural or artificial opening endoscopic, transpapillary	N		
0F9680D*	Drainage of left hepatic duct with drainage device, via natural or artificial opening endoscopic, transmural	N		
0F9680E*	Drainage of left hepatic duct with drainage device, via natural or artificial opening endoscopic, transpapillary	N		
0F9780D*	Drainage of common hepatic duct with drainage device, via natural or artificial opening endoscopic, transmural	N		
0F9780E*	Drainage of common hepatic duct with drainage device, via natural or artificial opening endoscopic, transpapillary	N		
0F9880D*	Drainage of cystic duct with drainage device, via natural or artificial opening endoscopic, transmural	N		
0F9880E*	Drainage of cystic duct with drainage device, via natural or artificial opening endoscopic, transpapillary	N		
0F9980D*	Drainage of common bile duct with drainage device, via natural or artificial opening endoscopic, transmural	N		
0F9980E*	Drainage of common bile duct with drainage device, via natural or artificial opening endoscopic, transpapillary	N		
0F9C80D*	Drainage of ampulla of vater with drainage device, via natural or artificial opening endoscopic, transmural	N		
0F9C80E*	Drainage of ampulla of vater with drainage device, via natural or artificial opening endoscopic, transpapillary	N		
0F9D80D*	Drainage of pancreatic duct with drainage device, via natural or artificial opening endoscopic, transmural	N		
0F9D80E*	Drainage of pancreatic duct with drainage device, via natural or artificial opening endoscopic, transpapillary	N		
0F9F80D*	Drainage of accessory pancreatic duct with drainage device, via natural or artificial opening endoscopic, transmural	N		
0F9F80E*	Drainage of accessory pancreatic duct with drainage device, via natural or artificial opening endoscopic, transpapillary	N		
0F9G80D*	Drainage of pancreas with drainage device, via natural or artificial opening endoscopic, transmural	N		
0F9G80E*	Drainage of pancreas with drainage device, via natural or artificial opening endoscopic, transpapillary	N		

0TXB0Z6	Transfer bladder to right ureter, open approach	Y	11	656-658
				659-661
			14	768-769
				817-819
			17	823-825
				829-830
				850
			18	853-855
				856-858
			19	876
			21	907-909
			23	939-941
			24	958-959
			25	969-970
0TXB0Z7	Transfer bladder to left ureter, open approach	Y	11	656-658
				659-661
			14	768-769
				817-819
			17	823-825
				829-830
				850
			18	853-855
				856-858
			19	876
			21	907-909
			23	939-941
			24	958-959
			25	969-970
0TXB4Z6	Transfer bladder to right ureter, percutaneous endoscopic approach	Y	11	656-658
				659-661
			14	768-769
				817-819
			17	823-825
				829-830
				850
			18	853-855
				856-858
			19	876
			21	907-909
			23	939-941
			24	958-959
			25	969-970
0TXB4Z7	Transfer bladder to left ureter, percutaneous endoscopic approach	Y	11	656-658
				659-661
			14	768-769
				817-819
			17	823-825
				829-830
				850
			18	853-855
				856-858
			19	876
			21	907-909
			23	939-941
			24	958-959
			25	969-970
0VT00ZE	Resection of prostate, open approach, capsule intact	Y	11	665-667
			12	707-708
			17	823-825
				829-830
				850
			18	853-855
				856-858
			19	876
			23	939-941
			25	969-970

0VT04ZE	Resection of prostate, percutaneous endoscopic approach, capsule intact	Y	11 12 17 18 19 23	665-667 707-708 823-825 829-830 850 853-855 856-858 876 939-941
0VT07ZE	Resection of prostate, via natural or artificial opening, capsule intact	Y	11 12 17 18 19 23	665-667 713-714 823-825 829-830 850 853-855 856-858 876 939-941
0VT08ZE	Resection of prostate, via natural or artificial opening endoscopic, capsule intact	Y	11 12 17 18 19 23	665-667 713-714 823-825 829-830 850 853-855 856-858 876 939-941
3E033AZ*	Introduction of embryonic stem cells into peripheral vein, percutaneous approach	N		
3E043AZ*	Introduction of embryonic stem cells into central vein, percutaneous approach	N		
4A0FXEJ*	Measurement of musculoskeletal body composition using air displacement plethysmography, external approach	N		
5A0221E	Assistance with cardiac output using blood flow modulator, continuous	Y	05 14 17 18 19 23 25	 270-272 768-769 817-819 823-825 829-830 850 853-855 856-858 876 939-941 969-970
F07DYD0**	Electrotherapeutic treatment of integumentary system - head and neck using microcurrent stimulation	N	23	945-946
F07EYD0**	Electrotherapeutic treatment of integumentary system - thorax / abdomen using microcurrent stimulation	N	23	945-946
F07FYD0**	Electrotherapeutic treatment of integumentary system - upper back / upper extremity using microcurrent stimulation	N	23	945-946
F07GYD0**	Electrotherapeutic treatment of integumentary system - lower back / lower extremity using microcurrent stimulation	N	23	945-946
F07HYD0**	Electrotherapeutic treatment of integumentary system - whole body using microcurrent stimulation	N	23	945-946
F08E5AZ**	Wound management treatment of integumentary system - thorax / abdomen using negative pressure therapy	N	23	945-946
F08E5BZ**	Wound management treatment of integumentary system - thorax / abdomen using physical agents	N	23	945-946
F08E5CZ**	Wound management treatment of integumentary system - thorax / abdomen using mechanical equipment	N	23	945-946
F08E5DZ**	Wound management treatment of integumentary system - thorax / abdomen using electrotherapeutic equipment	N	23	945-946
F08E5EZ**	Wound management treatment of integumentary system - thorax / abdomen using orthosis	N	23	945-946
F08E5FZ**	Wound management treatment of integumentary system - thorax / abdomen using assistive, adaptive, supportive or protective equipment	N	23	945-946
F08E5UZ**	Wound management treatment of integumentary system - thorax / abdomen using prosthesis	N	23	945-946

F08E5YZ**	Wound management treatment of integumentary system - thorax / abdomen using other equipment	N	23	945-946
F08E5ZZ**	Wound management treatment of integumentary system - thorax / abdomen	N	23	945-946
F08P5AZ**	Wound management treatment of musculoskeletal system - thorax / abdomen using negative pressure therapy	N	23	945-946
F08P5BZ**	Wound management treatment of musculoskeletal system - thorax / abdomen using physical agents	N	23	945-946
F08P5CZ**	Wound management treatment of musculoskeletal system - thorax / abdomen using mechanical equipment	N	23	945-946
F08P5DZ**	Wound management treatment of musculoskeletal system - thorax / abdomen using electrotherapeutic equipment	N	23	945-946
F08P5EZ**	Wound management treatment of musculoskeletal system - thorax / abdomen using orthosis	N	23	945-946
F08P5FZ**	Wound management treatment of musculoskeletal system - thorax / abdomen using assistive, adaptive, supportive or protective equipment	N	23	945-946
F08P5UZ**	Wound management treatment of musculoskeletal system - thorax / abdomen using prosthesis	N	23	945-946
F08P5YZ**	Wound management treatment of musculoskeletal system - thorax / abdomen using other equipment	N	23	945-946
F08P5ZZ**	Wound management treatment of musculoskeletal system - thorax / abdomen	N	23	945-946
X2723CB	Dilation of inferior vena cava and iliocaval confluence with open-structure polymer lattice intraluminal device, percutaneous approach, new technology group 11	Y	01 04 05 06 07 08 09 10 11 14 17 18 19 21 23 24 25	037-039 166-168 252-254 356-358 423-425 515-517 579-581 628-630 673-675 768-769 817-819 823-825 829-830 850 853-855 856-858 876 907-909 939-941 957-959 969-970
X2HM3GB	Insertion of lumenless small-diameter defibrillator lead into ventricular septum, percutaneous approach, new technology group 11	Y	05 14 17 18 19 23 25	265 768-769 817-819 823-825 829-830 850 853-855 856-858 876 939-941 969-970
X2HV3GB	Insertion of lumenless small-diameter defibrillator lead into right ventricle, percutaneous approach, new technology group 11	Y	05 14 17 18 19 23 25	265 768-769 817-819 823-825 829-830 850 853-855 856-858 876 939-941 969-970

X2K00FB	Bypass inferior vena cava using autologous cell seeded tissue engineered resorbable scaffold to pulmonary artery, open approach, new technology group 11	Y	05 14 17 18 19 23 25	228-229 768-769 817-819 823-825 829-830 850 853-855 856-858 876 939-941 969-970
X2KG0FB	Bypass hepatic vein using autologous cell seeded tissue engineered resorbable scaffold to pulmonary artery, open approach, new technology group 11	Y	05 14 17 18 19 23 25	228-229 768-769 817-819 823-825 829-830 850 853-855 856-858 876 939-941 969-970
X9HD01B	Insertion of temporary infusion device into right inner ear, open approach, new technology group 11	Y	03 14 17 18 19 23 25	143-145 768-769 817-819 823-825 829-830 850 853-855 856-858 876 939-941 969-970
X9HE01B	Insertion of temporary infusion device into left inner ear, open approach, new technology group 11	Y	03 14 17 18 19 23 25	143-145 768-769 817-819 823-825 829-830 850 853-855 856-858 876 939-941 969-970
X9HF01B	Insertion of temporary infusion device into bilateral inner ear, open approach, new technology group 11	Y	03 14 17 18 19 23 25	143-145 768-769 817-819 823-825 829-830 850 853-855 856-858 876 939-941 969-970
XU7G71B*	Dilation of vagina with temporary electromechanical intraluminal device, via natural or artificial opening, new technology group 11	N		
XW0330B*	Introduction of alpha1-proteinase inhibitor into peripheral vein, percutaneous approach, new technology group 11	N		
XW0331B**	Introduction of anitocabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 11	N	Pre-MDC	018
XW0430B*	Introduction of alpha1-proteinase inhibitor into central vein, percutaneous approach, new technology group 11	N		
XW0431B**	Introduction of anitocabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 11	N	Pre-MDC	018
XW0534B*	Introduction of somatic stem cells into peripheral artery, percutaneous approach, new technology group 11	N		
XW0632B*	Introduction of CPI-601 enzyme replacement therapy into cerebral ventricle, percutaneous approach, new technology group 11	N		
XW0E33B*	Introduction of DB-OTO via intracochlear infusion into ear(s), percutaneous approach, new technology group 11	N		

*As the procedure codes are designated as non-O.R. procedures, there is no assigned MDC or MS-DRG. The ICD-10 MS-DRG assignment is dependent on the reported principal diagnosis, any secondary diagnoses defined as a complication or comorbidity (CC) or major complication or comorbidity (MCC), procedures or services performed, age, sex, and discharge status.

**Non-O.R. procedure affecting the MS-DRG assignment.

BILLING CODE 4169–69–C

The 80 procedure codes are also reflected in Table 6B.—New Procedure Codes, which is available on the CMS website at: *https://www.cms.gov/*

Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS. As with the other new procedure codes and MS–DRG assignments included in Table 6B in association with the FY 2027 IPPS/LTCH PPS proposed rule, we solicited public comments on the most appropriate MDC, MS–DRG, and operating room status assignments for these codes for FY 2027, as well as any other options for the GROUPER logic. We discuss the comments we received on these assignments in section II.C.9. of this final rule as well as our finalized assignments, as reflected in Table 6B.—New Procedure Codes in association with this final rule.

In the proposed rule, we also noted that Change Request (CR) 14337, Transmittal 13562, titled ''April 2026 Update to the Medicare Severity-Diagnosis Related Group (MS–DRG) Grouper and Medicare Code Editor (MCE) Version V43.1'' was issued on December 23, 2025, (available on the CMS website at: *https://www.cms.gov/medicare/regulations-guidance/transmittals/2025-transmittals/r13562cp*) regarding the release of an updated version of the ICD–10 MS–DRG GROUPER and Medicare Code Editor software, Version V43.1, effective with discharges on and after April 1, 2026, reflecting the new procedure codes. The updated software, along with the updated ICD–10 MS–DRG Version 43.1 Definitions Manual and the Definitions of Medicare Code Edits Version 43.1 manual is available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

In the September 7, 2001, Medicare Program: Payments for New Medical Services and New Technologies Under the Acute Care Hospital Inpatient Prospective Payment System final rule implementing the IPPS new technology add-on payments (66 FR 46902), we indicated our intention to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of the Medicare Modernization Act (Pub. L. 108–173) included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) of Public Law 108–173 amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS by providing information on these new technologies at an earlier date. Data will be available six months earlier than would be possible with updates occurring only once a year on October 1.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting were considered for an April 1 update if a strong and convincing case was made by the requestor during the Committee's public meeting. The request needed to identify the reason why a new code was needed in April for purposes of the new technology process. Meeting participants and those reviewing the Committee meeting materials were provided with the opportunity to comment on the expedited request. We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950) for further discussion of the implementation of this prior April 1 update for purposes of the new technology add-on payment process.

As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950 through 44956), we adopted an April 1 implementation date, in addition to the annual October 1 update, beginning with April 1, 2022. We noted that the intent of this April 1 implementation date was to allow flexibility in the ICD–10 code update process. CMS uses the same process for consideration of all requests for an April 1 implementation date, including for purposes of the new technology add-on payment process (that is, the prior process for consideration of an April 1 implementation date only if a strong and convincing case was made by the requestor during the meeting no longer applies). We implement new codes through the April 1 code update, which includes displaying proposals for April 1 consideration in association with the Fall ICD–10 Coordination and Maintenance Committee code update, requesting public comments, reviewing the public comments, finalizing codes, and announcing the new codes with their assignments consistent with the new GROUPER release information. We note that under our established process, requestors indicate whether they are submitting their code request for consideration for an April 1 implementation date or an October 1 implementation date. The ICD–10 Coordination and Maintenance Committee makes reasonable efforts to accommodate the requested implementation date for each request submitted. However, the Committee ultimately determines which requests are to be presented for consideration for an April 1 implementation date or an October 1 implementation date. The ICD–10 Coordination and Maintenance Committee may not be able to consider all requests received for the next Committee code update and will determine if it would be appropriate to postpone consideration of any code requests to a future update. As discussed earlier in this section of the preamble of this final rule, there were procedure code proposals considered for an April 1, 2026 implementation for the Fall 2025 procedure code update. Following the receipt of public comments, the code proposals were approved and finalized, therefore, new codes were implemented on April 1, 2026.

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19388), consistent with the process we outlined for the April 1 implementation date, we announced the new codes and provided the updated code files in December 2025. The NCHS provided the ICD–10–CM Official Guidelines for Coding and Reporting in January 2026. On February 03, 2026, we made available the updated Version 43.1 ICD–10 MS–DRG GROUPER software and related materials on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

ICD–9–CM addendum and code title information are published on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/addendum.* ICD–10–CM and ICD–10–PCS addendum and code title information are published on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10.* CMS also sends electronic files containing all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their

systems and furnishing education to providers. Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can be found on the CDC website at *https://www.cdc.gov/nchs/icd/icd-10-cm/files.html.* Additionally, information on new, revised, and deleted ICD–10–CM diagnosis and ICD–10–PCS procedure codes is provided to the AHA for publication in the Coding Clinic for ICD–10. The AHA also distributes coding update information to publishers and software vendors.

In the proposed rule (91 FR 19389), we noted that for FY 2026, there are currently 74,719 diagnosis codes and 79,193 procedure codes. We also noted, as displayed in Table 6A.—New Diagnosis Codes and in Table 6B.—New Procedure Codes associated with the FY 2027 IPPS/LTCH PPS proposed rule (and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*), there are 184 new diagnosis codes and 81 new procedure codes that had been finalized at the time of the development of the FY 2027 IPPS/LTCH PPS proposed rule, with 80 of the new procedure codes that were effective with discharges on and after April 1, 2026. As previously noted, the code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee process. Thus, although we publish the code titles in association with the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

As discussed in section II.C.13 of the preamble of this final rule, we are making Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles and Table 6F.—Revised Procedure Code Titles available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* in association with this final rule. As shown in Table 6A.—New Diagnosis Codes, there were diagnosis codes proposed for the Spring 2026 ICD–10 Coordination and Maintenance Committee Update that were not finalized in time to include in the proposed rule. As shown in Table 6B.—New Procedure Codes, there were procedure codes proposed for the Spring 2026 ICD–10 Coordination and Maintenance Committee Update that were not finalized in time to include in the proposed rule and are identified with an asterisk. We refer the reader to Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes associated with this final rule and available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* for the detailed list of these six new diagnosis codes and the detailed list of these 101 new procedure codes finalized for FY 2027.

We also note, as reflected in Table 6C.—Invalid Diagnosis Codes, and in Table 6D.—Invalid Procedure Codes, there are a total of 30 diagnosis codes and 38 procedure codes that will become invalid effective October 1, 2026. Based on these code updates, effective October 1, 2026, there are a total of 74,879 ICD–10–CM diagnosis codes and 79,256 ICD–10–PCS procedure codes for FY 2027 as shown in the following table.

FY 2026 ICD-10-CM	74,719 total codes	FY 2026 ICD-10-PCS	79,193 total codes
FY 2027 ICD-10-CM	190 additions	FY 2027 ICD-10-PCS	101 additions
FY 2027 ICD-10-CM	30 deletions	FY 2027 ICD-10-PCS	38 deletions
FY 2027 ICD-10-CM	**74,879 total codes**	**FY 2027 ICD-10-PCS**	**79,256 total codes**

The public is provided the opportunity to comment on any proposals for new diagnosis or procedure codes that are discussed during an ICD–10 Coordination and Maintenance Committee Meeting or that are made available for public comments. The code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee process. Thus, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

16. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that subsequently failed or was recalled determined the base MS–DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Changes for FY 2027

As discussed in section II.C.3. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule, for FY 2027, under MDC 05, we are proposed to delete MS–DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with and without MCC, respectively) and MS–DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively) and create new MS–DRGs 210 and 211 (Cardiac Pacemaker Revision or Device Replacement with and without MCC, respectively). The procedures currently assigned to MS–DRGs 258, 259, 260, 261, and 262 were proposed for assignment to proposed new MS–DRGs 210 and 211.

Additionally, as discussed in section II.C.4. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and this final rule, for FY 2027, under MDC 08, we proposed to delete MS–DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively) and create new MS–DRG 449 (Revision of Hip or Knee Replacement). The procedures currently assigned to MS–DRGs 466, 467, and 468 were proposed for assignment to proposed new MS–DRG 449.

As stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24409), we generally map new MS–DRGs onto the list when they are formed from procedures previously assigned to MS–DRGs that are already on the list. Currently, MS–DRGs 258, 259, 260, 261, 262, 466, 467, and 468 are on the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a

credit as shown in the following table. Therefore, we proposed that if the applicable proposed MS–DRG changes are finalized, we also would add proposed new MS–DRGs 210 and 211 and proposed new MS–DRG 449 to the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit as reflected in the following table. We also proposed to continue to include the existing MS–DRGs currently subject to the policy.

As discussed in section II.C.3. of the preamble of this final rule, we are finalizing our proposals to delete MS–DRGs 258, 259, 260, 261, and 262, and to create new MS–DRGs 210 and 211. Additionally, as discussed in section II.C.4. of the preamble of this final rule, we are finalizing our proposal to delete MS–DRGs 466, 467, and 468 and to create new MS–DRG 449, with a modification to the proposed title. We did not receive any public comments opposing our proposals to add proposed new MS–DRGs 210, 211 and 449 to the list of MS–DRGs that will be subject to the replaced devices offered without cost or with a credit policy effective October 1, 2026. Therefore, we are finalizing our proposal to add new MS–DRGs 210, 211, and 449 to the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or credit for FY 2027.

We did not receive any public comments opposing our proposal to continue to include the existing MS–DRGs currently subject to the policy. Therefore, for the reasons summarized, we are finalizing the list of MS–DRGs in the following table that will be subject to the replaced devices offered without cost or with a credit policy effective October 1, 2026.

BILLING CODE 4169–69–P

MDC	MS-DRG	MS-DRG TITLE
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC
01	023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Antineoplastic Implant or Epilepsy with Neurostimulator
01	024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC
01	025	Craniotomy and Endovascular Intracranial Procedures with MCC
01	026	Craniotomy and Endovascular Intracranial Procedures with CC
01	027	Craniotomy and Endovascular Intracranial Procedures without CC/MCC
01	040	Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC
01	041	Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator
01	042	Peripheral, Cranial Nerve and Other Nervous System Procedures without CC/MCC
03	140	Major Head and Neck Procedures with MCC
03	141	Major Head and Neck Procedures with CC
03	142	Major Head and Neck Procedures without CC/MCC
05	209	Complex Aortic Arch Procedures
05	210	Cardiac Pacemaker Revision or Device Replacement with MCC
05	211	Cardiac Pacemaker Revision or Device Replacement without MCC
05	213	Endovascular Abdominal Aorta with Iliac Branch Procedures
05	215	Other Heart Assist System Implant
05	216	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC
05	217	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC
05	218	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC
05	219	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC
05	220	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC
05	221	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC
05	242	Permanent Cardiac Pacemaker Implant with MCC
05	243	Permanent Cardiac Pacemaker Implant with CC
05	244	Permanent Cardiac Pacemaker Implant without CC/MCC
05	245	AICD Generator Procedures
05	265	AICD Lead Procedures
05	266	Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC
05	267	Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC
05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
05	270	Other Major Cardiovascular Procedures with MCC
05	271	Other Major Cardiovascular Procedures with CC
05	272	Other Major Cardiovascular Procedures without CC/MCC
05	275	Cardiac Defibrillator Implant with Cardiac Catheterization and MCC
05	276	Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator
05	277	Cardiac Defibrillator Implant without MCC
05	319	Other Endovascular Cardiac Valve Procedures with MCC
05	320	Other Endovascular Cardiac Valve Procedures without MCC
08	449	Revision of Hip or Knee Prosthesis
08	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC
08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
08	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement
08	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC
08	521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
08	522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC

BILLING CODE 4169–69–C

The final list of MS–DRGs subject to the IPPS policy for replaced devices offered without cost or with a credit will be issued to providers in the form of a Change Request (CR).

17. Out of Scope Public Comments Received

We received public comments on MS–DRG related issues that were outside the scope of the proposals included in the FY 2027 IPPS/LTCH PPS proposed rule.

Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing them in this final rule. As stated in section II.C.1.b. of the preamble of this

final rule, we encourage individuals with comments about MS–DRG classifications to submit these comments no later than October 20, 2026, via MEARIS™ at: *https://mearis.cms.gov/public/home,* so that they can be considered for possible inclusion in the annual proposed rule. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

D. Recalibration of the FY 2027 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

Consistent with our established policy, in developing the MS–DRG relative weights for FY 2027, we proposed to use two data sources: claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2025 MedPAR data used in this final rule includes discharges occurring on October 1, 2024, through September 30, 2025, based on bills received by CMS through December 31, 2025, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS).

The FY 2025 MedPAR file used in calculating the relative weights includes data for approximately 6,961,093 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the March 2026 update of the FY 2025 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the relative weights for FY 2027 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. In addition, the data exclude Rural Emergency Hospitals (REHs), including hospitals that subsequently became REHs after the period from which the data were taken. We note that the FY 2027 relative weights are based on the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes from the FY 2025 MedPAR claims data, grouped through the ICD–10 version of the FY 2027 GROUPER (Version 44).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the Healthcare Cost Report Information System (HCRIS). In general, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, for this final rule, we used the March 2026 update of the FY 2024 HCRIS for calculating the FY 2027 cost-based relative weights. Consistent with our historical practice, for this FY 2027 final rule, we are providing the version of the HCRIS from which we calculated these 19 cost-to charge-ratios (CCRs) on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.* Click on the link on the left side of the screen titled ''FY 2027 IPPS Final Rule Home Page'' or ''Acute Inpatient Files for Download.''

2. Methodology for Calculation of the Relative Weights

a. General

We calculated the FY 2027 relative weights based on 19 CCRs. The methodology we proposed to use to calculate the FY 2027 MSDRG cost-based relative weights based on claims data in the FY 2025 MedPAR file and data from the FY 2024 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the FY 2027 MS–DRG classifications discussed in sections II.B. and II.C. of the preamble of this final rule.
- The transplant cases that were used to establish the relative weights for heart and lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2025 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis.

Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

Section 108 of the Further Consolidated Appropriations Act, 2020 provides that, for cost reporting periods beginning on or after October 1, 2020, costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant shall be paid on a reasonable cost basis. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for further discussion of the reasonable cost basis payment for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842). For FY 2022 and subsequent years, we subtract the hematopoietic stem cell acquisition charges from the total charges on each transplant bill that showed hematopoietic stem cell acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $30.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, implantable devices charges, supplies and equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood and blood products charges, anesthesia charges, cardiac catheterization charges, CT scan charges, and MRI charges were also deleted.
- At least 92.7 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the

geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.

• Effective October 1, 2008, because hospital inpatient claims include a Present on Admission (POA) field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

The charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. Statistical outliers were then removed. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2024 cost report data.

The 19 cost centers that we used in the relative weight calculation are shown in a supplemental data file, Cost Center HCRIS Lines Supplemental Data File, posted via the internet on the CMS website for this final rule and available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.* The supplemental data file shows the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center CCRs. In the proposed rule, we stated that if we receive comments about the groupings in this supplemental data file, we may consider these comments as we finalize our policy. We did not receive any comments on the groupings in this table and are finalizing the groupings as proposed.

Consistent with historical practice, we account for rare situations of non-monotonicity in a base MS–DRG and its severity levels, where the mean cost in the higher severity level is less than the mean cost in the lower severity level, in determining the relative weights for the different severity levels. If there are initially non-monotonic relative weights in the same base DRG and its severity levels, then we combine the cases that group to the specific non-monotonic MS–DRGs for purposes of relative weight calculations. For example, if there are two non-monotonic MS–DRGs, combining the cases across those two MS–DRGs results in the same relative weight for both MS–DRGs. The relative weight calculated using the combined cases for those severity levels is monotonic, effectively removing any non-monotonicity with the base DRG and its severity levels. For this FY 2027 final rule, this calculation was applied to address non-monotonicity for cases that grouped to the following: MS–DRG 217 and MS–DRG 218, MS–DRG 504 and MS–DRG 505, and MS–DRG 582 and MS–DRG 583. In the supplemental file titled AOR/BOR File, we include statistics for the affected MS–DRGs both separately and with cases combined.

We invited public comments on our proposals related to recalibration of the proposed FY 2027 relative weights and the changes in relative weights from FY 2026.

Comment: Commenters expressed concern that the current MS–DRG payment methodology systematically disadvantages rural hospitals relative to urban hospitals, as recalibrations reduce payments for the lower-acuity cases rural hospitals predominantly treat while denying them the benefits of rising relative weights for complex cases they rarely see. Commenters warned that this dynamic creates a self-reinforcing downward spiral in which persistently low case-mix indexes (CMI) constrain revenue, limiting investment in technology and specialty capacity, which in turn prevents rural hospitals from treating higher-acuity patients and improving their CMI—ultimately threatening the long-term viability of these critical community resources. A commenter urged CMS to examine whether its rate-setting methodology contributes to these disproportionate impacts and, if confirmed, to pursue corrective payment adjustments. Specifically, commenters suggested a CMI-based payment adjustment modeled after the low wage index hospital policy finalized in the FY 2020 IPPS rule, which they stated successfully addressed a comparable cycle of disadvantage for low-wage-index hospitals. Commenters further stated that CMS has both the statutory authority under section 1886(d)(5)(I)(i) of the Act and established precedent in the MS–DRG context to implement such an adjustment.

Response: We appreciate the commenters sharing their concerns regarding the impact of recalibration on payment for rural hospitals. We believe the relative weights determined under our recalibration methodology and using the best available data (as described previously) is consistent with the statutory requirement to adjust the MS–DRG relative weights at least annually to account for changes in relative resource consumption, reflecting changes in treatment patterns, technology, and any other factors that

may change the relative use of hospital resources. In addition, we believe the budget neutrality adjustments resulting from recalibration are fulfilling our statutory requirement to maintain budget neutrality. We note that in the CY 2026 OPPS final rule (90 FR 54019–54024), we finalized a change in our methodology to incorporate market-based rate information into our relative weight methodology. We believe that this change to our methodology will improve the accuracy of the resulting relative weights. To the extent that the care furnished by rural hospitals is classified into MS–DRGs that may experience increases in their relative weights under the market-based MS–DRG methodology then rural hospitals would see higher payments compared to the current methodology.

After consideration of the comments received, we are finalizing our proposals without modifications related to the recalibration of the FY 2027 relative weights. We summarize and respond to comments relating to the methodology for calculating the relative weight for MS–DRG 018 in the next section of this final rule.

b. Relative Weight Calculation for MS–DRG 018

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58451 through 58453), we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies. We also finalized our proposal to modify our existing relative weight methodology to ensure that the relative weight for MS–DRG 018 appropriately reflects the relative resources required for providing CAR T-cell therapy outside of a clinical trial, while still accounting for the clinical trial cases in the overall average cost for all MS–DRGs (85 FR 58599 through 58600). Specifically, we stated that clinical trial claims that group to new MS–DRG 018 would not be included when calculating the average cost for MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, so that the relative weight reflects the costs of the CAR T-cell therapy drug. We stated that we identified clinical trial claims as claims that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000, which was the average sales price of KYMRIAH and YESCARTA, the two CAR T-cell biological products licensed to treat relapsed/refractory large B-cell lymphoma as of the time of the development of the FY 2021 final rule. In addition, we stated that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for new MS–DRG 018 to the extent such cases can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for new MS–DRG 018 to the extent such cases can be identified in the historical data.

We also finalized our proposal to calculate an adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs and for purposes of budget neutrality and outlier simulations. We calculate this adjustor by dividing the average cost for cases that we identify as clinical trial cases by the average cost for cases that we identify as non-clinical trial cases, with the additional refinements that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be clinical trial cases to the extent such cases can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases to the extent such cases can be identified in the historical data. We stated that to the best of our knowledge, there were no claims in the historical data used in the calculation of this adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58842), we also finalized an adjustment to the payment amount for applicable clinical trial and expanded access use immunotherapy cases that group to MS–DRG 018, and indicated that we would provide instructions for identifying these claims in separate guidance. Following the issuance of the FY 2021 IPPS/LTCH PPS final rule, we issued guidance [16] stating that providers may enter a Billing Note NTE02 ''Expand Acc Use'' on the electronic claim 837I or a remark ''Expand Acc Use'' on a paper claim to notify the MAC of expanded access use of CAR T-cell therapy. In this case, the MAC would add payer-only condition code ''ZB'' so that Pricer will apply the payment adjustment in calculating payment for the case. In cases when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the provider may enter a Billing Note NTE02 ''Diff Prod Clin Trial'' on the electronic claim 837I or a remark ''Diff Prod Clin Trial'' on a paper claim. In this case, the MAC would add payer-only condition code ''ZC'' so that the Pricer will not apply the payment adjustment in calculating payment for the case.

In the FY 2022 IPPS/LTCH PPS final rule, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 44806). We also finalized our proposal to continue to use the proxy of standardized drug charges of less than $373,000 (86 FR 44965) to identify clinical trial claims. We also finalized use of this same proxy for the FY 2023 IPPS/LTCH PPS final rule (87 FR 48894).

Following the issuance of the FY 2023 IPPS/LTCH PPS final rule, we issued guidance [17] stating where there is expanded access use of immunotherapy, the provider may submit condition code ''90'' on the claim so that Pricer will apply the payment adjustment in calculating payment for the case. We stated that MACs would no longer append Condition Code 'ZB' to inpatient claims reporting Billing Note NTE02 ''Expand Acc Use'' on the electronic claim 837I or a remark ''Expand Acc Use'' on a paper claim, effective for claims for discharges that occur on or after October 1, 2022.

In the FY 2024 IPPS/LTCH PPS final rule, we explained that the MedPAR claims data now includes a field that identifies whether or not the claim includes expanded access use of immunotherapy. We stated that for the FY 2022 MedPAR claims data, this field identifies whether or not the claim includes condition code ZB, and for the FY 2023 MedPAR data and subsequent years, this field will identify whether or not the claim includes condition code 90. We further noted that the MedPAR files now also include a variable that indicates whether the claim includes the payer-only condition code ''ZC'', which identifies a case involving the clinical trial of a different product where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner.

[16] *https://www.cms.gov/files/document/r10571cp.pdf.*

[17] *https://www.cms.gov/files/document/r11727cp.pdf.*

Accordingly, and as discussed further in the FY 2024 IPPS/LTCH PPS final rule, we finalized two modifications to our methodology for identifying clinical trial claims and expanded access use claims in MS–DRG 018 (88 FR 58791). First, we finalized to exclude claims with the presence of condition code ''90'' (or, for FY 2024 ratesetting, which was based on the FY 2022 MedPAR data, the presence of condition code ''ZB'') and claims that contain ICD–10–CM diagnosis code Z00.6 without payer-only code ''ZC'' that group to MS–DRG 018 when calculating the average cost for MS–DRG 018. Second, we finalized to no longer use the proxy of standardized drug charges of less than $373,000 to identify clinical trial claims and expanded access use cases when calculating the average cost for MS–DRG 018. Accordingly, we finalized that in calculating the relative weight for MS–DRG 018 for FY 2024, only those claims that group to MS–DRG 018 that (1) contain ICD–10–CM diagnosis code Z00.6 and do not include payer-only code ''ZC'' or (2) contain condition code ''ZB'' (or, for subsequent fiscal years, condition code ''90'') would be excluded from the calculation of the average cost for MS–DRG 018. Consistent with this, we also finalized modifications to our calculation of the adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs. We refer readers to the FY 2024 IPPS/LTCH PPS final rule for further discussion of these modifications (88 FR 58791).

Consistent with the FY 2026 IPPS/LTCH PPS final rule, in the proposed rule, for FY 2027 we proposed to continue to use our methodology as modified in the FY 2024 IPPS/LTCH PPS final rule for identifying clinical trial claims and expanded access use claims in MS–DRG 018, with an additional modification as discussed in this section. First, we exclude claims with the presence of condition code ''90'' and claims that contain ICD–10–CM diagnosis code Z00.6 without payer-only code ''ZC'' that group to MS–DRG 018 when calculating the average cost for MS–DRG 018. Second, we no longer use the proxy of standardized drug charges of less than $373,000 to identify clinical trial claims and expanded access use cases when calculating the average cost for MS–DRG 018.

In the FY 2026 IPPS/LTCH PPS final rule, we finalized our proposal to apply the payment adjustment for clinical trial and expanded access use immunotherapy cases to other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost. To mirror this change within our relative weight methodology, we finalized our proposal to also exclude claims with standardized drug charges below the median standardized drug charge of claims identified as clinical trials in MS–DRG 018 when we calculate the average cost for MS–DRG 018. We proposed to apply this policy for 2 years (that is, in our relative weight methodology for MS–DRG 018 for FYs 2026 and 2027), until the claims data reflects the addition of the condition code indicating that the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, which then would be able to be used to identify these cases such that they can be identified for exclusion from the calculation of the average cost of MS–DRG 018. For the proposed rule, based on the December 2025 update of the FY 2025 MedPAR file, we estimated that the median standardized drug charge of claims identified as clinical trials in MS–DRG 018 is $25,323. For the purpose of performing this trim, we proposed to update the median standardized drug charge of claims identified as clinical trials in MS–DRG 018 based on more recent data for the final rule.

Accordingly, we proposed that in calculating the relative weight for MS–DRG 018 for FY 2027, in identifying clinical trial claims and expanded access use claims and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, only those claims that group to MS–DRG 018 that (1) contain ICD–10–CM diagnosis code Z00.6 and do not include payer-only code ''ZC'', (2) contain condition code ''90'', or (3) contain standardized drug charges below the median standardized drug charge of clinical trial cases in MS–DRG 018 would be excluded from the calculation of the average cost for MS–DRG 018.

We also proposed to continue to use the methodology as modified in the FY 2024 IPPS/LTCH PPS final rule to calculate the adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs, with the same proposed modification as described previously to identify other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost:

- Calculate the average cost for cases assigned to MS–DRG 018 that (a) contain ICD–10–CM diagnosis code Z00.6 and do not contain condition code ''ZC'', (b) contain condition code ''90'', or (c) contain standardized drug charges below the median standardized drug charge of clinical trial cases in MS–DRG 018.
- Calculate the average cost for all other cases assigned to MS–DRG 018.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply the adjustor calculated in step 3 to the cases identified in step 1 as applicable clinical trial or expanded access use cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, then add this adjusted case count to the non-clinical trial case count prior to calculating the average cost across all MS–DRGs.

Under our proposal to continue to apply this methodology, with the proposed modification as described, based on the December 2025 update of the FY 2025 MedPAR file used for the proposed rule, we estimated that the average costs of cases assigned to MS–DRG 018 that are identified as clinical trial cases ($71,039) were 17 percent of the average costs of the cases assigned to MS–DRG 018 that are identified as non-clinical trial cases ($412,218). Accordingly, as we did for FY 2026, we proposed to adjust the transfer-adjusted case count for MS–DRG 018 by applying the proposed adjustor of 0.17 to the applicable clinical trial and expanded access use immunotherapy cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, and to use this adjusted case count for MS–DRG 018 in calculating the national average cost per case, which is used in the calculation of the relative weights. Therefore, in calculating the national average cost per case for purposes of the proposed rule, each case identified as an applicable clinical trial or expanded access use immunotherapy case, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, was adjusted by 0.17. As we did for FY 2026, we applied the same adjustor for the applicable cases that group to MS–DRG 018 for purposes of budget neutrality and outlier simulations. We also proposed to update the value of the adjustor based on more recent data for the final rule.

Comment: Commenters broadly supported the continued use of the modified payment and rate-setting methodology for MS–DRG 018, including the exclusion of cases involving a clinical trial, expanded

access, or products not purchased in the usual manner, from the relative weight calculation. Commenters welcomed CMS's evolving use of claims-based identifiers—such as condition codes and diagnosis codes—to flag these cases, and urged CMS to conduct robust outreach and education to help hospitals navigate the upcoming transition from the drug charge threshold to condition code-based identification in FY 2028. Several commenters also called for greater transparency, requesting that CMS publish data on cases falling below the previous $373,000 threshold and monitor patient access and quality of care under the new methodology. A commenter cautioned that the base payment rate for MS–DRG 018 remains insufficient to cover the actual costs of CAR T-cell and other cellular immunotherapies, raising concerns about long-term Medicare beneficiary access. Additionally, commenters urged CMS to explore improvements to the base payment rate and consider separating cellular therapies from the broader Drugs and Cellular Therapies cost center, given the agency's own recognition of the distinct differences between traditional drugs and autologous cellular therapies.

Response: We appreciate commenters' support for our proposal. With respect to the request that CMS conduct outreach and education regarding the transition to the use of the condition codes, we note that when condition code ZD was implemented with CR 14247, an MLN article was published to educate providers on the requirement to report when they do not purchase the CAR T-cell therapy or other immunotherapy product in the usual manner. Therefore, we do not believe additional outreach and education is necessary at this time, but we will continue to monitor whether this might be necessary in the future. With respect to the request that CMS publish the details regarding specific cases, we note that information on obtaining the MedPAR Limited Data Set is available on the CMS website, at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/MEDPARLDSHospitalNational.* In response to comments about payment adequacy and the request to create a separate cellular therapy cost center, we refer the reader to the FY 2022 final rule (86 FR 44965), where we responded to similar comments. We will take these comments into consideration for future rulemaking as appropriate depending on how this clinical area continues to evolve.

After consideration of the public comments we received, we are finalizing our proposals without modifications regarding the calculation of the relative weight for MS–DRG 018. We note that for this final rule, based on the March 2026 update of the FY 2025 MedPAR file, we estimated that the median standardized drug charge of claims identified as clinical trials in MS–DRG 018 (that is, claims that (a) contain ICD–10–CM diagnosis code Z00.6 and do not include payer-only code ''ZC'' or (b) contain condition code ''90'') is $24,863. Applying this finalized methodology, based on the March 2026 update of the FY 2025 MedPAR file used for this final rule, we estimated that the average costs of cases assigned to MS–DRG 018 that are identified as clinical trial cases ($64,963) were 16 percent of the average costs of the cases assigned to MS–DRG 018 that are identified as nonclinical trial cases ($410,125).

Accordingly, as we did for FY 2026, we are finalizing our proposal to adjust the transfer-adjusted case count for MS–DRG 018 by applying the adjustor of 0.16 to the applicable clinical trial and expanded access use immunotherapy cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, and to use this adjusted case count for MS–DRG 018 in calculating the national average cost per case, which is used in the calculation of the relative weights. Therefore, in calculating the national average cost per case for purposes of this final rule, each case identified as an applicable clinical trial or expanded access use immunotherapy case, and other cases where immunotherapy product is not purchased in the usual manner, such as obtained at no cost, was adjusted by 0.16. As we did for FY 2026, we are applying this same adjustor for the applicable cases that group to MS–DRG 018 for purposes of budget neutrality and outlier simulations.

c. Cap for Relative Weight Reductions

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. We also finalized a budget neutrality adjustment to the standardized amount for all hospitals to ensure that application of the permanent 10-percent cap does not result in an increase or decrease of estimated aggregate payments. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion of this policy. In the Addendum to this IPPS/LTCH PPS final rule, we present the budget neutrality adjustment for reclassification and recalibration of the FY 2027 MS–DRG relative weights with application of this cap. We are also making available on the CMS website a supplemental file demonstrating the application of the permanent 10 percent cap for FY 2027. For a further discussion of the final budget neutrality adjustment for FY 2027, we refer readers to the Addendum of this final rule.

3. Development of National Average Cost-To-Charge Ratios (CCRs)

We developed the national average CCRs as follows:

Using the FY 2024 cost report data, we removed CAHs, REHs, Indian Health Service hospitals, all inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. Then we created CCRs for each provider for each cost center (see the supplemental data file for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. Then we took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost

for each MS–DRG was then divided by the national average standardized cost per case to determine the relative weight. The final FY 2027 cost-based relative weights were then normalized by an adjustment factor of 1.945743 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act. We then applied the permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year; specifically for those MS–DRGs for which the relative weight otherwise would have declined by more than 10 percent from the FY 2026 relative weight, we set the final FY 2027 relative weight equal to 90 percent of the FY 2026 relative weight. The relative weights for FY 2027 as set forth in Table 5 associated with this final rule and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* reflect the application of this cap.

The 19 national average CCRs for FY 2027 are as follows:

NATIONAL AVERAGE CCRS	
Group	**CCR**
Routine Days	0.375
Intensive Days	0.320
Drugs and Cellular Therapies	0.178
Supplies & Equipment	0.293
Implantable Devices	0.246
Inhalation Therapy	0.140
Therapy Services	0.253
Anesthesia	0.071
Labor & Delivery	0.379
Operating Room	0.149
Cardiology	0.084
Cardiac Catheterization	0.094
Laboratory	0.093
Radiology	0.120
MRIs	0.063
CT Scans	0.032
Emergency Room	0.132
Blood and Blood Products	0.230
Other Services	0.319

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We proposed to use that same case threshold in recalibrating the proposed MS–DRG relative weights for FY 2027. Using data from the FY 2025 MedPAR file, there are 8 MS–DRGs that contain fewer than 10 cases. For FY 2027, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we proposed to compute relative weights for the low volume MS–DRGs by adjusting their final FY 2026 relative weights by the percentage change in the average weight of the cases in other MS–DRGs from FY 2026 to FY 2027. The crosswalk table is as follows.

LOW-VOLUME MS-DRGS		
Low-Volume MS-DRG	**MS-DRG Title**	**Crosswalk to MS-DRG**
789	Neonates, Died or Transferred to Another Acute Care Facility	Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate	Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
791	Prematurity with Major Problems	Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
792	Prematurity without Major Problems	Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
793	Full-Term Neonate with Major Problems	Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
794	Neonate with Other Significant Problems	Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
795	Normal Newborn	Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
796	Vaginal Delivery with Sterilization and/or D&C with MCC	Final FY 2026 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)

We did not receive any public comments on this proposal and therefore are finalizing it for FY 2027 without modification.

E. Add-On Payments for New Services and Technologies for FY 2027

1. Background

Effective for discharges beginning on or after October 1, 2001, section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish a mechanism to recognize the costs of new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. The regulations at 42 CFR 412.87 implement these provisions and § 412.87(b) specifies three criteria for a new medical service or technology to receive the additional payment: (1) the medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. In addition, certain transformative new devices and antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway, as set forth in the regulations at § 412.87(c) and (d).

We note that section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act. Therefore, as discussed in prior rulemaking (72 FR 47307 through 47308), we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs.

In the proposed rule, we highlighted some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For further discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42300), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58736 through 58742).

a. New Technology Add-On Payment Criteria

(1) Newness Criterion

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will no longer be considered ''new'' for purposes of new medical service or technology add-on payments after CMS has recalibrated the MS–DRGs, based on available data, to reflect the cost of the technology. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a medical product receives a new FDA marketing authorization, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to another medical product that was market authorized by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically whether: (1) a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) a product is assigned to the same or a different MS–DRG; and (3) the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352) and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

(2) Cost Criterion

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the MS–DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS–DRGs if the new medical service or technology occurs in many different MS–DRGs). The MS–DRG threshold amounts generally used in evaluating new technology add-on payment applications for FY 2027 are presented in a data file that is available, along with the other data files associated with the FY 2026 IPPS/LTCH PPS final rule on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.*

We note that, under the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58603 through 58605), beginning with FY 2022, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for all applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year.

As finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41275), beginning with FY 2020, we include the thresholds applicable to the next fiscal year (previously included in Table 10 of the annual IPPS/LTCH PPS proposed and final rules) in the data files associated with the prior fiscal year. Accordingly, the final thresholds for applications for new technology add-on payments for FY 2028 are presented in a data file that is available on the CMS website, along with the other data files

associated with this FY 2027 final rule, by clicking on the FY 2027 IPPS Final Rule Home Page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*.

In the September 7, 2001, final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed that applicants should submit a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Specifically, applicants should submit a sample of sufficient size to enable us to undertake an initial validation and analysis of the data. We also discussed in the September 7, 2001, final rule (66 FR 46917) the issue of whether the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule at 45 CFR part 160 and subparts A and E of 45 CFR part 164, applies to claims information that providers submit with applications for new medical service or technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for further information on this issue.

(3) Substantial Clinical Improvement Criterion

Under the third criterion at § 412.87(b)(1), a medical service or technology must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292), we prospectively codified in our regulations at § 412.87(b) the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means—

++ The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

++ The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient;

++ The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following: a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or

++ The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

- Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.
- The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.
- The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292) for additional discussion of the evaluation of substantial clinical improvement for purposes of new technology add-on payments under the IPPS.

We note, consistent with the discussion in the FY 2003 IPPS final rule (67 FR 50015), that while FDA has regulatory responsibility for decisions related to marketing authorization (for example, approval, clearance, etc.), we do not rely upon FDA criteria in our evaluation of substantial clinical improvement for purposes of determining what services and technologies qualify for new technology add-on payments under Medicare. This criterion does not depend on the standard of safety and effectiveness on which FDA relies but on a demonstration of substantial clinical improvement in the Medicare population.

b. Alternative Inpatient New Technology Add-On Payment Pathway

Beginning with applications for FY 2021 new technology add-on payments, under the regulations at § 412.87(c), a medical device that is part of FDA's Breakthrough Devices Program may qualify for the new technology add-on payment under an alternative pathway. Additionally, under the regulations at § 412.87(d) for certain antimicrobial products, beginning with FY 2021, a drug that is designated by FDA as a Qualified Infectious Disease Product (QIDP), and, beginning with FY 2022, a drug that is approved by FDA under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), may also qualify for the new technology add-on payment under an alternative pathway. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for further discussion on this policy. We note that CMS reviews the application based on the information provided by the applicant only under the alternative pathway specified by the applicant at the time of application submission. To receive approval for the new technology add-on payment under that alternative pathway, the technology must have the applicable FDA designation and meet all other requirements in the regulations in § 412.87(c) and (d), as applicable. We note, in section II.E.7. of this final rule, we are finalizing our proposal to repeal

the alternative pathway for new technology add-on payment beginning with applications received for new technology add-on payments for FY 2028 and require all applicants for new technology add-on payments to demonstrate that the technology meets all eligibility requirements to receive add-on payments, unless specifically grandfathered under the alternative pathway eligibility criteria. (We refer the reader to section II.E.7. of this final rule for a complete discussion regarding this finalized policy.)

(1) Alternative Pathway for Certain Transformative New Devices

For applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, a medical device designated under FDA's Breakthrough Devices Program [18] that has received FDA marketing authorization will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement under § 412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this alternative pathway, a medical device that has received a Breakthrough Device designation, and then received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, FDA) for the indication covered by the Breakthrough Device designation, will need to meet the requirements of § 412.87(c). We note that in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736), we clarified our policy that a new medical device under this alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736) for further discussion regarding this clarification.

(2) Alternative Pathway for Certain Antimicrobial Products

For applications received for new technology add-on payments for certain antimicrobial products, beginning with FY 2021, if a technology is designated by FDA as a QIDP and received FDA marketing authorization, and, beginning with FY 2022, if a drug is approved under FDA's LPAD pathway and used for the indication approved under the LPAD pathway, it will be considered not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this alternative pathway for QIDPs and LPADs, a medical product that has received FDA marketing authorization and is designated by FDA as a QIDP or approved under the LPAD pathway will need to meet the requirements of § 412.87(d). We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for further discussion on this policy.

We note that, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739), we clarified that a new medical product seeking approval for the new technology add-on payment under the alternative pathway for QIDPs must receive FDA marketing authorization for the indication covered by the QIDP designation. We also finalized our policy to expand our alternative new technology add-on payment pathway for certain antimicrobial products to include products approved under the LPAD pathway and used for the indication approved under the LPAD pathway.

c. Additional Payment for New Medical Service or Technology

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. As noted previously, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (72 FR 47307 through 47308).

For discharges occurring before October 1, 2019, under § 412.88, if the costs of the discharge (determined by applying operating cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), CMS made an add-on payment equal to the lesser of: (1) 50 percent of the costs of the new medical service or technology; or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

Beginning with discharges on or after October 1, 2019, for the reasons discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300), we finalized an increase in the new technology add-on payment percentage, as reflected at § 412.88(a)(2)(ii). Specifically, for a new technology other than a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product approved under FDA's LPAD pathway, beginning with discharges on or after October 1, 2020, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. As set forth in § 412.88(b)(2), unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS–DRG payment plus 65 percent (or 75 percent for certain antimicrobial products (QIDPs and LPADs)) of the estimated costs of the new technology or medical service. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule

[18] Breakthrough Devices Program *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.*

(84 FR 42297 through 42300) for further discussion on the increase in the new technology add-on payment beginning with discharges on or after October 1, 2019.

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69245 through 69252), we finalized an increase in the new technology add-on payment percentage, reflected at § 412.88(a)(2)(ii)(C) and (b)(2)(iv), that for certain gene therapies approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule that are indicated and used specifically for the treatment of sickle cell disease (SCD), effective with discharges on or after October 1, 2024 and concluding at the end of the 2- to 3-year newness period for such therapy, if the costs of a discharge (determined by applying CCRs as described in § 412.84(h)) involving the use of such therapy for the treatment of SCD exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. We noted that these payment amounts would only apply to Casgevy™ (exagamglogene autotemcel) and Lyfgenia™ (lovotibeglogene autotemcel), when indicated and used specifically for the treatment of SCD, which were approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69128 through 69135, and 89 FR 69188 through 69196).

We note that, consistent with the prospective nature of the IPPS, we finalize the new technology add on payment amount for technologies approved or conditionally approved for new technology add-on payments in the final rule for each fiscal year and do not make mid-year changes to new technology add-on payment amounts. Updated cost information may be submitted and included in rulemaking to be considered for the following fiscal year.

Section 503(d)(2) of the MMA (Pub. L. 108–173) provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of the MMA, add-on payments for new medical services or technologies for FY 2005 and subsequent years have not been subjected to budget neutrality.

d. Evaluation of Eligibility Criteria for New Medical Service or Technology Applications

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulation at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We specified that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. In the FY 2021 IPPS/LTCH PPS final rule, to more precisely describe the various types of FDA approvals, clearances and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to the regulation to indicate that new technologies must receive FDA marketing authorization [19] [20] (such as pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request; or approval of a New Drug Application (NDA) or Biologics License Application (BLA)) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered (85 FR 58742). Consistent with our longstanding policy, we consider FDA marketing authorization as representing that a product has received FDA approval or clearance, or has been granted a De Novo classification request when considering eligibility for the new technology add-on payment.

Additionally, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58739 through 58742), we finalized our proposal to provide conditional approval for new technology add-on payment for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by July 1 prior to the particular fiscal year for which the applicant applied for new technology add-on payments, provided that the technology otherwise meets the applicable add-on payment criteria. Under this policy, cases involving eligible antimicrobial products would begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments. As noted, in section II.E.7. of this final rule, we are finalizing our proposal to repeal the alternative pathway for new technology add-on payment, such that beginning with applications received for new technology add-on payments for FY 2028, in order to be eligible for consideration for the new technology add on payment for the upcoming fiscal year, all applicants will need to receive FDA marketing authorization by May 1 prior to the particular fiscal year for which the application is being considered.

As discussed in the FY 2024 and FY 2025 IPPS/LTCH PPS final rules (88 FR 58948 through 58958 and 89 FR 69242 through 69245, respectively), beginning with the new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA market authorization request at the time of new technology add-on payment application submission and must provide documentation of FDA acceptance (for a 510(k) or De Novo Classification request submission) or filing (for a PMA, NDA, or BLA) to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. See § 412.87(e) and further discussion in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958) and the FY 2025 IPPS/LTCH PPS final rule (89 FR 69242 through 69245). As we have discussed in prior rulemaking, we consider the application to be complete when the full application has been submitted to FDA and FDA has provided documentation to the applicant indicating that FDA has determined that the application is sufficiently complete to allow for substantive review by FDA. We further stated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36661 through 36662) that we recognize that FDA processes

[19] How to Study and Market Your Device *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device.*

[20] Types of Applications *https://www.fda.gov/drugs/how-drugs-are-developed-and-approved/types-applications.*

and documentation may change over time, and the acceptance or filing documentation may vary depending on the type of FDA marketing authorization application the applicant has submitted to FDA. For example, we understand that FDA considers submission of a 510(k) or De Novo Classification request to be accepted for substantive review after the completion of either a refuse to accept (RTA) review or a technical screening process.[21] [22] Submissions of 510(k) and De Novo Classification requests undergo a technical screening process when they are submitted to FDA using the electronic Submission Template And Resource (eSTAR) process; 510(k) and De Novo Classification requests that are not submitted via eSTAR undergo an RTA review. Accordingly, FDA provides applicants using eSTAR with a review assignment notification to indicate that FDA has completed its technical screening process and has determined that the submission is sufficiently complete to allow for substantive review. Therefore, new technology add-on payment applicants that have submitted a 510(k) or De Novo Classification request submission to FDA through eSTAR must submit a copy of the review assignment notification to CMS (at the time of new technology add-on payment application) to establish the application is sufficiently complete to allow for substantive review by FDA. We noted that PMAs submitted using eSTAR that complete technical screening will still undergo a subsequent filing review by FDA, after which an application is determined to be sufficiently complete to allow for substantive review; therefore, we continue to require documentation of FDA filing for these applications. We also stated that we recognize that FDA does not conduct a new filing review for NDA or BLA applications that were the subject of a Complete Response Letter (CRL) and were subsequently resubmitted to FDA, even though resubmissions are considered a new review cycle.[23] [24]

Therefore, beginning with the new technology add-on applications submitted for FY 2027, these new technology add-on payment applicants must provide to CMS a copy of the resubmission acknowledgement letter from FDA that provides the new goal date for FDA review of the application. We further note that if there are other processes not described here, or if there are further changes to FDA's review processes, consistent with our policy, applicants must provide to CMS the most up-to-date documentation that indicates FDA has determined that the application is sufficiently complete to allow for substantive review by FDA.

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958), we also finalized that, beginning with FY 2025 applications, in order to be eligible for consideration for the new technology add-on payment for the upcoming fiscal year, an applicant for new technology add-on payments must have received FDA marketing authorization by May 1 (rather than July 1) of the year prior to the beginning of the fiscal year for which the application is being considered (except for an application that is submitted under the alternative pathway for certain antimicrobial products), as reflected at § 412.87(f)(2) and (3), as amended and redesignated in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958, 88 FR 59331). As noted, in section II.E.7. of this final rule, we are finalizing our proposal to repeal the alternative pathway for new technology add-on payment, such that beginning with the FY 2028 new technology add-on payment applications, in order to be eligible for consideration for the new technology add on payment for the upcoming fiscal year, all applicants will need to receive FDA marketing authorization by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered.

e. Pharmaceutical & Technology Ombudsman (PTO)

Many interested parties (including device/biologic/drug developers or manufacturers, industry consultants, others) engage with CMS for coverage, coding, and payment questions or concerns. In order to streamline engagement by centralizing the different innovation pathways within CMS including new technology add-on payments, CMS utilizes the Pharmaceutical & Technology Ombudsman as an initial resource for interested parties. This Ombudsman is available to assist with all of the following:

- Help to point interested parties to or provide information and resources where possible regarding process, requirements, and timelines.
- As necessary, coordinate and facilitate opportunities for interested parties to engage with various CMS components.
- Serve as a primary point of contact for interested parties and provide updates on developments where possible or appropriate.

We receive many questions from parties interested in pursuing new technology add-on payments who may not be entirely familiar with working with CMS. While we encourage interested parties to first review our resources available at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/new-medical-services-and-new-technologies,* we know that there may be additional questions about the application process. Interested parties with further questions regarding Medicare's coverage, coding, and payment processes, and how they can navigate these processes, whether for new technology add-on payments or otherwise, should review the updated resource guide available at: *https://www.cms.gov/medicare/coding-billing/guide-medical-technology-companies-other-interested-parties.* Parties that would like to further discuss questions or concerns with CMS should contact the Pharmaceutical & Technology Ombudsman at *PharmTechOmbud@cms.hhs.gov.*

f. Application Information for New Medical Services or Technologies

Applicants for add-on payments for new medical services or technologies for FY 2028 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/*

[21] FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals Guidance for Industry and Food and Drug Administration Staff Document issued on October 3, 2022. *https://www.fda.gov/media/73507/download.*

[22] FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals Guidance for Industry and Food and Drug Administration Staff Document issued on October 3, 2022. *https://www.fda.gov/media/107652/download.*

[23] SOPP 8405.1: Procedures for Resubmissions to an Application or Supplement. Version: 8 Effective Date: November 13, 2022. *https://www.fda.gov/media/84417/download.*

[24] 21 CFR 314.110, Complete response letter to the applicant *https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-314/subpart-D/section-314.110.*

new-medical-services-and-new-technologies.

To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2028, once the application deadline has closed, CMS will post on its website a list of the applications submitted, along with a brief description of each technology as provided by the applicant.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990), we finalized our proposal to publicly post online new technology add-on payment applications, including the completed application forms, certain related materials, and any additional updated application information submitted subsequent to the initial application submission (except certain volume, cost and other information identified by the applicant as confidential), beginning with the application cycle for FY 2024, at the time the proposed rule is published. We also finalized that with the exception of information included in a confidential information section of the application, cost and volume information, and materials identified by the applicant as copyrighted or not otherwise releasable to the public, the contents of the application and related materials may be posted publicly, and that we will not post applications that are withdrawn prior to publication of the proposed rule. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990) for further information regarding this policy. In addition, as discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36663 through 36664), beginning with the new technology add-on payment applications submitted for FY 2027, the public posting includes the applicant's explanation of the cost analysis methodology, including the step-by-step explanation of the columns used in the cost analysis spreadsheet attachment, any optional comments provided by the applicant, and information about the case weighted threshold and final inflated case weighted standardized charge per case, as is currently subject to discussion in the cost criterion analysis for each eligible application in the proposed rule. The cost analysis spreadsheet attachment and other cost or charge values that may have been provided in the applicant's responses in the cost criterion section are not included in the public posting. Certain cost and volume information may still be summarized and discussed in the proposed rule, but we are providing more succinct information as part of the summaries in the proposed and final rules regarding the applicant's assertions as to how the medical service or technology meets the cost criterion.

We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the formal request for add-on payments for new medical services and technologies to CMS. The aforementioned burden is subject to the PRA and approved under OMB control number 0938–1347 and has an expiration date of December 31, 2026.

2. Public Input Before Publication of a Notice of Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of the MMA, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement. The process for evaluating new medical service and technology applications requires the Secretary to do all of the following:

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries.
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending.
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement.
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2027 prior to publication of the FY 2027 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on September 10, 2025 (90 FR 43613), and held a virtual town hall meeting on December 10, 2025. In the announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for the FY 2027 new medical service and technology add-on payment applications before the publication of the FY 2027 IPPS/LTCH PPS proposed rule.

Approximately 190 individuals attended the virtual town hall meeting. We posted the recordings of the virtual town hall on the CMS web page at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/new-medical-services-and-new-technologies.*

We considered each applicant's presentation made at the town hall meeting, as well as written comments received by the December 15, 2025 deadline, in our evaluation of the new technology add-on payment applications for FY 2027 in the development of the FY 2027 IPPS/LTCH PPS proposed rule. In response to the published notice and the New Technology Town Hall meeting, we received written comments regarding the applications for FY 2027 new technology add-on payments. As explained earlier and in the **Federal Register** notice announcing the New Technology Town Hall meeting (90 FR 43613), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion with regard to pending new technology add-on payment applications for FY 2027. Therefore, we did not summarize any written comments in the proposed rule that were unrelated to the substantial clinical improvement criterion. In section II.E.5. of the preamble of the proposed rule, we summarized comments regarding individual applications, or, if applicable, indicated that there were no comments received in response to the New Technology Town Hall meeting notice or New Technology Town Hall meeting, at the end of each discussion of the individual applications.

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create,

delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes,* including guidelines for ICD–10–PCS Section ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

4. FY 2027 Status of Technologies Receiving New Technology Add-On Payments for FY 2026

In this section of the final rule, we discuss the FY 2027 status of the 54 new technology add-on payments approved for FY 2026, as set forth in the tables that follow. In the proposed rule, we presented our proposals to continue the new technology add-on payments for FY 2027 for those technologies that were approved for the new technology add-on payment for FY 2026, and which would still be considered ''new'' for purposes of new technology add-on payments for FY 2027. We also presented our proposals to discontinue new technology add-on payments for FY 2027 for those technologies that were approved for the new technology add-on payment for FY 2026, and which would no longer be considered ''new'' for purposes of new technology add-on payments for FY 2027.

Our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and, for technologies that were first approved for new technology add-on payments prior to FY 2025, we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year, and, in general, we have extended new technology add-on payments for these technologies for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69238 through 69242), we finalized that, beginning with new technology add-on payments for FY 2026, in assessing whether to continue the new technology add-on payments for those technologies that are first approved for new technology add-on payments in FY 2025 or a subsequent year, we will extend new technology add-on payments for an additional fiscal year when the 3-year anniversary date of the product's entry onto the U.S. market occurs on or after October 1 of that fiscal year. This change is effective beginning with those technologies that are initially approved for new technology add-on payments in FY 2025 or a subsequent year. For technologies that were first approved for new technology add-on payments prior to FY 2025, including for technologies we determine to be substantially similar to those technologies, we continue to use the midpoint of the upcoming fiscal year (April 1) when determining whether a technology would still be considered ''new'' for purposes of new technology add-on payments.

In the proposed rule, we provided Table II.E–01 listing the technologies that were first approved for new technology add-on payments in FY 2025 or a subsequent year, for which we proposed to continue making new technology add-on payments for FY 2027 because they were still considered ''new'' for purposes of new technology add-on payments because the 3-year anniversary date of the product's entry onto the U.S. market occurs on or after October 1, 2026. The table also presented the newness start date, new technology add-on payment start date, 3-year anniversary date of the product's entry onto the U.S. market, relevant final rule citations from prior fiscal years, proposed maximum add-on payment amount, and coding assignments for each technology. We referred readers to the cited final rules in the table for a complete discussion of the new technology add-on payment application, coding, and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

We noted that we conditionally approved CONTEPO™ (fosfomycin) for FY 2026 new technology add-on payments under the alternative pathway for certain antimicrobial products (90 FR 36831 through 36833), subject to the technology receiving FDA marketing authorization by July 1, 2026. CONTEPO™ received FDA marketing authorization on October 22, 2025, and was eligible to receive new technology add-on payments in FY 2026 beginning with discharges on or after January 1, 2026. As CONTEPO™ received FDA marketing authorization prior to July 1, 2026, and was approved for new technology add-on payments in FY 2026, we proposed to continue making new technology add-on payments for CONTEPO™ for FY 2027.

As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36666 through 36671), in response to comments from the applicant for ZEVTERA® requesting that CMS consider the beginning of the newness period for ZEVTERA® to commence on May 20, 2025, which it stated was the date on which ZEVTERA® became commercially available on the U.S. market, we noted that that date occurred after new technology add-on payments for ZEVTERA® began, as it was approved for new technology add-on payment for FY 2025 (starting October 1, 2024). While we agreed that per our policy, we may consider a documented delay in a technology's market availability in our determination of newness, we noted that the new technology add-on payment for claims reporting ICD–10–PCS procedure codes for ZEVTERA® (XW0335A (Introduction of ceftobiprole medocaril anti-infective into peripheral vein, percutaneous approach) and XW0435A (Introduction of ceftobiprole medocaril anti-infective into central vein, percutaneous approach)) was available beginning October 1, 2024.

Furthermore, we noted that beginning with new technology add-on payments for FY 2026, in assessing whether to continue the new technology add-on payments for those technologies that are first approved for new technology add-on payments in FY 2025 or a subsequent year, we will extend new technology add-on payments for an additional fiscal year when the 3-year anniversary date of the product's entry onto the U.S. market occurs on or after October 1 of that fiscal year. We stated that if we were to consider the beginning of the newness period to commence on May 20, 2025, the date on which the applicant states ZEVTERA® became commercially available on the U.S. market, under our policy, the technology would potentially be eligible for new technology add-on payment for up to four years. Although the applicant stated that CMS had delayed the newness start dates for other technologies when market availability was significantly later than the FDA approval date, and that like these other products, ZEVTERA®'s newness period should commence on the date on which the technology became commercially available, we noted that, unlike these other technologies, the applicant for ZEVTERA® was asserting a date of

commercial availability that occurred after its new technology add-on payment began.

We also noted that applicants may assert a delay in commercial availability due to business decisions made by the applicant. We were concerned that a delay in commercial availability extending beyond the implementation date for the new technology add-on payment would potentially allow applicants to postpone commercial availability for an indefinite period of time while the technology (and other technologies reported using the same codes) remains eligible for new technology add-on payment.

Therefore, we questioned whether, where the applicant asserts a date of commercial availability that occurred after the new technology add-on payment for the technology began, it would be appropriate to instead consider the beginning of the newness period to commence with the start of the technology's new technology add-on payment. We noted that regardless of whether we considered the beginning of the newness period to commence for ZEVTERA® on May 20, 2025, April 3, 2024, or a date in between, the three-year anniversary date would occur after April 1, 2026, and, therefore, the technology was considered new for FY 2026.

After further review, in the FY 2027 IPPS/LTCH PPS proposed rule, we stated we believed that it would be most appropriate to no longer consider commercial delays once a technology's new technology add-on payment becomes effective. We stated we have discussed in prior rulemaking (89 FR 36136) that, generally, we use the FDA marketing authorization date as the indicator of the time when a technology begins to become available on the market and data reflecting the costs of the technology begin to become available for recalibration of the DRG weights. In specific circumstances, we have recognized a date later than the FDA marketing authorization date as the appropriate starting point for the 2- to 3-year newness period. For example, we have recognized a later date where an applicant could prove a delay in actual availability of a product after FDA approval or clearance. However, due to the increasing volume and complexity of circumstances in which applicants assert a delay in commercial availability, we stated that we believed that a delay that extends to after implementation of a new technology add-on payment should no longer be considered. For example, we noted that, as discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36667), we were concerned that a delay in commercial availability extending beyond the implementation date for the new technology add-on payment would potentially allow applicants to postpone commercial availability for an indefinite period of time while the technology (and other technologies reported using the same codes) remain eligible for new technology add-on payment. We had also noted that applicants may be asserting a delay in commercial availability due to business decisions made by the applicant. In addition, because we now extend new technology add-on payments for an additional fiscal year when the 3-year anniversary date of a product's entry onto the U.S. market occurs on or after October 1 of that fiscal year (89 FR 69238 through 69242), we stated that commercial delays as asserted by manufacturers that extend to after the new technology add-on payment becomes effective could now have a bigger impact, as they could lead to new technology add-on payments being effective for four or more years under our current policy.

Therefore, while we stated that we have considered no longer recognizing a date later than the FDA marketing authorization date as the appropriate starting point for the 2- to 3-year newness period, we proposed that we may consider a documented delay in the beginning of a technology's newness period due to commercial availability only until the new technology add-on payment becomes effective for the fiscal year for which the applicant applied for new technology add-on payments. Under the proposal, for a technology that is not yet available for sale when its new technology add-on payment becomes effective, we would consider the newness period to begin on September 30 preceding the start of the new technology add-on payment for the technology.

As such, consistent with the proposal, because the new technology add-on payment for ZEVTERA® became effective on October 1, 2024, we stated that we considered the beginning of the newness period for ZEVTERA® to commence on September 30, 2024.

We invited public comments on our proposals to continue new technology add-on payments for FY 2027 for the technologies listed in Tables II.E.–01 of the proposed rule.

Comment: We received public comments regarding our proposal to consider a documented delay in the beginning of a technology's newness period due to commercial availability only until the new technology add-on payment becomes effective for the fiscal year for which the applicant applied for new technology add-on payments. Several commenters were supportive of CMS's efforts to provide greater transparency and consistency regarding its evaluation of technologies eligible for new technology add-on payment, specifically on the issue of commercial availability following FDA approval or clearance. A commenter stated that a range of factors can affect a technology's entry into the U.S. market, and clear and consistent CMS reasoning regarding how commercial availability is evaluated would improve predictability for stakeholders and support appropriate patient access to innovative technologies. Another commenter stated that it appreciated the flexibility that CMS has shown in evaluating circumstances in which there has been a significant gap between the receipt of marketing authorization from the FDA and the actual market introduction of a new medical device. Commenters stated that they understood CMS's concern that some successful new technology add-on payment applicants could seek to maximize their eligibility period by intentionally and strategically delaying market introduction. For that reason, the commenters supported the general rule that the start of the newness period would not be delayed any longer than the beginning of the fiscal year for which the manufacturer applied for new technology add-on payment. However, some commenters believed that CMS should continue to recognize a later newness start date in the limited circumstances when the delay in market introduction was demonstrably beyond the manufacturer's control. Commenters stated that these delays may include post-approval regulatory conditions imposed by FDA (such as requirements for PMA amendments, labeling revisions, or related approvals), or other specific and identifiable constraints on commercial availability.

Another commenter asked that CMS make clear that any request to delay the start of the newness period must continue to satisfy CMS's established standard for documented evidence of a delay in commercial availability. The commenter stated that the proposed limitation should not be understood to create a September 30 ''default'' newness start date, nor should CMS grant an alternative start date based on ordinary commercial launch activities in the absence of evidence of circumstances beyond the applicant's control, such as documented manufacturing or distribution capacity constraints or post-approval regulatory conditions imposed by FDA. The commenter stated that even with this

proposed clarification, there appeared to be inconsistencies in the way CMS applied its criteria for applicants to prove a delay in actual availability of a product after FDA approval or clearance. The commenter stated that while CMS has consistently stated that it does not consider the date of first sale of a product or first shipment of a product to be an indicator of the entry of a product onto the U.S. market, there has been less clarity regarding delays related to commercialization of the technology. The commenter provided examples for AeroPace® System, aprevo®-C cervical interbody fusion device, SAINT Neuromodulation System, and EchoGo® Heart Failure, where it stated that CMS previously declined to accept requests to delay the new technology add-on payment start date in response to ordinary commercial launch activities. The commenter stated that in apparent contrast to these determinations, however, CMS proposes to accept field sales training and hospital contracting as a reason to consider commercial availability to be delayed for purposes of the new technology add-on payment newness start date for another application under consideration in the proposed rule. The commenter stated that CMS should apply a uniform and transparent standard in determining which types of manufacturer commercialization activities constitute a delay in the actual availability of a product after FDA marketing authorization for purposes of establishing the new technology add-on payment newness start date. The commenter requested that CMS provide additional details in the final rule regarding the specific criteria it will use to identify such delays, including whether those criteria represent a change in CMS policy, and requested that CMS apply this standard across all applications under consideration, so that similarly situated technologies are not subject to different determinations absent a clear and reasoned basis.

Other commenters were not supportive of our proposal because they believed that starting the effective eligibility window too early may unintentionally reduce the time hospitals have to meaningfully integrate technologies into patient care. Commenters stated that CMS should retain its existing flexibility to account for legitimate commercial delays, which would preserve access to new technology add-on payment for therapies during the critical early-adoption period when an incentive for hospital uptake of innovative therapies is most needed. Commenters provided examples of technologies they stated frequently undergo gradual implementation across health systems and often require extensive physician education and procedural adoption before widespread availability is achieved. Some commenters requested that CMS either reconsider the proposal or create exceptions for FDA-designated Breakthrough Devices. Commenters also requested that CMS apply any modifications to the newness criterion prospectively, with a commenter further requesting an implementation date no fewer than two full new technology add-on payment application cycles following publication of the final rule to allow manufacturers and hospitals adequate planning time.

Commenters also believed that narrowing the newness period would undermine CMS's ability to set accurate DRG weights. A commenter explained that the new technology add-on payment functions as a data-generation mechanism as hospitals that adopt a new technology report claims that enter the MedPAR database and ultimately inform DRG recalibration. The applicant asserted that a full three-years of new technology add-on payment maximizes the volume, geographic diversity, and clinical breadth of that claims data. The commenter stated that when a technology receives FDA marketing authorization relatively close to the relevant application cutoff, even modest adjustments to the marketing authorization deadline or to the interpretation of the newness window can materially reduce the effective period during which new technology add-on payment is available, which may result in less hospital cost data being available to CMS. The commenter also asserted that numerous technologies have been planned and financed with the existing new technology add-on payment newness framework as a core assumption, and modifying the newness criterion in a manner that shortens effective eligibility or introduces interpretive uncertainty would harm these technologies mid-stream, after manufacturers have already committed substantial research, development, and commercialization resources based on an expected reimbursement pathway.

Commenters also expressed concern that this proposal taken in its totality with other proposals in the proposed rule, as well as other policies in prior rulemaking, reflected an increasingly restrictive approach toward new technology add-on payment. Commenters stated this change would further erode the incentive structure and prospective payment system reasonableness that Congress intended new technology add-on payment to provide. A commenter stated its concern that CMS's proposals reflect an increasing hostility to new technology add-on payment that it stated was at odds with both the statutory intent of the add-on payment and sound public policy. Another commenter stated that this proposal represented a marked departure from prior practice, which appropriately accounted for real-world delays between FDA marketing authorization and actual patient access. A commenter stated that for a service involving a new technology, CMS relies on the first year of claims data to set rates for the first fiscal year following new technology add-on payment expiration. The commenter stated that this first year is typically when a technology is coming to market, with relatively few claims as utilization ramps up. Commenters asserted that considering a product to be ''new'' when it was not commercially available would skew the data CMS collects during the new technology add-on payment period by injecting a period of zero claims into the data CMS uses for rate-setting, meaning that MS–DRG payment rates may not accurately reflect costs incurred by providers for the new technologies. Commenters were concerned that the proposal failed to reflect the operational and clinical realities of launching innovative therapies and would arbitrarily shorten the newness period for certain products, which would penalize manufacturers for circumstances that are often outside of their control or that reflect prudent and responsible launch planning, rather than an attempt to delay market entry. Another commenter stated that it did not believe that a blanket policy constricting the availability of a later newness start date based on ''commercial availability'' was the appropriate solution, particularly because CMS has not provided any evidence that this standard is in fact being exploited by new technology add-on payment applicants. The commenter stated that existing guidance required applicants to document and explain any delay between FDA marketing authorization and commercial availability, and CMS retained discretion to scrutinize claimed delays on a case-by-case basis. The commenter stated that capping the recognized delay at the new technology add-on payment effective date for the applied for fiscal year would reach legitimate launch timelines indistinguishably from any abusive ones. The commenter stated that the proposal effectively treats the rising number of requests as evidence

that the standard is being manipulated, but stated that the agency did not point to a single instance in which a recognized delay turned out to be inappropriate. The commenter stated that to the extent CMS's underlying concern is that recognizing a documented delay could push new technology add-on payment eligibility beyond three years, the appropriate response was a case-by-case denial.

Commenters were also specifically concerned about the effect of the proposal on cell and gene therapies. Commenters requested that given the unique patient timelines and manufacturing dynamics of autologous gene and cell therapies, CMS should maximize the new technology add-on payment effective duration by starting the clock on newness following the first administration billed to Medicare and by adopting a three-year new technology add-on payment and use the agency's exceptions and adjustments authority to extend new technology add-on payment for an additional two years for these technologies. A commenter also stated that CMS could combine data from all three new technology add-on payment data years in the case of low-volume data signals or examine projections of new technology add-on payment therapy use against claims data to assess whether additional time for data collection under new technology add-on payment is needed. The commenter stated that, for example, CMS listed that it expected exagamglogene autotemcel and lovotibeglogene autotemcel to be used in 117 and 40 cases in FY 2025, respectively; it did not know the actual number but suspected it to be far, far lower than CMS' projections. A commenter stated that when assuming a three-year new technology add-on payment eligibility period and given the two-year time lag in the data that CMS uses for rate-setting, the number of claims that will exist in the data by the second year of new technology add-on payment will be very low and it is unlikely that the agency will be able to recalibrate the MS–DRGs to reflect the cost of the technology. Another commenter stated that while the assignment of a billing code is a necessary condition for capturing claims data, the regulation expressly recognizes that the timing of data availability—not merely the existence of a code—is central to determining the newness period. The commenter stated that consistent with this structure, it is appropriate to interpret the newness period as beginning when claims reflecting use of the technology first appear and data begin to accumulate, rather than when a code is first assigned but not yet used in practice. The commenter also provided additional details regarding the structural factors contributing to delayed initial claims for ex vivo gene therapies that result in a material delay between code assignment and the generation of meaningful Medicare claims data in support of its request that CMS clarify that the new technology add-on payment newness period begins when claims data reflecting use of the technology first become available. In addition, the commenter requested that CMS review and share aggregate volume and charge data for ex vivo gene therapies from the most recent year of available claims because without this visibility, it was not possible to assess whether the existing data are sufficient to inform the new technology add-on payment start date or whether alternative policy approaches are warranted. The commenter believed that sharing summary information on the number of cases and associated charge levels for ex vivo gene therapies in the most recent year of IPPS claims data would promote transparency, improve the quality of stakeholder feedback, and support more timely and accurate development of MS–DRG payment policies.

Response: We thank commenters for their comments on our proposal. We agree with commenters that it is important to have a consistent and predictable approach when we consider a documented delay in a technology's market availability in our determination of newness. We also agree with commenters that we should maintain our flexibility to account for commercial availability delays. However, we disagree that our proposal narrows the effective eligibility window or introduces interpretive uncertainty. Under the proposal, we may consider a documented delay in the beginning of a technology's newness period due to commercial availability only until the new technology add-on payment becomes effective for the fiscal year for which the applicant applied for new technology add-on payments. We would still maintain the flexibility to consider commercial availability delays until the implementation date for the new technology add-on payment. We understand that technologies often apply for new technology add-on payments prior to receiving FDA market authorization, and must balance responsible launch planning activities with our new technology add-on payment timelines. These technologies, including those that may become available shortly after the fiscal year begins, would still remain eligible for a third year of new technology add-on payment, but would no longer inappropriately become eligible for a fourth year or beyond.

With respect to the specific criteria that we use to identify a documented delay of commercial availability, as noted, we believe it is important to maintain flexibility regarding the range of circumstances that may be identified by a new technology add-on payment applicant as resulting in a delay in commercial availability. We make these decisions on an individual basis and in consideration of any communications with applicants while developing the proposed rule and as a part of our annual notice-and-comment rulemaking. In general, although we require sufficient information to determine a newness date based on a documented delay in the technology's availability on the U.S. market, we generally rely on the applicant's narrative of the delay. As noted, we do not consider the date of first sale of a product, or first shipment of a product, as an indicator of the entry of a product onto the U.S. market; neither of these dates indicate when a technology in fact became available for sale. We often request additional information when it is unclear to us whether a technology was not yet available for sale or was on the market but in a limited capacity. As we have also noted, we do not believe that case volume is a relevant consideration for making the determination as to whether a product is considered ''new'' for purposes of new technology add-on payments. We have generally established a later newness start date resulting from a documented delay in commercial availability due to a variety of commercialization activities, for example, requiring a new capable commercial partner, acquisitions, or execution of distribution agreements. We disagree with a commenter's assertion that we have inconsistently declined to accept requests to delay the new technology add-on payment start date in response to commercial launch activities. First, as noted, we often request additional information when it is unclear to us when a technology was available for sale, as we did in the examples of AeroPace® System and SAINT Neuromodulation System cited by the commenter. For both technologies, after receiving additional information in subsequent rulemaking, we established a later newness start date resulting from a documented delay in commercial availability, as discussed later in this section and in the FY 2026

IPPS/LTCH PPS final rule (90 FR 36671), respectively. Similarly, we requested additional information regarding the documented delay in the commercial availability for the aprevo®-C cervical interbody fusion device, as, at the time, its applicant had asserted a tentative future date of commercial availability (90 FR 36783 through 36784). However, we note that we have not received this information. Finally, with respect to the applicant for EchoGo® Heart Failure's claim that the device was not available for sale until the date of its first customer contract, we had noted that the applicant's own press release had indicated that the device was commercially available months earlier than its stated date of first customer contract (90 FR 36672).

We do not believe that this proposal should apply only for future new technology add-on payment applications, or create exceptions for specific groups of technologies. We also disagree that this proposal, taken in its totality with the policy as discussed in section II.E.7 and prior rulemaking, reflects an increasingly restrictive approach to new technology add-on payment. For example, as finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69238 through 69242) to address how the prior change in the FDA marketing authorization deadline may limit the ability of new technology add-on payment applicants to be eligible for a third year of new technology add-on payments under our general practice for determining whether to extend the payment for an additional fiscal year, we now extend new technology add-on payments for an additional fiscal year when the 3-year anniversary date of the product's entry onto the U.S. market occurs on or after October 1 of that fiscal year. Overall, we continue to maintain a flexible approach to our review of an applicant's documented delay of commercial availability and generally do not require supporting documentation to substantiate an applicant's claims. We also note that we had stated we were considering this issue as early as the FY 2026 IPPS/LTCH PPS final rule (90 FR 36667; 90 FR 36671). Applicants that anticipate a significant delay in commercial availability may want to consider whether their anticipated commercial availability date would better align with a future rulemaking cycle. As we noted in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36667; 90 FR 36671), ZEVTERA® and SAINT Neuromodulation System both asserted a date of commercial availability that occurred after the new technology add-on payment for the technology began. If we were to consider the beginning of the newness period to commence on the date of commercial availability requested by the applicants, because we now extend new technology add-on payments for an additional fiscal year when the 3-year anniversary date of a product's entry onto the U.S. market occurs on or after October 1 of that fiscal year (89 FR 69238 through 69242), the technologies would be eligible for a fourth year of new technology add-on payment in FY 2028 and FY 2027, respectively. We believe it is necessary to establish an approach to address the specific scenario where a technology may have a legitimate commercial availability delay, but its new technology add-on payment has become effective and the technology (and other technologies reported using the same codes) have become eligible for new technology add-on payment, such that otherwise the technology may potentially be eligible for the new technology add-on payment for four or more years. We believe that implementing this proposal establishes a consistent approach, which would improve predictability for stakeholders. For the same reasons, we also disagree with establishing additional flexibilities specifically for cell and gene therapies, including starting the newness date with the first administration or extending new technology add-on payment to five years.

With regards to a commenter's belief that the proposal effectively treated the rising number of requests as evidence that the standard is being manipulated, without any record support for that inference, we note that we considered two requests in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36666 through 36667; 90 FR 36670 through 36671) where the delays may be attributed at least partially to factors within the applicants' control, including delays from entering into licensing and distribution agreements and delays from changing to a third-party manufacturer. Per the manufacturers, both decisions resulted in significant delays to commercialization that extended for over a year and overlapped with the start of their new technology add-on payment periods. Both applicants subsequently requested CMS consider delays in commercial availability that would have made these technologies eligible for a fourth year of new technology add-on payment. Although there may have been other related considerations that were outside of the applicants' control, due to the increasing complexity of these requests, it may be unclear the extent to which an applicant's asserted commercial availability delay results from such factors rather than a calculated business decision. We believe that due to the nature of the described delays, there may be a mixture of factors both within and outside of an applicant's control. Therefore, we believe the best approach to improve predictability for applicants would be to develop a consistent guideline across applications. We may continue to consider this policy in light of any other considerations that may arise, including any potential changes in the future.

We also disagree with commenters that considering a product to be ''new'' when it was not commercially available would skew the data collected during the new technology add-on payment period. As we stated in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58955), section 1886(d)(5)(K)(ii) of the Act establishes a period of not less than 2 years and not more than 3 years for the collection of data with respect to the costs of new services or technologies. We do not believe that 2 years' worth of data would be insufficient to inform rate-setting for the inpatient setting. In addition, although the technology that had applied for new technology add-on payment may not be on the market, it is possible that other technologies reported using the same codes may enter the market and would be eligible for the new technology add-on payment. Our current practice is to extend new technology add-on payments without a further application from the manufacturer of a competing product (85 FR 58679). As we've noted, procedure codes under the ICD–10–PCS are not manufacturer specific; rather, they are used to describe the hospital service that was performed. If, after consulting current official coding guidelines a hospital determines that an ICD–10–PCS procedure code associated with a new technology add-on payment describes the technology that it used in the performance of a procedure, the hospital may report the code and may be eligible to receive the associated new technology add-on payment (89 FR 69224). We also do not believe that case volume is a relevant consideration for making the determination as to whether a product is ''new.'' As mentioned in previous rulemaking, consistent with the statute and our implementing regulations, a technology is no longer considered as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently the medical service or technology has been used in the Medicare population (70 FR 47349, 85

FR 58610). As such, regardless of whether the use of the technology that had applied for new technology add-on payment or other technologies reported using the same code is frequent or infrequent in the Medicare population, we would consider the costs of the technology to be included in the MS–DRG relative weights. In addition, depending on the prevalence of a disease within the Medicare beneficiary population and the clinical factors associated with the treatments, some technologies may inherently have a minimal claim volume.

Therefore, we are finalizing as proposed that, for a technology that is not yet available for sale when its new technology add-on payment becomes effective, we will consider the newness period to begin on the date preceding the start of the new technology add-on payment for the technology.

As such, consistent with this finalized policy, because the new technology add-on payment for ZEVTERA® became effective on October 1, 2024, we consider the beginning of the newness period for ZEVTERA® to commence on September 30, 2024.

Comment: Multiple commenters supported CMS's proposed continuation of new technology add-on payments for FY 2027 for those technologies that were approved for the new technology add-on payment for FY 2026, and which would still be considered ''new'' for purposes of new technology add-on payments for FY 2027.

Response: We appreciate the commenters' support.

Comment: The applicant for the AGENT™ Paclitaxel-Coated Balloon Catheter submitted a comment updating the average cost of the technology based on updated clinical and claims data. Per the applicant, since the AGENT™ Paclitaxel-Coated Balloon Catheter received the FDA approval on February 29, 2023, the real-world data demonstrates that more than one device is routinely used across all sites of care. The applicant explained that due to clinical necessity, interventional cardiology practice frequently involves the use of multiple devices in a single case. Per the applicant, analysis of MedPAR data for the period between October 1, 2024, and September 30, 2025, shows 234 out of 1,539 claims (approximately 15 percent) involved the use of more than one device during a single procedure, with an average of 1.19 AGENT™ Paclitaxel-Coated Balloon Catheters used per case. The applicant also shared information from published clinical studies and international real-world registries, which it stated consistently demonstrated that clinicians use more than one AGENT™ Paclitaxel-Coated Balloon Catheter per case on average. Therefore, the applicant requested that CMS increase the FY 2027 maximum new technology add-on payment for a case involving the use of AGENT™ Paclitaxel-Coated Balloon Catheter™ to $4,776 to reflect real-world average utilization of 1.19 devices per case.

Response: We thank the applicant for its comment and the updated cost information. We have updated the new technology add-on payment amount for the AGENT™ Paclitaxel-Coated Balloon Catheter™ accordingly. The current maximum new technology add-on payment amount for the AGENT™ Paclitaxel-Coated Balloon Catheter™ is $4,013.75, which reflects the cost of one device (that is, 65 percent of the average cost of the technology of $6,175). For FY 2027, the maximum new technology add-on payment amount is $4,776.36, as reflected in Table II.E.–01 in this final rule.

Comment: The applicant for CONTEPO™ (fosfomycin) submitted a comment providing updated information on its commercial availability and to update its Wholesale Acquisition Cost (WAC). Per the applicant, CONTEPO™ was conditionally approved, and was eligible to receive new technology add-on payments in FY 2026 beginning with discharges on or after January 1, 2026; however, the applicant stated that CONTEPO™ was first made commercially available to patients in the U.S. in March 2026. The applicant encouraged CMS to continue to explore how products can obtain three years of new technology add-on payment from their market availability.

The applicant stated that CONTEPO™ became commercially available with a WAC of $182.74 per vial. Per the applicant, the standard dosing regimen for CONTEPO™ is 6 grams administered intravenously three times daily for 7 to 14 days, and a 10-day course is representative for inpatient cases. The applicant stated that at the standard regimen of three vials per day, the daily cost of therapy is $548.22, and, for an average inpatient treatment duration of 10 days, the total average inpatient cost per case is $5,482.20. Therefore, because CONTEPO™ holds a designation as a QIDP, the applicant requested that CMS update the maximum new technology add-on payment for a case involving the use of CONTEPO™ to $4,111.65 (that is, 75 percent of the average cost of the technology).

Response: We thank the applicant for its comment providing an updated cost information and recommendation. We have updated the new technology add-on payment amount for CONTEPO™ accordingly. For FY 2027, the maximum new technology add-on payment amount is $4,111.65, as reflected in Table II.E.–01 in this final rule.

Although the applicant states that CONTEPO™ became available to patients in March 2026, we did not receive information regarding a documented delay in market availability, and absent additional information from the applicant, we cannot determine a newness date based on a documented delay in the technology's availability on the U.S. market. Therefore, we continue to consider the beginning of the newness period to commence on October 22, 2025, the date of FDA marketing authorization for the indication covered by its QIDP designation.

With respect to the commenter's request that CMS continue to explore how products can obtain three years of new technology add-on payment from their market availability, as we stated in the FY 2024 IPPS/LTCH PPS final rule (*88 FR 58955*), section 1886(d)(5)(K)(ii) of the Act establishes a period of not less than 2 years and not more than 3 years for the collection of data with respect to the costs of new services or technologies; a full 3 years is not required. We do not believe that 2 years' worth of data would be insufficient to inform rate-setting for the inpatient setting.

However, as discussed in greater detail earlier in this section, we note that because we now extend new technology add-on payments for an additional fiscal year when the 3-year anniversary date of a product's entry onto the U.S. market occurs on or after October 1 of that fiscal year (89 FR 69238 through 69242), this could lead to new technology add-on payments being effective for greater than three years for conditionally approved technologies. Therefore, for QIDPs that were conditionally approved for new technology add-on payment, we are considering whether it would also be more appropriate to discontinue new technology add-on payment on the fiscal year quarter that results in 3 years of new technology add-on payment from the start of the new technology add-on payment for the technology. For example, for a conditionally approved QIDP that became eligible to receive new technology add-on payments in FY 2026 beginning with discharges on or after January 1, 2026, under this approach, we would discontinue new technology add-on payment no later

than December 31, 2028, after 3 years of new technology add-on payment.

Comment: The applicant for the AeroPace® System and a commenter submitted comments providing additional information on the technology's commercial availability delay and requested that CMS extend the technology's newness date to align with its commercial availability on October 16, 2025. The applicant stated that the PMA for AeroPace® System was accepted by FDA on May 8, 2024, and that based on the then-current average FDA PMA review time, which included a potential FDA Advisory Panel meeting, it anticipated FDA approval would occur in Q2 2025. The applicant stated that in October 2024, during FDA interactive review, FDA indicated a Panel Meeting was not required, and the applicant anticipated FDA approval between April and June of 2025. The applicant noted that on December 4, 2024, FDA approved the AeroPace® System based on draft labeling, subject to it submitting a PMA Amendment with final labeling revisions. The applicant explained that the revisions necessitated updating the Instructions for Use and the device label that is directly imprinted on the kit lid. The applicant stated that to mitigate manufacturing delays due to long procurement times, it ordered the kit lids in February 2025; FDA approved the updated labeling on March 5, 2025, which enabled the company to initiate manufacturing of the kits; and the applicant completed Quality Assurance/Quality Control (QA/QC) inspection of the labeled, sterilized kits on April 7, 2025. The applicant explained that this enabled it to initiate the UL certification process (or a similar certification) required for hospitals to meet Joint Commission requirements. The applicant stated that this process was completed and UL labels were received from its supplier on October 16, 2025. Per the applicant, the first AeroPace® System was installed on October 30, 2025, and the first commercial use was on December 9, 2025. The commenters stated that based on the CMS proposal, they acknowledged that CMS may consider the newness period for the AeroPace® System to begin on September 30, 2025, establishing a three-year NTAP anniversary date of Sept 30, 2028.

Response: We thank the applicant and commenter for the information regarding the documented delay in the technology's availability on the U.S. market. As discussed previously, under our finalized proposal, for a technology that is not yet available for sale when its new technology add-on payment becomes effective, we consider the newness period to begin on September 30 preceding the start of the new technology add-on payment for the technology. Therefore, we consider the beginning of the newness period for the AeroPace® System to commence on September 30, 2025.

After consideration of the public comments we received, we are finalizing our proposals to continue new technology add-on payments for FY 2027 for the technologies that were approved for new technology add-on payment for FY 2026 and would still be considered ''new'' for purposes of new technology add-on payments for FY 2027, as listed in the proposed rule and in the following Table II.E.–01 in this section of this final rule.

We note that the following Table II.E.–01 is the same as Table II.E.–01 that was presented in the proposed rule, but Table II.E.–01 in this final rule includes the updated newness start date for the AeroPace® System and the updated cost information for AGENT™ Paclitaxel-Coated Balloon Catheter™ and CONTEPO™ (fosfomycin), as discussed previously. Table II.E.–01 in this final rule also presents the newness start date, new technology add-on payment start date, 3-year anniversary date of the product's entry onto the U.S. market, relevant final rule citations from prior fiscal years, maximum add-on payment amount, and coding assignments for each technology. We refer readers to the final rules cited in the following tables for a complete discussion of the new technology add-on payment application, coding, and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

BILLING CODE 4169–69–P

TABLE II.E.-01: CONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2026 NEW TECHNOLOGY ADD-ON PAYMENTS STILL CONSIDERED NEW FOR FY 2027 BECAUSE THE 3-YEAR ANNIVERSARY DATE WILL OCCUR ON OR AFTER OCTOBER 1, 2026

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations	Maximum NTAP Amount for FY 2027	Coding Used to Identify Cases Eligible for NTAP
1	*Annalise Enterprise CTB Triage—OH*	*10/10/2023*	*10/01/2024*	*10/10/2026*	89 FR 69205 through 69208 90 FR 36665 through 36669	$241.39	XXE0X1A
2	*ASTar® System*	*04/26/2024*	*10/01/2024*	*04/26/2027*	89 FR 69208 through 69210 90 FR 36665 through 36669	$97.50	XXE5X2A
3	*Edwards EVOQUE™ Tricuspid Valve Replacement System ("EVOQUE™ System")*	*02/01/2024*	*10/01/2024*	*02/01/2027*	89 FR 69210 through 69213 90 FR 36665 through 36669	$31,850.00	X2RJ3RA
4	*GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device)*	*01/12/2024*	*10/01/2024*	*01/12/2027*	89 FR 69213 through 69215 90 FR 36665 through 36669	$47,238.75	X2VE3SA
5	*LimFlow™ System*	*11/01/2023*	*10/01/2024*	*11/01/2026*	89 FR 69215 through 69218 90 FR 36665 through 36669	$16,250.00	041M3JS, 041N3JS, 041P3JS, 041Q3JS, 041R3JS, 041S3JS, 041T3JS, or 041U3JS
6	*Paradise™ Ultrasound Renal Denervation System*	*11/7/2023*	*10/01/2024*	*11/07/2026*	89 FR 69218 through 69221 90 FR 36665 through 36669	$14,950.00	X051329
7	*PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter*	*12/13/2023*	*10/01/2024*	*12/13/2026*	89 FR 69221 through 69225 90 FR 36665 through 36669	$6,337.50	02583ZF
8	*Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter*	*11/17/2023*	*10/01/2024*	*11/17/2026*	89 FR 69225 through 69228 90 FR 36665 through 36669	$10,400.00	X05133A
9	*TriClip™ G4*	*04/01/2024*	*10/01/2024*	*04/01/2027*	89 FR 69228 through 69230 90 FR 36665 through 36669	$26,000.00	02UJ3JZ
10	*VADER® Pedicle System*	*02/26/2024*	*10/01/2024*	*02/26/2027*	89 FR 69230 through 69236 90 FR 36665 through 36669	$28,242.50	XRH60FA, XRH63FA, XRH64FA, XRH70FA, XRH73FA, XRH74FA, XRH80FA, XRH83FA, XRH84FA, XRHA0FA, XRHA3FA, XRHA4FA, XRHB0FA, XRHB3FA, XRHB4FA, XRHC0FA, XRHC3FA, XRHC4FA, XRHD0FA, XRHD3FA, or XRHD4FA **in combination with** one of the following: M46.20, M46.22, M46.23, M46.24, M46.25, M46.26, M46.27, M46.30, M46.32, M46.33, M46.34, M46.35, M46.36, M46.37, M46.39, M46.40, M46.42, M46.43, M46.44, M46.45, M46.46, M46.47, M46.49, M46.50, M46.51, M46.52, M46.53, M46.54, M46.55, M46.56, M46.57, M46.59, M46.80, M46.82, M46.83, M46.84, M46.85, M46.86, M46.87, M46.89, M46.90, M46.92, M46.93, M46.94, M46.95, M46.96, M46.97, or M46.99
11	*ZEVTERA™ (ceftobiprole medocaril); ABSSSI and CABP indications*	*09/30/2024*	*10/01/2024*	*09/30/2027*	89 FR 69236 through 69238 90 FR 36665 through 36669	$5,287.50	XW0335A or XW0435A

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations	Maximum NTAP Amount for FY 2027	Coding Used to Identify Cases Eligible for NTAP
12	*ZEVTERA™ (ceftobiprole medocaril); SAB indication*	*09/30/2024*	*10/01/2024*	*09/30/2027*	89 FR 69236 through 69238 90 FR 36665 through 36669	$16,215.00	XW0335A or XW0435A **in combination with** R78.81 (**in combination with** B95.61 or B95.62)
13	*CASGEVY™ (exagamglogene autotemcel); Sickle Cell Disease indication*	*12/08/2023*	*10/01/2024*	*12/08/2026*	89 FR 69128 through 69135 90 FR 36665 through 36669	$1,650,000.00	XW133J8 or XW143J8 **in combination with** one of the following: D57.1, D57.20, D57.40, D57.42, D57.44, or D57.80
14	*HEPZATO™ KIT (melphalan for injection/hepatic delivery system)*	*01/08/2024*	*10/01/2024*	*01/08/2027*	89 FR 69158 through 69170 90 FR 36665 through 36669	$118,625.00	XW053T9 **in combination with** 5A1C00Z
15	*LYFGENIA™ (lovotibeglogene autotemcel)*	*12/08/2023*	*10/01/2024*	*12/08/2026*	89 FR 69188 through 69196 90 FR 36665 through 36669	$2,325,000.00	XW133H9 or XW143H9
16	*4WEB Medical Ankle Truss System*	*01/31/2025*	*10/01/2025*	*01/31/2028*	90 FR 36770 through 36773	$15,275.00	XRGJ0B9, XRGK0B9, XRGL0B9, or XRGM0B9
17	*AeroPace® System*	*09/30/2025*	*10/01/2025*	*09/30/2028*	90 FR 36773 through 36776	$23,650.90	X2H13XB
18	*AGENT™ Paclitaxel-Coated Balloon Catheter*	*02/29/2024*	*10/01/2025*	*02/29/2027*	90 FR 36776 through 36779	$4,776.36	XW0J3HA, XW0J3JA, XW0J3KA, XW0J3LA, XW0K3HA, XW0K3JA, XW0K3KA, XW0K3LA, XW0L3HA, XW0L3JA, XW0L3KA, XW0L3LA, XW0M3HA, XW0M3JA, XW0M3KA, or XW0M3LA
19	*alfapump® system*	*12/20/2024*	*10/01/2025*	*12/20/2027*	90 FR 36779 through 36781	$21,450.00	0W1G3J6 **in combination with** 0JH80YZ
20	*aprevo®-C cervical interbody fusion device*	*11/15/2024*	*10/01/2025*	*11/15/2027*	90 FR 36781 through 36784	$21,125.00	XRG10RB, XRG13RB, XRG14RB, XRG20RB, XRG23RB, XRG24RB, XRG40RB, XRG43RB, or XRG44RB
21	*CERAMENT® G (open fracture indication)*	*03/13/2024*	*10/01/2025*	*03/13/2027*	90 FR 36784 through 36786	$5,687.50	XW0V0P7 **without** any of the ICD-10-CM diagnosis codes in category M86
22	*Emily's Care Nourish Test System (Model 1)*	*05/03/2024*	*10/01/2025*	*05/03/2027*	90 FR 36786 through 36792	$3,347.50	XXEZXAB **in combination with** one of the following: P05.01, P05.02, P05.03, P05.04, P05.05, P05.11, P05.12, P05.13, P05.14, P05.15, P07.00, P07.01, P07.02, P07.03, P07.14, or P07.15
23	*Esprit™ BTK Everolimus Eluting Resorbable Scaffold System*	*04/26/2024*	*10/01/2025*	*04/26/2027*	90 FR 36792 through 36795	$6,922.50	X27P3TA, X27Q3TA, X27R3TA, X27S3TA, X27T3TA, or X27U3TA
24	*EUROPA™ Posterior Cervical Fusion System*	*11/19/2024*	*10/01/2025*	*11/19/2027*	90 FR 36795 through 36798	$80,548.00	XRH10GB, XRH13GB, XRH14GB, XRH20GB, XRH23GB, XRH24GB, XRH40GB, XRH43GB, XRH44GB, XRH60GB, XRH63GB, or XRH64GB
25	*iFuse TORQ TNT™ Implant System*	*08/19/2024*	*10/01/2025*	*08/19/2027*	90 FR 36798 through 36803	$4,135.95	XRGE0HB, XRGE3HB, XRGF0HB, XRGF3HB, XNSN0HB, XNSN3HB, XNSP0HB, XNSP3HB, XNH60HB, XNH63HB, XNH70HB, or XNH73HB
26	*Merit Wrapsody® Cell Impermeable Endoprosthesis (CIE)*	*01/02/2025*	*10/01/2025*	*01/02/2028*	90 FR 36803 through 36806	$3,770.00	X27535B, X27635B, X27735B, X27835B, X27935B, X27A35B, X27B35B, X27C35B, X27D35B, or X27E35B

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations	Maximum NTAP Amount for FY 2027	Coding Used to Identify Cases Eligible for NTAP
27	*Minima Stent System*	*08/28/2024*	*10/01/2025*	*08/28/2027*	90 FR 36806 through 36808	$22,685.00	X27339B, X27439B, X27W39B, or X27X39B
28	*MY01 Continuous Compartmental Pressure Monitor*	*04/29/2025*	*10/01/2025*	*04/29/2028*	90 FR 36808 through 36810	$2,112.50	XX2F3W9
29	*PBC Separator with Selux AST System*	*02/15/2024*	*10/01/2025*	*02/15/2027*	90 FR 36810 through 36813	$87.78	XXE5XY9
30	*restor3d TIDAL™ Fusion Cage*	*03/24/2025*	*10/01/2025*	*03/24/2028*	90 FR 36817 through 36819	$18,196.75	XRGK0CA, XRGM0CA, XRGJ0CA, or XRGL0CA
31	*ShortCut™*	*09/27/2024*	*10/01/2025*	*09/27/2027*	90 FR 36819 through 36821	$9,750.00	X28F3VA
32	*The WiSE CRT System*	*04/11/2025*	*10/01/2025*	*04/11/2028*	90 FR 36821 through 36823	$41,145.00	X2HN37B **in combination with** XHH80HB
33	*TriVerity Test*	*01/10/2025*	*10/01/2025*	*01/10/2028*	90 FR 36823 through 36826	$243.75	XXE5XBB
34	*VITEK® REVEAL™ AST System*	*10/21/2024*	*10/01/2025*	*10/21/2027*	90 FR 36826 through 36829	$81.25	XXE5X4A
35	*EMBLAVEO™ (aztreonam-avibactam)*	*02/07/2025*	*10/01/2025*	*02/07/2028*	90 FR 36829 through 36831	$9,000.68	XW033PB or XW043PB
36	*CONTEPO™ (fosfomycin)*	*10/22/2025*	*01/01/2026*	*10/22/2028*	90 FR 36831 through 36834	$4,111.65	XW033WB or XW043WB
37	*AURLUMYN™ (iloprost injection)*	*11/01/2024*	*10/01/2025*	*11/01/2027*	90 FR 36680 through 36687	$28,600.00	XW033QB or XW043QB
38	*BREYANZI® (lisocabtagene maraleucel)*	*03/14/2024*	*10/01/2025*	*03/14/2027*	90 FR 36687 through 36695	$316,860.05	XW033N7 or XW043N7 **in combination with** one of the following: C83.00, C83.01, C83.02, C83.03, C83.04, C83.05, C83.06, C83.07, C83.08, C83.09, C91.10, or C91.12
39	*GRAFAPEX™ (treosulfan)*	*01/21/2025*	*10/01/2025*	*01/21/2028*	90 FR 36707 through 36717	$21,411.00	XW03388 or XW04388
40	*IMDELLTRA® (tarlatamab-dlle)*	*05/16/2024*	*10/01/2025*	*05/16/2027*	90 FR 36717 through 36727	$7,117.50	XW033NA or XW043NA
41	*TECELRA® (afamitresgene autoleucel)*	*08/01/2024*	*10/01/2025*	*08/01/2027*	90 FR 36753 through 36761	$472,550.00	XW03368 or XW04368

BILLING CODE 4169–69–C

In the proposed rule, we provided a Table II.E.–02 listing 12 technologies that were first approved for new technology add-on payments prior to FY

2025, including technologies determined to be substantially similar to such technologies, for which we were proposing to discontinue making new technology add-on payments for FY 2027 because they were no longer ''new'' for purposes of new technology add-on payments because the 3-year anniversary date of the product's entry onto the U.S. market occurs before April 1, 2027. This table also listed one technology that was first approved for new technology add-on payments in FY 2026, for which we were proposing to discontinue making new technology add-on payments for FY 2027 because it was no longer ''new'' for purposes of new technology add-on payments because the 3-year anniversary date of the product's entry onto the U.S. market occurs before October 1, 2026. For all technologies, the table also presented the newness start date, new technology add-on payment start date, the 3-year anniversary date of the product's entry onto the U.S. market, and relevant final rule citations from prior fiscal years. We referred readers to the cited final rules in the table for a complete discussion of each new technology add-on payment application and the coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

We noted in the proposed rule that while we were proposing to discontinue new technology add-on payments for FY 2027 for the Ceribell Status Epilepticus Monitor, Ceribell, Inc. was seeking new technology add-on payments for the Ceribell Delirium Monitor System for FY 2027 (as discussed in section II.E.6. of the preamble of the proposed rule), which is also identified by the ICD–10–PCS procedure code XX20X89 (Monitoring of brain electrical activity, computer-aided detection and notification, new technology group 9). In order to identify cases using the ICD–10–PCS procedure code XX20X89 related to the Ceribell Delirium Monitor System and not the Ceribell Status Epilepticus Monitor, which would no longer be new, we proposed to exclude cases that report the ICD–10–CM diagnosis codes that we believed would identify patients with status epilepticus in combination with the ICD–10–PCS procedure code XX20X89. We provided Table 10.2.—Ceribell Delirium Monitor System, associated with the proposed rule, for the list of ICD–10–CM diagnosis codes that we stated we believe would identify patients with status epilepticus, which we proposed to exclude from new technology add-on payment when reported in combination with ICD–10–PCS procedure code XX20X89. We invited public comments on our proposal to exclude cases reporting these ICD–10–CM diagnosis codes in combination with the ICD–10–PCS procedure code XX20X89, for purposes of the new technology add-on payment for FY 2027, if approved. As discussed in section II.E.6. of the preamble of this final rule, we are approving the Ceribell Delirium Monitor System for new technology add-on payments for FY 2027. We refer readers to that section for further discussion regarding the identification of cases associated with use of the Ceribell Status Epilepticus Monitor in patients diagnosed with status epilepticus, which would not be eligible for new technology add-on payment for FY 2027.

As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36666 through 36671), in response to public comments, including from the applicant for the SAINT Neuromodulation System, that requested that CMS recognize a delay in commercial availability of the technology to April 5, 2024, and subsequently extend new technology add-on payment for the SAINT Neuromodulation System for FY 2026, we questioned whether, where the applicant asserts a date of commercial availability that occurred after the new technology add-on payment for the technology began, it would be appropriate to instead consider the beginning of the newness period to commence with the start of the technology's new technology add-on payment. We noted that regardless of whether we considered the beginning of the newness period to commence for SAINT Neuromodulation System on April 5, 2024; a date that reflects the start of the technology's new technology add-on payment in FY 2024; or a date in between, the three-year anniversary date would occur after April 1, 2026, and, therefore, the technology was considered new for FY 2026.

We stated that, as discussed in greater detail previously in this section, after further consideration, we were proposing that we may consider a documented delay in the beginning of a technology's newness period due to commercial availability only until the new technology add-on payment becomes effective. Specifically, for a technology that is not yet available for sale when its new technology add-on payment becomes effective, we stated we would consider the newness period to begin on September 30 preceding the start of the new technology add-on payment for the technology.

As such, consistent with the proposal, because the new technology add-on payment for SAINT Neuromodulation System became effective on October 1, 2023, we stated that we considered the beginning of the newness period for SAINT Neuromodulation System to commence on September 30, 2023. As the SAINT Neuromodulation System was first approved for new technology add-on payments in FY 2024, we continue to use the midpoint of the upcoming fiscal year (April 1) when determining whether this technology would still be considered ''new'' for purposes of new technology add-on payments. We stated that because we considered the beginning of the newness period to commence on September 30, 2023, the three-year anniversary date would occur before April 1, 2027, and the technology would no longer be considered new for FY 2027.

We invited public comments on our proposals to discontinue new technology add-on payments for FY 2027 for the technologies listed in Table II.E.–02 of the preamble of the proposed rule.

Comment: The applicant for the TOPS™ System requested that CMS extend new technology add-on payment for the TOPS™ System for an additional year. The applicant stated that its MS–DRG reassignment request had been deferred from consideration during the current rulemaking cycle; however, it stated that claims data supported reassignment to a different MS–DRG, and absent MS–DRG reassignment, hospitals would experience a substantial reimbursement reduction following expiration of the new technology add-on payment. The applicant stated that extending new technology add-on payment eligibility for an additional 12 months would provide CMS with additional time to evaluate a larger and more mature body of Medicare claims data while avoiding disruption in patient access during the interim period. The applicant stated that given the relative novelty of posterior column arthroplasty technology and the continued accumulation of utilization and cost data, it believed such an extension would be consistent with the underlying policy objectives of the new technology add-on payment and would support CMS's broader goals of ensuring beneficiary access to innovative technologies while appropriate long-term reimbursement policies are established. The applicant stated that given the direct relationship between new technology add-on payment expiration and beneficiary access, technologies in this circumstance warranted particular consideration to avoid unintended disruptions in care

availability for Medicare beneficiaries. The applicant requested that CMS extend the new technology add-on payment associated with the TOPS™ System for an additional 12 months. The applicant noted that CMS had previously extended new technology add-on payment eligibility during the COVID–19 Public Health Emergency, and believed that similar consideration was appropriate to ensure continued beneficiary access while CMS completed its review.

Similarly, the applicant for the DETOUR System requested that CMS extend new technology add-on payment for the DETOUR System for an additional year because its MS–DRG reassignment request had been deferred from consideration. The applicant requested that CMS either extend new technology add-on payment for an additional year or reassign the procedures involving the DETOUR System to MS–DRGs that better achieved clinical and resource coherence. The applicant stated that the circumstances surrounding the DETOUR system warranted immediate attention in Medicare's hospital inpatient setting to protect patient access effective for FY 2027 because under the MS–DRG assignments proposed for FY 2027 and without new technology add-on payment status, the available Medicare data demonstrated that procedures involving the DETOUR System would be substantially under-reimbursed in FY 2027 and would jeopardize patient access. The applicant noted that CMS has extended new technology add-on payment when warranted in the past, and believed that extending the new technology add-on payment in lieu of MS–DRG reassignment would ensure that the goals of the new technology add-on payment were preserved until the Agency could evaluate the relevant year data set to fully reflect the costs of the DETOUR procedure.

Response: As further discussed in FY 2005 IPPS final rule (69 FR 49002), the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights. The costs of the new medical service or technology, once paid for by Medicare for this 2- to 3-year period, are accounted for in the MedPAR data that are used to recalibrate the DRG weights on an annual basis. Therefore, we stated it is appropriate to limit the add-on payment window for technologies that have passed this 2- to 3-year timeframe. Both the TOPS™ System and the DETOUR System were eligible for new technology add-on payment for three years, from FY 2024 through FY 2026, and are requesting an extension for a fourth year of new technology add-on payment through FY 2027.

We disagree that an extension is warranted for these technologies. We refer the commenters to the MS–DRG classification change request process that is discussed in section II.C. of the preamble of this final rule. We note that the process to request MS–DRG classification changes is separate and distinct from the new technology add-on payment application. We also note that the methodology for recalibration of the relative weights is discussed in section II.D. of the preamble of this final rule.

We note that we proposed a one-year extension of new technology add-on payments for those technologies for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022 because of our proposal to use FY 2019 data instead of FY 2020 data to develop the FY 2022 relative weights (86 FR 44977). As such, the costs for a new technology for which the 3-year anniversary date of the product's entry onto the U.S. market occurred prior to the latter half of the upcoming fiscal year (FY 2022) may not have been fully reflected in the MedPAR data used to recalibrate the MS–DRG relative weights for FY 2022. As the costs of the TOPS™ System and the DETOUR System have been paid for by Medicare for the first 2 to 3 years the products were on the market and are accounted for in the MedPAR data that are used to recalibrate the DRG weights on an annual basis, we are finalizing our proposals to discontinue new technology add-on payments for the TOPS™ System and the DETOUR System.

We did not receive any comment on our proposal to discontinue new technology add-on payment for the SAINT Neuromodulation System. Therefore, consistent with our policy finalized earlier in this section, because the new technology add-on payment for the SAINT Neuromodulation System became effective on October 1, 2023, we consider the beginning of the newness period for SAINT Neuromodulation System to commence on September 30, 2023. As the SAINT Neuromodulation System was first approved for new technology add-on payments in FY 2024, we continue to use the midpoint of the upcoming fiscal year (April 1) when determining whether this technology would still be considered ''new'' for purposes of new technology add-on payments. Because we consider the beginning of the newness period to commence on September 30, 2023, the three-year anniversary date would occur before April 1, 2027, and the technology is no longer be considered new for FY 2027.

After consideration of the public comments we received, we are finalizing our proposals to discontinue new technology add-on payments for the technologies as listed in the proposed rule and in the following Table II.E.–02 of this final rule for FY 2027 because they are no longer ''new'' for purposes of new technology add-on payments. We note that Table II.E.–02 is the same as Table II.E.–02 that was presented in the proposed rule. Table II.E.–02 presents the newness start date, new technology add-on payment start date, the 3-year anniversary date of the product's entry onto the U.S. market, and relevant final rule citations from prior fiscal years. We refer readers to the final rules cited in the following table for a complete discussion of each new technology add-on payment application and the coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

BILLING CODE 7169–69–P

TABLE II.E.-02: DISCONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2026 NEW TECHNOLOGY ADD-ON PAYMENTS NO LONGER CONSIDERED NEW FOR FY 2027

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations
DISCONTINUATION OF TECHNOLOGIES FIRST APPROVED FOR NEW TECHNOLOGY ADD-ON PAYMENTS PRIOR TO FY 2025 THAT ARE NO LONGER CONSIDERED NEW FOR FY 2027 BECAUSE THE 3-YEAR ANNIVERSARY DATE WILL OCCUR PRIOR TO APRIL 1, 2027					
1	*CYTALUX® (pafolacianine) (lung indication)*	*06/05/2023*	*10/01/2023*	*06/05/2026*	88 FR 58810 through 58818 89 FR 69120 through 69126 90 FR 36665 through 36669
2	*EPKINLY™ (epcoritamab-bysp) and COLUMVI™ (glofitamab-gxbm)*	*05/19/2023*	*10/01/2023*	*05/19/2026*	88 FR 58818 through 58835 89 FR 69120 through 69126 90 FR 36665 through 36669
3	*Aveir™ AR Leadless Pacemaker*	*06/29/2023*	*10/01/2023*	*06/29/2026*	88 FR 58919 through 58923 89 FR 69120 through 69126 90 FR 36665 through 36669
4	*Aveir™ Dual-Chamber Leadless Pacemaker*	*06/29/2023*	*10/01/2023*	*06/29/2026*	88 FR 58923 through 58925 89 FR 69120 through 69126 90 FR 36665 through 36669
5	*Ceribell Status Epilepticus Monitor*	*05/23/2023*	*10/01/2023*	*05/23/2026*	88 FR 58927 through 58930 89 FR 69120 through 69126 90 FR 36665 through 36669
6	*DETOUR System*	*06/07/2023*	*10/01/2023*	*06/07/2026*	88 FR 58930 through 58932 89 FR 69120 through 69126 90 FR 36665 through 36669
7	*DefenCath® (taurolidine/heparin)*	*11/15/2023*	*01/01/2024*	*11/15/2026*	88 FR 58942 through 58944 89 FR 69120 through 69126 90 FR 36665 through 36669
8	*Phagenyx® System*	*04/12/2023*	*10/01/2023*	*04/12/2026*	88 FR 58935 through 58937 89 FR 69120 through 69126 90 FR 36665 through 36669
9	*REZZAYO™ (rezafungin for injection)*	*07/19/2023*	*10/01/2023*	*07/19/2026*	88 FR 58944 through 58946 89 FR 69120 through 69126 90 FR 36665 through 36669
10	*SAINT Neuromodulation System*	*09/30/2023*	*10/01/2023*	*09/30/2026*	88 FR 58937 through 58939 89 FR 69120 through 69126 90 FR 36670 through 36673
11	*TOPS™ System*	*06/15/2023*	*10/01/2023*	*06/15/2026*	88 FR 58940 through 58942 89 FR 69120 through 69126 90 FR 36665 through 36669
12	*XACDURO® (sulbactam/durlobactam)*	*05/23/2023*	*10/01/2023*	*05/23/2026*	88 FR 58946 through 58948 89 FR 69120 through 69126 90 FR 36665 through 36669
DISCONTINUATION OF TECHNOLOGY FIRST APPROVED FOR NEW TECHNOLOGY ADD-ON PAYMENTS IN FY 2026 THAT IS NO LONGER CONSIDERED NEW FOR FY 2027 BECAUSE THE 3-YEAR ANNIVERSARY DATE WILL OCCUR PRIOR TO OCTOBER 1, 2026					
1	*RECELL® Autologous Cell Harvesting Device*	*06/07/2023*	*10/01/2025*	*06/07/2026*	90 FR 36813 through 36817

BILLING CODE 7169–69–C

5. FY 2027 Applications for New Technology Add-On Payments (Traditional Pathway)

As discussed previously, as finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990) and subsequently updated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36662 through 36664), we publicly post online applications for new technology add-on payment beginning with FY 2024 applications. As noted in these final rules, while we are continuing to provide discussion of the concerns or issues we identified with respect to applications submitted under the traditional pathway, we are providing more succinct information as part of the summaries in the proposed and final rules regarding the applicant's assertions as to how the medical service or technology meets the newness, cost, and substantial clinical improvement criteria. We refer readers to *https://mearis.cms.gov/public/publications/ntap* for the publicly posted FY 2027 new technology add-on payment applications and supporting information (with the exception of certain cost and volume information, and information or materials identified by the applicant as confidential or copyrighted), including tables listing the ICD–10–CM codes, ICD–10–PCS codes, and/or MS–DRGs related to the analyses of the cost criterion for certain technologies for the FY 2027 new technology add-on payment applications.

We received 15 applications for new technology add-on payments for FY 2027 under the new technology add-on payment traditional pathway. In accordance with the regulations under § 412.87(f), applicants for FY 2027 new technology add-on payments must have received FDA marketing authorization by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered. As previously discussed, beginning with the new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA market authorization request at the time of new technology add-on payment application submission and must provide documentation of FDA acceptance or filing to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. See § 412.87(e) and further discussion in the FY 2024 and FY 2025 IPPS/LTCH PPS final rules (88 FR 58948 through 58958; 89 FR 69242 through 69245). Of the 15 applications received under the traditional pathway, 3 applicants were not eligible for consideration for new technology add-on payment because they did not meet these requirements, and 4 applicants withdrew their applications prior to the issuance of the proposed rule. Typically, in the annual proposed rule, we provide a summary of each traditional pathway application and describe any concerns we may have regarding whether the technology meets a specific new technology add-on payment criterion. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19409 through 19429), for technologies that have already received FDA marketing authorization, we proposed to approve or disapprove each of these applications for new technology add-on payment. We have stated in prior rulemaking that we do not believe it is appropriate for CMS to determine whether a medical service or technology represents a substantial clinical improvement over existing technologies before FDA makes a determination as to whether the medical service or technology is safe and effective (86 FR 45047). Therefore, we did not propose to approve or disapprove applications for technologies that had not yet received FDA marketing authorization for new technology add-on payment.

Subsequently, prior to the issuance of this final rule, one additional application for Orca-T was withdrawn. We are not including in this final rule the description and discussion of applications that were withdrawn or that are ineligible for FY 2027 consideration. We are addressing the remaining 7 applications. We are not approving new technology add-on payments for four technologies: COBENFY™ (xanomeline and trospium chloride), Command Center Electronic Glycemic Management System, RAPIBLYK™ (landiolol), and WASKYRA™ (etuvetidigene autotemcel), for the reasons discussed in the following sections. We are approving FY 2027 new technology add-on payments for three technologies, GAMIFANT® (emapalumab-lzsg), YARTEMLEA® (narsoplimab-wuug), and ZEVASKYN™ (prademagene zamikeracel). A discussion of these applications is presented in the following sections.

a. COBENFY™ (Xanomeline and Trospium Chloride)

Bristol Myers Squibb submitted a FY 2027 application for new technology add-on payments for COBENFY™. According to the applicant, COBENFY™ is an oral combination drug consisting of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist, indicated for the treatment of schizophrenia in adults. COBENFY™ has 3 approved dose strengths (50 mg/20 mg, 100 mg/20 mg, and 125 mg/30 mg) in capsule form. The applicant stated the per-day treatment cost is the same across all dosages and that the average inpatient length of stay for patients taking COBENFY™ is 7.5 days. We noted that the applicant submitted a FY 2026 new technology add-on payment application for this technology, which was not approved, as discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36695 through 36702).

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for COBENFY™ and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251006PD218.*

		Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS code(s)		XW0DXVB	No concerns.
Newness	**Newness Period**	NDA approved on September 26, 2024, for the treatment of schizophrenia in adults. Commercial availability delay to October 9, 2024.	Newness date: October 9, 2024.
	Substantial Similarity	Uses a new mechanism of action.	Not substantially similar to existing treatments.
Cost Criterion		23,422 claims mapping to 9 MS-DRGs, with 93.4% of claims mapping to MS-DRG 885 (Psychoses). Final inflated average case-weighted standardized charge per case of $48,938 exceeded the average case-weighted threshold amount of $47,224.	Meets cost criterion.
Substantial Clinical Improvement Criterion		Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments. Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available. Provided 5 published and 2 unpublished studies assessing the technology, and other information.	See following discussion.

Newness Criterion

In the proposed rule, regarding substantial similarity, based on information available at the time of the proposed rule and as previously stated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36697), we stated we agreed with the applicant that COBENFY™ uses a unique mechanism of action, because it is the first schizophrenia treatment for adults to target muscarinic receptors in the brain by combining the muscarinic agonist, xanomeline, and the muscarinic antagonist, trospium chloride, unlike typical and atypical antipsychotics currently used to treat schizophrenia which antagonize dopamine receptors. Therefore, based on information available at the time of the proposed rule, we stated our belief that COBENFY™ is not substantially similar to existing treatment options and meets the newness criterion. As discussed in the FY 2026 IPPS/LTCH PPS final rule, we consider the beginning of the newness period to commence on October 9, 2024, the date on which COBENFY™ became commercially available.

We invited public comments on whether COBENFY™ is substantially similar to existing technologies and whether COBENFY™ meets the newness criterion.

Comment: The applicant submitted a public comment agreeing with CMS's initial determination that COBENFY™ meets the newness criterion.

Response: We thank the applicant for its comment. Based on our review of the comment received and information submitted by the applicant as part of its FY 2027 new technology add-on payment application for COBENFY™, we agree that COBENFY™ uses a unique mechanism of action, because it is the first schizophrenia treatment for adults to target muscarinic receptors in the brain by combining the muscarinic agonist, xanomeline, and the muscarinic antagonist, trospium chloride, compared to current typical and atypical antipsychotics used to treat schizophrenia which antagonize dopamine receptors. Therefore, we agree that COBENFY™ is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence on October 9, 2024, the date on which COBENFY™ became commercially available.

Cost Criterion

Regarding the cost criterion, we stated we agreed with the applicant that the technology meets the cost criterion. We invited public comments on whether COBENFY™ meets the cost criterion.

Comment: The applicant submitted a public comment reiterating that COBENFY™ meets the cost criterion.

Response: We thank the applicant for its comment. We agree with the applicant that the technology meets the cost criterion.

Substantial Clinical Improvement Criterion

We also received a public comment in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for COBENFY™, which we summarized in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19410 through 19411).

In the proposed rule, after review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we stated we had the following concerns regarding whether COBENFY™ meets the substantial clinical improvement criterion.

In support of its assertions that COBENFY™ provides a treatment option for a patient population unresponsive to or ineligible for currently available therapies and that COBENFY™ improves clinical outcomes, the applicant provided studies that were also included in its FY 2026 new technology add-on payment application in addition to three new references: a post-hoc analysis and two posters.[25] [26] [27] In its FY 2027 new

[25] Cutler, A.J., Zhong, Y., Gillard, K., Appio, J., Gao, C., Laliberté, F., Rubio, J.M. *Real-World Use of Xanomeline-Trospium in Schizophrenia: Patient Characteristics and Antipsychotic Treatment Patterns.* Presentation at Psych Congress, September 17–21, 2025, San Diego, CA.

[26] Horan W.P., Targum S.D., Claxton A., Kaul I., Yohn S.E., Marder S.R., Miller A.C., Brannan S.K. Efficacy of KarXT on negative symptoms in acute schizophrenia: A post hoc analysis of pooled data from 3 trials. *Schizophr Res.* 2024 Dec;274:57–65. *https://doi.org/10.1016/j.schres.2024.08.001.*

[27] Hickey, C., Sidovar, M., Garcia, A., Kramer, K., Chang, J.A, Kupas, K., Telukuntla, V., Cutler, A.J. *Comparative Efficacy, Safety, and Tolerability of Xanomeline and Trospium Chloride versus Eight*

technology add-on payment application, the applicant submitted six similar claims to those provided in its FY 2026 new technology add-on payment application, as well as additional claims stating: COBENFY™ offers a treatment option for schizophrenia patients with extensive prior antipsychotic use, COBENFY™ shows strong real-world persistence and adherence, and COBENFY™ shows superior effectiveness.

In the proposed rule, after review of this information, we stated that we continued to question whether COBENFY™ provides a treatment option for a patient population unresponsive to or ineligible for currently available therapies or improves clinical outcomes relative to existing technologies.

With regards to a new claim in its FY 2027 new technology add-on payment application that COBENFY™ offers a treatment option for schizophrenia patients with extensive prior antipsychotic use, we noted that this claim does not identify a patient population for which COBENFY™ could be used that is unresponsive to or ineligible for other available treatments since patients with prior antipsychotic use could still try other antipsychotics such as clozapine, which is indicated for patients who do not respond to other antipsychotics. We also questioned whether the evidence provided for this claim demonstrates the applicant's assertion. The applicant provided Cutler et al. (2025), a retrospective observational study of claims data for adults with schizophrenia in the U.S. before and after COBENFY™ initiation. Because Cutler et al. (2025) relied upon administrative claims data, we stated we could not be sure whether patients actually took the prescribed oral medication(s). Consequently, we stated we were unable to determine whether all patients treated in this study had extensive prior antipsychotic use or if the patients actually took COBENFY™. We also stated that the study measured medication adherence at 60 and 90 days following COBENFY™ treatment initiation. However, we noted that injectable antipsychotics, which patients adhere to because they are long-acting drugs that require professional administration, are typically administered at intervals of 2 to 12 weeks.[28] Therefore, we stated we were concerned that measuring adherence at 60 and 90 days may be inadequate to accurately assess differences between COBENFY™ and existing schizophrenia treatments. We also questioned long-term adherence rates since the average follow-up was only 2.6 months. Finally, we stated we were concerned that Cutler et al. (2025) does not demonstrate that COBENFY™ has improved clinical outcomes compared to other therapies because this evidence does not include a comparison of adherence data to existing schizophrenia treatments.

We stated that as discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36702), after consideration of public comments, we continued to have concerns as to whether COBENFY™ meets the substantial clinical improvement criterion, including with respect to the applicant's claims that COBENFY™ may be an effective treatment option for patients experiencing disruptive negative symptoms and that COBENFY™ is a valuable option for patients who respond inadequately to current treatments. We stated that the applicant submitted similar claims in its FY 2027 new technology add-on payment application but did not provide additional supporting evidence. Therefore, we stated that we continued to question whether the evidence provided for these claims in the FY 2027 new technology add-on payment application demonstrates that COBENFY™ offers a treatment option for patients unresponsive to or ineligible for other therapies, without data supporting that other antipsychotics cannot be used in patients with negative symptoms or who have not responded to other antipsychotics.

With respect to the assertion that COBENFY™ provides improved clinical outcomes relative to previously available therapies by improving symptom response and reducing metabolic side effects compared to several atypical antipsychotics, the applicant provided Hickey et al. (2025), a network meta-analysis poster, which used data from 58 randomized controlled trials lasting between 4 and 6 weeks and indirectly compared COBENFY™ to aripiprazole, cariprazine, olanzapine, risperidone, brexpiprazole, quetiapine, clozapine, and lumateperone. However, we stated that the poster does not consistently show a statistically significant difference in favor of COBENFY™ (such as with respect to PANSS response, change from baseline weight, and sedation). We also noted that the poster did not provide a comparison to typical antipsychotics or other atypical antipsychotics, such as olanzapine/samidorphan, which includes samidorphan to reduce weight gain. For these reasons, we questioned whether this study demonstrates COBENFY™ improves clinical outcomes compared to other available therapies. Additionally, we noted that Hickey et al. (2025) found that COBENFY™ had statistically significant higher odds of discontinuation due to all causes compared to all comparators except cariprazine, for which results were unfavorable but not statistically significant. As a result, we further questioned the applicant's claim that COBENFY™ demonstrates improved persistence and adherence compared to currently available treatments.

Finally, we noted that in support of its assertion of improved clinical outcomes compared to previously available therapies, the applicant also provided four claims in its FY 2027 new technology add-on payment application that were similar to the claims provided in its FY 2026 new technology add-on payment application. We noted the only additional evidence submitted for these claims in the applicant's FY 2027 new technology add-on payment application was Horan et al. (2024), a post-hoc analysis of pooled data from the three 5-week EMERGENT studies, which was also the only evidence provided for the claim regarding long-term reduction in symptoms and a persistently well-tolerated side effect profile. However, the studies included in this analysis compared COBENFY™ to placebo, and therefore, we stated we were unable to assess whether there is a long-term reduction of symptoms and a favorable side effect profile compared to existing schizophrenia treatments. In addition, we questioned this claim given the short duration of the trials and the lack of discussion on side effects in the article. Lastly, since the applicant did not submit evidence comparing COBENFY™ to other available therapies with regard to efficacy, safety, or discontinuation rates, we stated in the proposed rule that we continued to question whether the evidence demonstrates improved clinical outcomes compared to previously available therapies with respect to these claims, as stated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36702).

After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall

Atypical Antipsychotics for the Acute Treatment of Adults with Schizophrenia—A Network Meta-Analysis. Presentation at the 2025 Annual Congress of the Schizophrenia International Research Society (SIRS), March 29-April 2, 2025, Chicago, Illinois.

[28] Stroup, T.S. & Marder, S. (2025). Schizophrenia in adults: Maintenance therapy and side effect management. *UpToDate.* Retrieved October 7, 2025, from *https://www.uptodate.com/contents/schizophrenia-in-adults-maintenance-therapy-and-side-effect-management.*

meeting, we stated in the proposed rule that we were unable to determine that COBENFY™ represents a substantial clinical improvement over existing technologies, and therefore, we proposed to disapprove new technology add-on payments for COBENFY™ for FY 2027.

We invited public comments on whether COBENFY™ meets the substantial clinical improvement criterion and our proposal to disapprove new technology add-on payments for COBENFY™ for FY 2027.

Comment: A few commenters expressed support for approving new technology add-on payment status for COBENFY™. Commenters highlighted the current societal and financial costs of schizophrenia. In expressing support for approval of COBENFY™, commenters stated many patients with schizophrenia may not respond to conventional treatment or may discontinue treatment due to side effects such as weight gain, metabolic complications, sedation, cognitive blunting, movement disorders, fluid retention, sexual dysfunction, and hyperarousal. These commenters expressed their belief that patients should have COBENFY™ as a treatment option due to its novel mechanism of action and minimal adverse events.

A commenter stated that while patients who have not responded to or who have discontinued a previous antipsychotic could try another antipsychotic, they should have an additional option with COBENFY™, especially due to its new mechanism of action. The commenter also stated that most Medicare enrollees who are hospitalized with schizophrenia and psychotic symptoms are not individuals experiencing first-episode psychosis but are usually either adults over 65 who have lived with schizophrenia for decades or individuals under 65 with schizophrenia who are on Medicare due to disability status (with schizophrenia being the likely disabling condition). This commenter added that a majority of these patients are experiencing psychosis due to medication failure or discontinuation and are likely to be readmitted in the future for the same reason, which is a negative and costly outcome. The commenter noted that some individuals respond to and adhere to both COBENFY™ and clozapine, while others respond to and adhere to COBENFY™ but not to clozapine. The commenter stated that for these latter patients, the proposed CMS disapproval is condemning them to another psychotic episode, likely rehospitalization, and maybe even death. The commenter added that excluding a new medication that works differently from all other pharmacological options when the current likelihood of failure is already much too high seems like an unwise decision that lowers the probability of individuals achieving recovery.

Another commenter stated that the side effects associated with antipsychotics can contribute to significant nonadherence rates, which can be as high as 65 percent in some studies.[29] Therefore, the commenter stated the need for new treatments and new mechanisms of action is immense, and COBENFY™'s novel mechanism of action provides an innovative treatment option so that patients, especially those who respond poorly to currently available treatments, may avoid many of these side effects. The commenter noted COBENFY™ has been effective in reducing schizophrenia symptoms with minimal adverse events.[30] The commenter expressed concern that CMS's comparisons in the proposed rule take an incomplete look at the larger treatment landscape for schizophrenia. The commenter stated that, while injectable antipsychotic medications might serve a role and aid in higher rates of adherence, these types of treatments might not be suitable for the larger patient population, and real-world evidence shows COBENFY™ has an encouraging adherence profile for a patient population that has historically struggled to maintain continuity on oral treatments.[31] The commenter also stated that COBENFY™'s demonstrated lack of negative side effects due to its mechanism of action is critical and COBENFY™ provides a clear alternative to patients who otherwise would stop pursuing treatment or were unsuccessful on previous treatments. The commenter further stated that even when patients did show signs of metabolic side effects, these were often mild to moderate in severity and resolved themselves over a 52-week course of treatment [32] and this demonstrates a significant improvement in the current standard of care, particularly for patients with a history of extensive antipsychotic use, ultimately allowing for long-term symptom reduction and improved tolerability from current options. The commenter encouraged CMS to prioritize policies that allow and encourage new treatment options for serious mental illness and stated that new treatment options with novel mechanisms of action offer hope to millions living with schizophrenia.

A commenter stated that non-adherence with schizophrenia treatments drives relapse, rehospitalization, or traumatic interactions with the justice system. The commenter cited the April 2026 Schizophrenia & Psychosis Action Alliance study, which reported that 65 percent of community respondents reported that gaps in the mental health system had resulted in hospitalization, while 50 percent, 44 percent, and 44 percent reported these gaps resulted in job loss, housing instability, and justice system involvement, respectively.[33] The commenter stated that currently available therapies are not a viable option for many of these patients and that CMS should weigh downstream outcomes (reduced subsequent hospitalization, reduced morbidity, and improved quality of life). The commenter also added that the study found that 62 percent of the public and 89 percent of schizophrenia community members reported that hospital availability for serious mental illness is inadequate, with only 11 percent of schizophrenia community members describing current schizophrenia treatments as ''very effective.'' In addition, the commenter cited a January 2026 study (Kraser et al., 2026) which analyzed the cost of schizophrenia in the United States.[34] Krasa et al. (2026) estimated that schizophrenia's total societal cost in 2024 was $366.8 billion, affecting approximately 3.07 million American adults, with a per-person annual burden of $119,436. The commenter stated its belief that three findings from Krasa et al. (2026) are

[29] Zwide GE, Dewet AT, Sokudela FB. Medication Non-Adherence in Re-Admitted Patients at a Psychiatry Hospital: A Qualitative Study. S Afr J Psychiatr. 2025; 31:2345. doi: 10.4102/sajpsychiatry.v31i0.2345.

[30] Neporent, L ''Emergent Trial Data For KarXT Shows Promise in Schizophrenia'' *Psychiatrist.com,* May 30, 2023, *https://www.psychiatrist.com/news/emergent-trial-data-for-karxt-shows-promise-in-schizophrenia/.*

[31] Cutler, A.J., Zhong, Y., Gillard, K., Appio, J., Gao, C., Laliberte´, F., Rubio, J.M. Real-World Use of Xanomeline-Trospium in Schizophrenia: Patient Characteristics and Antipsychotic Treatment Patterns. Presentation at Psych Congress, September 17–21, 2025, San Diego, CA.

[32] Kuntz L. New Data Demonstrates KarXT's Positive Long-Term Metabolic Profile. Psychiatrictimes.com, April 12, 2024, *https://www.psychiatrictimes.com/view/new-data-demonstrates-karxt-positive-long-term-metabolic-profile.*

[33] *Voters Agree: Serious Mental Illness Care Needs Urgent Action—SPAN.* (2026, April 30). SPAN—Schizophrenia Policy Action Network. Available at *https://span-scz.org/mental-illness-care-poll/.*

[34] Krasa, H.B., Baumgardner, J.R., Brewer, I.P., Chou, J.W., Flottemesch, T., Markowitz, J.T., Williams, C., & Nagendra, A. (2026). National and State Societal Costs of Schizophrenia in the U.S. in 2024. *JAMA Psychiatry. https://doi.org/10.1001/jamapsychiatry.2025.4383.*

directly relevant to CMS's evaluation of COBENFY™'s substantial clinical improvement. First, the commenter stated that Krasa et al. (2026) found that only $36.7 billion (approximately 9 percent) of schizophrenia's annual burden of $366.8 billion is healthcare spending. The commenter stated that, while the remaining cost is not paid by CMS, Medicare's decisions can influence lost productivity, premature mortality, supportive housing and homelessness, justice system involvement, and uncompensated caregiving. The commenter stated that this is relevant because inpatient hospitalization is often the moment at which a patient's longer-term trajectory is set, as early and effective intervention in psychosis is associated with better outcomes across measures like fewer relapses, reduced treatment discontinuation, improved school and work participation, lower rates of psychiatric hospitalization, and superior quality of life.[35] The commenter added that inpatient payment rules that limit access to a different treatment option are not just a hospital cost-control factor, they also shape what happens to the patient long after discharge, especially in the case of schizophrenia, where the timing of a successful early intervention can be the most critical factor in a diagnosed person's life. Second, the commenter highlighted that Krasa et al. (2026) estimated that schizophrenia generates $4.3 billion annually in Social Security Disability Insurance (SSDI) payments, with approximately 422,000 adults with schizophrenia receiving SSDI. The commenter stated that because SSDI eligibility confers Medicare coverage after a 24-month waiting period, a substantial share of the adult schizophrenia population becomes Medicare-eligible well before age 65.[36] Further, the commenter noted SSDI eligibility on the basis of schizophrenia commonly requires documentation that the illness has been severe enough to prevent stable employment despite treatment, which means the Medicare-via-disability population disproportionately reflects patients who have tried existing therapies that did not produce functional recovery.[37] The commenter stated that this population has typically cycled through multiple antipsychotic regimens, accumulated the side-effect burden of long-term dopamine antagonism, and is most likely to need a novel option during inpatient stabilization. The commenter stated its belief that when CMS evaluates whether COBENFY™ offers substantial clinical improvement, it is evaluating that question for schizophrenia patients arriving at hospitalization with treatment histories that already document inadequacy of conventional options. Third, the commenter stated Krasa et al. (2026) attributed $165 billion annually to caregiver burden alone, including unpaid labor, caregiver health impacts, and out-of-pocket costs, with an additional $47.5 billion attributed to premature mortality (people with schizophrenia have a life expectancy approximately 15 years shorter than the general population). The commenter stated its opinion that the combination of Krasa et al. (2026) and insights from the community of diagnosed schizophrenia patients and caregivers demonstrates that schizophrenia is an inadequately treated disease with an enormous cost and urged CMS to weigh the costs to patients, families, and public systems alongside the cost of new technology.

Response: We thank the commenters for their input and have taken it into consideration in determining whether COBENFY™ meets the substantial clinical improvement criterion as discussed later in this section. While we acknowledge the burden of schizophrenia cited by commenters and that COBENFY™ has a new mechanism of action compared to previously available treatments, we note that we did not receive any comments including data to support efficacy of COBENFY™ in patients who have failed these other treatments. We further note that whether a technology receives new technology add-on payments or not does not affect coverage of the technology or the ability for hospitals to provide a technology to patients where appropriate. Even if a technology does not receive new technology add-on payments, CMS continues to pay for new technologies through the regular payment mechanism established by the DRG payment methodology (90 FR 36672).

Comment: The applicant for COBENFY™ submitted a public comment regarding the substantial clinical improvement criterion and provided responses to our concerns from the proposed rule. The applicant asserted that COBENFY™ satisfies the substantial clinical improvement criteria under 42 CFR 412.87(b) and stated that CMS's determination rests solely on COBENFY™ failing to demonstrate substantial clinical improvement.

The applicant stated that CMS established the new technology add-on payments to ensure that the Medicare payment system does not become a barrier to clinical innovation, enabling hospitals to provide patients access to genuinely innovative therapies without absorbing unsustainable financial losses. The applicant stated that COBENFY™ fits squarely within this framework as it provides a differentiated mechanism of action and expands treatment options for patients who are unable to tolerate or safely use existing therapies, addressing precisely the access and innovation concerns new technology add-on payments were designed to remedy. Further, the applicant stated that FDA approval of COBENFY™ was supported by clinical data evaluating its efficacy, safety, and tolerability in adults with schizophrenia across acute and longer-term studies. According to the applicant, COBENFY™ therefore represents a novel and clinically meaningful advancement in the treatment of schizophrenia that aligns directly with new technology add-on payments' purpose of supporting access to innovative treatments that deliver meaningful clinical benefit. The applicant asserted that COBENFY™ satisfies each of the three new technology add-on payment criteria, and granting new technology add-on payments for COBENFY™ will not only appropriately recognize its therapeutic value, mitigate access barriers associated with its introduction, and ensure Medicare beneficiaries can benefit from this important new treatment, but also effectuate CMS's intended objective under the program.

The applicant also asserted that, under the governing regulatory framework, CMS must evaluate substantial clinical improvement based on the totality of the circumstances to determine whether a service or technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. The applicant added that the regulations establish multiple independent pathways by which a technology satisfies the substantial clinical improvement criterion, each of which is independently sufficient to meet the criterion and must be

[35] Correll CU, Galling B, Pawar A, et al. Comparison of early intervention services vs treatment as usual for early-phase psychosis: a systematic review, meta-analysis, and meta-regression. JAMA Psychiatry. 2018;75(6):555–565. doi:10.1001/jamapsychiatry.2018.0623.

[36] Social Security Act § 226(b), 42 U.S.C. 426(b).

[37] 20 CFR pt. 404, subpt. P, app. 1, §§ 12.00G2, 12.03(C). See also U.S. Social Security Administration, ''Disability Evaluation Under Social Security: 12.00 Mental Disorders—Adult,'' *https://www.ssa.gov/disability/professionals/bluebook/12.00-MentalDisorders-Adult.htm.*

considered within the totality of the circumstances, and stated the requirements set forth in these regulations.

The applicant stated that in assessing whether a technology meets substantial clinical improvement, CMS must consider a broad range of evidence, including both published and unpublished data, and that the regulations further clarify that neither low disease prevalence among Medicare beneficiaries nor the fact that a benefit is limited to a subpopulation disqualifies a technology from meeting the substantial clinical improvement criterion. The applicant further stated that, to the contrary, the regulations expressly provide that a technology may satisfy substantial clinical improvement by demonstrating substantial improvement in the diagnosis or treatment of a defined subpopulation. The applicant expressed that COBENFY™ satisfies the substantial clinical improvement criterion under the totality of the circumstances based on the evidentiary record which establishes that COBENFY™: (1) introduces a novel mechanism of action based on M1/M4 muscarinic agonism with peripheral antagonism via trospium, representing a fundamentally different therapeutic approach relative to existing antipsychotics; (2) provides a treatment option for patient populations that are unresponsive to or ineligible for currently available therapies, satisfying 42 CFR 412.87(b)(1)(ii)(A) and the related subpopulation provision at (b)(1)(v); and (3) yields clinically meaningful improvements in outcomes relative to existing antipsychotics across efficacy, safety, and real-world endpoints, satisfying 42 CFR 412.87(b)(1)(ii)(C). Further, the applicant asserted that the regulations make clear that satisfaction of any one of these pathways is sufficient, and COBENFY™ meets all three.

Per the applicant, the analysis of COBENFY™ in the FY 2027 IPPS/LTCH PPS proposed rule does not apply the required totality of the circumstances standard and instead isolates individual studies and rejects each in turn, thereby misapplying both 42 CFR 412.87(b)(1)(ii)(A) and the separate subpopulation provision at 42 CFR 412.87(b)(1)(v). The applicant stated its belief that if carried forward into this final rule, this approach would depart from CMS's own governing regulation, and in the absence of a legally coherent approach, would constitute arbitrary and capricious final agency action under the Administrative Procedure Act and undercut the new technology add-on payment program's core purpose in promoting and ensuring access to new and innovative technologies. The applicant also stated that by effectively narrowing the new technology add-on payment program's application beyond the regulatory standard to therapies that fit within rigid, established clinical frameworks, rather than encompassing truly novel technologies, CMS risks chilling investment in critical innovation. The applicant also asserted that novel mechanisms, by definition, often lack direct comparators and that imposing evidentiary standards that exceed regulatory requirements may lead to de facto head-to-head trials where they are often not feasible for truly novel mechanisms like COBENFY™.

The applicant suggested that CMS's interpretation of the unresponsive to, or ineligible for criterion in the FY 2027 IPPS/LTCH PPS proposed rule misapplies the substantial clinical improvement standard and imposes a requirement that does not appear in the regulatory text. The applicant stated CMS's assertion in the proposed rule that COBENFY™ does not identify a patient population for which COBENFY™ could be used that is unresponsive to or ineligible for other available treatments since patients with prior antipsychotic use could still try other antipsychotics such as clozapine and stated its belief that the governing regulation contains no requirement that a new technology be reserved as a last-line option after exhaustion of all existing therapies, including clozapine. The applicant stated its belief that CMS's interpretation is inconsistent with the regulatory standard, which instead asks whether the technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. The applicant stated that the United States Department of Veterans Affairs has established specific clinical criteria for COBENFY™, effectively positioning it as a last line treatment by requiring that a patient first experience treatment failure with clozapine and demonstrate an insufficient response or intolerance to multiple antipsychotics.[38]

The applicant stated that the treatment-experienced population initiating COBENFY™ is clinically distinct and well-defined. The applicant stated that Cutler et al. (2025) reported nearly half (49 percent) of patients had used 3 or more antipsychotic agents in the prior 12 months and 39 percent had used long-acting injectables, thereby demonstrating extensive prior exposure to, and failure of, dopamine-pathway monotherapy, the very class of treatments that CMS suggests patients should continue trying. The applicant further stated that for this patient population, COBENFY™ is not a duplicative option, but instead, is a mechanistically distinct alternative, which is precisely what makes COBENFY™ a treatment option fitting squarely within the meaning of 42 CFR 412.87(b)(1)(ii)(A) for a patient population that, by definition, has not responded adequately to the dopamine-pathway therapies CMS would have them continue trying.

The applicant stated its belief that CMS's articulation of the evidentiary standard effectively rewrites the regulatory standard by transforming a requirement that patients be unresponsive to, or ineligible for, currently available treatments into a demand for proof that the treatment cannot be used in other patients. The applicant specifically cited CMS's concern that it continues to question whether the evidence provided for these claims in the FY 2027 new technology add-on payment application demonstrates that COBENFY™ offers a treatment option for patients unresponsive to or ineligible for other therapies, without data supporting that other antipsychotics cannot be used in patients with negative symptoms or who have not responded to other antipsychotics. The applicant stated that the regulation defines a qualifying patient population as one that is ineligible for currently available treatments and that the evidence submitted in its application, including evidence from the EMERGENT program, supports a determination of substantial clinical improvement for this population under the regulation's plain text. The applicant cited results from Horan et al. (2024) and stated that the effects in the prominent-negative-symptoms subgroup remained statistically significant after controlling for improvements in positive symptoms, depression/anxiety, disorganization, and hostility—suggesting that the observed negative-symptom signal is not solely an artifact of positive-symptom improvement. The applicant stated that it submitted this evidence as supportive, not dispositive, of a substantial clinical improvement determination for this population. The applicant also acknowledged that COBENFY™'s FDA-approved label does not include a specific indication for negative-symptom predominance and that the

[38] Department of Veterans Affairs. (November 2024). Trospium-Xanomeline (COBENFY™) Criteria for Use. Available at *https://www.va.gov/formularyadvisor/DOC_PDF/CFU_Trospium_Xanomeline_COBENFY_Criteria_Nov_2024.pdf.*

available data are post hoc and exploratory.

The applicant stated that, compared to currently available antipsychotics, the FDA-approved labeling for COBENFY™ demonstrates that the technology offers a treatment option for a defined population of adult patients with schizophrenia who are ineligible for currently available treatments and thereby satisfies the ineligible patient population criterion, because it identifies patient populations for whom the risks of adverse side effects are clinically significant. The applicant stated that currently available antipsychotics operate through dopamine D2 receptors, a mechanism that carries class boxed warnings and precautions inherent to dopamine receptor antagonism with significant adverse effects, including extrapyramidal symptoms, tardive dyskinesia, neuroleptic malignant syndrome, metabolic changes, and QT prolongation.[39] [40] [41] The applicant stated that in practice, these risks define patient populations for whom continued treatment with dopamine-based therapies is clinically inappropriate, and for certain adult patients with schizophrenia, these considerations render these treatments inappropriate due to pre-existing conditions or clinical histories. The applicant added that COBENFY™ does not rely on D2 receptors and does not carry those same warnings, thereby offering a treatment option for patients who would otherwise lack a viable alternative due to COBENFY™'s decreased likelihood of triggering these burdensome side effects and its ability to address real-world discontinuation drivers.[42] The applicant added that COBENFY™ significantly reduces the risk of these dopamine-related adverse effects, with an adverse reaction profile primarily including manageable and transient effects such as nausea and dyspepsia,[43] [44] [45] [46] thereby representing an available treatment option for adults with schizophrenia, who, for example, have an active or prior history of extrapyramidal symptoms, are at high risk of cardiometabolic morbidity, or have a history of neuroleptic malignant syndrome.

The applicant suggested that Hickey et al. (2025) provides the comparative evidence with regard to efficacy, safety, or discontinuation rates, that CMS claims is lacking from its application, because the study is a Bayesian random-effects analysis following National Institute for Health and Care Excellence Technical Support Document guidance, which draws on a connected network of 58 randomized controlled trials and pre-specified Population, Intervention, Comparison, Outcome, and Study Design (PICOS) criteria. The applicant stated that Hickey et al. (2025) compare COBENFY™ directly to eight atypical antipsychotics on efficacy, safety, and discontinuation. The applicant cited the study's results and expressed its belief that the base-case efficacy findings demonstrate comparative superiority on multiple clinically meaningful endpoints and overwhelmingly establish that COBENFY™ provides clinically meaningful efficacy improvements relative to commonly used atypical antipsychotics. The applicant added that Hickey et al. (2025)'s safety findings independently and directly satisfy the regulatory criterion at 42 CFR 412.87(b)(1)(ii)(C)(1), which recognizes a reduction in at least one clinically significant adverse event as a basis for determining substantial clinical improvement.

In regard to CMS's concern that the poster did not provide comparison to typical antipsychotics or other atypical antipsychotics, such as olanzapine, the applicant stated that the regulation imposes no requirement to compare a technology against every available therapy. The applicant highlighted that Hickey et al. (2025)'s eight-comparator scope captures clinically relevant agents that drive the United States schizophrenia treatment landscape, with typical antipsychotics appropriately excluded from the comparator set. The applicant further stated that market data and prescribing trends demonstrate that second-generation antipsychotics have long been preferred as a first-line treatment over first-generation antipsychotics,[47] and therefore, the study's focus on atypical antipsychotics reflects current clinical practice. The applicant noted that olanzapine/samidorphan is a fixed-dose combination product rather than a monotherapy, and the pre-specified PICOS criteria appropriately limited inclusion to monotherapy oral, atypical antipsychotics. The applicant cited an independent study (Schneider-Thoma et al., 2026), which it asserted addresses CMS's concern and further supports COBENFY™'s differentiated profile relative to olanzapine-samidorphan.[48] Schneider-Thoma et al. (2026) is a network meta-analysis of 388 randomized controlled trials with 78,193 participants across 24 antipsychotics, including COBENFY™. The applicant stated that the study found that olanzapine-samidorphan resulted in 2.44 kg of weight gain compared to placebo (95% CI 1.48 to

[39] Lieberman, J.A., Stroup, T.S., McEvoy, J.P., Swartz, M.S., Rosenheck, R.A., Perkins, D., . . . & Hsiao, J.K. (2005). Effectiveness of antipsychotic drugs in patients with chronic schizophrenia. The New England Journal of Medicine, 353(12), 1209–1223. *https://doi.org/10.1056/NEJMoa051688.*

[40] Leucht, S., Cipriani, A., Spineli, L., Mavridis, D., Örey, D., Richter, F., Samara, M., Barbui, C., Engel, R.R., Geddes, J.R., Kissling, W., Stapf, M.P., Lässig, B., Salanti, G., & Davis, J.M. (2013). Comparative efficacy and tolerability of 15 antipsychotic drugs in schizophrenia: a multiple-treatments meta-analysis. The Lancet, 382(9896), 951–962. *https://doi.org/10.1016/s0140-6736(13)60733-3.*

[41] Huhn, M., Nikolakopoulou, A., Schneider-Thoma, J., Krause, M., Samara, M., Peter, N., Arndt, T., Bäckers, L., Rothe, P., Cipriani, A., Davis, J., Salanti, G., & Leucht, S. (2019). Comparative Efficacy and Tolerability of 32 Oral Antipsychotics for the Acute Treatment of Adults with multi-episode schizophrenia: a Systematic Review and Network meta-analysis. The Lancet, 394(10202). *https://doi.org/10.1016/s0140-6736(19)31135-3.*

[42] Read J, Williams J. Positive and Negative Effects of Antipsychotic Medication: An International Online Survey of 832 Recipients. Curr Drug Saf. 2019;14(3):173–181. doi: 10.2174/1574886314666190301152734. PMID: 30827259; PMCID: PMC6864560.

[43] Brannan SK, Sawchak S, Miller AC, Lieberman JA, Paul SM, Breier A. Muscarinic Cholinergic Receptor Agonist and Peripheral Antagonist for Schizophrenia. N Engl J Med. 2021 Feb 25;384(8):717–726. doi: 10.1056/NEJMoa2017015. PMID: 33626254; PMCID: PMC7610870.

[44] Kaul I, Sawchak S, Correll CU, Kakar R, Breier A, Zhu H, Miller AC, Paul SM, Brannan SK. Efficacy and safety of the muscarinic receptor agonist KarXT (xanomeline-trospium) in schizophrenia (EMERGENT–2) in the USA: results from a randomised, double-blind, placebo-controlled, flexible-dose phase 3 trial. Lancet. 2024 Jan 13;403(10422):160–170. doi: 10.1016/S0140–6736(23)02190–6. Epub 2023 Dec 14. Erratum in: Lancet. 2024 Jun 1;403(10442):2380. doi: 10.1016/S0140–6736(24)01041–9. PMID: 38104575.

[45] Kaul I, Sawchak S, Walling DP, Tamminga CA, Breier A, Zhu H, Miller AC, Paul SM, Brannan SK. Efficacy and Safety of Xanomeline-Trospium Chloride in Schizophrenia: A Randomized Clinical Trial. JAMA Psychiatry. 2024 Aug 1;81(8):749–756. doi: 10.1001/jamapsychiatry.2024.0785. Erratum in: JAMA Psychiatry. 2024 Aug 1;81(8):846. doi: 10.1001/jamapsychiatry.2024.2002. PMID: 38691387; PMCID: PMC11063924.

[46] Amy Claxton, George Konis, Inder Kaul, Andrew C. Miller, Steven M. Paul, Stephen K. Brannan, Ronald Marcus (2024). Long-Term Metabolic Outcomes Associated With KarXT (Xanomeline and Trospium): Interim Results From Pooled, Long-Term Safety Studies EMERGENT–4 and EMERGENT–5. Presentation at the 2024 Annual Conference of the Schizophrenia International Research Society (SIRS), April 3–7, 2024, Florence, Italy.

[47] Leucht S, Corves C, Arbter D et al. Second-generation versus first-generation antipsychotic drugs for schizophrenia: a meta-analysis. The Lancet, 2008; 373, 31–41.

[48] Schneider-Thoma, J., Zhu, Y., Qin, M., Dong, Y., Guan, S., Wang, J., Tian, J., Lin, X., Rodolico, A., Siafis, S., Bighelli, I., Wehner, M., Veith, C., Krayer, F., Scheuring, E., Davis, J. M., Priller, J., Nikolakopoulou, A., Salanti, G., & Li, C. (2026). Comparative efficacy and tolerability of antidopaminergic and muscarinic antipsychotics for acute schizophrenia: a network meta-analysis of randomised controlled trials indexed in international English and Chinese databases. *The Lancet, 407* (10531), 876–891. *https://doi.org/10.1016/s0140-6736(25)02365-7.*

3.39), placing it among the antipsychotics with greater weight gain than at least 3 comparators, whereas COBENFY™ ranked first of 23 antipsychotics on weight gain (MD −0.37 kg; 95% CI −1.27 to 0.53). The applicant stated that the Schneider-Thoma et al. (2026) study's conclusion that samidorphan reduced olanzapine-related weight gain only slightly (0.47 kg less) directly addresses CMS's concern and demonstrates that COBENFY™ significantly improves at least one clinical outcome by likely reducing at least one clinically significant adverse event (weight gain) and supports an improved quality of life by avoiding excessive weight gain.

Regarding CMS's statement that Hickey et al. (2025) found that COBENFY™ had statistically significant higher odds of discontinuation due to all causes compared to all comparators except cariprazine, the applicant stated that the poster explains why this finding reflects a mathematical artifact rather than a real-world adherence problem. Specifically, the applicant highlighted that unadjusted absolute discontinuation rates from EMERGENT-1, -2, and -3 were lower than rates from comparator trials in both intervention and placebo arms, and a smaller absolute difference relative to a lower placebo rate produces a larger odds ratio. The applicant further stated that a vast majority of discontinuation was not due to adverse events or a lack of efficacy, a pattern that is common particularly in inpatient schizophrenia trials. Instead, the applicant stated that real-world data show that COBENFY™ achieves clinically meaningful adherence and persistence in practice, reinforcing that the discontinuation finding in Hickey et al. (2025) does not translate into a real-world adherence problem: 72 percent of patients achieved a proportion of days covered (PDC) ≥ 80 percent during follow-up, and Kaplan-Meier estimation showed 80.9 percent persistence at month 4.[49]

The applicant stated that CMS's concerns regarding Cutler et al. (2025) do not provide a valid basis for discounting its relevance. Regarding CMS's concern that Cutler et al. (2025) relied upon administrative claims data and, thus, cannot be sure whether patients actually took the prescribed oral medication, the applicant suggested that if such a standard is adopted, claims-based real-world evidence would be effectively disqualified, which is inconsistent with the regulation's express recognition of evidence from published or unpublished information sources from within the United States or elsewhere. The applicant stated that claims-based analyses are a well-established and routinely accepted form of evidence in health services research and policy evaluation and that CMS itself accepts pharmacy-claims-based PDC as a validated adherence metric in its own Merit-based Incentive Payment System (MIPS) quality-measure program.

Regarding CMS's concerns that Cutler et al. (2025)'s adherence measures (reported at 60 and 90 days) are insufficient to evaluate differences between COBENFY™ and existing therapies and that the long-term adherence rates for COBENFY™ are uncertain due to an average follow-up of only 2.6 months, the applicant stated that the concern mischaracterizes the study's primary adherence findings, as the 60- and 90-day figures are not the study's primary adherence finding. The applicant stated that Cutler et al. (2025)'s primary adherence outcome reports a mean PDC of 0.86 over an average 92-day observation period, with 72 percent of patients meeting the PDC ≥0.8 threshold that CMS itself recognizes as the validated adherence definition for individuals with schizophrenia under the MIPS program. The applicant further stated that if CMS's concern is that PDC measurement over a relatively short window cannot capture comparator long-acting injectables dosed at 2- to 12-week intervals, that concern is misplaced since COBENFY™ is an oral therapy, and the appropriate comparator class for adherence assessment is other oral antipsychotics, for which short-window PDC measurement is the established and accepted standard, including under MIPS Measure 383. Lastly, the applicant stated that Cutler et al. (2025) represented the longest-term data available at the time of the analysis, which is typical for such a novel technology being evaluated so soon after FDA approval.

The applicant cited a new study (Rubio et al., 2026), which the applicant described as a refresh of Cutler et al. (2025) using the same Komodo Research Database extended through August 31, 2025. The applicant stated that Rubio et al. (2026) included 2,613 adults with schizophrenia who initiated COBENFY™ (an 81 percent larger sample than Cutler et al. (2025)) and followed them for a mean of 150.1 days (nearly twice the average follow-up period in Cutler et al. (2025)) with 916 patients followed for at least 180 days and Kaplan-Meier persistence estimates extending through month 6.[50] The applicant stated that the Rubio et al. (2026) study's 5-month follow-up duration (with substantial numbers of patients followed for 6 months or more) eliminates any factual basis for the agency's prior concern, and as a result, the findings in Cutler et al. (2025), as supplemented by Rubio et al. (2026), establish substantial clinical improvement under 42 CFR 412.87(b)(1)(ii)(C)(2) by showing a decreased rate of at least one subsequent therapeutic intervention. The applicant further stated that Cutler et al. (2025) found a meaningful reduction in subsequent pharmacological interventions following COBENFY™ initiation. The applicant cited results from Cutler et al. (2025) and stated that Rubio et al. (2026) replicated and extended Cutler et al.'s polypharmacy-reduction findings, confirming Cutler et al. (2025)'s directionally identical and statistically significant reductions in concomitant medication use. The applicant also cited the following results from Rubio et al. (2026): post-COBENFY™ initiation, oral antipsychotic use decreased 23 percent (rate ratio 0.77; 95 percent CI 0.74, 0.79; P<0.001), long-acting injectable antipsychotic use decreased 20 percent (rate ratio 0.80; 95 percent CI 0.76, 0.84; P<0.001), anticholinergic use decreased 15 percent (rate ratio 0.85; 95 percent CI 0.81, 0.90; P<0.001), and mood stabilizer use declined by 6 percent (rate ratio 0.94; 95 percent CI 0.90, 0.99; P=0.009).

The applicant stated that Rubio et al. (2026) reports a separate set of outcomes that independently satisfy the substantial clinical improvement criterion through a distinct regulatory pathway not previously included in its application and cited § 412.87(b)(1)(ii)(C)(3): a decreased number of future hospitalizations or physician visits. The applicant noted that Rubio et al. (2026) found that, post-COBENFY™ initiation, the rate of all-cause hospitalizations decreased 16 percent (rate ratio 0.84; 95 percent CI 0.74, 0.97; P=0.014), the rate of mental health-related hospitalizations decreased 17 percent (rate ratio 0.83; 95 percent CI 0.72, 0.96; P=0.014), the rate of schizophrenia-related hospitalizations decreased 23 percent

[49] Cutler AJ, Zhong Y, Gillard K, Appio J, Gao C, Laliberté F, Rubio JM. Real-World Use of Xanomeline-Trospium in Schizophrenia: Patient Characteristics and Antipsychotic Treatment Patterns. Poster presented at: Psych Congress; September 17–21, 2025; San Diego, CA.

[50] Rubio J.M., Zhong Y., Gillard K., Gao C., Laliberté F. Real-World Use of Xanomeline and Trospium Chloride in Schizophrenia: Patient Characteristics, Treatment Patterns, and Outcomes. Presentation at American Psychiatric Association Annual Meeting; May 16–20, 2026; San Francisco, CA.

(rate ratio 0.77; 95 percent CI 0.63, 0.93; P=0.007), and outpatient visit rates decreased 8 percent for all-cause visits (rate ratio 0.92; 95 percent CI 0.89, 0.95; P<0.001), 9 percent for mental health–related visits (rate ratio 0.91; 95 percent CI 0.87, 0.95; P<0.001), and 8 percent for schizophrenia-related visits (rate ratio 0.92; 95 percent CI 0.86, 0.97; P=0.003). The applicant stated that these hospitalization and outpatient-visit reductions translate into significant downstream cost reductions that further support a finding under 42 CFR 412.87(b)(1)(ii)(C)(6) (improved quality of life) and under the totality-of-the-information standard at 42 CFR 412.87(b)(1)(ii)(D). The applicant further cited Rubio et al. (2026) which found that compared to pre-initiation of treatment with COBENFY™, post-initiation mental health-related total medical costs declined by $2,563 per patient per year (95 percent CI −$4,588, −$537; P=0.013), and schizophrenia-related total medical costs declined by $2,140 per patient per year (95 percent CI −$3,973, −$307; P=0.022). The applicant added that Rubio et al. (2026) observed that hospitalization-specific costs declined significantly across all categories: all-cause hospitalization costs by $1,632 per patient per year (95 percent CI −$3,080, −$183; P=0.027), mental health–related hospitalization costs by $1,923 per patient per year (95 percent CI −$3,729, −$116; P=0.037), and schizophrenia-related hospitalization costs by $1,512 per patient per year (95 percent CI −$2,820, −$204; P=0.023). The applicant added that the study also found that non-COBENFY™ pharmacy costs declined by $2,188 per patient per year (95 percent CI −$3,396, −$981; P<0.001). The applicant acknowledged that the difference in all-cause total medical costs (−$1,488 per patient per year; 95 percent CI −$3,143, $167) did not reach statistical significance (P=0.078) and stated that it does not rely on that endpoint but that, taken as a whole, the broader cost picture is consistent with the hospitalization-rate findings.

With regard to CMS's concern about Horan et al. (2024) due to lack of comparison to other treatments, the applicant stated its belief that CMS misapplied the new technology add-on payment regulatory framework, which does not subordinate placebo-controlled evidence to head-to-head trials but rather, 42 CFR 412.87(b)(1)(iii) authorizes evidence from published or unpublished information sources without distinguishing between trial designs. The applicant stated that placebo-controlled randomized controlled trials remain the accepted scientific and regulatory standard for establishing efficacy. The applicant further stated that Horan et al. (2024) and Hickey et al. (2025) serve complementary roles and emphasized that Horan et al. (2024) supports a signal that COBENFY™'s negative symptoms benefit is independent of other symptom domains, while Hickey et al. (2025) provides the comparative evidence CMS identifies as missing. The applicant suggested that when the two studies are considered together, Horan et al. (2024) and Hickey et al. (2025) provide the internal validity necessary to establish clinically meaningful effects and the comparative context necessary to evaluate those effects against available treatments.

In reference to CMS's concern regarding the short duration of the 5-week trials studied in Horan et al. (2024), the applicant stated its belief that CMS's concern is inconsistent with both regulatory expectations and accepted clinical trial design in schizophrenia, as a 5-week trial duration reflects the standard, FDA-accepted design for establishing acute efficacy in schizophrenia [51] [52] [53] and the governing regulation does not impose any minimum trial-duration requirement for determining substantial clinical improvement. The applicant highlighted that Horan et al. (2024)'s negative-symptom finding is precisely the kind of preliminary signal a 5-week placebo-controlled design is well-suited to generate, and that additional studies are assessing COBENFY™'s long-term durability. The applicant stated that CMS cannot reasonably expect applications to include long-term data that do not exist at the time of submission, particularly given that the new technology add-on payment framework is designed to facilitate and support earlier adoption of novel technologies.

In reference to CMS's concern about Horan et al. (2024)'s lack of discussion on side effects, the applicant stated its belief that CMS's concern is inaccurate. The applicant noted that Horan et al. (2024) provided a within-trial analysis of pseudospecificity—the methodological concern arising in trials of acutely psychotic patients whereby apparent negative-symptom benefits may represent a secondary artifact of positive-symptom improvement rather than an independent treatment effect.[54] The applicant further highlighted that in the study's post-hoc, exploratory prominent-negative-symptoms subgroup, COBENFY™'s effect on PANSS Marder Negative Factor remained statistically significant at weeks 4 and 5 after accounting for changes in positive symptoms, depression/anxiety, disorganization, and hostility (all P<.01). The applicant suggested that while these findings are exploratory and not part of COBENFY™'s FDA-approved labeling, they speak to pseudo-specificity by suggesting that the observed negative-symptoms benefit persists even after accounting for improvements across other symptom domains.

The applicant stated that Schneider-Thoma et al. (2026) supports COBENFY™'s differentiated clinical profile relative to existing therapies and situates COBENFY™ within the broader antipsychotic evidence base to permit evaluation using a standardized cross-trial comparative framework. The applicant stated that Schneider-Thoma et al. (2026) places COBENFY™ among the more effective agents on overall symptom reduction due to its findings that COBENFY™ ranked in the top quarter of 24 antipsychotics for the primary outcome of overall symptom reduction, with a standardized mean difference (SMD) of −0.57 versus placebo (95 percent CI −0.76 to −0.37). The applicant added that the study separately identified lumateperone, brexpiprazole, iloperidone, cariprazine, and lurasidone (each an FDA-approved atypical) as reducing symptoms less than at least three other antipsychotics, while COBENFY™ was not so identified. The applicant stated that Schneider-Thoma et al. (2026)'s pairwise data connecting COBENFY™ directly to these antipsychotics are limited (the network's xanomeline-trospium evidence is anchored primarily to placebo), so the comparative ranking presents evidence of COBENFY™'s competitive efficacy among atypical antipsychotics.

The applicant further stated that regarding the analysis of positive-symptom reduction in Schneider-Thoma et al. (2026), COBENFY™ ranked fourth of 23 antipsychotics (after

[51] Horan WP, Targum SD, Claxton A, Kaul I, Yohn SE, Marder SR, Miller AC, Brannan SK. Efficacy of KarXT on negative symptoms in acute schizophrenia: A post hoc analysis of pooled data from 3 trials.

[52] Schizophr Res. 2024 Dec;274:57–65. doi: 10.1016/j.schres.2024.08.001. Epub 2024 Sep 10. PMID: 39260339.

[53] U.S. Food and Drug Administration. Drug Trials Snapshot: Cobenfy. U.S. Food and Drug Administration. *https://www.fda.gov/drugs/drug-trials-snapshots/drug-trials-snapshot-cobenfy.*

[54] *See* Kirkpatrick B, Fenton WS, Carpenter WT Jr, Marder SR. The NIMH–MATRICS consensus statement on negative symptoms. Schizophr Bull. 2006 Apr;32(2):214–9. doi: 10.1093/schbul/sbj053. Epub 2006 Feb 15. PMID: 16481659; PMCID: PMC2632223.

clozapine, amisulpride, and risperidone) by surface under the cumulative ranking curve, with a SMD of −0.59 versus placebo (95 percent CI −0.78 to −0.40). The applicant suggested that this ranking reflects COBENFY™'s placebo-anchored efficacy combined with the network position of comparator drugs, rather than by direct pairwise comparisons. The applicant also highlighted that COBENFY™ met the study's clinical meaningfulness threshold for negative symptom reduction (95 percent CI excluding very small effects) with an SMD of −0.33 versus placebo (95 percent CI −0.51 to −0.16). The applicant stated its belief that this independent, peer-reviewed finding helps contextualize CMS's concern that Horan et al. (2024)'s negative-symptoms data was placebo-only and post hoc. The applicant added that Schneider-Thoma et al. (2026) only included studies with appropriate randomization confirmed by author contact and placed COBENFY™'s placebo-anchored performance on negative-symptom measures within the broader antipsychotic field. The applicant added that this finding is based on placebo-anchored SMDs within the network rather than direct head-to-head comparisons in a negative-symptom-predominant population and that COBENFY™'s FDA-approved labeling does not include a specific negative-symptom indication.

The applicant suggested that COBENFY™'s weight-gain profile alone is sufficient to meet the substantial clinical improvement criterion under 412.87(b)(1)(ii)(C)(1). The applicant again highlighted that in the study, COBENFY™ ranked first of 23 antipsychotics (MD −0.37 kg vs. placebo; 95 percent CI −1.27 to 0.53), with a point estimate in the direction of weight loss relative to baseline, although the 95 percent CI compared to placebo crosses zero. The applicant stated its belief that the pairwise network findings are more directly responsive to the substantial clinical improvement inquiry as COBENFY™ demonstrated statistically meaningful superiority on weight gain over 11 of 22 comparator antipsychotics (95 percent CIs excluding very small effects), the highest such count of any antipsychotic in the network. The applicant further suggested that these findings independently confirm and substantially extend Hickey et al. (2025)'s weight-gain findings.

The applicant also stated that Schneider-Thoma et al. (2026) reported favorable findings for COBENFY™ on two other well-documented harms of dopamine-blocking antipsychotics. The applicant explained that the study found COBENFY™ demonstrated a statistically meaningful prolactin profile superior to five antipsychotics (MD 0.20 ng/ml vs. placebo; 95 percent CI −12.19 to 12.59). Additionally, the applicant stated that while Schneider-Thoma et al. (2026)'s antiparkinsonian-drug-use data for COBENFY™ are limited (one trial reporting the outcome, odds ratio 0.33 vs. placebo with a wide 95 percent CI of 0.01 to 8.90), it believed that this limitation reflects that extrapyramidal symptoms were rare in the EMERGENT program rather than evidence of concern.

Furthermore, the applicant stated that Schneider-Thoma et al. (2026) reported expected tradeoffs that do not negate or otherwise undermine a substantial clinical improvement determination. The applicant added that the study identified that COBENFY™ had higher cholinergic adverse-event rates than most other antipsychotics (inferior to 16 of 22 antipsychotics by the article's S|I metric requiring 95 percent CIs to exclude very small effects), a more limited anticholinergic burden (inferior to 3 of 24), and the highest all-cause discontinuation rate in the network (inferior to 10 of 24 comparators). Additionally, the applicant highlighted that the study authors stated only one COBENFY™ participant discontinued for inefficacy across the EMERGENT trials; instead, the primary reason was withdrawn consent, which the applicant stated is a common phenomenon in schizophrenia clinical trials and is not indicative of treatment failure.[55]

The applicant stated its belief that the substantial clinical improvement standard does not require a technology to be without trade-offs as 42 CFR 412.87(b)(1)(ii)(C)(1) expressly provides that a reduction in at least one clinically significant adverse event is sufficient to support a determination of substantial clinical improvement. The applicant suggested that COBENFY™'s first-place weight-gain ranking in Schneider-Thoma et al. (2026) independently satisfies this standard as it demonstrates statistically meaningful superiority versus 11 antipsychotics and directly addresses one of the most well-documented metabolic harms of dopamine-blocking antipsychotics. The applicant stated that the clinical significance of antipsychotic-induced weight gain (AIWG) and the corresponding downstream effects are well-established. The applicant cited Rotella et al. (2020), a meta-analysis of 92 randomized controlled trials, which confirmed that antipsychotics are associated with significant weight gain and carry a demonstrated link to serious adverse cardiometabolic outcomes, including increased risk of type 2 diabetes, among a patient population that bears a higher prevalence of cardiovascular mortality.[56] The applicant added that Rotella et al. (2020) found that cardiovascular disease is the most frequent cause of death in patients with schizophrenia, with cardiovascular mortality at least five-fold greater than mortality from suicide. The applicant also stated that in addition to these immediate health concerns, AIWG poses a major risk to patient adherence and treatment discontinuation. The applicant cited De et al. (2025), a systematic review and meta-analysis which found that overweight or obese patients who reported weight gain in relation to antipsychotic use had more than twice the odds of nonadherence than normal weight individuals (OR 2.37; 95 percent CI 1.51–3.73; p = 0.0002).[57] The applicant added that De et al. (2025) also found that olanzapine was associated with 3.32 times increased likelihood of nonadherence or discontinuation compared to antipsychotics that impact weight gain to a lesser degree (95 percent CI 2.32–4.74; p <0.00001).

In summary, the applicant stated its belief that CMS's analysis departs from its own regulation in several respects, contrary to settled law requiring agencies to adhere to their own rules, and these departures result in a framework that differs materially from the one that CMS must apply as set forth in regulation. The applicant further stated that such departures are internally inconsistent with the agency's own regulations and the intent of the new technology add-on payment program to create meaningful access to new and innovative therapies. Additionally, the applicant suggested that these departures are not only technical but will have profound

[55] Schoemaker JH, Vingerhoets AJJM, Emsley RA. Factors associated with poor satisfaction with treatment and trial discontinuation in chronic schizophrenia. CNS Spectrums. 2019;24(4):380–389. doi:10.1017/S109285291700044X.

[56] Rotella, F., Cassioli, E., Calderani, E., Lazzeretti, L., Ragghianti, B., Ricca, V., & Mannucci, E. (2020). Long-term metabolic and cardiovascular effects of antipsychotic drugs. A meta-analysis of randomized controlled trials. European Neuropsychopharmacology. *https://doi.org/10.1016/j.euroneuro.2019.12.118.*

[57] De, R., Emily, Janani Navagnanavel, Au, E., Kateryna Maksyutynska, Papoulias, M., Singh, R., Panganiban, K. J., Humber, B., Grimur Høgnason Mohr, Mette Ødegaard Nielsen, Ebdrup, B. H., Remington, G., Sri Mahavir Agarwal, & Hahn, M. K. (2024). The impact of weight gain on antipsychotic nonadherence or discontinuation: A systematic review and meta-analysis. *Acta Psychiatrica Scandinavica. https://doi.org/10.1111/acps.13758.*

implications on the new technology add-on payment program's governing framework and agency action as a whole. The applicant stated its opinion that CMS's preliminary determination, if finalized, would constitute arbitrary and capricious agency action under the Administrative Procedure Act, defined as when an agency entirely fails to consider an important aspect of the problem or offers an explanation for its decision that runs counter to the evidence before it. The applicant asserted that CMS does both: the FY 2027 IPPS/LTCH PPS proposed rule isolates individual studies—Cutler et al. (2025)'s claims-based design, Hickey et al. (2025)'s discontinuation odds ratio, and Horan et al. (2024)'s placebo-controlled comparator—and rejects each in turn, without evaluating the integrated evidentiary record that the regulation expressly requires it to assess under the totality of the circumstances. The applicant stated that the regulation requires CMS's review under this standard and it does not permit CMS to discharge that obligation through piecemeal dismissal of individual evidence, and that CMS's own regulation compels approval of COBENFY™ for new technology add-on payments.

Response: We thank the applicant and commenters for their comments regarding the substantial clinical improvement criterion. Based on the additional information received and all data received to date, we continue to have concerns as to whether COBENFY™ meets the substantial clinical improvement criterion to be approved for new technology add-on payment status. Specifically, it remains unclear whether COBENFY™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments for schizophrenia in adults and whether the use of COBENFY™ significantly improves clinical outcomes over existing technologies.

The applicant asserted that CMS must evaluate substantial clinical improvement based on the totality of the circumstances and that CMS misapplied its substantial clinical improvement criterion. While we agree with the applicant that determinations of substantial clinical improvement are based on the totality of the evidence and circumstances, we disagree that we misapplied the regulations. We also note that the substantial clinical improvement criterion does not require head-to-head comparative trials and does not require a technology not to have trade-offs. CMS is not imposing evidentiary standards beyond those set forth in § 412.87. Comparative information may be demonstrated through any valid form of evidence, and our evaluation of COBENFY™ is consistent with this regulatory framework. The substantial clinical improvement criterion does not require a technology to be last-line or to only be used in certain patient populations, and CMS has not applied such a standard in assessing the evidence provided by the applicant in support of substantial clinical improvement. Under § 412.87(b)(1), demonstrating substantial clinical improvement requires sufficient evidence to establish that a new technology represents an advance that substantially improves, relative to services or technologies previously available, the treatment of Medicare beneficiaries. Consistent with § 412.87(b)(1)(iii), we consider all relevant evidence, including published and unpublished information sources such as clinical trials, peer-reviewed journal articles, study results, meta-analyses, consensus statements, white papers, and other listed sources. Because our evaluation for new technology add-on payment requires a comparison against existing technologies used for Medicare beneficiaries, for a clinical area with a larger number of relevant comparator technologies, more information may be needed to demonstrate that a technology meets our criterion. In making our determination, we evaluate the merits of each study to determine the validity of its results and consider the totality of the circumstances and evidence to determine whether a technology represents a substantial clinical improvement over existing technologies consistent with § 412.87(b)(1)(i) and (ii)(D). In the FY 2027 IPPS/LTCH PPS proposed rule, we did not dismiss the individual evidence provided by the applicant, but rather discussed our concerns with respect to the evidence in the context of the substantial clinical improvement criterion. The public comment period allows the applicant and other commenters to respond to these concerns. After consideration of the totality of the circumstances and evidence submitted, including the public comments we received, we do not believe the evidence provided demonstrates that COBENFY™ substantially improves the treatment of Medicare beneficiaries relative to currently available treatments.

The applicant and commenters asserted that COBENFY™ offers a treatment option for schizophrenia patients with extensive prior antipsychotic use and may be able to help patients who do not respond to or are intolerant of other therapies. We agree with the applicant that § 412.87(b)(1)(ii)(A) does not require a technology to be used only as a last-line therapy after failure of all existing treatments, including clozapine. However, we disagree that COBENFY™ meets the regulatory criterion because we did not receive evidence demonstrating that it provides a treatment option for a defined patient population that is unresponsive to or ineligible for currently available therapies. CMS's application of this standard is consistent with the regulation and with past practice. The assertions by the applicant and commenters were based on COBENFY™'s mechanism of action and associated lack of FDA class-wide boxed warnings for its approved indication or other side effects in the prescribing information. We note that warnings or potential side effects alone do not indicate a patient population that is unresponsive to, or ineligible for other antipsychotics, as side effect profiles among antipsychotics vary by agent such that a patient with a given side effect may be successful on a different antipsychotic with a lower risk of the side effect. In addition, rare and long-term side effects may not yet appear in 5-week clinical trials; thus, the lack of inclusion in prescribing from short-term trials does not mean COBENFY™ cannot cause these side effects. We also did not receive evidence that indicated that other antipsychotics cannot manage negative symptoms of schizophrenia. As such, we remain unclear whether COBENFY™ is the only treatment option available for patients unresponsive or intolerant to treatment with antipsychotics or for those with negative symptoms. Rather, it appears COBENFY™ is an alternative treatment option with a different mechanism of action available to patients in addition to these existing treatment options.

We note that the evidence for increased adherence and persistence, as well as decreased healthcare resource utilization and healthcare costs in Cutler et al. (2025) and Rubio et al. (2026) was inconclusive about COBENFY™'s effect. Specifically, we did not receive a comparison of adherence and persistence to other antipsychotics nor did we receive data indicating that COBENFY™ was effective for these patients in Cutler et al. (2025) or Rubio et al. (2026). While the applicant stated that long-acting injectables are not an appropriate comparator to COBENFY™ since it is an oral therapy, we disagree because

both injectable and oral antipsychotics are indicated for the treatment of schizophrenia in adults and thus, should be considered as comparators to COBENFY™. In addition, we note the healthcare resource utilization and costs data, including a reduction in hospitalizations and physician visits, compared 3.8 months leading up to dispensing COBENFY™ to an average of 3.8 months of on-treatment follow-up. This does not compare an equivalent period of time, but rather compares the last 3.8 months of prior therapy to the first 3.8 months of COBENFY™. This is a short duration to assess for future hospitalizations and office visits. In addition, we are concerned that adherence was a confounding factor since adherence tends to decrease over time, as exhibited in Cutler et al. (2025) and Rubio et al. (2026), and thus, the change in healthcare resources could be related to a decrease in adherence over time, rather than to a change in therapy to COBENFY™. In addition, regarding the claim that COBENFY™ decreases the rate of at least one subsequent therapeutic intervention by reducing subsequent pharmacological interventions, we question whether this is due to improved outcomes with COBENFY™. For instance, when starting COBENFY™ or a different antipsychotic, it is reasonable for a patient to stop their prior therapy for schizophrenia, and a patient may reduce use of anticholinergic drugs when starting COBENFY™, since it has anticholinergic side effects.

With regard to the assertion that COBENFY™ improves clinical outcomes relative to previously available therapies, we have concerns as to whether the comparative data received in Hickey et al. (2025) and Schneider-Thoma et al. (2026) demonstrate improved clinical outcomes for COBENFY™. As previously stated in Hickey et al. (2025), COBENFY™ was not favored compared to numerous drugs in PANSS and CGI–S, and COBENFY™ was not favored compared to numerous drugs with regard to sedation. We also note that Hickey et al. (2025) did not include typical antipsychotics, and while atypicals are the usual first-line agents, typical antipsychotics are options for patients who either don't respond adequately to atypicals or tolerate them poorly. In addition, while the seven percent weight gain outcome favored COBENFY™, another outcome comparing weight, the change from baseline weight, did not favor COBENFY™ compared to numerous drugs. We also note that this analysis did not include other available options that tend to cause less weight gain, such as ziprasidone and lurasidone, and the included trials were 4 to 6 weeks, which are short durations for the assessment of weight changes. Therefore, we do not believe the evidence from Hickey et al. (2025) demonstrates a reduction in a clinically significant adverse event that would meet the criterion at § 412.87(b)(1)(ii)(C)(1). While the applicant provided an explanation for the discontinuation findings in Hickey et al. (2025), the comparative data for discontinuation rates did not favor COBENFY™ in Hickey et al. (2025) or in Schneider-Thoma et al. (2026), and we continue to question whether COBENFY™ improves adherence relative to other therapies. Additionally, the article states that comparisons with other antipsychotics are needed to confirm the ranking of COBENFY™ due to the inclusion of only placebo-controlled trials for COBENFY™. However, even when looking at the results in Schneider-Thoma et al. (2026), numerous drugs ranked higher than COBENFY™ for treating overall symptoms, positive symptoms, and negative symptoms, in addition to many having lower odds for discontinuation, cholinergic events, anticholinergic events, sedation, use of antiparkinsonian drugs, change in prolactin, and change in QTc. With regard to a change in weight, while the applicant highlighted COBENFY™ was superior to 11 antipsychotics, ziprasidone had similar results, with the mean differences overlapping between COBENFY™ and ziprasidone (–0.37 [95% CI –1.27 to 0.53] and –0.12 [95% CI –0.53 to 0.29], respectively), so we question if COBENFY™ offers a clinically meaningful improvement over ziprasidone for this outcome. We also question if weight gain could occur for COBENFY™ after the 5-week trials included in Schneider-Thoma et al. (2026), as weight gain may be a side effect that may not yet appear in 5 weeks' time. While commenters noted that having another treatment option with COBENFY™ could reduce hospitalization and morbidity, as well as improve quality of life, data were not provided to demonstrate this.

After consideration of all the information received from the applicant as well as the public comments we received, we are unable to determine that COBENFY™ represents a substantial clinical improvement over existing technologies for the reasons discussed in the proposed rule and in this final rule, and therefore, we are not approving new technology add-on payments for COBENFY™ for FY 2027.

b. Command Center Electronic Glycemic Management System

Glytec, LLC submitted a FY 2027 application for new technology add-on payments for Command Center Electronic Glycemic Management System (Command Center). According to the applicant, Command Center is an electronic medical record (EMR)-integrated cloud-based software designed to maintain blood glucose in hospitalized patients by recommending personalized insulin dosing. According to the applicant, the technology utilizes inputs collected from EMRs to direct ongoing insulin dosage management and daily monitoring related glycemic variables (such as labs and diet) during an inpatient stay until insulin is discontinued or the patient is sent home. Per the applicant, direct per-patient charge for the use of Command Center follows a subscription model.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for Command Center and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251005YD7PG.*

		Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS code(s)		Request submitted.	N/A.
Newness Criterion	**Newness Period**	510(k) clearance for Glytec Glucommander on August 4, 2017, to evaluate current as well as cumulative patient blood glucose values coupled with patient information including age, weight, and height, and, based on the aggregate of these measurement parameters, whether one or many, recommend an IV dosage of insulin, glucose or saline or a subcutaneous basal and bolus insulin dosing recommendation to adjust and maintain the blood glucose level towards a configurable physician-determined target range. It is indicated for use in adults and pediatric (ages 2 to 17 years) patients.	Newness date: August 4, 2017. See following discussion.
	Substantial Similarity	Uses a new mechanism of action. Treats a new disease or patient population.	See following discussion.
Cost Criterion		845 claims mapping to 4 MS-DRGs, with 40.12 percent of claims mapping to MS-DRG 640 (Miscellaneous Disorders of Nutrition, Metabolism, Fluids, and Electrolytes with MCC). The final inflated average case-weighted standardized charge per case was not provided.	See following discussion.
Substantial Clinical Improvement Criterion		Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments. Assertion #2: The technology offers the ability to diagnose a medical condition in a patient population where that condition is currently undetectable or earlier than allowed by currently available methods, and that use of the technology to make a diagnosis affects the management of the patient. Assertion #3: The technology significantly improves clinical outcomes relative to services or technologies previously available. Provided 1 published study assessing the technology, 3 published and 5 unpublished studies assessing precursor technologies, and other information.	See following discussion.

Newness Criterion

We stated in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19413) that, regarding the newness date, the applicant provided an FDA 510(k) clearance letter for Glytec Glucommander (K152300), dated August 4, 2017, to support its new technology add-on payment application for Command Center. Per the 510(k) summary, the predicate device for Glytec Glucommander is Glucommander™ System (K113853).[58] Per the applicant, Command Center was available for sale immediately after FDA marketing authorization. Therefore, we stated the newness period for Command Center commenced on the date of FDA clearance, August 4, 2017, or earlier, as discussed further in this section. Because the 3-year anniversary date of the entry of Command Center onto the U.S. market (August 4, 2020, or earlier) occurred prior to FY 2027, we stated in the proposed rule that we did not believe that the device is eligible for new technology add on payments for FY 2027. Consistent with the statute and our implementing regulations, we stated a technology is no longer considered ''new'' once it is more than 2 to 3 years old, irrespective of how frequently the medical service or technology has been used in the Medicare population (70 FR 47349). Accordingly, we proposed to disapprove Command Center for new technology add on payments for FY 2027.

In addition, regarding substantial similarity, we questioned whether Command Center has the same or similar mechanism of action as existing technologies that manage glycemic dosing. The applicant stated that Command Center differs from other insulin management methods because it is an intelligent, algorithm-based analytic technology that uses multiple administrative, technical, and clinical inputs to develop an optimized insulin and glycemic management system to control glucose metabolism while minimizing hyper- and hypoglycemic episodes. Per the applicant, glycemic management is typically performed by nurses and doctors using a paper and pencil sliding scale algorithm to estimate the amount of insulin needed based on blood glucose values. According to the applicant, while other digital glycemic management systems can be built into EMR tables or in stand-alone systems, none are as sophisticated or as well-documented as Command Center. However, we noted there are several existing software-based, EMR-integrated glycemic management systems. For example, we stated that the 2012 Glucommander™ System,[59] the GlucoStabilizer Insulin Dosing Calculator 3.0,[60] the EndoTool™ Drug

[58] FDA, May 8, 2012, Glucommander™ System (*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K113853,* accessed 2/9/2026).

[59] FDA, May 8, 2012, K113853 Glytec LLC Glucommander™ System (*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K113853,* accessed 1/2/2026).

[60] FDA, September 15, 2014, K141321, Glucostabilizer Insulin Dosing Calculator (*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K141321,* accessed 1/2/2026).

Dose Calculator,[61] and the EndoTool SubQ™ [62] are all FDA-cleared glycemic management tools that monitor patient blood glucose and generate personalized insulin dosing recommendations. Therefore, we disagreed with the applicant that Command Center uses a different mechanism of action compared to existing technologies to achieve a therapeutic outcome. Additionally, we stated we disagreed with the applicant that the use of Command Center involves the treatment of a different type of disease or patient population compared to existing technology. The applicant stated that Command Center will better address glycemic management needs in patients where higher degrees of blood glucose control accuracy are required, including post-coronary artery bypass graft (CABG) surgery patients, patients with diabetic ketoacidosis or hyperosmolar coma, stroke patients, pregnant patients, or children, and can be used in populations where advanced endocrinology expertise is not readily available. However, as we noted in the proposed rule, several technologies are currently available for insulin and glycemic management for the same or similar type of disease and patient populations. Furthermore, we noted per the FDA 510(k) summary for K152300, the indications for use for this device are the same as those for its predicate device (K113853). We stated we agreed with the applicant that Command Center maps to the same MS–DRG as existing technologies. As a result, we stated we believed that Command Center is substantially similar to existing technologies because it uses the same or similar mechanism of action, maps to the same MS–DRG, and involves the treatment of the same or similar type of disease and patient population when compared to existing technologies, including its predicate device (K113853). We noted that, per our policy, if technologies are substantially similar to each other, we use the earliest market availability date as the beginning of the newness period for the technologies. Accordingly, we stated that if we determined that Command Center is substantially similar to existing glycemic management systems as described previously, because they were all FDA-cleared prior to Command Center, the newness period for Command Center would have commenced even earlier than its FDA clearance date in 2017. We invited public comments on our proposal to disapprove new technology add-on payments for Command Center, including whether the technology is substantially similar to existing technologies and whether it meets the newness criterion.

Comment: The applicant submitted a public comment in support of Command Center regarding the newness criterion. The applicant asserted that CMS's proposed denial turns largely on the newness criterion under 42 CFR 412.87(b)(2), which ties newness to when billing data begins to reflect inpatient hospital codes, per section 1886(d)(5)(K)(iii) of the Act. The applicant stated that no such data exists for its product, not because the technology is old, but because it has never had a code to generate such data. The applicant further stated this is precisely the situation the framework was designed to address, where technologies, like this one, are innovative enough to matter clinically but too new to have generated the billing history CMS typically relies on. The applicant added that its technology is a clear example that the absence of prior billing data is not evidence that the product is not new; rather, it is evidence that it is new.

The applicant also stated that the technology implementation for its product is currently indirect via hospital software licensing, and reimbursement is uncovered. The applicant added that no systematically available patient billing data exists to enable the calculation of newness according to prior rulemaking in FY 2005 and FY 2022. Additionally, the applicant stated that section 1886(d)(5)(K)(iii) of the Act defines inpatient hospital code as including ICD codes and subsequent revisions, and hospital claims reflecting a new ICD–10–PCS code will not become available until after the code is implemented, which is in 2026 for this technology. The applicant asserted that per CMS, the 2 to 3 year newness period generally begins when a technology becomes available on the market for sale. The applicant stated that in the case of complex software, it takes several years before a technology can integrate commercially into standing electronic medical record systems, such as EPIC and Cerner. The applicant stated that its product first appeared in EPIC in 2024.

The applicant also asserted that its product today is not the device FDA cleared in 2017. According to the applicant, the 2017 510(k) covered Glytec Glucommander as a dosing calculator, while Command Center as it exists today has capabilities that did not exist in 2017, including predictive analytics, system-wide benchmarking, surveillance, and workflow management. Per the applicant, Glucommander's predictive analytics, system-wide Glucosurveillance, and EMR-native workflow integration represent capabilities that do not exist in legacy glycemic management tools, and that lumping them together as equivalent would mischaracterize both the technology and the clinical problem it solves. Per the applicant, the 510(k) was the regulatory vehicle, not the product definition.

The applicant noted that FDA recently issued a new 510(k) clearance (K254102) [63] for this technology, and stated that this is not a minor update, as a new FDA clearance reflects a determination by FDA that the current product is sufficiently distinct to warrant independent review and authorization. The applicant argued that if FDA treats this as a new device, CMS should as well, and urged CMS to weigh this clearance as direct, concurrent federal agency evidence that its product's current platform meets the newness standard under 42 CFR 412.87(b)(2). The applicant encouraged CMS to reconsider its proposed denial of new technology add-on payment status for Command Center and reiterated its belief that it meets the newness criterion. The applicant added that new technology add-on payment approval rates hovering around 30 to 41 percent per cycle suggest the current framework may be filtering out the very technologies it was designed to support. The applicant concluded that its product is a clear example of how the absence of prior billing data is evidence that the product is new and that approval of Command Center would reflect both the letter and the spirit of the new technology add-on payment program.

Response: We appreciate the additional information from the applicant with respect to whether Command Center meets the newness criterion. However, we disagree with the applicant that Command Center meets the newness criterion and believe it is substantially similar to existing glycemic management systems.

We disagree with the applicant's assertion that Command Center is new because it historically lacked a specific

[61] FDA, June 14, 2006, K053137 EndoTool™ Drug Dose Calculator (*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K053137,* accessed 1/2/2026).

[62] FDA, April 24, 2015, K142918 EndoTool SubQ™ (*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K142918,* accessed 1/2/2026).

[63] FDA, Glucommander, K254102, 5/27/2026 (*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K254102,* accessed 6/18/2026).

code through which billing data could be collected and that the newness period begins only upon assignment of a new ICD–10–PCS code. As we explained in the FY 2005 and FY 2022 IPPS final rules (69 FR 49002 through 49003 and 86 FR 45151, respectively), using the date on which a specific code is assigned to a technology is not an appropriate test of newness as we noted, in many instances, a technology may have been in use for several years, or even several decades, prior to the assignment of a new code. As stated previously, consistent with the statute and our implementing regulations, a technology is no longer considered new once it is more than 2 to 3 years old, irrespective of how frequently the medical service or technology has been used in the Medicare population (70 FR 47349). We further note that the applicant has not provided documentation regarding a delay in commercial availability. While the applicant asserted that its product's integration into EPIC occurred in 2024, this does not mean that the technology was not available for sale prior to that date. We further note that the applicant indicated in its application that the technology was available for sale immediately following FDA market authorization in 2017. As such, in this case, because Command Center has been available on the U.S. market for more than 2 to 3 years, we consider the costs to have been included in the MS–DRG relative weights.

With regard to the applicant's statement that the device is different than that under the 2017 FDA 510(k) clearance, we disagree that these changes affect the newness date. According to the applicant, Command Center is a cloud-based, EMR-integrated clinical decision support platform with capabilities that did not exist in 2017. According to the applicant's website,[64] Command Center is a non-device clinical data visualization and analytics platform that displays current and historical glycemic data, supports quality improvement, and enables performance benchmarking. This website also noted that Command Center does not provide patient-specific treatment recommendations, generate alerts requiring immediate clinical action, or automate clinical decisions. Per the website, Glucommander® is a device that provides patient-specific dosing recommendations at the point of care. However, we note that Medicare IPPS payments are made for inpatient hospital services furnished to individual beneficiaries and are based on the costs associated with patient discharges. Consistent with this framework, the new technology add-on payment provisions rely on claims- and patient-level utilization data involving the technology to determine whether the costs of the new technology are adequately reflected in the MS–DRG payment system. We note that because the Command Center clinical data visualization and analytics platform is not a medical device and is not developed for patient-specific clinical treatment delivery, its costs cannot be attributed to inpatient services in the manner contemplated under the new technology add-on payment statutory and regulatory framework.

We also disagree that Command Center uses a different mechanism of action than other legacy glycemic management tools, including its predicate versions. While the applicant stated that its technology includes predictive analytics, system-wide Glucosurveillance, and EMR-native workflow integration, we do not consider workflow tools or integration to be related to a technology's mechanism of action, as they do not change the therapeutic effect of monitoring blood glucose and recommending insulin doses for patients. Therefore, we are unable to determine that Command Center has a new mechanism of action.

Furthermore, the recent 2026 FDA 510(k) clearance for Glucommander is not eligible for consideration for new technology add-on payment for FY 2027 under § 412.87(e)(2) and § 412.87(f)(2) because documentation of FDA acceptance or filing of the marketing authorization request that indicates that FDA has determined that the application is sufficiently complete to allow for substantive review by FDA, was not provided to CMS at the time of new technology add-on payment application submission, and because CMS only considers, for add-on payments for a particular fiscal year, an application for which the new medical service or technology has received FDA marketing authorization by May 1 prior to the particular fiscal year. In addition, we note that the FDA 510(k) summaries for the 2012, 2017, and 2026 510(k)s all share the same intended use and indications for use. The 2026 FDA 510(k) clearance for Glucommander describes modifications to the 2017 predicate version as updating cybersecurity controls and the addition of a predetermined change-control plan for dose calculation updates, expanding alert contents, enhancing record keeping, modernizing the user interface, and adding another data input source. However, we note that none of these updates describe a difference in the way the technology works for the purposes of mechanism of action under our substantial similarity criteria.

After review of the comments and the information provided to date, we continue to disagree that Command Center uses a new mechanism of action and involves the treatment of a different type of disease or patient population compared to existing glycemic management systems. As we discussed in the proposed rule, we agree with the applicant that Command Center maps to the same MS–DRGs as existing technologies. In addition, we continue to disagree with the applicant's assertion that Command Center provides a treatment option to patients who are ineligible for or do not respond to treatments delivered by existing glycemic management software-support systems. Accordingly, we have determined that Command Center meets all three of the substantial similarity criteria. Therefore, we believe Command Center is substantially similar to existing software-based EMR-integrated glycemic management systems, including the 2012 Glucommander™ System. As noted in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19414), we consider the beginning of the newness period for Command Center to commence on the FDA clearance date for the previously described existing glycemic management systems, which commenced even earlier than Glucommander's FDA clearance date in 2017. Since these technologies have been on the U.S. market for longer than 3 years, and Command Center is substantially similar to these technologies, the 3-year anniversary date of Command Center's entry onto the market occurred prior to FY 2027. Therefore, Command Center does not meet the newness criterion and is not eligible for new technology add-on payments for FY 2027.

We note that we received public comments with regard to the cost and substantial clinical improvement criteria for this technology, but because we have determined that the technology does not meet the newness criterion and therefore is not eligible for approval for new technology add-on payments for FY 2027, we are not summarizing comments received or making a determination on those criteria in this final rule.

[64] Glytec® FAQs. What is the difference between Glucommander® and Command Center? (*https://glytec.com/faqs/#:~:text=What%20is%20the%20difference%20between%20Glucommander%C2%AE%20and%20Command%20Center%3F,* accessed 6/25/2026).

c. GAMIFANT® (emapalumab-lzsg)

Sobi, Inc. submitted an FY 2027 application for new technology add-on payments for GAMIFANT®. According to the applicant, GAMIFANT® is an interferon gamma (IFNγ)-blocking antibody that targets and neutralizes IFNγ to stop the hyperinflammatory feedback loop of macrophage activation syndrome (MAS). Per the applicant, GAMIFANT® is an intravenous infusion consisting of a 6 mg/kg loading dose or a 3 mg/kg treatment dose administered over 1 hour. The applicant stated that in the GAMIFANT® studies, adults received 10 infusions (1 loading dose of 6 mg/kg and 9 treatment doses of 3 mg/kg) over a median 29 days in the inpatient setting. We noted in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19415) that the applicant is seeking new technology add-on payments for GAMIFANT® for its indication for the treatment of adult and pediatric (newborn and older) patients with hemophagocytic lymphohistiocytosis (HLH)/MAS in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.[65]

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for GAMIFANT® and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP250926GGG85.*

		Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS code(s)		XW033MA and XW043MA	No concerns.
Newness Criterion	**Newness Period**	sBLA on June 27, 2025, for the treatment of adult and pediatric (newborn and older) patients with HLH/ MAS in known or suspected Still's disease, including systemic sJIA, with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.	Newness date: June 27, 2025.
	Substantial Similarity	Uses a new mechanism of action. Maps to a new MS-DRG. Treats a new disease and/or a new patient population.	Not substantially similar to existing treatments.
Cost Criterion		Scenario 1: 143 claims mapping to 13 MS-DRGs, with none exceeding more than 8% of the total identified claims. Scenario 2: 22 claims mapping to 2 MS-DRGs, with 50% of claims mapping to each MS-DRG 516 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with CC) and MS-DRG 545 (Connective Tissue Disorders with MCC). Scenario 3: 308 claims mapping to 22 MS-DRGs, with none exceeding more than 4% of the total identified claims per year. Scenario 4: 66 claims mapping to 4 MS-DRGs, with none exceeding more than 17% of the total identified claims per year. Final inflated average case-weighted standardized charge per case (Scenario 1 – $5,979,504; Scenario 2 – $5,956,537; Scenario 3 - $5,984,804; Scenario 4 - $5,956,716) exceeded the average case-weighted threshold amount (Scenario 1 – $111,457; Scenario 2 – $87,773; Scenario 3 – $104,117; Scenario 4 – $93,390).	Meets cost criterion.
Substantial Clinical Improvement Criterion		Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments. Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available. Provided 1 published study and 6 unpublished references assessing the technology, 2 practice guidelines, and other information.	See following discussion.

ICD–10 Coding

In the proposed rule, after review of the information provided by the applicant, we stated we believed the relevant ICD–10–CM diagnosis codes to identify the indication of the treatment of adult and pediatric (newborn and older) patients with HLH/MAS in known or suspected Still's disease, including sJIA, with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS are:

[65] In 2018, FDA granted GAMIFANT® approval under a BLA application for the treatment of adult and pediatric (newborn and older) patients with primary HLH with refractory, recurrent, or progressive disease or intolerance with conventional therapy.

ICD–10–CM code	Description
M06.10	Adult-onset Still's disease
M08.211	Juvenile rheumatoid arthritis with systemic onset, right shoulder
M08.212	Juvenile rheumatoid arthritis with systemic onset, left shoulder
M08.221	Juvenile rheumatoid arthritis with systemic onset, right elbow
M08.222	Juvenile rheumatoid arthritis with systemic onset, left elbow
M08.231	Juvenile rheumatoid arthritis with systemic onset, right wrist
M08.232	Juvenile rheumatoid arthritis with systemic onset, left wrist
M08.241	Juvenile rheumatoid arthritis with systemic onset, right hand
M08.242	Juvenile rheumatoid arthritis with systemic onset, left hand
M08.251	Juvenile rheumatoid arthritis with systemic onset, right hip
M08.252	Juvenile rheumatoid arthritis with systemic onset, left hip
M08.261	Juvenile rheumatoid arthritis with systemic onset, right knee
M08.262	Juvenile rheumatoid arthritis with systemic onset, left knee
M08.271	Juvenile rheumatoid arthritis with systemic onset, right ankle and foot
M08.272	Juvenile rheumatoid arthritis with systemic onset, left ankle and foot
M08.28	Juvenile rheumatoid arthritis with systemic onset, vertebrae
M08.29	Juvenile rheumatoid arthritis with systemic onset, multiple sites
M08.2A	Juvenile rheumatoid arthritis with systemic onset, other specified site

We invited public comments on the use of these ICD–10–CM diagnosis codes to identify this indication for purposes of the new technology add-on payment, if approved.

We did not receive any comments on the relevant ICD–10–CM diagnosis codes to identify the indication of adult and pediatric (newborn and older) patients with HLH/MAS in known or suspected Still's disease, including sJIA, with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS. As previously discussed, based on the information submitted by the applicant as part of its new technology add-on payment application, we believe the list of ICD–10–CM diagnosis codes in the previous table identify this indication for purposes of the new technology add-on payment.

Newness Criterion

In the proposed rule, regarding substantial similarity, we stated that based on the information available at the time of the proposed rule, we agreed with the applicant that GAMIFANT® has a new mechanism of action and treats a new type of disease or patient population compared to existing technology, because it is the only FDA-approved treatment for HLH/MAS in known or suspected Still's disease. We noted that the applicant did not provide an explanation for why GAMIFANT® would not map to the same MS–DRGs as other therapies for HLH/MAS in Still's disease. Therefore, based on information available at the time of the proposed rule, we stated our belief that GAMIFANT® is not substantially similar to existing technology and meets the newness criterion. We stated we consider the beginning of the newness period to commence on June 27, 2025, the date on which GAMIFANT® received FDA market authorization for this indication.

We invited public comments on whether GAMIFANT® is substantially similar to existing technologies and whether GAMIFANT® meets the newness criterion.

Comment: The applicant reiterated that GAMIFANT® meets the newness criterion and stated that the technology is not the same or substantially similar to any therapies that are currently used in the treatment of HLH/MAS in Still's disease, nor to any included in the 2024 100% Medicare Provider Analysis and Review (MedPAR) Limited Data Set. The applicant stated that it agrees with CMS's assessment that GAMIFANT® has a new mechanism of action and treats a new type of disease or patient population compared to existing technology, because it is the only FDA-approved treatment for HLH/MAS in known or suspected Still's disease. The applicant concurred with CMS that the beginning of the newness period should commence on June 27, 2025, the date on which GAMIFANT® received FDA marketing authorization for this indication.

Response: We thank the applicant for its comment. Based on our review of the comment received and information submitted by the applicant as part of its FY 2027 new technology add-on payment application for GAMIFANT®, we agree that GAMIFANT® has a new mechanism of action and treats a new type of disease or patient population compared to existing technology, because it is the only FDA-approved treatment for HLH/MAS in known or suspected Still's disease. Therefore, we agree that GAMIFANT® is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence on June 27, 2025, the date on which GAMIFANT® received FDA marketing authorization for the treatment of adult and pediatric patients with HLH/MAS in known or suspected Still's disease, including systemic sJIA, with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.

Cost Criterion

In the proposed rule, regarding the cost criterion, we stated we agreed with the applicant that the technology meets the cost criterion. We invited public comments on whether GAMIFANT® meets the cost criterion.

Comment: The applicant agreed with CMS's assessment that GAMIFANT® meets the cost criterion.

Response: We thank the applicant for its comment. We agree with the applicant that the technology meets the cost criterion.

Substantial Clinical Improvement Criterion

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19417), after review of the information provided by the applicant, we stated we had the following concerns regarding whether GAMIFANT® meets the substantial clinical improvement criterion. The applicant asserted GAMIFANT® offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments since GAMIFANT® is the first and only FDA-approved treatment for HLH/MAS in known or suspected Still's disease with an inadequate

response or intolerance to glucocorticoids, or with recurrent MAS. However, we questioned whether GAMIFANT® offers a treatment option for patients unresponsive to, or ineligible for, currently available treatments, because several second- and third-line therapies, including cyclosporine, etoposide, anakinra, and intravenous immunoglobulin, can also treat patients with an inadequate response or intolerance to glucocorticoids or with recurrent MAS.[66] [67] [68] [69]

Furthermore, we stated we were unable to assess the applicant's assertion that GAMIFANT® significantly improves clinical outcomes relative to other available services or technologies without a comparison of outcomes to other therapies for patients with an inadequate response or intolerance to glucocorticoids or with recurrent MAS. In addition, while the applicant stated that GAMIFANT® achieves substantially improved clinical outcomes with a clear and positive benefit:risk profile in treating HLH/MAS patients who had an inadequate response to glucocorticoids and that GAMIFANT® initiation results in a clinically meaningful reduction of glucocorticoid dosing and contributes to the positive benefit:risk profile for the treatment of patients with HLH/MAS, we questioned whether having a positive benefit:risk profile is a relevant outcome under § 412.87(b)(1)(ii)(C) because it does not address how GAMIFANT® improves clinical outcomes relative to other therapies that may be used to treat HLH/MAS patients who had an inadequate response to glucocorticoids or with recurrent MAS.

We also noted that to support its assertion regarding improved clinical outcomes, the applicant provided results from two clinical studies, NI–0501–06 and NI–0501–14. We stated that all patients in the studies responded inadequately to high-dose glucocorticoids prior to study treatment, and providers would typically initiate other second- and third-line therapies in this patient population. While the applicant claimed GAMIFANT® reduces glucocorticoid dosing, we noted it is unclear whether GAMIFANT® significantly reduces glucocorticoid dosing compared to other therapies that may be used in these patients. In addition, some therapies used for MAS in Still's disease such as anakinra and cyclosporine were allowed during these studies and could have affected the outcomes, and thus, we stated we were unclear how these studies support the assertion of improved outcomes relative to other available treatments.

While the applicant claimed a positive benefit:risk profile for GAMIFANT®, we stated that the submitted clinical information does not clearly explain how it was determined whether serious adverse events were related to GAMIFANT®, nor does it provide sufficient detail on the reported serious adverse events. Specifically, we noted that while De Benedetti et al. (2023) states that there were 9 serious adverse events in NI–0501–06 and the long-term follow-up, which appear to include one cytomegalovirus reactivation, one SJIA flare, one edema of the ankle, one MAS episode, one cardiopulmonary failure, and one severe neutropenia, we noted it was unclear what the other three reactions were and which were related to GAMIFANT®. Grom et al. (2025) also stated there were 7 serious adverse events in NI–0501–14, but we noted it was unclear what these events were and which were related to GAMIFANT®.

Furthermore, we noted we would appreciate more detail on the visual analogue scale (VAS) scoring system used in the clinical trials in order to fully assess the efficacy outcome data. We also noted that the long-term clinical trials included up to 12 months of follow-up, and we questioned if this is enough time to assess for MAS recurrence.

After review of the information provided by the applicant, we stated we were unable to determine whether GAMIFANT® represents a substantial clinical improvement over existing technologies, and therefore, we proposed to disapprove new technology add-on payments for GAMIFANT® for FY 2027.

We invited public comments on whether GAMIFANT® meets the substantial clinical improvement criterion and our proposal to disapprove FY 2027 new technology add-on payments for GAMIFANT®.

Comment: A few commenters submitted comments in support of new technology add-on payment status for GAMIFANT®. Commenters highlighted the efficacy and safety outcomes in the clinical trials. They also stated that clinical experience reflects outcomes noted in the clinical trial and suggest that GAMIFANT® improves survival rates, reduces exposure to various other toxic medications (such as corticosteroids), and decreases the need for intensive care and the overall length of hospitalization. Some commenters also stated that, with approval of GAMIFANT®, clinicians can provide high value, evidence-based care to patients with MAS/sHLH, and clinicians and hospitals can be adequately reimbursed without financial concerns.

A commenter further stated that MAS is treated with high-dose glucocorticoids with satisfactory response in one-third of the patients, and for patients unresponsive to glucocorticoids, cyclosporin is usually added, while other approaches, including cyclophosphamide, etoposide, intravenous immunoglobulin, etanercept, anakinra, tocilizumab, JAK inhibitors and plasmapheresis, have been described in case reports or small series. According to the commenter, none of these regimens have been prospectively investigated, and these treatments lack selectivity and are very toxic. The commenter stated that, until the introduction of GAMIFANT®, mortality rates for patients with MAS had been around 20 percent. Further, the commenter highlighted that GAMIFANT® is the first targeted, prospectively studied therapy for MAS and that the Phase 2–3 trials of GAMIFANT® in patients who have failed to respond to high-dose glucocorticoids demonstrated that interferon-γ has a pathogenic role in MAS and that its targeted neutralization leads to MAS remission with a safety profile that is very reassuring.

Another commenter stated that MAS/sHLH not uncommonly occurs as a complication of, and it is very often the presenting clinical manifestation of, Adult-onset Still's disease (AOSD). Further, the commenter expressed that depending upon the severity of disease at the time of admission, patients may respond to first line therapy with high dose corticosteroids and interleukin-1 targeted therapy such as anakinra, but a significant minority do not, often with fatal outcomes from progressive hyper-inflammation or significant complications from protracted dosing with corticosteroids required to adequately manage their disease. Further, the commenter stated that the

[66] Shakoory B, et al. The 2022 EULAR/ACR points to consider at the early stages of diagnosis and management of suspected haemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS). *Ann Rheum Dis.* 2023;82(10):1271–1285.

[67] Hines MR, et al. Consensus-based guidelines for the recognition, diagnosis, and management of hemophagocytic lymphohistiocytosis in critically ill children and adults. *Crit Care Med.* 2022;50(5):860–872.

[68] Baldo F, et al. Current treatment in MAS worldwide: a systematic literature review to inform the METAPHOR project. *Rheumatology* (Oxford). 2025, 64, 32–44.

[69] Minoia F, et al. Clinical features, treatment, and outcome of macrophage activation syndrome complicating systemic juvenile idiopathic arthritis, a multinational, multicenter study of 362 patients. *Arthritis Rheumatol.* 2014;81(2);112–117.

consistent improvements observed in the status of patients otherwise destined for fatal outcomes have rendered the availability of GAMIFANT transformative. The commenter stated that barriers to accessing GAMIFANT® are most notable for hospitalized Medicare beneficiaries, whereby it is the expectation that the treatment costs for GAMIFANT® be covered in the context of MS–DRG reimbursement. The commenter also highlighted that currently, the cost for GAMIFANT® significantly exceeds the MS–DRG payment for this condition, a consideration that it said gives hospitals pause for designating GAMIFANT® as a formulary drug. This commenter also shared a personal anecdote about treating a hospitalized Medicare beneficiary patient with MAS/sHLH and suspected AOSD who expired before providers could obtain patient access to GAMIFANT® due to this reimbursement dynamic.

A commenter also stated that, while corticosteroids and other immunosuppressive therapies remain important components of care, these treatments can be associated with substantial side effects, particularly when administered at high doses or for extended periods. The commenter explained that patients and families often face difficult tradeoffs between controlling disease activity and managing treatment-related complications. The commenter stated that for rare diseases, such as HLH/MAS, therapeutic innovation is critically important, and the development of additional treatment options offers hope to patients and healthcare providers confronting complex and severe disease presentations. The commenter further added that expanding the availability of therapies that address unmet medical needs may help improve outcomes and provide clinicians with additional tools to manage these highly challenging conditions. The commenter also stated that mechanisms such as the new technology add-on payment play an important role in reducing financial barriers that may otherwise limit timely patient access to emerging treatment options during the critical periods of care.

Response: We thank the commenters for their input and have taken it into consideration in determining whether GAMIFANT® meets the substantial clinical improvement criterion as discussed later in this section. We note that whether a technology receives new technology add-on payments or not does not affect coverage of the technology or the ability for hospitals to provide a technology to patients where appropriate. Even if a technology does not receive new technology add-on payments, CMS continues to pay for new technologies through the regular payment mechanism established by the DRG payment methodology (90 FR 36672).

Comment: The applicant submitted a public comment regarding the substantial clinical improvement criterion and provided responses to CMS's concerns from the proposed rule.

In response to CMS's question as to whether GAMIFANT® offers a treatment option for patients unresponsive to, or ineligible for, currently available treatments, the applicant stated that there has been a critical need for a targeted therapy that can halt the cytokine storm and control hyperinflammation in patients with HLH/MAS in Still's disease who have an inadequate response or intolerance to glucocorticoids, or with recurrent MAS. The applicant reiterated that GAMIFANT® is the first and only FDA-approved treatment for adult and pediatric (newborn and older) patients with HLH/MAS in known or suspected Still's disease, including sJIA, with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS, and that it works by binding to soluble and receptor-bound forms of IFNγ, ultimately inhibiting macrophage activation and the downstream release of proinflammatory cytokines.

The applicant also stated that data presented in support of GAMIFANT® confirm that treatment with GAMIFANT® reduces disease activity in patients with MAS associated with Still's disease, including sJIA, who have failed previous treatments, and is well-tolerated without the medication-related toxicities associated with conventional therapy. Specifically, the applicant highlighted that patients studied in the phase II/III clinical trials were refractory to HLH/MAS treatment. The applicant stated that 36 percent of patients had previous MAS episodes and stated that 100 percent of this patient population had previous treatment with glucocorticoids, including 80 percent who had previous treatment with anakinra, and in all, 77 percent of patients had failed additional (1 to 4) therapies for the index MAS episode before GAMIFANT® initiation, in addition to glucocorticoid therapy. The applicant stated that patients in the trial had been treated with prior medications that included glucocorticoids, intravenous immunoglobulins (IVIg), calcineurin inhibitors (CNIs) (including cyclosporine), and interleukin inhibitors (anakinra, tocilizumab, and canakinumab). The applicant further reiterated that none of these therapies, including etoposide and cyclosporine, which CMS referenced in the proposed rule, have been prospectively studied, nor are they approved for the treatment of HLH/MAS. The applicant explained that some of these products used off-label for MAS have contraindications and risks that make them challenging to use in this patient population. The applicant stated that etoposide is contraindicated in patients with severe myelosuppression and severe hepatic impairment, which are both commonly observed in MAS patients,[70] and that cyclosporine poses a risk to patients with difficult cases of MAS. The applicant also stated that, to that end, during its 2025 Convergence conference, the American College of Rheumatology (ACR) announced updated guidelines for MAS/sJIA management wherein biological disease-modifying antirheumatic drugs (DMARDs), including emapalumab (GAMIFANT®), are recommended.[71] The applicant restated its belief that GAMIFANT® provides a treatment option for patients with HLH/MAS who are not responsive to, or ineligible for, the off-label therapies which have been used in the absence of prospectively studied and FDA-approved therapies.

In response to CMS's concern about being unable to assess the applicant's assertion that GAMIFANT® significantly improves clinical outcomes relative to other therapies for patients with an inadequate response or intolerance to glucocorticoids or with recurrent MAS, the applicant stated that the clinical evidence submitted reflects GAMIFANT®'s outcomes in patients who had, in many cases, exhausted other off-label treatment options, like cyclosporine and anakinra. The applicant explained that because randomized clinical trials are challenging, even unethical, in small populations with rare and fatal complications, the inclusion of patients with long MAS treatment courses in the phase II/III studies provides evidence similar to a crossover study design. The applicant further stated that the high percentage of study participants that had failed additional therapies were enrolled in the GAMIFANT® phase II/III studies by their physicians with the hope that patients would experience

[70] Etoposide prescribing information. *https://labeling.pfizer.com/ShowLabeling.aspx?id=15276*.

[71] ACR Convergence 2025. Panelists explain ACR's expanding JIA guidelines. October 2025. *https://www.acrconvergencetoday.org/panelists-explain-acrs-expanding-jia-guidelines/*.

substantial clinical improvement with GAMIFANT®.

In response to CMS's concern that it is unclear whether GAMIFANT® significantly reduces glucocorticoid dosing compared to other therapies that may be used in these patients, the applicant stated that 77 percent of patients failed to reduce their glucocorticoid dose while taking other MAS therapies prior to enrolling in the clinical trial and starting GAMIFANT® therapy. The applicant added that GAMIFANT® quickly enabled glucocorticoids to be reduced by 70 percent and 92 percent at week 2 and week 8, respectively. The applicant stated that GAMIFANT® enabled patients to aggressively decrease their exposure to glucocorticoids while obtaining responses despite the significant reduction in glucocorticoids.

In response to CMS's concern that some therapies used for MAS in Still's disease, such as anakinra and cyclosporine, were allowed during the two clinical studies (NI–0501–06 and NI–0501–14) and could have affected the outcomes, the applicant stated that canakinumab, JAK inhibitors, tumor necrosis factor (TNF)—a inhibitors, tocilizumab, etoposide, and anakinra at doses greater than 4 mg/kg/day at the time of GAMIFANT® initiation were excluded from the GAMIFANT® studies. The applicant cited Shakoory et al. (2023) and explained that, based on published expert opinion, doses of anakinra less than 4mg/kg/day are not high enough to treat a MAS episode. The applicant explained that because GAMIFANT® does not treat or control the underlying Still's disease, it is important to maintain interleukin (IL)–1 inhibition to control the underlying Still's disease so that the patient does not experience a Still's flare. The applicant further stated that the NI–0501–06 study originally excluded all doses of anakinra, but the protocol was later amended to allow doses less than 4mg/kg/day because patients were having flares of their underlying Still's disease. Specifically, the applicant noted that six patients who either were not on anakinra or discontinued anakinra had Still's flares compared to zero flares seen in patients on dosages of anakinra less than 4mg/kg/day. The applicant also stated that cyclosporine could not be started after GAMIFANT® initiation but could be continued if started at least 3 days before initiating GAMIFANT®. The applicant explained that, despite anakinra and/or cyclosporine having an immunosuppressive effect, patients enrolled in this study presented with MAS, so these concomitant medications were not considered by investigators to confound the study outcomes.

In response to CMS's question whether having a positive benefit:risk profile is a relevant outcome under § 412.87(b)(1)(ii)(C) because it does not address how GAMIFANT® improves clinical outcomes relative to other therapies that may be used to treat HLH/MAS patients who had an inadequate response to glucocorticoids or with recurrent MAS, the applicant reiterated that the GAMIFANT® studies included a refractory patient population and restated various outcomes included in its application.

In response to CMS's concern that the submitted clinical information does not clearly explain how it was determined whether serious adverse events were related to GAMIFANT®, nor does it provide sufficient detail on the reported serious adverse events, the applicant stated that a total of 16 patients (41.0 percent) experienced 41 treatment-emergent adverse events (TEAEs) assessed by the investigator as related to GAMIFANT®, with the most frequently reported TEAE being cytomegalovirus (CMV) infection reactivation (four patients [10.3 percent]). The applicant also stated that 13 patients (33.3 percent) experienced 24 serious TEAEs with the most frequently reported serious TEAEs being condition aggravation (three patients [7.7 percent]), pneumonia (two patients [5.1 percent]), and Still's disease (two patients [5.1 percent]) with all other serious TEAEs reported in one patient (2.6 percent) each. The applicant also stated that four patients (10.3 percent) experienced six serious TEAEs that were assessed by the investigator as related to GAMIFANT® treatment, which included one patient in Study NI–0501–06 (CMV infection reactivation) and three patients with five events in Study NI–0501–14 (CMV infection, pneumonia, pulmonary arterial hypertension, multiple organ dysfunction syndrome, and sepsis).

In response to CMS's request for additional detail on the clinical trials' VAS scoring system to fully assess the efficacy outcome data, the applicant stated that for both GAMIFANT® studies, investigators were asked to assess MAS activity based on the clinical signs and symptoms of the patient using the 10-point VAS, where the MAS clinical activity VAS is reported in centimeters (cm) on a scale that ranges from 0 to 10 cm where higher values indicate greater MAS disease activity and lower values indicate clinical improvement/remission. The applicant explained that investigator-assessed MAS clinical activity VAS was considered to represent an absence of MAS clinical signs and symptoms at a score of less than or equal to 1/10 cm. The applicant reiterated the finding that the VAS activity score of less than or equal to 1/10 was achieved by 84.6 percent of GAMIFANT®-treated patients within a median of 3.3 weeks.

In response to CMS's question whether a 12-month follow-up is enough time to assess MAS recurrence, the applicant stated that GAMIFANT® was studied to show efficacy and safety in resolving a MAS episode, either from an initial MAS episode or in a recurrent MAS episode in patients who have had multiple previous MAS events. The applicant added that GAMIFANT® was not studied in preventing MAS recurrence. The applicant also explained that in the clinical trials, 14 patients had previous MAS episodes, and in the 12 months prior to trial enrollment, those 14 patients experienced a total of 27 MAS events (range: 0 to 5 per patient). The applicant stated that after the administration of GAMIFANT®, only one patient had a single MAS recurrence during first year of follow up or last visit.

The applicant reiterated that GAMIFANT® is a monoclonal antibody that binds to and neutralizes IFNγ, provides a targeted approach to controlling the hyperinflammatory surge, minimizing off-target effects, and is the only prospectively studied and FDA-approved, IFNγ-blocking antibody indicated for treatment of patients with MAS in Still's disease. The applicant stated that the pooled safety and efficacy results of two interventional studies demonstrate substantial clinical improvement for patients who were refractory to prior off-label treatments. The applicant further stated that GAMIFANT® addresses a critical unmet need with a novel agent that can induce remission of MAS in Still's disease and protect patients from detrimental effects of prolonged MAS episodes, high-dose and longer-term glucocorticoids, and multiple escalating lines of therapy. The applicant concluded that it demonstrated that GAMIFANT® meets the three criteria for new technology add-on payment and urged CMS to approve new technology add-on payments for GAMIFANT®, effective October 1, 2026, to ensure access to GAMIFANT® treatment for Medicare beneficiaries with HLH/MAS.

Response: We thank the applicant for its comments regarding the substantial clinical improvement criterion. After consideration of the additional information we received from the applicant and other commenters, and

the totality of the available evidence, we agree that GAMIFANT® provides a treatment option for patients who are unresponsive to, or ineligible for, currently available treatments. GAMIFANT® is the first and only FDA-approved treatment option for adult and pediatric (newborn and older) patients with HLH/MAS in known or suspected Still's disease, including sJIA, who have an inadequate response or intolerance to glucocorticoids, or recurrent MAS, with a study population that consisted of heavily pretreated and treatment-refractory patients, all of whom had previously received glucocorticoids, 80 percent of whom had previously received anakinra, and 77 percent of whom had failed one or more additional therapies before receiving GAMIFANT®, and resulted in a complete response in 53.8 percent of patients and an overall response in 82.1 percent of patients before week 8 of treatment.

After consideration of the public comments we received and the information included in the applicant's new technology add-on payment application, we have determined that GAMIFANT® meets the criteria for approval for new technology add-on payments. Therefore, we are approving GAMIFANT® for new technology add-on payments for FY 2027. Cases involving the use of GAMIFANT® that are eligible for new technology add-on payments will be identified by ICD–10–PCS code XW033MA (Introduction of emapalumab-izsg anti-IFNy monoclonal antibody into peripheral vein, percutaneous approach, new technology group 10) or XW043MA (Introduction of emapalumab-izsg anti-IFNy monoclonal antibody into central vein, percutaneous approach, new technology group 10) *in combination with* any of the ICD–10–CM codes listed in the following table:

ICD–10–CM code	Description
M06.10	Adult-onset Still's disease
M08.211	Juvenile rheumatoid arthritis with systemic onset, right shoulder
M08.212	Juvenile rheumatoid arthritis with systemic onset, left shoulder
M08.221	Juvenile rheumatoid arthritis with systemic onset, right elbow
M08.222	Juvenile rheumatoid arthritis with systemic onset, left elbow
M08.231	Juvenile rheumatoid arthritis with systemic onset, right wrist
M08.232	Juvenile rheumatoid arthritis with systemic onset, left wrist
M08.241	Juvenile rheumatoid arthritis with systemic onset, right hand
M08.242	Juvenile rheumatoid arthritis with systemic onset, left hand
M08.251	Juvenile rheumatoid arthritis with systemic onset, right hip
M08.252	Juvenile rheumatoid arthritis with systemic onset, left hip
M08.261	Juvenile rheumatoid arthritis with systemic onset, right knee
M08.262	Juvenile rheumatoid arthritis with systemic onset, left knee
M08.271	Juvenile rheumatoid arthritis with systemic onset, right ankle and foot
M08.272	Juvenile rheumatoid arthritis with systemic onset, left ankle and foot
M08.28	Juvenile rheumatoid arthritis with systemic onset, vertebrae
M08.29	Juvenile rheumatoid arthritis with systemic onset, multiple sites
M08.2A	Juvenile rheumatoid arthritis with systemic onset, other specified site

In its application, the applicant estimated that the cost of GAMIFANT® is $1,035,010 per patient. According to the applicant, the mean duration of days of treatment with GAMIFANT® in the inpatient setting was 29 days with 10 infusions, including one loading dose [6 mg/kg] ($185,212) followed by 9 treatment doses [3 mg/kg every 3 days for 5 doses, then twice per week until remission] ($94,422 per dose). The applicant stated one treatment dose for an average adult patient weight of 84 kg is 252 mg, which corresponds to two 100 mg/20ml vials ($36,316 per vial), one 50 mg/10ml vial ($18,158 per vial), and one 10 mg/2ml vial ($3,632 per vial). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of GAMIFANT® is $672,756.50 for FY 2027.

d. RAPIBLYK™ (landiolol)

AOP Health US LLC submitted a FY 2027 application for new technology add-on payments for RAPIBLYK™. According to the applicant, RAPIBLYK™ is a beta-1 (β1) adrenergic blocker that inhibits adrenaline and noradrenaline's effects on the heart for short-term reduction of ventricular rate in adults with supraventricular tachycardia (SVT), including atrial fibrillation (AF) and atrial flutter (AFL). RAPIBLYK™ is supplied as a 280 mg lyophilized powder in a single-dose vial (equivalent to 300 mg of landiolol HCl) and, following reconstitution, is administered as a continuous intravenous infusion titrated according to ventricular rate.[72] The applicant stated that during an inpatient stay, the average patient requires five RAPIBLYK™ vials.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment

[72] AOP Orphan Pharmaceuticals. (2024, November). *RAPIBLYK (landiolol) for injection, for intravenous use: highlights of prescribing information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217202s000lbl.pdf.*

application for RAPIBLYK™ and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251006EVR3D.*

		Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS code(s)		Request submitted.	No concerns.
Newness Criterion	**Newness Period**	NDA approval on November 22, 2024, for the short-term reduction of ventricular rate in adults with SVT including AF and AFL. Commercial availability delay to July 21, 2025.	See following discussion.
	Substantial Similarity	Uses a new mechanism of action. Treats a new disease and/or a new patient population.	See following discussion.
Cost Criterion		53,447 claims mapping to 577 MS-DRGs, with none exceeding more than 10% of the total identified claims. Final inflated average case-weighted standardized charge per case ($108,394) exceeded the average case-weighted threshold amount ($84,401).	Meets cost criterion.
Substantial Clinical Improvement Criterion		Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments. Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available. Provided 3 published studies assessing the technology, 1 published study assessing comparator technology, and 1 practice guideline.	See following discussion.

Newness Criterion

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19420 through 19421), regarding commercial availability, we noted that the applicant stated that, after its NDA approval on November 22, 2024, RAPIBLYK™ was not immediately for sale and became commercially available on July 21, 2025, because the applicant needed to work through a number of time-intensive steps to facilitate U.S. commercial launch, including establishing a new entity for U.S. operations, identifying and contracting with a third-party logistics vendor and distributor, and identifying and contracting with wholesalers and group purchasing organizations. We stated we were interested in additional information regarding the cause of the delay in commercial availability.

Regarding substantial similarity, we stated in the proposed rule that we disagreed with the applicant that RAPIBLYK™ uses a different mechanism of action compared to existing heart rate control technologies. Per the applicant, RAPIBLYK™ directly blocks β1-adrenergic receptors on cardiac myocytes preventing catecholamine-induced increases in heart rate and conduction velocity. According to the applicant, unlike traditional beta blockers that rely on hepatic metabolism, have 3- to 12-hour half-lives, and exhibit lower β_1/β_2 selectivity ratios, RAPIBLYK™ is rapidly hydrolyzed by tissue and plasma esterases, yielding an ultra-short half-life of approximately 3 to 4 minutes without requiring hepatic clearance, and demonstrates an exceptionally high β_1/β_2 selectivity ratio. We stated that while we recognize that RAPIBLYK™ is metabolized and cleared differently compared to other beta blockers, we do not believe that this constitutes a unique mechanism of action because RAPIBLYK™, like other beta blockers, blocks β1-adrenergic receptors, reducing sympathetic stimulation.

Additionally, we stated we disagreed with the applicant that RAPIBLYK™ treats a new patient population or disease compared to existing technology because there are other beta blockers, such as esmolol, that are FDA-approved for the treatment of adults with SVT, including AF and AFL. According to the applicant, RAPIBLYK™ is uniquely suited to resolve acute AF in a patient population with impaired cardiac function and hemodynamic instability because it is designed to safely manage tachyarrhythmias in patients with hemodynamic instability and hypotension. However, we noted that other therapies, such as esmolol, can also be used to treat acute AF patients with impaired cardiac function. While the applicant stated that in RAPIBLYK™'s prescribing label, a dosing regimen is included for patients with impaired cardiac function, we noted that the absence of a dosing regimen for cardiac impairment in the prescribing label [73] for esmolol does not preclude the use of this drug in this patient population. Furthermore, in regards to the applicant's claim that RAPIBLYK™ can be used in acute AF patients with hemodynamic instability, we noted that according to both prescribing labels, esmolol and RAPIBLYK™ have the same contraindications for use in patients with hemodynamic instability, including those with severe sinus bradycardia, heart block greater than first degree, sick sinus syndrome, decompensated heart failure, and cardiogenic shock. While the applicant made several statements related to RAPIBLYK™'s dosing regimen, safety profile, and suitability for cardiac impaired patients, we stated we believed this is relevant to the assessment of substantial clinical improvement, rather than of newness. We also noted that we did not receive evidence identifying a new patient population or type of disease which

[73] WG Critical Care, LLC. (1986, December). *Esmolol hydrochloride in water for injection, for intravenous use: highlights of prescribing information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/205703s003lbl.pdf.*

RAPIBLYK™ treats that cannot be treated with existing technologies such as esmolol, amiodarone, or digoxin.

Accordingly, we stated that as it appears that RAPIBLYK™ and esmolol may use the same or similar mechanism of action to achieve a therapeutic outcome, are assigned to the same MS–DRG, and treat the same or similar patient population and disease, that is, adult patients with SVT including AF and AFL, we believe that these technologies are substantially similar to each other.

We noted that, per our policy, if technologies are substantially similar to each other, we use the earliest market availability date as the beginning of the newness period for the technologies. Accordingly, if we determine that RAPIBLYK™ is substantially similar to esmolol, we stated we believe the newness period for RAPIBLYK™ would begin on December 31, 1986, the date esmolol received FDA approval. Since esmolol has been on the U.S. market since 1986, the 3-year anniversary date of its entry onto the market occurred prior to FY 2027. Therefore, we stated that RAPIBLYK™ would not be considered new and would be ineligible for new technology add-on payments for FY 2027.

We invited public comments on whether RAPIBLYK™ is substantially similar to existing technologies and whether RAPIBLYK™ meets the newness criterion.

Comment: The applicant and a few commenters submitted public comments regarding the newness criterion for RAPIBLYK™. The applicant asserted that RAPIBLYK™ satisfies the newness criterion because it meets the 2- to 3-year threshold for being new to the U.S. market under CMS regulations and is not substantially similar to any existing technology.

In response to CMS's request for additional information regarding the cause of delay in commercial availability, the applicant stated that following FDA approval, it undertook a number of time-intensive steps to facilitate the commercial launch of RAPIBLYK™ in the U.S. The applicant explained that prior to FDA approval, it established a new, U.S.-based entity for operations by working with a U.S. consultancy for commercial readiness in August 2024 and that following FDA approval in November 2024, it began medical outreach and education to customers while building commercial infrastructure. The applicant added that since RAPIBLYK™ was their first product for AOP Health in the U.S., it took time to establish a U.S. presence following FDA approval. The applicant stated that it next identified and contracted with a third-party logistics vendor and distributor in March 2025 and that the first shipment of RAPIBLYK™ to this vendor occurred on May 20, 2025. The applicant additionally stated that it identified and contracted with wholesalers and group purchasing organizations between the months of July and October 2025. The applicant asserted that it undertook these essential steps as quickly and efficiently as possible following RAPIBLYK™'s FDA approval, and they could not have been completed prior to FDA approval. The applicant requested that, consistent with CMS policy, RAPIBLYK™'s newness period should begin on July 21, 2025, the date of its commercial availability.

In regards to substantial similarity, the applicant stated that RAPIBLYK™ is not substantially similar to any existing technology while noting that the substantially similar test for newness is set forth only in rulemaking preamble language and is not codified in statute or regulations. The applicant further stated that CMS had declined to adopt rigid criteria to define substantial similarity because such criteria would restrict unduly the Agency's ability to make appropriate determinations regarding whether a product should qualify for new technology add-on payments. The applicant agreed with avoiding rigid criteria, particularly given the broad statutory and regulatory language related to newness for new technology add-on payment purposes, and recommended that CMS apply the newness criterion consistently with the text and underlying purpose of the new technology add-on payment statute and regulations, which are intended to support timely access to innovative new therapies for Medicare beneficiaries during the period before costs are recognized in MS–DRG weights.

The applicant asserted that RAPIBLYK™ meets newness standards and is not substantially similar to existing technology because it does not have the same or similar mechanism of action compared to existing technology to achieve a therapeutic outcome, and RAPIBLYK™ usage does not involve treatment of the same or similar type of patient population when compared to an existing technology. Specifically, the applicant stated that RAPIBLYK™'s unique mechanism of action results from key characteristics that lead to the distinct way RAPIBLYK™ is processed by and produces an effect in the body, and, as such, how it achieves a therapeutic outcome. The applicant suggested that the mechanism of action includes not only blocking of β1-adrenergic receptors but also the receptor target, the molecular structure, β1 receptor interaction, how it is metabolized, its effect duration, length of time in the body, and how these combine to be meaningfully distinct from other available control agents. The applicant added that three characteristics distinguish RAPIBLYK™ from other heart rate control agents: (1) a unique molecular structure resulting in distinct β1 super-selectivity and limited negative inotropic effect, unlike other agents including beta blockers like esmolol and metoprolol; (2) distinct plasma esterase-based metabolism reflecting a unique way of being processed by the body compared to previously available heart rate control agents that are metabolized through hepatic and renal pathways; and (3) a uniquely short half-life, producing a distinctly short duration of effect allowing rapid on/rapid off rate control in acute care settings.

The applicant and a commenter stated that RAPIBLYK™'s unique molecular structure as a pure S,S-enantiomer directly affects how the body metabolizes and processes it. The applicant and a commenter explained that its molecular structure is responsible for its ultra-high cardio-selective activity and allows for rapid heart rate reduction without compromising mean arterial blood pressure, eliminating the negative impact of cardiac output seen with esmolol. According to the applicant, RAPIBLYK™ has a β1 to β2 ratio of 255:1, making it about 7.7 and 100 times more β1-selective than esmolol and metoprolol, respectively. The applicant stated that RAPIBLYK™'s ultra-high β1 selectivity minimizes off-target effects on β2 receptors, thereby reducing bronchoconstriction and peripheral vasoconstriction risks and providing effective heart rate control with minimal effects on bronchial tone or blood pressure. The applicant and a commenter added that RAPIBLYK™ has only limited inotropic effects, unlike esmolol, which they stated is a racemic R- and S-enantiomeric structure and confers negative inotropic effects that weaken heart muscle contraction, dilate blood vessels, and can lead to heart failure symptoms, particularly for vulnerable patients in intensive care and acute settings where quick titration and reversal are important. The applicant further stated that RAPIBLYK™ is characterized by rapid metabolism via plasma esterases (pseudocholinesterases and carboxylesterases), resulting in a short elimination half-life of approximately 4

minutes and a low distribution volume. The applicant explained that RAPIBLYK™'s metabolism by plasma esterases yields the active metabolite M1, which has approximately 1/40th of the pharmacological activity of esmolol. The applicant added that RAPIBLYK™ is processed in a manner distinct from esmolol such that the drugs differ in metabolites, with esmolol yielding the toxic metabolite methanol. The applicant stated that RAPIBLYK™'s esterase-based metabolism pathway avoids liver- and kidney-reliant metabolism, fundamentally differentiating it from metoprolol (hepatic metabolism), amiodarone (extensive hepatic metabolism), and digoxin (renal elimination). The applicant added that, as a result of RAPIBLYK™'s esterase-based metabolism, no specific dose adjustment is needed for patients with renal impairment, in direct contrast to metoprolol and digoxin. Additionally, the applicant stated that the metabolism of RAPIBLYK™ minimizes the potential for drug accumulation and dose-dependent adverse events, particularly among patients with renal impairment. The applicant cited a pharmacokinetic study that evaluated RAPIBLYK™ in adult patients with septic shock and persistent tachycardia and demonstrated that dialysis exerts minimal influence on RAPIBLYK™ clearance while substantially eliminating M1. According to the applicant, this finding aligns with current renal impairment dosing recommendations and supports no dose adjustments are required during renal replacement therapy with RAPIBLYK™, unlike a number of previously available agents used for heart rate control.

The applicant stated that RAPIBLYK™'s uniquely short half-life produces a distinctly short effect duration with a half-life of approximately 4 to 4.5 minutes, allowing unprecedented rapid on/rapid off rate control in acute care settings. The applicant explained that this pharmacokinetic profile contributes to RAPIBLYK™'s distinct suitability for precise titration and rapid effect cessation, as the ultra-short half-life allows titration that is impossible with other alternatives. Additionally, the applicant stated that RAPIBLYK™'s half-life is approximately half that of esmolol's approximately 9-minute half-life and is exponentially shorter than the half-life of metoprolol (3 to 7 hours), digoxin (36 to 44 hours), or amiodarone (20 to 47 days). The applicant asserted that this key characteristic of RAPIBLYK™'s processing and effects in the body enables real-time titration and rapid reversal if a patient's hemodynamic status changes. The applicant concluded that no previously available intravenous rate control agent, including but not limited to esmolol, is processed by and produces an effect in the body in the same way as RAPIBLYK™, giving it a unique mechanism of action. In addition, the applicant compared RAPIBLYK™ to other acute rate-control therapies, noting its distinction from not only esmolol but also metoprolol, diltiazem, amiodarone, and digoxin. The applicant stated that antiarrhythmic agents are generally divided into four classes and that RAPIBLYK™ is a Class II medication that directly blocks β-adrenergic receptors on cardiac myocytes, preventing catecholamine-induced increases in heart rate and conduction velocity. The applicant stated that this receptor-level blockade results in immediate negative chronotropic effects that are independent of parasympathetic pathways, allowing RAPIBLYK™ to rapidly reduce heart rate even during heightened sympathetic activity, such as in acute stress or perioperative settings. The applicant cited a recent Cardiology in Review article that focuses on RAPIBLYK™'s pharmacology, pharmacokinetics, and pharmacodynamics and stated that the analysis underscores its unique attributes compared to conventional beta blockers, particularly esmolol. The applicant highlighted that the study's authors state that although RAPIBLYK™ and esmolol are both short-acting and cardioselective β1-adrenoceptor-blocking agents, the two drugs possess distinct characteristics and that RAPIBLYK™'s distinctive pharmacokinetics and pharmacodynamics, including its short half-life, high cardioselectivity, and limited impact on blood pressure, differentiate it from other beta blockers. The applicant stated that although certain previously available agents may share some aspects of RAPIBLYK™'s mechanism of action, no previously existing agent shares all aspects of RAPIBLYK™'s mechanism of action and included a table comparing treatments' differences in therapeutic class, rapid action onset (<20 minutes), half-life, negative inotropic effect, incidence of hypotension, metabolization issues, drug interactions, acute renal failure warnings, and use in cardiac dysfunction. The applicant concluded that RAPIBLYK™ has a unique mechanism of action because it combines specific features of an ultra-short half-life, extreme β1 selectivity, limited negative inotropy, esterase-based metabolism, low interaction burden, and suitability in cardiac dysfunction, which no other agents have. The applicant further asserted that CMS has recognized on multiple occasions that being the first FDA-approved therapy for a particular indication or particular patient population demonstrates a unique mechanism of action and satisfies the new technology add-on payment newness criterion in previous final rules.

In regard to whether RAPIBLYK™ treats a same or similar patient population or disease when compared to an existing technology, the applicant stated that RAPIBLYK™ offers a new antiarrhythmic treatment option for certain patients with cardiac impairment and hypotension or risk of hypotension, where previously available beta blockers have not been recommended due to negative effects on hypotension and cardiac function (left ventricular ejection fraction less than 40 percent). The applicant stated that with RAPIBLYK™'s availability, previously available beta blockers and other alternatives are no longer an appropriate treatment option for a vulnerable patient sub-population due to their significant adverse event risks and poor outcomes. The applicant stated that RAPIBLYK™ is the only beta blocker with specific, FDA-approved administration instructions for patients with impaired cardiac function. The applicant stated that these instructions, which FDA included in the technology's labeling based on the published, peer-reviewed studies submitted with RAPIBLYK™'s New Drug Application, provide compelling evidence of safety specifically in this vulnerable patient population. The applicant further asserted that this makes RAPIBLYK™ distinct from all previously existing agents used for short-term ventricular rate reduction in patients with SVTs. The applicant added that it revised RAPIBLYK™'s FDA-approved labeling in February 2026 to add a specific indication for the short-term reduction of ventricular rate in pediatric patients with SVT, making RAPIBLYK™ the first and only FDA-approved intravenous beta blocker for treatment of acute-onset SVTs in pediatric patients (from birth to less than 18 years of age). The applicant stated that this should be sufficient in demonstrating that RAPIBLYK™ treats a new patient population or disease compared to existing technology.

The applicant and a few commenters also stated that RAPIBLYK™ is uniquely suited to resolve acute AF in

a patient population with impaired cardiac function and hypotension or risk of hypotension. According to the applicant, CMS stated in the proposed rule that other therapies, such as esmolol, can also be used to treat acute AF patients with impaired cardiac function and further stated that the absence of a dosing regimen for cardiac impairment in the prescribing label for esmolol does not preclude the use of this drug in this patient population. However, the applicant commented that while a therapy could be used to treat acute AF patients with impaired cardiac function even if the FDA-approved labeling does not include a specific dosing regimen for such patients, it remains the case that there is a sub-population for whom treatment with esmolol, or other previously existing rate control agents, presents significantly heightened clinical risks due to a combination of impaired cardiac function and additional comorbidities, such as hypotension or risk of hypotension or renal impairment. According to the applicant, RAPIBLYK™ addresses an unmet clinical need for these patients and provides a new option for effective rate control with markedly reduced risks of serious adverse events. The applicant and a few commenters, who are healthcare professionals, explained that as healthcare professionals seek to navigate complex conditions for vulnerable patients in acute and critical care settings, the clinical reality is that, for at least some patients with impaired cardiac function and other comorbidities like heart failure, hypotension or risk of hypotension, treatment with esmolol or another previously existing rate control agent may not be tolerable or clinically appropriate, especially now that RAPIBLYK™ is available, with a few commenters noting that RAPIBLYK™ was added to their hospital system's formulary. The applicant and a few commenters stated that, therefore, RAPIBLYK™ provides an option for patients who cannot tolerate or be safely treated by esmolol or other rate control agents, including those with hypotension, worsening heart failure, adverse inotropic effects, renal accumulation, and organ toxicity, and as such, RAPIBLYK™ involves treatment of a different patient population as compared to previously existing technologies. A commenter also stated that although the warnings, precautions, and contraindications on formal labeling may be similar for some of these rate control agents, they differ in fundamentally critical respects from a clinical perspective, and clinical realities create a subpopulation of patients who are not well served by previously existing rate control agents and for whom RAPIBLYK™ addresses an important unmet need.

The applicant also directly compared RAPIBLYK™'s molecular features, outcomes, and adverse effects to those of esmolol, metoprolol, diltiazem, amiodarone, and digoxin in acute AF patients with impaired cardiac function and hypotension or risk of hypotension, and, for digoxin, in pediatric patients with SVT. Additionally, the applicant cited newly published evidence that shows RAPIBLYK™'s clinical use in patients who received and did not respond to other antiarrhythmic agents, including those with hemodynamic instability and cardiogenic shock, across the full Society for Cardiovascular Angiography and Interventions Shock Classification spectrum. The applicant concluded that the availability of alternative treatments does not preclude a finding that RAPIBLYK™ uniquely serves a distinct patient population and that the fact esmolol, other beta blockers, or heart rate control agents can be administered to patients with reduced ejection fractions or other comorbidities does not mean those agents are clinically appropriate, safe, or guideline-recommended for all patients or for the distinct population that RAPIBLYK™ serves.

Response: We appreciate the additional information from the applicant and commenters with respect to whether RAPIBLYK™ is substantially similar to existing technologies. However, we disagree with the applicant and commenters that RAPIBLYK™ has a different mechanism of action and treats a different disease and patient population.

With respect to our flexibility to define substantial similarity, we note that, as discussed in prior rulemaking, and as set forth in the FY 2010 IPPS final rule (74 FR 43813 through 43814), our long-established policy is to consider (1) whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, (2) whether a product is assigned to the same or a different DRG, and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population to determine whether a new technology is substantially similar to one or more existing technologies. We agree with the applicant that we should apply these criteria consistently with the text and underlying purpose of the new technology add-on payment statute and regulations, as reflected in our assessment of RAPIBLYK™.

With respect to whether a technology uses the same or similar mechanism of action to achieve a therapeutic outcome, we continue to disagree that RAPIBLYK™ has a unique mechanism of action compared to existing rate control technologies. While the applicant and commenters asserted that RAPIBLYK™ has a new mechanism of action due to a variety of reasons including its molecular structure, plasma esterase-based metabolism, short half-life and low distribution volume, and pharmacokinetic/pharmacodynamic profile, we disagree that these represent the mechanism of action by which RAPIBLYK™ achieves its therapeutic effect of reducing sympathetic stimulation and ventricular rate. Further, while commenters stated these differences lead to super-selectivity and limited negative inotropic effects for RAPIBLYK™ compared to other beta blockers, and that these attributes may reduce complications or side effects, we note that these relate to an assessment of substantial clinical improvement rather than to differentiating its mechanism of action. Similarly, we acknowledge the applicant's assertions that RAPIBLYK™ is differentiated from other rate control agents by its receptor target, β1 receptor interaction, metabolism, duration of effect, length of presence, and how these characteristics combine. However, as similarly described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45000), we do not believe these differences constitute a different mechanism of action because, as discussed previously, RAPIBLYK™ achieves the same therapeutic effect by blocking β1-adrenergic receptors to reduce sympathetic stimulation and ventricular rate as other existing beta blockers, such as esmolol.

With respect to whether a technology treats the same or similar type of disease and patient populations, we continue to disagree that the evidence provided demonstrates that RAPIBLYK™ treats a different type of disease or patient population compared to existing rate control therapies. Although the applicant asserted that RAPIBLYK™ has FDA-approved administration instructions for patients with impaired cardiac function, we do not believe this establishes that RAPIBLYK™ treats a different disease or patient population than existing technologies used for rate control in SVT, including AF or AFL. Specifically, we note that RAPIBLYK™'s FDA label includes the warning about the risk of hypotension, bradycardia, and cardiac failure. Therefore, it seems that the factors the

applicant described relate to treatment preferences and logistical considerations within the same patient population (adults with SVT, including AF and AFL) rather than identifying a different patient population. Similarly, while commenters stated that RAPIBLYK™ may be particularly useful in adult patients with impaired cardiac function, hypotension or risk of hypotension, renal impairment, or other comorbidities for whom other beta blockers are not clinically recommended due to adverse event risks and poor outcomes, we do not believe these factors identify a different disease or meaningfully different patient population for purposes of the substantial similarity analysis. Rather, these represent clinical practice considerations, treatment tolerance and preferences, dosing considerations, or potential clinical improvement within the same or similar patient population, who may also be treated by esmolol, rather than distinct patient populations. The applicant also cited evidence regarding RAPIBLYK™'s safety and tolerability in certain high-risk patients compared to existing beta blockers. However, we believe that while these differences may lead to improved clinical outcomes, they do not identify treatment of a new disease or patient population when compared to an existing technology.

In addition, we acknowledge the applicant's comment regarding RAPIBLYK™'s February 2026 FDA approval for the short-term reduction of ventricular rate in pediatric patients with SVT, which is stated makes RAPIBLYK™ the first and only FDA-approved intravenous beta blocker for the treatment of acute onset SVTs in pediatric patients. However, RAPIBLYK™'s new technology add-on payment application included only the FDA indication for short-term reduction of ventricular rate in adult patients with SVT, including AF and AFL, and as such, only the adult indication is eligible for consideration for FY 2027 new technology add-on payment.

We also note that many of the comments and cited studies regarding RAPIBLYK™'s real-world evidence, as well as comparisons with esmolol, metoprolol, amiodarone, diltiazem, or digoxin, relate to whether RAPIBLYK™ may improve clinical outcomes relative to existing rate control technologies. However, as discussed previously, these issues relate to an assessment of substantial clinical improvement, rather than to whether RAPIBLYK™ is substantially similar to existing technologies for purposes of the newness criterion.

After review of the information provided in the comments, we continue to disagree that RAPIBLYK™ uses a new mechanism of action and treats a new patient population or disease compared to previously available technologies. Specifically, we believe RAPIBLYK™ and esmolol use the same mechanism of action to achieve a therapeutic outcome: β1-adrenergic receptors blocker on cardiac myocytes, which results in the reduction of sympathetic stimulation and ventricular rate to treat adults with SVT, including AF and AFL. We also believe RAPIBLYK™ treats the same or similar patient population and disease as esmolol, which is also used to treat adults with SVT, including AF and AFL. Because we agree with the applicant that RAPIBLYK™ will be assigned to the same MS–DRG as previously available technologies, RAPIBLYK™ meets all three of the substantial similarity criteria. Therefore, we believe RAPIBLYK™ is substantially similar to esmolol.

While we acknowledge the applicant's comments about the delay in commercial availability, in accordance with our policy, because RAPIBLYK™ is substantially similar to esmolol, we consider the beginning of the newness period for RAPIBLYK™ to begin on the date that esmolol became commercially available. Because esmolol has been on the U.S. market since December 31, 1986, the 3-year anniversary of its entry onto the market occurred prior to FY 2027, and therefore, RAPIBLYK™ does not meet the newness criterion and is not eligible for new technology add-on payments for FY 2027.

We note that we received public comments with regard to the cost and substantial clinical improvement criteria for this technology, but because we have determined that the technology does not meet the newness criterion and therefore is not eligible for approval for new technology add-on payments for FY 2027, we are not summarizing comments received or making a determination on those criteria in this final rule.

e. WASKYRA™ (etuvetidigene autotemcel)

Fondazione Telethon submitted an FY 2027 application for new technology add-on payments for WASKYRA™. According to the applicant, WASKYRA™ is a one-time, cell-based autologous gene therapy indicated for the treatment of pediatric patients 6 months and older and adults with Wiskott-Aldrich Syndrome (WAS) who have a mutation in the *WAS* gene for whom hematopoietic stem cell transplantation (HCT) is appropriate and no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available. Per the applicant, following reduced-intensity conditioning, WASKYRA™ is administered intravenously as a single autologous infusion of gene-corrected cluster of differentiation (CD)34+ hematopoietic stem and progenitor cells (HSPCs), with a minimum recommended dose of 7.0×10^6 CD34+ cells/kg, individualized by patient weight and leukapheresis yield.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for WASKYRA™ and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP2510033XJPK.*

		Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS code(s)		Request submitted.	N/A.
Newness Criterion	**Newness Period**	BLA approved on December 9, 2025, for the treatment of pediatric patients aged 6 months and older and adults with WAS who have a mutation in the *WAS* gene for whom HCT is appropriate and no suitable HLA-matched related stem cell donor is available. Commercial delay expected until March 31, 2026.	See following discussion.
	Substantial Similarity	Treats a new disease and/or a new patient population.	See following discussion.
Cost Criterion		Scenario 1: 110 claims mapping to 10 MS-DRGs, with none exceeding 10.0% of the total identified cases. Scenario 2: 99 claims mapping to 9 MS-DRGs, with none exceeding 11.1% of the total identified cases. Final inflated average case-weighted standardized charge per case (Scenario 1 – $16,446,982; Scenario 2 – $16,469,706) exceeded the average case-weighted threshold amount (Scenarios 1 and 2 – $1,885,660).	Meets cost criterion.
Substantial Clinical Improvement Criterion		Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments. Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available. Provided no published or unpublished studies assessing the technology, practice guidelines, or other information.	See following discussion.

Newness Criterion

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19424), we noted that the applicant stated that the technology would not be commercially available until March 31, 2026, due to the applicant's need to establish commercial infrastructure, finalize import logistics, and plan for U.S. market compliance. We stated we were interested in additional information regarding when the technology first became available for sale and the cause of any delay in the technology's commercial availability, such as additional details regarding the establishment of commercial infrastructure.

Regarding substantial similarity, we stated that the applicant asserted that WASKYRA™ treats a new disease and/or a new patient population because it is a curative treatment designed for patients lacking a suitable HCT donor and noted that HCT is limited by donor availability, age, and risk of graft failure or graft-versus-host disease. However, based on information available at the time of the proposed rule, we stated we disagreed with the applicant that WASKYRA™ treats a new disease or new patient population because there are several other therapies FDA-approved for WAS in patients that cannot receive a HCT, such as ALYGLO™ and ASCENIV™, which are indicated for treatment of primary humoral immunodeficiency in patients with WAS, and corticosteroids indicated for eczema. We noted that the applicant did not assert that WASKYRA™ has a new mechanism of action compared to existing treatments for WAS or that it changes the MS–DRG assignment. Therefore, based on information available at the time of the proposed rule, we stated we were unclear whether WASKYRA™ is substantially similar to existing treatments.

We invited public comments on whether WASKYRA™ is substantially similar to existing technologies and whether WASKYRA™ meets the newness criterion. We did not receive any public comments on whether WASKYRA™ meets the newness criterion.

We continue to remain unclear as summarized in the proposed rule as to whether WASKYRA™ is substantially similar to other products that are currently available on the U.S. market. Despite the information the applicant previously submitted with its application describing WASKYRA™ as a curative treatment designed for patients ineligible for HCT, we disagree that WASKYRA™ treats a new disease or new patient population because there are other therapies indicated for patients with WAS who are not eligible for HCT. In addition, as noted, the applicant did not assert that WASKYRA™ has a new mechanism of action compared to existing treatments for WAS or that it changes the MS–DRG assignment. Therefore, we are unable to determine that WASKYRA™ meets the newness criterion.

Cost Criterion

Regarding the cost criterion, we stated we agreed with the applicant that the technology meets the cost criterion. We invited public comments on whether WASKYRA™ meets the cost criterion.

We did not receive any comments on whether WASKYRA™ meets the cost criterion. Based on the information submitted by the applicant as part of its FY 2027 new technology add-on payment application, the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, WASKYRA™ meets the cost criterion.

Substantial Clinical Improvement Criterion

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19425), after review of the information provided by the applicant, we stated we had the following concerns regarding whether WASKYRA™ meets the substantial clinical improvement criterion. We noted that the applicant did not provide

any evidence to support its claims, as further discussed in this section, as to why the technology represents a substantial clinical improvement over existing technologies. We stated we were unable to evaluate substantial clinical improvement in the absence of supporting evidence.

Furthermore, with respect to the applicant's claims, we noted that the applicant asserted that WASKYRA™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments because it provides a treatment option for WAS patients without HLA-identical related donors. However, we noted that this claim does not explain why these patients would be ineligible for HCT with an HLA-matched unrelated donor. In addition, while the applicant claimed that WASKYRA™ reduces WAS disease burden, offers a safer disease-modifying option for patients eligible for HCT, demonstrates sustained engraftment of gene-corrected cells and long-term clinical benefit, and directly addresses the genetic defect underlying WAS through lentiviral gene transfer, we stated that these claims do not identify a patient population that is unresponsive to, or ineligible for, currently available supportive care treatments and HCT. We further noted that the applicant asserted that WASKYRA™ significantly improves clinical outcomes relative to services or technologies previously available but did not identify specific outcomes. For example, the applicant claimed that WASKYRA™ offers a safer option for WAS patients compared to HCT, but did not describe a clinical outcome, such as a reduction in at least one clinically significant adverse event as provided by § 412.87(b)(1)(ii)(C)(1). Also, as previously noted, the applicant did not provide evidence to support any of its claims and therefore we stated we were unable to evaluate whether WASKYRA™ represents a substantial clinical improvement over existing technologies.

After review of the information provided by the applicant, we stated we were unable to determine that WASKYRA™ represents a substantial clinical improvement over existing technologies, and therefore, we proposed to disapprove new technology add-on payments for WASKYRA™ for FY 2027.

We invited public comments on whether WASKYRA™ meets the substantial clinical improvement criterion and our proposal to disapprove new technology add-on payments for WASKYRA™ for FY 2027.

Comment: A commenter encouraged CMS to assign new technology add-on payment status for WASKYRA™ and stated that doing so will remove a potential barrier to patients accessing innovative treatments and tools advancing a personalized medicine approach to care.

Response: We thank the commenter for their comment.

We did not receive any public comments addressing the concerns we indicated in the proposed rule regarding whether WASKYRA™ meets the substantial clinical improvement criterion. Accordingly, after consideration of the public comment we received, we are unable to determine that WASKYRA™ represents a substantial clinical improvement over existing technologies.

Based on the information submitted by the applicant as part of its FY 2027 new technology add-on payment application and the public comment we received for WASKYRA™, we are unable to determine that WASKYRA™ meets the newness criterion and represents a substantial clinical improvement over existing technologies for the reasons discussed in the proposed rule and in this final rule. Therefore, we are not approving new technology add-on payments for WASKYRA™ for FY 2027.

f. YARTEMLEA® (narsoplimab-wuug)

Omeros Corporation submitted an FY 2027 application for new technology add-on payments for YARTEMLEA® (narsoplimab-wuug). According to the applicant, YARTEMLEA® is a fully human monoclonal antibody designed to treat and alleviate the detrimental consequences of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA–TMA) by targeting and inhibiting mannan-binding lectin-associated serine protease 2 (MASP–2), an effector enzyme that activates the lectin pathway of the complement system. YARTEMLEA® is administered as a 30-minute intravenous infusion once weekly, and the recommended dose is 370 mg for patients greater than or equal to 50 kg and is 4 mg/kg for patients weighing less than 50 kg. The applicant estimated that patients receive an average total dosage of 4,218 mg per inpatient stay. We noted in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19425) that the applicant submitted an application for new technology add-on payments for this technology for FY 2022 (86 FR 25282 through 25286; 86 FR 44979) and FY 2023 (87 FR 28274 through 28279; 87 FR 48920).

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for YARTEMLEA® and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251006R7LMC.*

		Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS code(s)		XW03357 and 7XW04357	No concerns.
Newness Criterion	**Newness Period**	BLA approved on December 23, 2025, for the treatment of adult and pediatric patients 2 years of age and older with hematopoietic stem cell TA-TMA.	Newness date: December 23, 2025
	Substantial Similarity	Uses a new mechanism of action. Maps to a new MS-DRG. Treats a new disease and/or a new patient population.	Not substantially similar to existing treatments.
Cost Criterion		176 claims mapping to 16 MS-DRGs, with none exceeding more than 6.25% of the total identified cases. Final inflated average case-weighted standardized charge per case ($178,290) exceeded the average case-weighted threshold amount ($117,676).	Meets cost criterion.
Substantial Clinical Improvement Criterion		Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments. Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available. Provided 4 published and 1 unpublished studies assessing the technology, 9 studies assessing comparator technologies, and other information.	See following discussion.

Newness Criterion

In the proposed rule, regarding substantial similarity, based on the information available at the time of the proposed rule, we stated we agreed with the applicant that YARTEMLEA® has a new mechanism of action and treats a new type of disease or patient population compared to existing technology, because YARTEMLEA® is the only FDA-approved therapy indicated for the treatment of adult and pediatric patients 2 years of age and older with hematopoietic stem cell TA–TMA. We noted that we disagreed with the applicant that YARTEMLEA® is assigned to a different MS–DRG compared to existing technology because patients diagnosed with TA–TMA, including those treated with YARTEMLEA®, map to MS–DRGs 545–547. Therefore, based on information available at the time of the proposed rule, we stated our belief that YARTEMLEA® is not substantially similar to existing technology and meets the newness criterion. We stated that we consider the beginning of the newness period to commence on December 23, 2025, the date on which YARTEMLEA® received FDA market authorization for this indication.

We invited public comments on whether YARTEMLEA® is substantially similar to existing technologies and whether YARTEMLEA® meets the newness criterion.

Comment: The applicant submitted a public comment asserting that YARTEMLEA® satisfies the newness criterion. The applicant stated its agreement with CMS that YARTEMLEA® has a novel mechanism of action as the only approved therapy for TA–TMA and treats a new type of disease or patient compared to existing technologies.

Response: We thank the applicant for its comment. Based on our review of the comment received and information submitted by the applicant as part of its FY 2027 new technology add-on payment application for YARTEMLEA®, we agree that YARTEMLEA® has a new mechanism of action and treats a new type of disease or patient population compared to existing technology because YARTEMLEA® is the only FDA-approved therapy indicated for the treatment of adult and pediatric patients 2 years of age and older with hematopoietic stem cell TA–TMA. Therefore, we agree that YARTEMLEA® is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence on December 23, 2025, the date on which YARTEMLEA® received FDA market authorization for this indication.

Cost Criterion

Regarding the cost criterion, we stated we agreed with the applicant that the technology meets the cost criterion. We invited public comments on whether YARTEMLEA® meets the cost criterion.

Comment: The applicant stated it agreed with CMS that YARTEMLEA® meets the cost criterion and requested that CMS calculate the maximum new technology add-on payment based on the cost of 12 vials per Medicare inpatient stay. The applicant noted that the average total dosage of YARTEMLEA® per inpatient stay is 4,218 mg, as stated in the proposed rule. Further, the applicant stated that because YARTEMLEA® is supplied in single-dose 370 mg/2 mL vials, this average dosage requires 11.4 vials, which must be rounded up to 12 vials per inpatient stay. The applicant commented that this approach reflects the clinical and operational realities of inpatient administration, because hospitals must acquire and use whole single-dose vials and cannot acquire or administer fractional vials. According to the applicant, at a wholesale acquisition cost of $36,805 per vial, 12 vials result in an estimated average drug cost of $441,660 per Medicare inpatient stay. The applicant stated that applying 65 percent yields a maximum new technology add-on payment of $287,079, which it recommended CMS establish for YARTEMLEA® in the final rule.

Response: We thank the applicant for its comment. We agree with the applicant that YARTEMLEA® meets the cost criterion, and we have taken this comment into consideration in calculation of the new technology add-on payment, as discussed later in this section.

Substantial Clinical Improvement Criterion

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19426), after review of the information provided by the applicant, we stated we agreed with the applicant that YARTEMLEA® is the first and only FDA-approved treatment option for patients who develop TA–TMA and offers a treatment option for patients who have failed prior treatment with other available therapies including C5 inhibitors and other TA–TMA

directed therapies with a one-year overall survival (OS) of 42.7 percent (95% CI: 19.7, 65.8) in adult patients.[74] Therefore, we stated we agreed that YARTEMLEA® would offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. Based on the information available at the time of the proposed rule, because YARTEMLEA® appears to meet the criteria for approval for new technology add-on payments, we proposed to approve YARTEMLEA® for new technology add-on payments for FY 2027.

We invited public comments on whether YARTEMLEA® meets the substantial clinical improvement criterion and on our proposal to approve YARTEMLEA® for new technology add-on payments.

Comment: The applicant reiterated that YARTEMLEA® meets the substantial clinical improvement criterion, because YARTEMLEA® offers a treatment option for a patient population unresponsive to, or ineligible for, available treatments.

Response: We thank the applicant for its comment regarding the substantial clinical improvement criterion. We agree with the applicant that YARTEMLEA® represents a substantial clinical improvement over existing technologies, because it is the first and only FDA-approved treatment option for patients who develop TA–TMA and offers a treatment option for patients who have failed prior treatment with other available therapies, including C5 inhibitors and other TA–TMA directed therapies, with a 1-year overall survival of 42.7 percent (95 percent CI: 19.7, 65.8) in adult patients.

After consideration of the public comments we received and the information included in the applicant's new technology add-on payment application, we have determined that YARTEMLEA® meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2027. Cases involving the use of YARTEMLEA® that are eligible for new technology add-on payments will be identified by ICD–10–PCS code XW03357 (Introduction of narsoplimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 7) or XW04357 (Introduction of narsoplimab monoclonal antibody into central vein, percutaneous approach, new technology group 7).

In its application and comment, the applicant estimated that the cost of YARTEMLEA® is $441,660 per patient ($36,805 per vial * 12 vials). According to the applicant, the cost for a 370 mg/2 mL single-dose vial is $36,805, and adults receive an average of 11.4 administrations, which corresponds to 12 vials. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of YARTEMLEA® is $287,079 for FY 2027.

g. ZEVASKYN™ (prademagene zamikeracel)

Abeona Therapeutics®, Inc. submitted an FY 2027 application for new technology add-on payments for ZEVASKYN™. According to the applicant, ZEVASKYN™ is an autologous cell sheet-based gene therapy which contains functional copies of the *collagen type VII alpha 1 chain (COL7A1)* transgene for the treatment of adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB). The applicant stated that autologous patient material procured by two 8mm punch biopsies will produce up to twelve 5.5 cm x 7.5 cm gene-corrected cellular sheets available for application in a single surgical session. The number of gene-corrected cellular sheets produced and available for application is not dependent on body size or age. The recommended dose of ZEVASKYN is based on the surface area of the wound(s).

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for ZEVASKYN™ and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251003GPVPQ*.

[74] Schoettler ML, Pusarla SK, Nangia N, et al. Narsoplimab Results in Excellent Survival in Adults and Children With Hematopoietic Cell Transplant Associated Thrombotic Microangiopathy (TA–TMA). *Am J Hematol.* 2025d Aug 29. *https://doi.org/10.1002/ajh.70044.* Epub ahead of print.

		Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS code(s)		XHR0XGA, XHR1XGA, XHR2XGA, XHR3XGA, XHR4XGA, XHR5XGA, XHR6XGA, and XHR7XGA	No concerns.
Newness Criterion	**Newness Period**	BLA approval on April 28, 2025, for the treatment of wounds in adult and pediatric patients with RDEB. Commercial delay to June 15, 2025.	See following discussion.
	Substantial Similarity	Uses a new mechanism of action. Maps to a new MS-DRG. Treats a new disease and/or a new patient population.	See following discussion.
Cost Criterion		33 claims mapping to 3 MS-DRGs, with 33.33% of claims mapping to each MS-DRG 576 (Skin Graft Except for Skin Ulcer or Cellulitis with MCC), 577 (Skin Graft Except for Skin Ulcer or Cellulitis with CC), and 595 (Major Skin Disorders with MCC). Final inflated average case-weighted standardized charge per case ($3,653,712) exceeded the average case-weighted threshold amount ($115,388).	Meets cost criterion.
Substantial Clinical Improvement Criterion		Assertion #1: The technology offers a treatment option for patients unresponsive to or ineligible for currently available treatments. Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available. Provided 2 published and 2 unpublished studies assessing the technology, 4 studies assessing comparator technologies, and other information.	See following discussion.

Newness Criterion

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19427), we noted that regarding commercial availability, the applicant stated that ZEVASKYN™ became available for sale on June 15, 2025, 2 months after it received BLA approval on April 28, 2025, because the applicant needed to onboard and train hospitals on the proper procedures for collecting specimens and applying the technology. We stated we were interested in additional information regarding the cause of any delay in the technology's commercial availability, including whether ZEVASKYN™ was available for purchase before June 15, 2025, during the period the applicant trained hospitals.

Regarding substantial similarity, we stated that based on the information available at the time of the proposed rule, we agreed with the applicant that ZEVASKYN™ uses a new mechanism of action of transducing the full-length *COL7A1* gene into a patient's own keratinocytes to create up to 12 gene-corrected cellular sheets for the treatment of RDEB wounds, as compared to VYJUVEK®, a topical gene therapy that delivers a functional copy of the *COL7A1* gene to affected skin cells using a non-replicating HSV–1 vector and FILSUVEZ®, a botanical gel with an unknown mechanism of action. We also stated we agreed that ZEVASKYN™ maps to a new MS–DRG as compared to VYJUVEK® and FILSUVEZ®. We noted that we disagreed that ZEVASKYN™ does not treat the same or similar type of disease or the same or similar patient population when compared to existing technology because other therapies, such as VYJUVEK® and FILSUVEZ®, are available to treat wounds in adult and pediatric patients with dystrophic epidermolysis bullosa (DEB), of which RDEB is a subtype. Therefore, based on information available at the time of the proposed rule, we stated our belief that ZEVASKYN™ is not substantially similar to existing technology and meets the newness criterion.

We invited public comments on whether ZEVASKYN™ is substantially similar to existing technologies and whether ZEVASKYN™ meets the newness criterion.

Comment: The applicant submitted a public comment agreeing with CMS's assessment that ZEVASKYN™ meets the newness criterion. With respect to commercial availability, the applicant stated that, between April 28 and June 15, 2025, it took necessary steps to identify patients eligible to receive ZEVASKYN™, to train Qualified Treatment Centers (QTCs) to administer ZEVASKYN™, and to begin extensive payer engagement activities, including benefits investigations, prior authorization submissions, and single case agreement negotiations. The applicant further explained that following these administrative steps, QTCs could order the product and schedule patients for biopsy.

Response: We thank the applicant for its comment. Based on the information submitted by the applicant as part of its FY 2027 new technology add-on payment application for ZEVASKYN™, we agree that ZEVASKYN™ uses a new mechanism of action of transducing the full-length *COL7A1* gene into a patient's own keratinocytes to create up to 12 gene-corrected cellular sheets for the treatment of RDEB wounds and maps to a new MS–DRG as compared to VYJUVEK® and FILSUVEZ®. Therefore, we agree that ZEVASKYN™ is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence on June 15, 2025, the date on which ZEVASKYN™ became commercially available for the treatment of adult and pediatric patients with RDEB.

Cost Criterion

Regarding the cost criterion, we stated we agreed with the applicant that the technology meets the cost criterion. We invited public comments on whether ZEVASKYN™ meets the cost criterion.

Comment: The applicant stated its appreciation for CMS's assessment that ZEVASKYN™ meets the cost criterion.

Response: We thank the applicant for its comment. We agree with the applicant that the technology meets the cost criterion.

Substantial Clinical Improvement Criterion

We stated in the proposed rule that we also received a public comment in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for ZEVASKYN™, which we summarized in the proposed rule (91 FR 19247 through 19429).

After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we stated in the proposed rule that we had the following concerns regarding whether ZEVASKYN™ meets the substantial clinical improvement criterion.

Regarding the assertion that ZEVASKYN™ offers a treatment option for a patient population unresponsive to, or ineligible for, current available treatments, we noted that the claims and supporting evidence do not identify a patient population treated with ZEVASKYN™ who cannot otherwise receive existing treatments, such as VYJUVEK® or FILSUVEZ®. The applicant claimed that RDEB patients suffer from severe large wounds that are highly debilitating and there currently are no treatments available to address large chronic RDEB wounds. However, we noted that both VYJUVEK® and FILSUVEZ® do not have a maximum dose in their prescribing label [75] [76] that would preclude the use of either treatment in difficult-to-treat large and chronic RDEB wounds. Similarly, the applicant claimed that no currently available treatment options effectively target chronic pain and itching experienced by RDEB patients and that chronic RDEB wounds pose a high risk of developing squamous cell carcinoma (SCC) and multiple systemic infections, stating that ZEVASKYN™ is the only approved therapy that provides durable healing for these wounds. However, we stated that neither the presence of chronic pain and itching nor a high risk of developing SCC and multiple systemic infections preclude these patients from receiving treatment with VYJUVEK® or FILSUVEZ®. Accordingly, we questioned whether these claims describe improvements in clinical outcomes over existing therapies rather than identifying a distinct patient population unresponsive to, or ineligible for, current available treatments that ZEVASKYN™ can treat.

In addition, while the applicant asserted that ZEVASKYN™ significantly improves clinical outcomes for patients with RDEB, we noted that we did not receive sufficient evidence comparing ZEVASKYN™ to currently available treatments. The applicant stated that ZEVASKYN™ is the only autologous, cell-based gene therapy to demonstrate significantly improved wound healing even in the most difficult-to-treat large and chronic RDEB wounds; however, we noted that both VYJUVEK® and FILSUVEZ® demonstrated statistically significant wound healing in their respective clinical trials. Therefore, we questioned whether ZEVASKYN™ significantly improves wound healing compared to these treatments. The applicant had cited Tang et al. (2025),[77] a randomized, open-label, intra-patient-controlled phase 3 trial that included 11 RDEB patients who had 86 matched and randomized wound pairs treated with either ZEVASKYN™ or control such as daily bandaging and other palliative measures. This study observed that 81 percent of ZEVASKYN™-treated wounds were at least 50 percent healed from baseline compared with 16 percent of control wounds (mean difference: 67 percent; 95 percent CI: 50–89, p=<0.0001) and that complete wound healing from baseline was observed in 16 percent of ZEVASKYN™-treated wounds compared to 0 percent of control wounds (mean difference 13 percent; 95 percent CI 2–26, p = 0.016). However, we noted that in Guide et al. (2022),[78] a double-blind intra-patient randomized, placebo-controlled phase 3 trial consisting of 31 patients (30 with RDEB) who received either VYJUVEK® or placebo weekly for 26 weeks, 65 percent of patients achieved complete wound closure with VYJUVEK® compared to 26 percent with placebo. Similarly, in Kern et al. (2023),[79] a randomized, double-blind, placebo-controlled phase 3 trial consisting of 223 patients (175 with RDEB) who received either FILSUVEZ® or placebo, 44 percent of RDEB patients treated with FILSUVEZ® achieved first complete closure of the target wound within 45 days compared to 26.2 percent of the patients who received placebo.

We noted that the applicant also asserted that ZEVASKYN™ is the only treatment for RDEB that has demonstrated significant reductions in both pain and itch and that ZEVASKYN™ results in durable wound healing. However, we noted that the comparator data we received did not specifically measure pain and itch, and follow-up time for wound healing was limited to 6 months for VYJUVEK® and 90 days for FILSUVEZ®, which we stated limits meaningful comparisons to ZEVASKYN™. Additionally, although the applicant asserted that ZEVASKYN™ provides durable wound healing following a single treatment application, we stated we were concerned that wounds that have not achieved complete closure may require additional treatment, which raises questions regarding the durability of the treatment and whether this can be considered a one-time treatment as asserted by the applicant. According to So et al. (2022),[80] a single-center, non-randomized, open-label phase I/IIa trial that included seven patients who received ZEVASKYN™ on 38 chronic wounds while following patients for a mean of 5.9 years (range: 4–8 years), 70 percent of ZEVASKYN™-treated sites had greater than or equal to 50 percent wound healing and 63 percent had greater than or equal to 75 percent wound healing at 5 years. We noted that given that a subset of treated wounds achieved complete closure and a substantial proportion demonstrated only partial healing, we were uncertain that a single application of ZEVASKYN™ is sufficient and durable for all patients.

Furthermore, we noted that although the applicant asserted that ZEVASKYN™ has a favorable safety

[75] Krystal Biotech, Inc. (2025, Sept.) *VYJUVEK® (beremagene geperpavec-svdt) biological suspension mixed with excipient gel for topical application: highlights of prescribing information. https://www.krystallabel.com/pdf/vyjuvek-us-pi.pdf.*

[76] Chiesi USA, Inc. (2024, May.) *FILSUVEZ® (birch triterpenes) topical gel: highlights of prescribing information. https://resources.chiesiusa.com/Filsuvez/FILSUVEZ_PI.pdf.*

[77] Tang JY, Marinkovich MP, Wiss K, McCarthy D, Truesdale A, Chiou AS, Eid E, McIntyre JK, Bailey I, Furukawa LK, Gorell ES, Harris N, Khosla RK, Peter Lorenz H, Lu Y, Nazaroff J, Grachev ID, Moore AJ. Prademagene zamikeracel for recessive dystrophic epidermolysis bullosa wounds (VIITAL): a two-centre, randomised, open-label, intrapatient-controlled phase 3 trial. Lancet. 2025 Jul 12;406(10499):163–173. *https://doi.org/10.1016/S0140-6736(25)00778-0.*

[78] Guide, S.V., Gonzalez, M.E., Bağcı, I.S., Agostini, B., Chen, H., Feeney, G., Steimer, M., Kapadia, B., Sridhar, K., Quesada Sanchez, L., Gonzalez, F., Van Ligten, M., Parry, T.J., Chitra, S., Kammerman, L.A., Krishnan, S., & Marinkovich, M.P. (2022). Trial of Beremagene Geperpavec (B–VEC) for Dystrophic Epidermolysis Bullosa. *New England Journal of Medicine, 387*(24), 2211–2219. *https://doi.org/10.1056/NEJMoa2206663.*

[79] Kern, J.S., Sprecher E., Fernandez M.F., et al. Efficacy and safety of Oleogel-S10 (birch triterpenes) for epidermolysis bullosa: results from the phase III randomized double-blind phase of the EASE study. *British Journal of Dermatology,* 188(1), 12–21, *https://doi.org/10.1093/bjd/ljac001.*

[80] So JY. et al. Long-term safety and efficacy of gene-corrected autologous keratinocyte grafts for recessive dystrophic epidermolysis bullosa. *Orphanet Journal of Rare Diseases.* 2022(17):377. *https://doi.org/10.1186/s13023-022-02546-9.*

profile with no serious treatment-emergent adverse events (TEAEs) related to the study treatment and no reports of SCC in ZEVASKYN-treated wounds, the applicant did not compare this with TEAEs and rates of SCC seen with available treatments such as VYJUVEK® and FILSUVEZ®. Therefore, we stated we cannot determine an improvement in safety for ZEVASKYN™ over existing technologies.

After review of the information provided by the applicant and the public comments received in response to the New Technology Town Hall meeting, we stated we were unable to determine that ZEVASKYN™ represents a substantial clinical improvement over existing technologies, and therefore, we proposed to disapprove new technology add-on payments for ZEVASKYN™ for FY 2027.

We invited public comments on whether ZEVASKYN™ meets the substantial clinical improvement criterion and our proposal to disapprove new technology add-on payments for ZEVASKYN™ for FY 2027.

Comment: The applicant and a commenter expressed support for approving new technology add-on payment status for ZEVASKYN™. The commenter stated that doing so will remove a potential barrier to patients accessing innovative treatments and tools advancing a personalized medicine approach to care. The applicant disagreed with CMS's preliminary determination that ZEVASKYN™ does not meet the substantial clinical improvement criterion and requested CMS reconsider its proposal and approve ZEVASKYN™ for new technology add-on payment.

In response to our concern that the claims and supporting evidence failed to identify a patient population treated with ZEVASKYN™ who cannot otherwise receive existing treatments, the applicant stated that, in clinical trials, ZEVASKYN™ was uniquely studied in large, chronic wounds each larger than 20 cm^2 and open for 6 months or more. The applicant asserted that all clinical trial outcomes, including long-term follow up, were reported following a one-time surgical application to these tough-to-treat, large, chronic RDEB wounds. The applicant cited Tang et al. (2025) and So et al. (2022), stating that large and chronic wounds are a common occurrence in RDEB patients and that these wound characteristics, not simply the underlying RDEB diagnosis, define the population for whom no adequate alternative exists.[81] [82] The applicant added that the unmet need in this context is wound-specific, not patient-specific, and CMS's current framework does not adequately account for this distinction. The applicant further stated that, while existing therapies, including VYJUVEK® and FILSUVEZ®, are also indicated for the treatment of wounds in DEB patients, RDEB patients have wounds of various sizes, shapes, and duration of chronicity. The applicant cited Guide et al. (2022), Kern et al. (2023), and Tang et al. (2025), asserting that VYJUVEK®'s and FILSUVEZ®'s respective clinical trials showed clinical responses primarily in smaller wounds (median wound size: 10.6 cm^2 and 16.0 cm^2, respectively) with weekly dosing, while ZEVASKYN™ has demonstrated wound healing and pain reduction in large (median size: 160 cm^2) and chronic wounds.

In response to our concern that both VYJUVEK® and FILSUVEZ® do not have a maximum dose that precludes the use of either treatment in difficult-to-treat, large, and chronic RDEB wounds, the applicant clarified that, according to VYJUVEK®'s prescribing information, the therapy has a maximum weekly dose equal to 2×10^9 plaque forming units (PFU) (1 mL) for patients younger than 3 years old and a maximum weekly dose of 4×10^9 PFU (2 mL) for patients 3 years of age or older. The applicant further explained that the VYJUVEK® prescribing information states that a 40 to 60 cm^2 wound requires 1.2×10^9 PFU or 0.6 mL of VYJUVEK® and that one should apply VYJUVEK® gel to wounds until they are closed before selecting new wound(s) to treat. The applicant also stated that based on this information, a patient may cover a maximum wound surface area of 133 to 200 cm^2 with one VYJUVEK® vial (calculation: (4.0 PFU/mL/1.2 PFU/mL = 3.33) × 60 cm^2 = 200 cm^2)) and must continue treating the same wounds each week until those wounds are closed.

In addition, the applicant stated that FILSUVEZ® was studied in wounds of 10 to 50 cm^2, and it is unaware of data that suggests FILSUVEZ® could be used to treat wounds as large as those that ZEVASKYN™ can treat. The applicant noted that the FILSUVEZ® prescribing information specifies that one 25 mL tube, containing 23.4 g of 10 percent birch triterpene gel, covers up to 250 cm^2 per application at wound dressing changes. The applicant asserted that while the label does not explicitly limit the number of tubes per dressing change, the per tube body surface area ceiling of 250 cm^2 creates a meaningful, practical, and economic constraint. The applicant stated that FILSUVEZ®, like VYJUVEK®, has not demonstrated clinical benefit in the large, chronic, non-healing wounds. The applicant reiterated that each ZEVASKYN™ gene-modified cellular sheet can cover 41.25 cm^2 of wound area and that up to 12 ZEVASKYN™ gene-modified cellular sheets are delivered for a single treatment of a patient, which can cover a total wound area of 495 cm^2 (12 × 41.25 cm^2). The applicant stated that ZEVASKYN™ can treat 2.5 to 8.7 times more wound area than VYJUVEK®. The applicant asserted that ZEVASKYN™ provides greater body surface area coverage than other therapies, and therefore, is a clinically meaningful advancement for this patient population. The applicant concluded that ZEVASKYN™ addresses a distinct and severe wound phenotype that other existing therapies, by virtue of their mechanism, dosing limitations, and clinical profiles, cannot address.

In response to our concerns that we did not receive sufficient evidence comparing ZEVASKYN™ to currently available treatments, the applicant asserted that CMS's comparison of ZEVASKYN™ with VYJUVEK® and FILSUVEZ® is not scientifically supportable, because these treatments have different mechanisms of action, are categorically distinct, and achieve different clinical outcomes and are thus not interchangeable. The applicant stated that FILSUVEZ® is a tree-bark extract with an unknown mechanism of action and does not correct the underlying defect in the *COL7A1* gene,[83] while VYJUVEK® uses a non-integrating herpes simplex viral (HSV–1) vector that expresses the *COL7A1* gene in the nucleus of treated skin cells.[84] The applicant added that the HSV–1 genetic material does not integrate into the cellular genome of transduced cells and thus is diluted with each cellular division of treated skin cells, requiring repeated VYJUVEK® application for wound healing. The applicant stated that VYJUVEK® and FILSUVEZ® typically

[81] Tang et al. Prademagene zamikeracel for recessive dystrophic epidermolysis bullosa wounds (VIITAL): a two-centre, randomized, open-label, intrapatient-controlled phase 3 trial. *Lancet.* 2025. 406(10499):163–173.

[82] So et al. Long-term safety and efficacy of gene-corrected autologous keratinocyte grafts for recessive dystrophic epidermolysis bullosa. *Orphanet Journal of Rare Diseases.* 2022. 17:377.

[83] Schwieger-Briel et al. Mechanism of Oleogel-S10—A triterpene preparation for the treatment of EB. *Dermatologic Therapy.* 2019. Jul;32(4).

[84] Guide et al. Trial of Bermmagene Geparpavec (B–VEC) for Dystrophic Epidermolysis Bullosa. *N Engl J Med.* 2022. Dec 15;387(24):2211–2219.

require life-long, weekly applications to maintain their clinical effect. In contrast, the applicant highlighted that ZEVASKYN™ is designed to be a one-time treatment for wounds and uses a replication incompetent gamma retroviral vector, whose genetic material integrates into transduced cells' cellular genome, delivering a fully functional *COL7A1* gene that stably integrates into the genome and is maintained throughout repeated cell division while negating the requirement for repeated application.[85] The applicant cited So et al. (2022), Eid et al. (2026),[86] and Gaona et al. (2026)[87] and stated that ZEVASKYN™ is unique among approved RDEB treatments because it delivers a fully functional and persisting copy of the *COL7A1* gene and is thus a one-time gene therapy that persists after treatment. The applicant concluded that because ZEVASKYN™ is a one-time treatment and VYJUVEK® and FILSUVEZ® require continued reapplication to wound healing, these interventions are categorically distinct and achieve different clinical outcomes.

In response to our concern that pain and itch were not endpoints in the VYJUVEK® or FILSUVEZ® clinical trials and that this limits meaningful comparisons to ZEVASKYN™, the applicant stated that VYJUVEK®'s clinical trial data did not achieve statistical significance for pain,[88] and FILSUVEZ® demonstrated improvement in pain only at Day 14 in patients of ages 4 years and older, with no statistically significant findings at timepoints beyond 14 days.[89] The applicant also noted that VYJUVEK® generated no meaningful data on itch and that FILSUVEZ® showed statistically significant improvement in itch only at Day 60 compared to placebo, with no sustained signal beyond that single timepoint. The applicant contrasted these findings to ZEVASKYN™'s pivotal VIITAL trial (Tang et al., 2025) which found a mean change in wound pain from baseline to week 24 of −3.07 for ZEVASKYN™ and -0.90 for control wounds (mean pairwise difference −2.23 (−3.45 to -0.66), p = 0.0002) and a mean change in itch severity from baseline to week 24 of −2.0 for ZEVASKYN versus -0.05 for control wounds (mean pairwise difference -1.56 (95% CI −2.95 to -0.26; p = 0.0044)).[90] The applicant stated that Tang et al. (2025) was powered for analyzing difference in pain, whereas difference in itch was an exploratory endpoint. The applicant suggested that ZEVASKYN™'s pain and itch data demonstrates greater rigor and significance than data available for VYJUVEK® and FILSUVEZ®. The applicant asserted that ZEVASKYN™ is the only therapy to have studied pain and itch alongside wound healing following treatment.

In response to our concern that the wounds that did not achieve full closure with ZEVASYKN™ may need additional treatment, the applicant disagreed with CMS's characterization that these concerns undermine ZEVASYKN™'s durability. The applicant asserted that ZEVASKYN™ has demonstrated long-term efficacy at treated wound sites. The applicant stated that ZEVASKYN™ is designed as a non-systemic cell-based gene therapy, distinguishing it from other gene therapies approved in the United States, and that this localized approach enables the therapy to act precisely where it is needed, supporting durable and clinically meaningful wound closure. The applicant further asserted that not a single wound of the 144 wounds treated across ZEVASKYN™'s clinical trials had been re-treated, and in the cases where patients returned for subsequent treatments, those treatments addressed wounds at new anatomic locations and not the retreatment of wounds already treated with ZEVSAKYN™, asserting the crucial distinction that retreatment in this context bears no relationship to ZEVASKYN™'s durability. The applicant stated that ZEVASKYN™'s durability is further supported by biological evidence of long-term persistence, including histologic confirmation of anchoring fibril restoration and collagen VII expression at treated sites across 2 years follow-up, and durable wound healing up to 12 years post-application as shown by Eichstadt et al. (2019),[91] So et al. (2022), Eid et al. (2026), and Gaona et al. (2026). The applicant also clarified that partial healing of a wound does not negate durable engraftment and these are not mutually exclusive outcomes. The applicant concluded that long-term follow-up data (up to 12 years to date and ongoing) provides additional evidence of ZEVASKYN™'s sustained biologic activity and that ZEVASKYN™ is the only therapy to demonstrate durable, single-treatment genomic correction with multi-year biologic persistence in treated wounds.

In response to our concern that the applicant did not compare ZEVASKYN™'s safety profile to those of other available treatments, the applicant asserted that requiring such comparative evidence exceeds the evidentiary standard applicable to new technology add-on payment determinations according to 42 CFR 412.87(b)(1)(iii) regarding evidence for substantial clinical improvement, and suggested that the statute and implementing regulations do not require direct, head-to-head safety comparisons to existing therapies. The applicant asserted that denial of new technology add-on payment status for ZEVASKYN™ would critically impair patient access to a therapy that represents a genuine and substantial clinical advance for one of the most vulnerable rare disease patient populations.

Response: We thank the applicant and commenter for their comments regarding the substantial clinical improvement criterion. After consideration of the public comments and the information included in the applicant's new technology add-on payment application, we agree that ZEVASKYN™ represents a substantial clinical improvement over existing technologies because ZEVASKYN™ is a one-time gene therapy for the treatment of large, chronic wounds up to 495 cm^2 and significantly reduces pain in patients with RDEB, with a mean change in wound pain from baseline to week 24 of −3.07 points (mean pairwise difference −2.23 [−3.45 to −0.66]; p = 0.0002). In contrast, the available data for VYJUVEK® and FILSUVEZ® did not demonstrate statistically significant reductions in pain from baseline (at

[85] Tang et al. Prademagene zamikeracel for recessive dystrophic epidermolysis bullosa wounds (VIITAL): a two-centre, randomized, open-label, intrapatient-controlled phase 3 trial. *Lancet.* 2025. 406(10499):163–173.

[86] Eid et al. Sustained wound healing and long-term safety of prademagene zamikeracel (pz-cel) in recessive dystrophic epidermolysis bullosa (RDEB): Five-year results from the VIITAL phase 3 trial [Poster presentation]. *Society for Investigational Dermatology.* 2026.

[87] Gaona et al. Long-term safety and clinical outcomes of pz-cel gene therapy in a single patient with recessive dystrophic epidermolysis bullosa: a 12-year case report [Poster presentation]. *Society for Investigative Dermatology.* 2026.

[88] Guide et al. Trial of Bermmagene Geparpavec (B–VEC) for Dystrophic Epidermolysis Bullosa. *N Engl J Med.* 2022. Dec 15;387(24):2211–2219.

[89] Kern et al. Efficacy and safety of Oleogel-S10 (birch triterpenes) for epidermolysis bullosa: results from the phase III randomized double-blind phase of the EASE study. *Br. J. Dermatol.* 2023. 188: 12–21.

[90] Tang et al. Prademagene zamikeracel for recessive dystrophic epidermolysis bullosa wounds (VIITAL): a two-centre, randomized, open-label, intrapatient-controlled phase 3 trial. *Lancet.* 2025. 406(10499):163–173.

[91] Eichstadt et al. Phase 1/2a clinical trial of gene-corrected autologous cell therapy for recessive dystrophic epidermolysis bullosa. *JCI Insight.* 2019. Oct 3;4(19).

timepoints beyond 14 days for FILSUVEZ®).[92]

Based on the information available at the time of this final rule, we have determined that ZEVASKYN™ meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2027. Cases involving the use of ZEVASKYN™ that are eligible for new technology add-on payments will be identified by any of the ICD–10–PCS codes listed in the following table:

ICD-10-PCS code	Description
XHR0XGA	Replacement of head and neck skin with prademagene zamikeracel, genetically engineered autologous cell therapy, external approach
XHR1XGA	Replacement of chest skin with prademagene zamikeracel, genetically engineered autologous cell therapy, external approach
XHR2XGA	Replacement of abdomen skin with prademagene zamikeracel, genetically engineered autologous cell therapy, external approach
XHR3XGA	Replacement of back skin with prademagene zamikeracel, genetically engineered autologous cell therapy, external approach
XHR4XGA	Replacement of right upper extremity skin with prademagene zamikeracel, genetically engineered autologous cell therapy, external approach
XHR5XGA	Replacement of left upper extremity skin with prademagene zamikeracel, genetically engineered autologous cell therapy, external approach
XHR6XGA	Replacement of right lower extremity skin with prademagene zamikeracel, genetically engineered autologous cell therapy, external approach
XHR7XGA	Replacement of left lower extremity skin with prademagene zamikeracel, genetically engineered autologous cell therapy, external approach

In its application, the applicant estimated that the cost of ZEVASKYN™ is $3,147,000 per patient. According to the applicant, ZEVASKYN™ is supplied as 41.25 cm^2 gene-corrected keratinocyte sheets with up to 12 sheets available for application in a single surgical session. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of ZEVASKYN™ is $2,045,550 for FY 2027.

6. FY 2027 Applications for New Technology Add-On Payments (Alternative Pathways)

As discussed previously, beginning with applications for FY 2021, a medical device designated under FDA's Breakthrough Devices Program that has received marketing authorization as a Breakthrough Device for the indication covered by the Breakthrough Device designation may qualify for the new technology add-on payment under an alternative pathway. Additionally, beginning with FY 2021, a medical product that is designated by FDA as a Qualified Infectious Disease Product (QIDP) and has received marketing authorization for the indication covered by the QIDP designation, and, beginning with FY 2022, a medical product that is a new medical product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and used for the indication approved under the LPAD pathway, may also qualify for the new technology add-on payment under an alternative pathway. Under an alternative pathway, a technology will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS and will not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These technologies must still be within the 2- to − 3-year newness period to be considered ''new,'' and must also still meet the cost criterion. We refer readers to section II.H.8. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) for further discussion of the alternative new technology add-on payment pathways for these technologies. As previously noted, in section II.E.7. of this final rule, we are finalizing our proposal to repeal the alternative pathway for new technology add-on payment beginning with applications received for new technology add-on payments for FY 2028 and require all applicants for new technology add-on payments to demonstrate that the technology meets all eligibility requirements to receive add-on payments, unless specifically grandfathered under the alternative pathway eligibility criteria. (We refer readers to section II.E.7. of this final rule for a complete discussion of this finalized policy.)

As discussed previously, as finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990) and subsequently updated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36662 through 36664), we publicly post online applications for new technology add-on payment beginning with FY 2024 applications. As noted in those final rules, we are continuing to provide discussion of the concerns or issues we identified with respect to applications submitted under the alternative pathway, but we are providing more succinct information as part of the summaries in the proposed and final rules regarding the applicant's assertions as to how the medical service or technology meets the applicable new technology add-on payment criteria. We refer readers to *https://mearis.cms.gov/public/publications/ntap* for the publicly posted FY 2027 new technology add-on payment applications and supporting information (with the exception of certain cost and volume information, and information or materials identified by the applicant as confidential or copyrighted), including tables listing the ICD–10–CM codes, ICD–10–PCS codes, and/or MS–DRGs related to the analyses of the cost

[92] Tang et al. Prademagene zamikeracel for recessive dystrophic epidermolysis bullosa wounds (VIITAL): a two-centre, randomized, open-label, intrapatient-controlled phase 3 trial. *Lancet.* 2025. 406(10499):163–173.

criterion for certain technologies for the FY 2027 new technology add-on payment applications.

In addition, for certain FY 2027 new technology add-on payment applications, in the proposed rule, we made available separate tables listing the ICD–10–PCS codes or ICD–10–CM codes that would be used to identify the Breakthrough Device-designated indication, or would be appropriate to exclude for cases related to a different technology, for purposes of the new technology add-on payment, if approved, in Table 10 associated with the proposed rule, available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.* To access Table 10, click on the link titled ''FY 2027 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download'' on the left side of the screen, at the CMS website. Please see section VI of the Addendum of the proposed rule for additional information regarding tables associated with the proposed rule.

Table 10 associated with this final rule reflects the finalized tables listing the ICD–10–PCS codes or ICD–10–CM codes that would be used to identify the relevant indication, or exclude cases related to a different technology, for these technologies for purposes of the new technology add-on payment for FY 2027, and is available on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps.*

We received 32 applications for new technology add-on payments for FY 2027 under the new technology add-on payment alternative pathway. As previously discussed, beginning with the new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA marketing authorization request at the time of new technology add-on payment application submission and must provide documentation of FDA acceptance or filing to CMS at the time of application submission, consistent with the type of FDA marketing submission the applicant has submitted to FDA. See § 412.87(e) and further discussion in the FY 2024 and FY 2025 IPPS/LTCH PPS final rules (88 FR 58948 through 58958; 89 FR 69242 through 69245). Of the 32 applications received under the alternative pathway, 7 applications were not eligible for consideration for new technology add-on payment because they did not meet these requirements; and 3 applicants withdrew their applications prior to the issuance of the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19312). Subsequently, prior to the issuance of this final rule, 5 additional applicants (for CERAMENT® V, MediBeacon® Transdermal GFR Measurement System [TGFR], Micro Medical Solutions MicroStent and the MicroStent XL Peripheral Vascular Stent System, PMCardio® STEMI AI ECG Model, and VUNO Med-DeepCARS®) withdrew their applications or did not meet the May 1 deadline for FDA approval or clearance of the technology, and therefore are not eligible for consideration for new technology add-on payments for FY 2027. While we do not typically address in the final rule those applications for which the technology has not received FDA marketing authorization as a Breakthrough Device for the relevant indication by the May 1 deadline, we are summarizing and responding to comments we received regarding whether the CARA System has received the required FDA marketing authorization for this product by May 1. We are also addressing the remaining 16 applications, all of which received marketing authorization as a Breakthrough Device from FDA.

In accordance with the regulations under § 412.87(f)(2), applicants for new technology add-on payments for FY 2027 for Breakthrough Devices must have FDA marketing authorization by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Under § 412.87(f)(3), applicants for new technology add-on payments for FY 2027 for QIDPs and technologies approved under the LPAD pathway must have FDA marketing authorization by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. The policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58742) provides for conditional approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products (QIDPs and LPADs) at § 412.87(d) that does not receive FDA marketing authorization by July 1 prior to the particular fiscal year for which the applicant applied for new technology add-on payments, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for a complete discussion of this policy (85 FR 58737 through 58742). As previously noted, in section II.E.7. of this final rule, we are finalizing our proposal to repeal the alternative pathway for new technology add-on payment, such that beginning with applications received for new technology add-on payments for FY 2028, in order to be eligible for consideration for the new technology add-on payment for the upcoming fiscal year, all applicants will need to receive FDA marketing authorization by May 1 prior to the particular fiscal year for which the application is being considered.

As we did in the FY 2026 IPPS/LTCH PPS proposed rule, for applications under the alternative new technology add-on payment pathway, in the proposed rule we proposed to approve or disapprove each of the 22 applications for FY 2027 new technology add-on payments. Therefore, in this section of the preamble of this final rule, we provide the overview table from the proposed rule of each remaining new technology add-on payment application and CMS's preliminary assessment for each alternative pathway application, and our determination on whether or not each technology is eligible for the new technology add-on payment for FY 2027.

We stated in the proposed rule that we received multiple applications for subscription-based technologies for FY 2027. We further noted that we stated in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58630) and in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69207) that we understand that there are unique circumstances with respect to determining a cost per case for a technology that utilizes a subscription for its cost and we will continue to consider the issues relating to calculation of the cost per unit of technologies sold on a subscription basis as we gain more experience in this area. We stated that we continue to welcome comments from the public as to the appropriate method to determine a cost per case for such technologies, including comments on whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for add-on payment.

Comment: A commenter raised concerns regarding new technology add-on payment applications for software applications and electronic health record (EHR) tools that are integrated with hospital EHR systems and stated its belief that the new technology add-on payment program is not designed, nor is it the most appropriate avenue, to

account for provider costs from investments in software and equipment that is deployed across the enterprise through an EHR. The commenter stated that claims for additional new technology add-on payment are on a per-patient basis, and EHR software platforms are not deployed at the per-patient level. The commenter stated that, because these tools may be available across many patient populations and MS–DRGs, their costs may resemble administrative and general information technology operating costs that are reportable on the Medicare cost report but not typically separately chargeable on a per-patient basis. The commenter stated that CMS had asked for comment on the cost criterion for one of these EHR tools and whether the technology would replace any prior technology, and stated that for the uses described there were already clinical criteria, decision support tools, and other rubrics in use by providers. The commenter stated that clinical decision-making is up to the treating provider regardless of the use of such tools.

The commenter further stated a new technology add-on payment application for an EHR-integrated tool was for a subscription service that is billed according to hospital size rather than on a per-patient basis. The commenter questioned whether CMS could elaborate on how a provider would appropriately charge a patient account and report utilization on an individual inpatient claim, given this cost structure. The commenter also questioned how these technologies, if approved, would be recognized for new technology add-on payment on inpatient claims. The commenter stated that new technology add-on payment claims are identified through the use of ICD–10–PCS procedure codes, which requires physician documentation of the procedure utilizing the new technology. The commenter questioned if the procedure identifying the use of these EHR tools would be specifically documented by clinicians and reportable for new technology add-on payment for individual claims, and if this would result in unnecessary documentation burden.

The commenter recommended that CMS provide additional guidance for technologies seeking new technology add-on payment when the technology is an EHR-integrated software platform, and stated that CMS consider establishing a dedicated administrative and general cost center for clinical information technology applications or software so that such costs could be directly assigned or stepped down to benefiting service lines for rate setting purposes. The commenter stated that the function of the new technology add-on payment program may be diluted if it is utilized broadly to provide minimal supplemental payment for these software costs to a facility.

Another commenter expressed its support for CMS's broadening approach to evaluating emerging software, including software as a service (SaaS) and software as a medical device (SaMD) under the new technology add-on payment program. The commenter stated that CMS is demonstrating flexibility in evaluating technologies that do not align with traditional per-case reimbursement frameworks and that this represents an important step towards ensuring that innovative, AI-enabled solutions can be considered within the Medicare payment system. The commenter recommended that CMS develop more standardized and transparent methodologies for evaluating the costs of subscription-based and artificial intelligence-driven solutions for new technology add-on payment purposes. The commenter stated that clearer expectations regarding cost allocation, utilization assumptions, and the definition of technology use within an inpatient stay would reduce reliance on varying approaches across applicants and improve predictability. The commenter stated that a more accessible and well-defined pathway would support appropriate hospital payment for these technologies and help ensure beneficiary access to tools that may enhance clinical decision-making, improve efficiency, and support better patient outcomes.

Response: We thank the commenters for their support and recognition of the inherent complexities. We recognize that software-based, subscription-based, EHR-integrated, and artificial intelligence-driven technologies may present differently than technologies that are furnished as a more discrete item or service during an inpatient stay. We also acknowledge commenters' interest in additional clarity regarding how hospitals may report the use of such technologies on claims, how costs may be allocated to inpatient cases, and how applicants may support the cost criterion for purposes of new technology add-on payment.

As we have evaluated technologies priced through subscriptions or other non-per-patient arrangements for new technology add-on payment eligibility, we have reviewed estimated average costs of the technology for eligible inpatient cases, including relevant utilization assumptions, cost allocation methodology, and how use of the technology would be identified and supported by documentation and coding (for example, 85 FR 58625 through 58636, 89 FR 69205 through 69208). ICD–10–PCS codes are typically used to identify eligible new technology add-on payments, under the same process as other claims. The addition of ICD–10–CM codes may be used to identify technologies for new technology add-on payments, but only where the technology is otherwise not uniquely identifiable. Eligible new technology add-on payments are calculated using the methodology detailed at *42 CFR 412.88.*

Regarding the request that CMS develop more standardized and transparent methodologies for evaluating the costs of subscription-based and artificial intelligence-driven solutions for new technology add-on payment purposes, and that clearer expectations regarding cost allocation, utilization assumptions, and the definition of technology use within an inpatient stay would reduce reliance on varying approaches across applicants and improve predictability, we note that subscription-based approaches to pricing can vary significantly, and we have accommodated those differences in evaluating each applicant individually, rather than requiring a certain methodology by which subscription-based technology providers must calculate the price to hospitals for their services/products.

We will continue to evaluate the cost information submitted for subscription-based technologies under the applicable new technology add-on payment criteria. For applicants that seek new technology add-on payment for technologies that are licensed, subscribed to, or otherwise priced on a basis other than a discrete per-patient charge, we expect the application to clearly describe the methodology used to estimate the average cost of the technology for eligible inpatient cases, including the assumptions used to identify relevant utilization, allocate costs to inpatient cases, and distinguish the cost of the technology from other administrative, general, or information technology costs, which might be considered capital costs. We also expect applicants to describe how cases involving use of the technology would be identified for purposes of any new technology add-on payment, including whether use of the technology can be supported by the applicable coding and medical record documentation. We may consider whether additional guidance would be useful for future rulemaking or other subregulatory materials as we

gain experience with more of these types of technologies.

With respect to the recommendation to establish a dedicated administrative and general cost center for clinical information technology applications or software, we appreciate the commenter's suggestion. We are not adopting such a cost-reporting change in this final rule. We may consider whether further analysis of cost-reporting treatment for clinical software or EHR-integrated tools would be appropriate in future rulemaking and whether the cost analyses should be updated for each year for which the technology may be eligible for add-on payment.

a. Alternative Pathway for Breakthrough Devices

1. Bayesian Health Sepsis Flagging Device

Bayesian Health, Inc. submitted a FY 2027 application for new technology add-on payments for the Bayesian Health Sepsis Flagging Device. According to the applicant, the Bayesian Health Sepsis Flagging Device is artificial intelligence and machine learning-based Software as a Medical Device (SaMD) intended for use in conjunction with clinical assessments and other laboratory findings to aid the early detection and/or risk prediction of sepsis within the next 4 days.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for the Bayesian Health Sepsis Flagging Device and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP25100520EEP.*

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	Request submitted.	N/A
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** Targeted Real-time Early Warning System (TREWS) is artificial intelligence and machine learning-based software as a medical device intended for use in conjunction with clinical assessments and other laboratory findings to aid the early detection and/or risk prediction of sepsis within the next 4 days. TREWS uses a machine learning algorithm to analyze patient data from the Electronic Healthcare Record (EHR), which includes a combination of the following variables: patient information, comorbidities, the chief complaint documented at presentation to the emergency department, laboratory measurements and vital signs, and procedures, medications, and consult orders. TREWS outputs a semi-quantitative flag ("high risk for sepsis" and "risk for sepsis") that is displayed within the EHR. TREWS is to be used in combination with other clinical and laboratory data by healthcare providers when providing patient care. TREWS is indicated for use in adult patients in the emergency, observation, general ward, and intensive care units. TREWS is intended to be used upon ED presentation or hospital admission throughout the duration of the patient's stay. TREWS is a prescription-use only device. Per the applicant, the Targeted Real-time Early Warning System (TREWS) device named in the Breakthrough Device designation letter is the same device as the Bayesian Health Sepsis Flagging Device. **FDA Indication:** Pending.	Pending FDA marketing authorization.
Newness Period	FDA decision anticipated by May 1, 2026, consistent with its Breakthrough Device designation. No commercial availability delay expected.	Pending FDA marketing authorization.
Cost Criterion	Scenarios 1 and 2: 3,498,833 claims mapping to 739 MS-DRGs, with 14.67 percent of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC). Final inflated average case-weighted standardized charge per case (Scenario 1 – $83,896; Scenario 2 – $81,748) exceeded the average case-weighted threshold amount (Scenarios 1 and 2 – $73,678).	Meets cost criterion.
Technology Cost	The cost of the Bayesian Health Sepsis Flagging Device is a subscription that is tiered based on the bed size of the hospitals in the seven health systems currently using the technology, and the average cost per patient per health system will vary based on the number of hospital stays where the technology is used. An average cost to the hospital per patient of $95.14 was estimated, based on total costs for inpatient use of the technology divided by total inpatient stays across the seven health systems. The overall cost per case was then calculated as the sum of costs-per-case across the seven health systems, divided by the number of health systems.	Maximum new technology add-on payment: $61.84

Cost Criterion

In the proposed rule, we stated that after review of the information provided by the applicant, we agreed with the applicant that the Bayesian Health Sepsis Flagging Device meets the cost criterion and therefore proposed to approve the Bayesian Health Sepsis Flagging Device for new technology add-on payments for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

Based on preliminary information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of the Bayesian Health Sepsis Flagging Device would be $61.84 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether the Bayesian Health Sepsis Flagging Device meets the cost criterion and our proposal to approve new technology add-on payments for the Bayesian Health Sepsis Flagging Device for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

Comment: Multiple commenters expressed support for the approval of the Bayesian Health Sepsis Flagging Device to address high morbidity, mortality and cost burden associated with sepsis and potentially allow for earlier recognition to improve outcomes when used in conjunction with clinician judgment and evidence-based sepsis care. In addition, a commenter suggested that CMS closely monitor real-world performance, including false positive and false negative rates across diverse patient populations and care settings, and to require robust post-implementation evaluation to ensure that algorithmic tools do not exacerbate disparities in sepsis recognition or treatment for historically marginalized communities.

Response: We thank the commenters for their comments.

Comment: A commenter expressed performance concerns regarding the Bayesian Health Sepsis Flagging Device based on its FDA 510(k) summary, asserting that the device performance would be on par with other devices, but substantially less than what the commenter referred to as the state-of-the-art generative AI model performance reported in the literature.

Response: We thank the commenter for its comment. We note that performance concerns are not within the scope of CMS's evaluation for new technology add-on payment under the alternative pathway, as defined in § 412.87(c). As discussed previously, a technology applying under an alternative pathway does not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. (*84 FR 42296*).

Comment: A commenter expressed concern regarding EHR-integrated software tools with wide-spread use across the majority of MS–DRGs, specifically referencing the Bayesian Health Sepsis Flagging Device. The commenter stated that this technology's cost criterion analysis showed that it would be applicable to 739 MS–DRGs, and further stated this is nearly all MS–DRGs. The commenter stated that such broad applicability suggests the technology functions more like an EHR module or tool, which would already be baked into the MS–DRG and IPPS payment system as a whole, as an administrative and general information technology operating cost, reportable on hospital cost reports, but not typically separately chargeable per patient.

Response: We thank the commenter for its comment. As discussed previously, for technologies priced through subscriptions or other non-per-patient arrangements, such as the Bayesian Health Sepsis Flagging Device, we review estimated average cost of the technology for eligible inpatient cases, including relevant utilization assumptions, cost allocation methodology, and how use of the technology would be identified and supported by documentation and coding.

Comment: The applicant submitted a public comment in support of approving new technology add-on payments for the Bayesian Health Sepsis Flagging Device for FY 2027 as proposed, stating that it meets alternative pathway eligibility criteria, and that the Bayesian Health Sepsis Flagging Device received FDA 510(k) clearance for the same indication as that of the Breakthrough Device designation on April 30, 2026.

Response: We thank the applicant for its comment. Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the Bayesian Health Sepsis Flagging Device meets the cost criterion. The technology received 510(k) clearance from FDA as a Breakthrough Device on April 30, 2026 with an indication for use by Health Care Providers (HCPs) in conjunction with clinical assessments and other laboratory data to aid in the early detection and/or risk prediction of sepsis developing within 24 hours for adult patients (≥18 years old) upon Emergency Department (ED) presentation or hospital admission throughout the duration of the patient's stay in acute care settings,[93] which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the Bayesian Health Sepsis Flagging Device for FY 2027. We consider the beginning of the newness period to commence on April 30, 2026, the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the Bayesian Health Sepsis Flagging Device is $95.14. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the Bayesian Health Sepsis Flagging Device is $61.84 for FY 2027 (that is, 65 percent of the average cost of the technology).

The applicant was granted approval for a unique ICD–10–PCS procedure code for the Bayesian Health Sepsis Flagging Device beginning in FY 2027. Therefore, cases involving the use of the Bayesian Health Sepsis Flagging Device that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code: XEZZXJC (High dimensional mixture-of-experts computer-aided assessment of inflammatory response and organ function, for notification and triage, new technology group 12).

2. BriefCase-Triage: CARE (Clinical AI Reasoning Engine) Multi-Triage CT Body

Aidoc Medical Ltd., Inc. submitted a FY 2027 application for new technology add-on payments for BriefCase-Triage: CARE Multi-Triage CT Body (BriefCase-Triage). According to the applicant, BriefCase-Triage is a radiological triage device used for the analysis of contrast and non-contrast CT images that flags

[93] *https://www.accessdata.fda.gov/cdrh_docs/pdf25/K250680.pdf*

and communicates suspected positive findings for a wide range of clinically actionable, time-sensitive conditions in the abdominopelvic region.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for BriefCase-Triage and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251004A9NVV.*

BILLING CODE 4169–69–C

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	Request submitted.	N/A
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** BriefCase-Triage: CARE (Clinical AI Reasoning Engine) Multi-Triage CT Body is a radiological computer aided triage and notification software for use in the analysis of contrast and non-contrast CT images of the chest, abdomen, and/or pelvis, in adults or transitional adolescents aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive findings, per study, of: diverticulitis; abdominal-pelvic abscess; appendicitis; intestinal ischemia and/or pneumatosis; obstructive renal stone; small bowel obstruction; large bowel obstruction; spleen injury; liver injury; kidney injury; and pelvic fracture. **FDA Indication:** BriefCase-Triage: CARE (Clinical Al Reasoning Engine) Multi-Triage CT Body is a radiological computer aided triage and notification software indicated for use in the analysis of contrast and non-contrast CT images of the chest, abdomen, and/or pelvis, in adults or transitional adolescents aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive findings, per study, of: 1. Diverticulitis; 2. Abdominal-pelvic abscess; 3. Appendicitis; 4. Intestinal ischemia and/or pneumatosis; 5. Obstructive renal stone; 6. Small bowel obstruction; 7. Large bowel obstruction; 8. Spleen injury; 9. Liver injury; 10. Kidney injury; 11. Pelvic fracture. The device flags cases with at least one suspected finding to assist with triage/prioritization of medical images. The device will provide a flag for each suspected finding within this study. A preview image will be provided for each distinct suspected finding. BriefCase-Triage uses a foundation model-based artificial intelligence (Al) system to analyze images and highlight cases with detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images for each suspected finding that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical images and is not intended to be used as a diagnostic device. The results of BriefCase-Triage are intended to be used in conjunction with other patient information and based on their professional judgment to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.	FDA indication is appropriate for consideration under the alternative pathway.
Newness Period	510(k) clearance on 1/7/2026.	Newness date: 1/7/2026.
Cost Criterion	Scenario 1: 3,747,413 claims mapping to 755 MS-DRGs, with 11.05 percent of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC). Scenario 2: 3,307,953 claims mapping to 749 MS-DRGs, with 12.18 percent of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV>96 Hours with MCC) Final inflated average case-weighted standardized charge per case (Scenario 1 – $101,272; Scenario 2 – $103,615) exceeded the average case-weighted threshold amount (Scenario 1 – $75,836; Scenario 2 – $76,621).	Meets cost criterion.
Technology Cost	The technology is a subscription-based model, with annual fees varying according to hospital bed size. Each hospital would be charged $1,210 per bed. To calculate an average cost per case, the applicant did an analysis using total estimated subscription fees from all IPPS hospitals and divided by expected stays when the technology would be used by that hospital. Taking the average cost per case associated with inpatient stays across all hospitals identified, the applicant calculated an average cost per patient of $211.59.	Maximum new technology add-on payment: $137.53

BILLING CODE 4169–69–C

Cost Criterion

In the proposed rule, we stated that after review of the information provided by the applicant, we agreed with the applicant that BriefCase-Triage meets the cost criterion and therefore proposed to approve BriefCase-Triage for new technology add-on payments for FY 2027 for the FDA-cleared indication covered by the Breakthrough Device designation listed in the table. We stated

we considered the beginning of the newness period to commence on January 7, 2026, the date on which BriefCase-Triage received FDA marketing authorization.

Based on preliminary cost information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of BriefCase-Triage would be $137.53 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether BriefCase-Triage meets the cost criterion and our proposal to approve new technology add-on payments for BriefCase-Triage: CARE Multi-Triage CT Body for FY 2027.

Comment: The applicant submitted a public comment in support of the proposal to approve BriefCase-Triage for new technology add-on payment. The applicant provided assertions regarding the technology's clinical impact and asserted that BriefCase-Triage is not substantially similar to existing technology. The applicant reiterated the cost analyses done at the time of application and agreed with CMS's proposed newness date and cost per case of $137.53.

Response: We thank the applicant for its comment. We note that substantial similarity and substantial clinical improvement are not within the scope of CMS's evaluation for new technology add-on payment eligibility under the alternative pathway, as defined in § 412.87(c) and as previously stated. Based on the information provided in the application for new technology add-on payments, and after consideration of the public comment we received, we believe BriefCase-Triage meets the cost criterion. The technology received marketing authorization from FDA as a Breakthrough Device on January 7, 2026 with an indication covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for BriefCase-Triage for FY 2027. We consider the beginning of the newness period to commence on January 7, 2026, the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of BriefCase-Triage is $211.59. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of BriefCase-Triage is $137.53 for FY 2027 (that is, 65 percent of the average cost of the technology).

The applicant was granted approval for a unique ICD–10–PCS procedure code for the BriefCase-Triage beginning in FY 2027. Therefore, cases involving the use of BriefCase-Triage that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code: XEZ5XKC (Computer-aided triage and notification for imaging abnormalities in computed tomography of chest, abdomen and pelvis, new technology group 12).

3. CARA System

Cara Medical submitted a FY 2027 application for new technology add-on payments for the CARA System. According to the applicant, the CARA System software simulates the path of a patient's cardiac conduction system using anatomical landmarks identifiable on routine CT angiography (CTA) imaging to enable Conduction Guided Intervention (CGI). Per the applicant, CARA augmented fluoroscopy can be used to help the operator visualize, during the procedure, the proximity of his tools and device to the patient's conduction system.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for the CARA System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251006TVQL6.*

BILLING CODE 4169–69–P

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	Request submitted.	N/A
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** The Cara System is a medical device comprising two integrated functions: 1. Cara Metis Simulator is a diagnostic imaging Software as a Medical Device (SaMD) product that identifies the personalized anatomical location of the cardiac conduction system derived from the patient's computed tomographic angiography (CTA). 2. Cara Atlas Navigator is an imaging guidance system (hardware and software) that overlays the personalized anatomical location of the cardiac conduction system (generated by the CARA Metis Simulator) onto real-time, intra-procedural, fluoroscopic imaging to assist in fluoroscopic-guided interventional heart procedures. The Cara System is intended for preplanning and guidance of medical interventions in an area known to contain or be adjacent to the cardiac conduction system, such as percutaneous or surgical structural heart (SHD) procedures, including transcatheter aortic valve replacement (TVAR), transcatheter mitral valve replacement (TMVR), and transcatheter tricuspid valve replacement (TTVR), or in medical procedures where the physician desires to deliver therapy to the patient's cardiac conduction system or to a targeted location within it. Visualization of the patient's cardiac conduction system path can significantly reduce the risk of procedure related, iatrogenic cardiac conduction system disease with hemodynamic compromise (CDHC) following SHD procedures and can improve the effectiveness and outcomes of cardiac pacing procedures treating CDHC. **FDA Indication:** Pending.	Pending FDA marketing authorization.
Newness Period	Applicant anticipates FDA decision by May 1, 2026, consistent with its Breakthrough Device designation. No commercial availability delay expected.	Pending FDA marketing authorization.
Cost Criterion	145,429 claims mapping to 23 MS-DRGs, with 23.96 percent of claims mapping to MS-DRG 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC) Final inflated average case-weighted standardized charge per case ($372,183) exceeded the average case-weighted threshold amount ($180,548).	Meets cost criterion.
Technology Cost	The system is billed to hospitals on a per use basis, and costs vary depending on whether the procedure is an interventional procedure done in the catheterization lab with the CARA Atlas™ Navigator ($10,500) and CARA Metis™ Simulator ($7,000) for a total cost of $17,500, or if it is a surgical procedure done in the operating room with the CARA Atlas™ Navigator ($6,500) and CARA Metis™ Simulator ($7,000) for a total cost of $13,500, or if only CARA Metis™ Simulator ($7,000) is used for procedural planning. The Cara Atlas™ Navigator is used for real-time, fluoroscopic overlay of the patient's conduction system during interventional procedures and for display of the original Metis™ pre-planning image with surgical landmarks in surgical procedures. The hardware for the CARA System is provided at no cost if the institution commits to purchase 100 total procedures. The applicant anticipates 90% of procedures will use both CARA Atlas™ Navigator and CARA Metis™ Simulator, and the market split between interventional to surgical application of CARA Atlas™ Navigator and CARA Metis™ Simulator will be 80% and 20%, respectively. The applicant anticipates 10% of procedures will only use CARA Metis™ Simulator. The applicant calculated a weighted average cost of $15,700 per patient for the CARA System.	Maximum new technology add-on payment: $10,205.00 See following discussion.

BILLING CODE 4169–69–C

Cost Criterion

In the proposed rule, after review of the information provided by the applicant, we stated that we agreed with the applicant that the CARA System meets the cost criterion and are therefore proposing to approve the CARA System for new technology add-on payments for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

However, we questioned whether a surgical procedure done in the operating

room with the CARA Atlas™ Navigator would correspond to the FDA Breakthrough Device designated indication involving real-time, intraprocedural, fluoroscopic imaging to assist in fluoroscopic-guided interventional heart procedures. We stated that we would be interested in information clarifying the components and process for use of the CARA Atlas™ Navigator, accounting for the difference in cost between a surgical procedure and an interventional procedure. We also questioned whether procedures using only the CARA Metis™ Simulator would correspond to the FDA Breakthrough Device designated indication, as a medical device comprising two integrated functions (that is, integrated functions of both the CARA Metis™ Simulator and CARA Atlas™ Navigator). We noted that under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment for FY 2027. We stated that we would be interested in detailed information clarifying the different uses of the CARA System components related to the Breakthrough Device designated indication. Based on preliminary information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of the CARA System would be $10,205.00 for FY 2027 (that is, 65% of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether the CARA System meets the cost criterion and our proposal to approve new technology add-on payments for the CARA System for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

We note that the CARA System was market authorized for use in adult patients (18 years of age and older) on February 20, 2026 (K252500 [94]) for preplanning and guidance of medical interventions in an area known to contain or be adjacent to the cardiac conduction system, such as percutaneous or surgical procedures, for example, transcatheter aortic valve replacement (TAVR), as well as medical procedures where the physician desires to deliver therapy to the patient's cardiac conduction system or to a targeted location within it (CSP). However, as of the May 1, 2026 deadline, FDA has not market authorized the CARA System as a Breakthrough Device. Because the applicant asserts that the CARA System qualifies for new technology add-on payments under the alternative pathway for FY 2027, we are discussing the applicant's related comments in this final rule.

Comment: The applicant submitted a comment, asserting that the CARA System should be eligible for the alternative pathway based on its Breakthrough Device designation and FDA-cleared indication, stating that the cleared indication is ''covered by'' its Breakthrough Device designation indication. The applicant stated that CMS—not FDA—administers the eligibility criteria for the alternative pathway for Breakthrough Devices under § 412.87(c). The applicant stated that CMS relies on different statutory and regulatory authority from FDA when it makes its own coverage and payment determinations for Medicare, just as a ''safe and effective'' determination by FDA is distinct from a ''reasonable and necessary'' determination for Medicare. Accordingly, the applicant stated that the application of CMS's own regulations and precedent—not FDA's separate decision regarding public disclosure on its Breakthrough Devices website—governs whether the CARA System qualifies under the alternative pathway.

The applicant asserted that CARA System satisfies both elements of § 412.87(c)(1). The applicant stated that first, the device is ''part of'' FDA's Breakthrough Devices Program: it received FDA Breakthrough Device designation (Q250281) and the company then engaged with FDA through the Breakthrough Devices Program to secure marketing authorization, ultimately obtaining 510(k) clearance (K252500). The applicant asserted that CMS has consistently treated designation plus the pursuit of marketing authorization as sufficient to establish that a device is ''part of'' the program; for example, in the FY 2023 IPPS/LTCH PPS final rule CMS determined that the GORE® TAG® TBE device was ''part of the Breakthrough Devices Program'' based on its designation. The applicant asserted that neither CMS regulation nor guidance conditions this determination on a device appearing on FDA's Breakthrough Devices website, and that CMS has made alternative pathway eligibility determinations in the FY 2021 and FY 2022 cycles before that website existed. The applicant stated that second, the CARA System's FDA-cleared indication is ''covered by'' its FDA Breakthrough Device designation indication. The applicant asserted that CMS does not require the market-authorized indication and the designation indication to be identical or verbatim; it asks whether the cleared indication falls within the scope of the broader designated indication. The applicant stated that under both indications, the CARA System is used for preplanning and guidance of medical interventions in an area known to contain or be adjacent to the cardiac conduction system, including TAVR and conduction system pacing procedures. Per the applicant, CMS has approved alternative pathway new technology add-on payment applications on this basis even where the cleared indication was narrower than the designation indication and removed a specific claim. The applicant stated that in the FY 2026 IPPS/LTCH PPS final rule, CMS approved the Emily's Care Nourish Test System for new technology add-on payment even though its 510(k)-cleared indication both narrowed the treated population and removed a ''treatment'' claim that had been part of its designation indication. The applicant further asserted that CMS concluded the cleared indication was ''covered by'' the broader designation indication and simply limited the scope of new technology add-on payment recognition accordingly, and that CMS reached a comparable conclusion in the FY 2025 cycle.

The applicant and another commenter also asserted that if CMS decided to not grant the CARA System approval under the new technology add-on payment alternative pathway, it should be granted consideration under the traditional pathway, and the applicant attached a separate letter that it stated laid out the claims and supportive evidence for how the Cara System meets the substantial clinical improvement criterion. The applicant stated that when applying for new technology add-on payment, applicants are required to note if they are applying via the traditional or the alternative pathway at the time of new technology add-on payment application submission, and that it used the alternative pathway because it believed the device met the eligibility criteria for the alternative

[94] *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K252500.*

pathway based on the Breakthrough Device designation that the Cara System had received.

Response: As we stated previously, a medical device designated under FDA's Breakthrough Devices Program that has received marketing authorization as a Breakthrough Device, for the indication covered by the Breakthrough Device designation, may qualify for the new technology add-on payment under an alternative pathway. Because the CARA System has not received marketing authorization as a Breakthrough Device for the indication covered by the Breakthrough Device designation, the CARA System does not qualify for new technology add-on payments under the alternative pathway for FY 2027.

Although the applicant concluded that CMS has consistently treated designation plus the pursuit of marketing authorization as sufficient to establish that a device is ''part of'' the Breakthrough Devices program, this has not been our approach; neither do we condition our determination on a device appearing on FDA's Breakthrough Devices website. As we noted in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42295) to implement the alternative pathways, we were committed to continue to work collaboratively with FDA, as FDA's expedited programs, including the Breakthrough Devices Program, evolve. We have continuously consulted with FDA to confirm whether devices are designated Breakthrough devices and to establish whether FDA has market authorized each device that applies under this pathway for an indication consistent with its Breakthrough Device designation, including with respect to the prior technologies as cited by the applicant, as well as the CARA System. We do not believe it would be appropriate for CMS to make our determination of eligibility under the alternative pathway before or in lieu of FDA's determination that an FDA-designated Breakthrough Device has obtained marketing authorization as a Breakthrough Device for an indication consistent with its Breakthrough Device designation.

With respect to public disclosure on FDA's Breakthrough Devices web page, we note that in its 2023 guidance on the Breakthrough Devices Program,[95] FDA stated that once a designated Breakthrough Device obtains marketing authorization for an indication consistent with its Breakthrough Device designation, FDA intends to publicly disclose its Breakthrough Device designation status for that indication for use. The FDA guidance further notes that because Breakthrough Device designation is granted for a device and its indication for use, if a designated Breakthrough Device receives marketing authorization for an indication other than the indication covered by its designation, it is not considered a market-authorized Breakthrough Device and would not be disclosed as such. FDA's Breakthrough Devices web page lists the Breakthrough Devices that have obtained marketing authorization for an indication consistent with its Breakthrough Designation.[96] FDA's website further states that because Breakthrough Device designation is granted for a device and its indication for use, if a designated Breakthrough Device receives marketing authorization for an indication other than the indication covered by its designation, it is not considered a market-authorized Breakthrough Device and would not be included in this list. We note that while the CARA System received FDA 510(k) clearance on February 20, 2026 (K252500), it is not listed on FDA's Breakthrough Devices Program web page, which includes a list of Breakthrough Devices that have obtained marketing authorization for an indication consistent with its Breakthrough Designation through March 31, 2026.

We also disagree with the applicant's understanding of CMS's determination as to whether an FDA-cleared indication is ''covered by'' a technology's Breakthrough Device designated indication. We do not make a determination as to whether an FDA-cleared indication is covered by the technology's Breakthrough Device-designated indication until after FDA has determined that the device has obtained FDA marketing authorization as a Breakthrough Device. As an FDA marketing submission may be broader in scope and may cover both Breakthrough Device-designated and non-Breakthrough Device-designated indications, there may be differences in the patient population and/or disease treated between the FDA market authorized indication and the Breakthrough Device-designated indication. In these situations, because under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment, we must make a determination as to which uses of the device would be relevant for purposes of the new technology add-on payment.

With respect to the applicant and commenter's suggestion that if CMS does not approve new technology add-on payments for the technology under the alternative pathway, CMS should consider approving the CARA System under the traditional pathway, we note that, as stated previously, CMS reviews applications based on the information provided by the applicant under the pathway specified by the applicant at the time of application submission (*90 FR 36662*).

Therefore, because the CARA System has not received FDA marketing authorization as a Breakthrough Device, it does not qualify for new technology add-on payments for FY 2027. With respect to the comments we received regarding the technology's value and clinical impact, the importance of new technology add-on payments for the technology, and the different uses of the CARA System components with regard to the cost criterion, as noted, the technology has not received FDA marketing authorization as a Breakthrough Device and is not eligible for new technology add-on payments for FY 2027 under the pathway specified by the applicant at the time of application submission.

4. Ceribell Delirium Monitor System

Ceribell, Inc. submitted a FY 2027 application for new technology add-on payments for the Ceribell Delirium Monitor System. According to the applicant, the Ceribell Delirium Monitor System is a medical device system comprised of proprietary software, signal acquisition headbands and a recorder. Per the applicant, the software utilizes a machine learning model to analyze EEG signals to detect features indicative of delirium.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for the Ceribell Delirium Monitor System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251006WFMK2.*

[95] Breakthrough Devices Program—Guidance for Industry and Food and Drug Administration Staff (September 15, 2023) *https://www.fda.gov/media/162413/download.*

[96] FDA's Breakthrough Devices Program web page is available at: *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.*

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	XX20X89	See following discussion.
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** The Ceribell Delirium Monitor System is intended to analyze features associated with diffuse slowing electroencephalogram (EEG) patterns that may be indicative of delirium. The Ceribell Delirium Monitor System is intended to aid in the screening and monitoring of delirium with clinical assessments in adult patients aged 65 and older in critical care settings within hospitals. **FDA Indication:** The Ceribell Delirium Monitor System is intended to analyze features associated with diffuse slowing electroencephalogram (EEG) patterns that may be indicative of delirium. The Ceribell Delirium Monitor software is intended to aid in the screening and monitoring of delirium with clinical assessments in adult patients in critical care settings within hospitals. The Ceribell Delirium Monitor System analyzes discrete segments of EEG to notify clinicians when EEG patterns associated with delirium are detected while monitoring the patient. Changes in patient condition that are detected by the device should be verified before commencing any interventions.	See following discussion.
Newness Period	510(k) clearance on 12/8/2025.	Newness date: 12/8/2025.
Cost Criterion	Scenario 1: 2,448,833 claims mapping to 738 MS-DRGs, with 12 percent of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV>96 Hours with MCC) Scenario 2: 1,825,687 claims mapping to 732 MS-DRGs, with 16.08 percent of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV>96 Hours with MCC) Final inflated average case-weighted standardized charge per case (Scenario 1 - $114,157; Scenario 2 - $127,752) exceeded the average case-weighted threshold amount (Scenario 1 - $95,951; Scenario 2 - $95,038).	Meets cost criterion.
Technology Cost	The total anticipated cost to the hospital is $3,340 per patient, based on the $799 operating costs of the Ceribell Delirium Monitor System Software and Headband which are packaged together and the anticipated weighted average length of stay of patients of 4.18 days ($799 x 4.18 days = $3,340). A new headband must be used for each day of monitoring due to technical considerations relating to usability and achieving optimal EEG signal quality. For example, each electrode of the headband contains a sealed packet of electroconductive gel which remains at optimal effectiveness for approximately one day once dispensed.	Maximum new technology add-on payment: $2,171

In the proposed rule we stated that after review of the information provided by the applicant, we noted that under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment for FY 2027. As stated by the applicant, the FDA-cleared indication is different and is not limited to adult patients aged 65 and older, as noted in the Breakthrough Device designation. Therefore, we stated that only the use of the Ceribell Delirium Monitor System for patients aged 65 and older, and the FDA Breakthrough Device designation it received for that use, would be relevant for purposes of the new technology add-on payment application for FY 2027.

ICD–10 Coding

In addition, we stated that as noted by the applicant, the ICD–10–PCS procedure code XX20X89 (Monitoring of brain electrical activity, computer-aided detection and notification, new technology group 9) is used for a different technology (the Ceribell Status Epilepticus Monitor) to help diagnose status epilepticus, which is not the subject of this new technology add-on payment application. Therefore, the applicant submitted a request for ICD–10–CM codes to differentiate use of the Ceribell Delirium Monitor System from use of the Ceribell Status Epilepticus Monitor, which was approved for new technology add-on payments for FY 2024 through FY 2026 (88 FR 58927 through 58930; 89 FR 70009; 90 FR 37260) and for which we proposed to discontinue making new technology add-on payments for FY 2027 because it will no longer be considered new (as discussed in section II.E.4. of the preamble of this final rule, we are finalizing our proposal to discontinue making new technology add-on payments for the Ceribell Status Epilepticus Monitor for FY 2027).

Furthermore, for purposes of the new technology add-on payment, if approved, we stated we believed it would be appropriate to exclude cases reporting the ICD–10–PCS procedure code XX20X89 in patients with status epilepticus, which would instead identify use of the Ceribell Status Epilepticus Monitor. Please see Table 10.2.—Ceribell Delirium Monitor System, associated with the proposed

rule, for the list of ICD–10–CM diagnosis codes that we stated we believed would identify patients with status epilepticus, which we proposed to exclude from new technology add-on payment when reported in combination with ICD–10–PCS procedure code XX20X89.

We invited public comments on our proposal to exclude cases reporting these ICD–10–CM diagnosis codes in combination with the ICD–10–PCS procedure code XX20X89, for purposes of the new technology add-on payment for FY 2027, if approved.

Comment: We received several comments, including from the applicant, expressing support for our proposal to approve new technology add-on payment for the Ceribell Delirium Monitor System. Multiple commenters described their assertions regarding the potential clinical impact of Ceribell Delirium Monitor System.

Response: We thank the commenters for their comments. As previously noted, clinical performance is not within the scope of CMS's evaluation for new technology add-on payment under the alternative pathway.

Comment: In response to our proposal to exclude cases reporting the status epilepticus ICD–10–CM diagnosis codes in combination with the ICD–10–PCS procedure code XX20X89, which was previously used for another technology, the Ceribell Status Epilepticus Monitor, the applicant stated that it agreed with CMS's proposed approach of utilizing ICD–10–PCS procedure code XX20X89 and excluding the 28 diagnosis codes listed for status epilepticus. Other commenters expressed concerns with the reliance on diagnosis code-based exclusions to distinguish between the use of the monitor for status epilepticus versus delirium. A commenter stated that the monitor may be utilized where there is no diagnosis and only a symptom would be reported. The commenter stated that it's also possible for a patient to have both conditions and it would be inappropriate to exclude delirium from new technology add-on payments for the system based on co-existing conditions. Some commenters recommended that CMS reconsider its proposal to exclude cases reporting diagnosis codes for status epilepticus, or create a distinct ICD–10–PCS code for the Ceribell Delirium Monitor System, or consider using ICD–10–CM signs and symptom codes that may be clinically representative of delirium, such as codes for altered mental status or confusion.

Response: We thank the applicant and the other commenters for their comments. We appreciate the commenters raising their concerns regarding the potential use of the monitoring systems in cases where there is no diagnosis of either delirium or status epilepticus, as well as concerns regarding cases in which both conditions may be present. We continue to believe that the use of the ICD–10–PCS code XX20X89 in combination with the specified status epilepticus ICD–10–CM diagnosis code exclusions represents the most appropriate approach to identify cases associated with use of the Ceribell Status Epilepticus Monitor, which we proposed to exclude from new technology add-on payment. While we recognize that there may be instances in which patients are being monitored for delirium, but have a co-existing diagnosis of status epilepticus, we believe that this approach would provide an appropriate mechanism to exclude cases where the monitor is used for status epilepticus. As previously stated, ICD–10–PCS procedure code XX20X89 (Monitoring of brain electrical activity, computer-aided detection and notification, new technology group 9) is also used for the Ceribell Status Epilepticus Monitor, for which we are discontinuing new technology add-on payments for FY 2027 because it will no longer be considered new, and therefore coding between the two technologies must be differentiated to the extent of current capabilities. Further, we note that the suggested use of ICD–10–CM signs and symptoms codes that may be clinically representative of delirium, such as codes for altered mental status or confusion, would not be specific for delirium and may also inappropriately include cases with status epilepticus.

However, we note that, following publication of the proposed rule, we were notified by the ICD–10 Coordination and Maintenance Committee that the applicant withdrew their request for new ICD–10–CM codes to differentiate use of the Ceribell Delirium Monitor System from use of the Ceribell Status Epilepticus Monitor. We question whether, without such codes, we would be able to differentiate use of the Ceribell Status Epilepticus Monitor for at-risk patients who do not ultimately receive a diagnosis of status epilepticus, from use of the Ceribell Delirium Monitor System for at-risk patients who do not ultimately receive a diagnosis of delirium. Therefore, we are considering whether it would be necessary to use ICD–10–PCS code XX20X89 in combination with ICD–10–CM diagnosis codes for delirium to identify cases using the Ceribell Delirium Monitor System that would be eligible for the new technology add-on payment.

At this time, we are finalizing our proposal to use the ICD–10–PCS code XX20X89 in combination with ICD–10–CM diagnosis codes describing status epilepticus in Table 10.2.—Ceribell Delirium Monitor System (associated with this final rule) to identify cases associated with use of the Ceribell Status Epilepticus Monitor in patients diagnosed with status epilepticus, which would not be eligible for new technology add-on payment for FY 2027.

Cost Criterion

We stated we agreed with the applicant that the Ceribell Delirium Monitor System meets the cost criterion and therefore proposed to approve the Ceribell Delirium Monitor System for new technology add-on payments for FY 2027, for the FDA-cleared indication covered by the Breakthrough Device designation listed in the table. We stated we considered the beginning of the newness period to commence on December 8, 2025, the date on which the Ceribell Delirium Monitor System received FDA marketing authorization.

Based on preliminary information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of the Ceribell Delirium Monitor System would be $2,171 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether the Ceribell Delirium Monitor System meets the cost criterion and our proposal to approve new technology add-on payments for the Ceribell Delirium Monitor System for FY 2027.

Comment: The applicant submitted a public comment confirming that the expected hospital per-patient cost of the Ceribell Delirium Monitor is $3,340 and requested that CMS finalize its proposal to approve new technology add-on payment for this technology, effective October 1, 2026.

Response: We thank the applicant for its comment.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the Ceribell Delirium Monitor System meets the cost criterion. The technology received marketing authorization from FDA as a Breakthrough Device on December 8,

2025, for an indication covered by its Breakthrough Device designation, as described previously. Therefore, we are finalizing our proposal to approve new technology add-on payments for the Ceribell Delirium Monitor System for FY 2027. We consider the beginning of the newness period to commence on December 8, 2025, the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the Ceribell Delirium Monitor System is $3,340. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the Ceribell Delirium Monitor System is $2,171 for FY 2027 (that is, 65 percent of the average cost of the technology).

As noted earlier in this section, only the use of the Ceribell Delirium Monitor System for patients aged 65 and older, and the FDA Breakthrough Device designation it received for that use, is relevant for purposes of the new technology add-on payment application for FY 2027. For FY 2027, cases involving the use of the Ceribell Delirium Monitor System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XX20X89 (Monitoring of brain electrical activity, computer-aided detection and notification, new technology group 9) without any of the ICD–10–CM diagnosis codes listed in Table 10.2.—Ceribell Delirium Monitor System associated with this final rule. However, as discussed earlier, we question whether it would be appropriate to also use ICD–10–PCS code XX20X89 in combination with ICD–10–CM diagnosis codes for delirium to identify cases using the Ceribell Delirium Monitor System for patients with delirium that would be eligible for the new technology add-on payment. We may revisit the codes used to identify cases involving the use of the Ceribell Delirium Monitor System that are eligible for new technology add-on payments in future rulemaking.

5. CMORE® CT System (posterior cervico-thoracic system)

Icotec ag submitted a FY 2027 application for new technology add-on payments for the CMORE® CT System. According to the applicant, the CMORE® CT System is a posterior cervico-thoracic fixation system manufactured from BlackArmor® Carbon/PEEK material for standard posterior fixation of the spinal column which features a variety of screw sizes and types, as well as rod shapes, to accommodate patient anatomy.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for the CMORE® CT System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP2510034V5CK.*

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	Request submitted.	See following discussion.
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** The CMORE® CT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3): Traumatic spinal fractures and/or traumatic dislocations; Instability or deformity; Failed previous fusions (e.g. pseudarthrosis); Degenerative disease, including intractable radiculopathy and/or myelopathy; Neck and/or arm pain of discogenic origin as confirmed by radiographic studies; Degenerative disease of the facets with instability; Patients with spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression. **FDA Indication:** The CMORE® CT System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In patients requiring adjuvant radiotherapy following spinal stabilization, metal markers at the screw tips can be used as fiducial markers in radiotherapy treatments (e.g., SBRT, proton therapy). The CMORE® CT System is intended to provide immobilization and stabilization of spinal segments with anterior interbody support implanted at the same spinal level/s as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3): Traumatic spinal fractures and/or traumatic dislocations; Instability or deformity; Failed previous fusions (e.g. pseudarthrosis); Degenerative disease, including intractable radiculopathy and/or myelopathy; Neck and/or arm pain of discogenic origin as confirmed by radiographic studies; Degenerative disease of the facets with instability; Patients with spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression. The CMORE® CT System is intended to be used with anterior interbody support implanted at the same spinal level/s with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The CMORE® CT System may be connected to the VADER® Pedicle System using connectors.	See following discussion.
Newness Period	510(k) clearance on 11/12/2025. Commercial availability delay to 12/8/2025 – Applicant stated that this was the date on which the CMORE® CT System implants and instrument sets arrived at their U.S.-based logistics center, for sale in the U.S.	Newness date: 12/8/2025.
Cost Criterion	48,900 claims mapping to 43 MS-DRGs, with 33 percent of claims mapping to MS-DRG 472 (Cervical Spinal Fusion with CC). Final inflated average case-weighted standardized charge per case ($566,662) exceeded the average case-weighted threshold amount ($167,312).	Meets cost criterion.
Technology Cost	The total anticipated cost to the hospital is $93,700 for an average construction per patient. The applicant stated there are approximately 59 different components associated with the CMORE® CT System, all of which are operating costs, and the device cost per patient is a weighted average across multiple elements: Polyaxial Screws, Shank Screws, Rods (straight and curved), Nut Screws, Axial Connectors, and Parallel Connectors. An average construction for the CMORE® CT System utilizes: 10 Polyaxial or Shank Screws ($79,500), 2 Rods ($10,200), and 10 Locking/Nut screws ($4,000).	Maximum new technology add-on payment: $60,905

In the proposed rule, we noted that after review of the information provided by the applicant, as previously stated, under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment for FY 2027. We noted that the indication for use for the CMORE®

CT System in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, is not included in its Breakthrough Device designation. Therefore, we stated that the CMORE® CT System would only be eligible for new technology add-on payment for its Breakthrough Device-designated indication, as an adjunct to fusion of the cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3), if approved.

ICD–10 Coding

Please see Table 10.1.—CMORE® CT System, associated with the proposed rule, for the list of relevant ICD–10–PCS procedure codes that we believed would be appropriate to report in combination with use of the CMORE® CT System to identify use of the technology for the Breakthrough Device-designated indication, as an adjunct to fusion of the cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3). We invited public comments on the use of these ICD–10–PCS procedure codes to identify use of the technology for the Breakthrough Device-designated indication for purposes of the new technology add-on payment, if approved.

We did not receive any comments related to the list of relevant ICD–10–PCS for the CMORE® CT System Breakthrough Device-designated indication.

Cost Criterion

In the proposed rule, we stated we agreed with the applicant that the CMORE® CT System meets the cost criterion and therefore proposed to approve the CMORE® CT System for new technology add-on payments for FY 2027, for the FDA-cleared indication covered by the Breakthrough Device designation listed in the table and as described previously. We considered the beginning of the newness period to commence on December 8, 2025, the date on which the CMORE® CT System became commercially available.

Based on preliminary information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of the CMORE® CT System would be $60,905 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether the CMORE® CT System meets the cost criterion and our proposal to approve new technology add-on payments for the CMORE® CT System for FY 2027.

We did not receive any comments related to the CMORE® CT System.

Based on the information provided in the application for new technology add-on payments, we believe the CMORE® CT System meets the cost criterion. The technology received marketing authorization from FDA as a Breakthrough Device on November 12, 2025, as described previously. Therefore, we are finalizing our proposal to approve new technology add-on payments for the CMORE® CT System for FY 2027. We consider the beginning of the newness period to commence on December 8, 2025, the date on which the technology became commercially available for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the CMORE® CT System is $93,700. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the CMORE® CT System is $60,905 for FY 2027 (that is, 65 percent of the average cost of the technology).

As noted earlier in this section, the indication for use for the CMORE® CT System in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, is not included in its Breakthrough Device designation. Therefore, only the use of the CMORE® CT System as an adjunct to fusion of the cervical spine (C1 to C7) and the upper thoracic spine (T1 to T3), and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2027. In addition, the applicant was granted approval for unique ICD–10–PCS procedure codes for the CMORE® CT System beginning in FY 2027. Therefore, cases involving the use of the CMORE® CT System that are eligible for new technology add-on payments will be identified by any of the following ICD–10–PCS procedure codes in combination with any of the ICD–10–PCS procedure codes listed in Table 10.1.—CMORE® CT System, associated with this final rule.

ICD-10-PCS Code	Description
XRH10NC	Insertion of carbon/peek spinal stabilization device into cervical vertebral joint, open approach, new technology group 12
XRH13NC	Insertion of carbon/peek spinal stabilization device into cervical vertebral joint, percutaneous approach, new technology group 12
XRH14NC	Insertion of carbon/peek spinal stabilization device into cervical vertebral joint, percutaneous endoscopic approach, new technology group 12
XRH20NC	Insertion of carbon/peek spinal stabilization device into 2 or more cervical vertebral joints, open approach, new technology group 12
XRH23NC	Insertion of carbon/peek spinal stabilization device into 2 or more cervical vertebral joints, percutaneous approach, new technology group 12
XRH24NC	Insertion of carbon/peek spinal stabilization device into 2 or more cervical vertebral joints, percutaneous endoscopic approach, new technology group 12
XRH40NC	Insertion of carbon/peek spinal stabilization device into cervicothoracic vertebral joint, open approach, new technology group 12
XRH43NC	Insertion of carbon/peek spinal stabilization device into cervicothoracic vertebral joint, percutaneous approach, new technology group 12
XRH44NC	Insertion of carbon/peek spinal stabilization device into cervicothoracic vertebral joint, percutaneous endoscopic approach, new technology group 12
XRH60NC	Insertion of carbon/peek spinal stabilization device into thoracic vertebral joint, open approach, new technology group 12
XRH63NC	Insertion of carbon/peek spinal stabilization device into thoracic vertebral joint, percutaneous approach, new technology group 12
XRH64NC	Insertion of carbon/peek spinal stabilization device into thoracic vertebral joint, percutaneous endoscopic approach, new technology group 12

6. GORE® VIABAHN® FORTEGRA Venous Stent

W.L. Gore & Associates, Inc. submitted a FY 2027 application for new technology add-on payments for the GORE® VIABAHN® FORTEGRA Venous Stent. According to the applicant, the GORE® VIABAHN® FORTEGRA Venous Stent is an open-structure polymer lattice device providing intraluminal support in the inferior vena cava and, if clinically warranted, the common iliac veins, at the iliocaval confluence in patients with symptomatic vessel obstruction.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for the GORE® VIABAHN® FORTEGRA Venous Stent and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251006MBT8G.*

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	Request submitted.	N/A
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** Indicated for treatment of symptomatic inferior vena cava obstruction with or without combined Iliofemoral obstruction. **FDA Indication:** This device is indicated for use in the treatment of symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction.	FDA indication is appropriate for consideration under the alternative pathway.
Newness Period	PMA approval on 12/19/2025	Newness date: 12/19/2025.
Cost Criterion	337 claims mapping to 25 MS-DRGs, with 11.87 percent of claims mapping to MS-DRG 270 (Other Major Cardiovascular Procedures with MCC). Final inflated average case-weighted standardized charge per case ($295,766) exceeded the average case-weighted threshold amount ($136,998).	Meets cost criterion.
Technology Cost	The total anticipated cost to the hospital is $11,056 per patient. An average of 5.12 stents were used per case (1.15 large diameter and 3.97 small diameter stents) based on clinical trial (VNS-21-05). Per the applicant, large diameter stent cost per component is $3,400 ($3,400 x 1.15 = $3,910) and small diameter stent cost per component is $1,800 ($1,800 x 3.97 = $7,146).	Maximum new technology add-on payment: $7,186.40

Cost Criterion

In the proposed rule, we stated that after review of the information provided by the applicant, we agreed with the applicant that the GORE® VIABAHN® FORTEGRA Venous Stent meets the cost criterion and therefore proposed to approve the GORE® VIABAHN® FORTEGRA Venous Stent for new technology add-on payments for FY 2027, for the FDA-approved indication

covered by the Breakthrough Device designation listed in the table. We considered the beginning of the newness period to commence on December 19, 2025, the date on which the GORE® VIABAHN® FORTEGRA Venous Stent received FDA marketing authorization.

Based on preliminary cost information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of the GORE® VIABAHN® FORTEGRA Venous Stent would be $7,186.40 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether the GORE® VIABAHN® FORTEGRA Venous Stent meets the cost criterion and our proposal to approve new technology add-on payments for the GORE® VIABAHN® FORTEGRA Venous Stent for FY 2027.

Comment: Multiple commenters, including the applicant, expressed support for the proposal to approve the GORE® VIABAHN® FORTEGRA Venous Stent for new technology add-on payments and agreed that this technology meets eligibility requirements. The applicant stated its support of a maximum payment amount of $7,186.40.

Response: We thank the applicant and other commenters for their comments.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the GORE® VIABAHN® FORTEGRA Venous Stent meets the cost criterion. The technology received marketing authorization from FDA as a Breakthrough Device on December 19, 2025 for the indication covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the GORE® VIABAHN® FORTEGRA Venous Stent for FY 2027. We consider the beginning of the newness period to commence on December 19, 2025, the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the GORE® VIABAHN® FORTEGRA Venous Stent is $11,056. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the GORE® VIABAHN® FORTEGRA Venous Stent is $7,186.40 for FY 2027 (that is, 65 percent of the average cost of the technology).

The applicant was granted approval for a unique ICD–10–PCS procedure code for the GORE® VIABAHN® FORTEGRA Venous Stent beginning in FY 2026. Therefore, cases involving the use of the GORE® VIABAHN® FORTEGRA Venous Stent that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code: X2723CB (Dilation of inferior vena cava and iliocaval confluence with open-structure polymer lattice intraluminal device, percutaneous approach, new technology group 11).

7. Infuse™ Bone Graft

Medtronic Sofamor Danek USA, Inc. submitted a FY 2027 application for new technology add-on payments for Infuse™ Bone Graft. According to the applicant, Infuse™ Bone Graft—is a bone graft material designed to promote bone formation at the site of implantation for transforaminal lumbar interbody fusion (TLIF), at one or two adjacent levels from L2–S1 in the treatment of degenerative disc disease (DDD). Per the applicant, it consists of two primary components, recombinant human bone morphogenetic protein-2 (rhBMP–2) and an absorbable collagen sponge which serves as a delivery matrix and scaffold for bone growth.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for Infuse™ Bone Graft and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP250929NNTP8.*

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	Request submitted.	See following discussion.
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** Infuse™ Bone Graft with an intervertebral body fusion device and a commercially available Medtronic metallic screw and rod system is intended for use in a transforaminal lumbar interbody fusion (TLIF) surgical approach at one or two adjacent levels from L2-S1 in the treatment of degenerative disease of the lumbosacral spine. **FDA Indication:** Infuse™ Bone Graft with an FDA cleared intervertebral body fusion device and metallic screw-and-rod system is indicated for use in a transforaminal lumbar interbody fusion (TLIF) surgical approach at one or two adjacent levels from L2-S1 in the treatment of symptomatic degenerative disc disease (DDD) confirmed by patient history and radiographic studies and having at least six months of nonoperative treatment attempted prior to treatment with Infuse™ Bone Graft.	FDA indication is appropriate for consideration under the alternative pathway.
Newness Period	PMA approval on 2/13/2026	Newness date: 2/13/2026.
Cost Criterion	Scenarios 1 and 2: 4,475 claims mapping to 4 MS-DRGs with 58.73 percent of claims mapping to MS-DRG 451 (Single Level Spinal Fusion Except Cervical without MCC). Scenario 3: 2,771 claims mapping to 2 MS-DRGs with 94.84 percent of claims mapping to 451 (Single Level Spinal Fusion Except Cervical without MCC). Final inflated average case-weighted standardized charge per case (Scenario 1 – $218,383; Scenario 2 – $195,608; Scenario 3 – $194,873) exceeded the average case-weighted threshold amount (Scenarios 1 and 2 – $147,656; Scenario 3 – $135,414).	Meets cost criterion.
Technology Cost	The total anticipated cost to the hospital is $6,764 per patient, which is the cost of an Infuse™ Bone Graft Medium kit. There are several kit sizes available with different amounts of rhBMP-2 which a hospital may use in 1- or 2-level TLIF procedures (range: XX Small kit at 1.05mg to Large kit at 12mg). The Medium kit provides 8.4mg of rhBMP-2. The applicant expects that inpatient cases among Medicare beneficiaries will be clinically complex and will commonly receive a 2-level fusion with Infuse™ Bone Graft at 4.2mg per level.	Maximum new technology add-on payment: $4,396.60

ICD–10 Coding

In the proposed rule, we stated that after review of the information provided by the applicant, we noted that Infuse™ Bone Graft has been granted other FDA approvals beyond the scope of its Breakthrough Device designation. We stated we believed the relevant ICD–10–PCS procedure codes that would be appropriate to report in combination with use of Infuse™ Bone Graft, to identify use of the technology for the Breakthrough Device-designated indication in a TLIF surgical approach at one or two adjacent levels from L2–S1 in the treatment of degenerative disease of the lumbosacral spine for purposes of the new technology add-on payment, if approved, would be the following codes:

ICD-10-PCS Code	Description
0SG00AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG03AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG04AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG10AJ	Fusion of lumbar vertebral joints, 2 or more with interbody fusion device, posterior approach, anterior column, open
0SG13AJ	Fusion of lumbar vertebral joints, 2 or more with interbody fusion device, posterior approach, anterior column, percutaneous
0SG14AJ	Fusion of lumbar vertebral joints, 2 or more with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic
0SG30AJ	Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG33AJ	Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG34AJ	Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach

We invited public comments on the use of these ICD–10–PCS procedure codes to identify use of the technology for the Breakthrough Device-designated indication for purposes of the new technology add-on payment, if approved.

Comment: The applicant submitted a public comment stating that it agreed with CMS's assessment of the relevant ICD–10–PCS procedure codes that would be appropriate to report in combination with the use of Infuse Bone Graft™ to identify use of the technology for the Breakthrough Device-designated indication in a TLIF surgical approach for purposes of new technology add-on payments.

Response: We thank the applicant for its support.

Cost Criterion

In the proposed rule we stated we agreed with the applicant that Infuse™ Bone Graft meets the cost criterion and therefore proposed to approve Infuse™ Bone Graft for new technology add-on payments for FY 2027, for the FDA-approved indication covered by the Breakthrough Device designation listed in the table and as described previously. We stated we considered the beginning of the newness period to commence on February 13, 2026, the date on which Infuse™ Bone Graft received FDA marketing authorization.

Based on preliminary information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of Infuse™ Bone Graft would be $4,396.60 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether Infuse™ Bone Graft meets the cost criterion and our proposal to approve new technology add-on payments for Infuse™ Bone Graft for FY 2027.

Comment: The applicant submitted a public comment supporting CMS's proposal to approve new technology add-on payments for Infuse™ Bone Graft for use in transforaminal lumbar interbody fusion (TLIF) procedures for degenerative disc disease. The applicant agreed with CMS's cost assessment and CMS's proposal to approve the technology with the proposed maximum payment amount of $4,396.60.

Response: We thank the applicant for its comment.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we continue to believe Infuse™ Bone Graft meets the cost criterion. The technology received marketing authorization from FDA as a Breakthrough Device on February 13, 2026 for the indication covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for Infuse™ Bone Graft for FY 2027. We consider the beginning of the newness period to commence on February 13, 2026, the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of Infuse™ Bone Graft is $6,764. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of Infuse™ Bone Graft is $4,396.60 for FY 2027 (that is, 65 percent of the average cost of the technology).

As noted earlier in this section, Infuse™ Bone Graft has received FDA marketing authorization for multiple indications, and only the use of Infuse™ Bone Graft for the Breakthrough Device-designated indication in a TLIF surgical approach at one or two adjacent levels from L2–S1 in the treatment of degenerative disease of the lumbosacral spine is relevant for purposes of the new technology add-on payment application for FY 2027. In addition, the applicant was granted approval for a unique ICD–10–PCS procedure code for the Infuse™ Bone Graft beginning in FY 2027. Therefore, cases involving the use of Infuse™ Bone Graft that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XW0U0CC (Introduction of recombinant human bone morphogenetic protein-2 with collagen scaffold into joints, open approach, new technology group 12), in combination with any of the following ICD–10–PCS procedure codes:

ICD-10-PCS Code	Description
0SG00AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG03AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG04AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG10AJ	Fusion of lumbar vertebral joints, 2 or more with interbody fusion device, posterior approach, anterior column, open
0SG13AJ	Fusion of lumbar vertebral joints, 2 or more with interbody fusion device, posterior approach, anterior column, percutaneous
0SG14AJ	Fusion of lumbar vertebral joints, 2 or more with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic
0SG30AJ	Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG33AJ	Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG34AJ	Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach

8. InVision Precision Cardiac Amyloid

Invision Medical Technology submitted a FY 2027 application for new technology add-on payments for InVision Precision Cardiac Amyloid (InVision PCA). According to the applicant, InVision PCA is a SaMD machine-learning disease detection algorithm to identify high suspicion of cardiac amyloidosis from routinely obtained echocardiogram videos. Per the applicant, the device assists clinicians in the diagnosis of cardiac amyloidosis.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for InVision PCA and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251002J7D89.*

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	Request submitted.	N/A
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** InVision Precision Cardiac Amyloidosis Screening is intended to process transthoracic cardiac ultrasound images to aid clinicians with identification of patients at high risk for cardiac amyloidosis from echocardiogram videos. This measurement can be used to assist the clinician in identifying patients that would benefit from downstream cardiac evaluation and testing. The device is intended for adult population of 22 years or older. **FDA Indication:** InVision Precision Cardiac Amyloid is a machine learning-based decision support system indicated as a screening tool for adult patients aged 65 years and over undergoing cardiovascular assessment using echocardiography. When utilized by an interpreting physician, this device provides information alerting the physician for referral to confirmatory investigations. InVision Precision Cardiac Amyloid is indicated in adult populations over 65 years of age. Patient management decisions should not be made solely on the results of the InVision Precision Cardiac Amyloid.	FDA indication is appropriate for consideration under the alternative pathway.
Newness Period	510(k) clearance on 5/21/2025.	Newness date: 5/21/2025.
Cost Criterion	80,241 claims mapping to 643 MS-DRGs, with none exceeding more than 10 percent of the total identified cases. Final inflated average case-weighted standardized charge per case ($129,789) exceeded the average case-weighted threshold amount ($97,126).	Meets cost criterion.
Technology Cost	The total anticipated cost to the hospital is $250 per patient.	Maximum new technology add-on payment: $162.50

Cost Criterion

In the proposed rule, we stated that after review of the information provided by the applicant, we agreed with the applicant that InVision PCA meets the cost criterion and therefore proposed to approve InVision PCA for new technology add-on payments for FY 2027, for the FDA-cleared indication covered by the Breakthrough Device designation listed in the table. We stated we considered the beginning of the newness period to commence on May 21, 2025, the date on which InVision PCA received FDA market authorization.

Based on preliminary information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of InVision PCA would be $162.50 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether InVision PCA meets the cost criterion and our proposal to approve new technology add-on payments for InVision PCA for FY 2027.

Comment: Multiple commenters including the applicant submitted public comments expressing agreement that InVision PCA meets the eligibility requirements including the cost criterion, and supporting our proposal to approve new technology add-on payments for FY 2027. The applicant stated that the per-patient cost of the InVision PCA has changed since the filing of their application. The applicant stated that, following extensive market and competitive research, the final per-patient cost is $3,500, reflecting the rarity of the disease, the clinical value to patients, and increased costs associated with Graphics Processing Unit (GPU) computing infrastructure required for the application. The applicant submitted an updated cost analysis to CMS, and stated that the cost criterion is still met at this updated price. The applicant requested that CMS finalize the new technology add-on payment application at this new per-patient cost, effective October 1, 2026.

Response: We thank the commenters and applicant for their comments. We also thank the applicant for the updated cost and cost analysis. We note that the updated final inflated average case-weighted standardized charge per case ($167,579) still exceeds the average case-weighted threshold amount ($97,126).

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe InVision PCA meets the cost criterion. The technology received marketing authorization from FDA as a Breakthrough Device on May 21, 2025 for the indication covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for InVision PCA for FY 2027. We consider the beginning of the newness period to commence on May 21, 2025, the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the updated cost per case of InVision PCA is $3,500. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of InVision PCA is $2,275.00 for FY 2027 (that is, 65 percent of the average cost of the technology).

The applicant was granted approval for a unique ICD–10–PCS procedure code for the InVision PCA beginning in FY 2027. Therefore, cases involving the use of InVision PCA that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code: XEZZXLC (Computer-aided detection and notification for imaging abnormalities in echocardiography, new technology group 12).

9. Nelli™ Seizure Monitoring System

Neuro Event Labs submitted a FY 2027 application for new technology add-on payments for the Nelli™ Seizure Monitoring System. According to the applicant, the Nelli™ Seizure Monitoring System is a prescription-only device that is designed to be used as an adjunct to seizure monitoring in healthcare facilities during periods of rest. Per the applicant, the device utilizes automated analysis of audio and video (media) to identify epileptic and non-epileptic seizure events with a positive motor component. We note that the applicant submitted an application for new technology add-on payments for this technology for FY 2026 (90 FR 18189 through 18191; 90 FR 36770), FY2024 (88 FR 26940 through 26942; 88 FR 58919), and FY 2023 (87 FR 28341 through 28342; 87 FR 48960).

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for the Nelli™ Seizure Monitoring System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP2509294WQJJ.*

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	XXE0X48	No concerns.
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** Nelli software is intended for the automated analysis of audio and video data to identify seizure events with a positive motor component in children and adults. The software provides objective summaries of semiological components of identified events (including velocity and acceleration of movements, seizure frequency, seizure duration, heart rate, and respiratory rate). Nelli software provides A/V data for physicians to characterize seizures and peri-ictal events. **FDA Indication:** Nelli is indicated for use as an adjunct to seizure monitoring of patients aged 18 years and above in healthcare facilities during periods of rest. The device utilizes automated analysis of audio and video (media) to identify epileptic and non-epileptic seizure events with a positive motor component. The system provides prioritization of identified major seizures and other motor events for review and media playback by a qualified healthcare professional.	FDA indication is appropriate for consideration under the alternative pathway.
Newness Period	510(k) clearance on November 21, 2025. Commercial availability delay until January 20, 2026 - Applicant stated that the company needed to set up its distribution operations in the U.S., and the technology became available for use by hospitals on this date.	Newness date: 1/20/2026.
Cost Criterion	Scenario 1: 13,347 claims mapping to 19 MS-DRGs, with 53.85 percent of claims mapping to MS-DRG 101 (Seizures without MCC). Scenario 2: 26,833 claims mapping to 19 MS-DRGs, with 34.25 percent of claims mapping to MS-DRG 101 (Seizures without MCC). Final inflated average case-weighted standardized charge per case (Scenario 1 – $91,096; Scenario 2 – $129,564) exceeded the average case-weighted threshold amount (Scenario 1 – $63,676; Scenario 2 – $72,384).	Meets cost criterion.
Technology Cost	The total anticipated cost to the hospital is $1,589 per patient which includes one-time real time AI analysis during inpatient hospital stay at $1,500 and a capital cost of $89. The $89 capital cost is based on the $2,500 cost of the Nelli® Personal Recording Unit (PRU) with camera and microphone, 5 year depreciation of capital, an average of 10 devices per hospital, and an average 56 patients using the device per year per hospital.	Maximum new technology add-on payment: $975 See following discussion.

Cost Criterion

In the proposed rule, we stated that after review of the information provided by the applicant, we agreed with the applicant that the Nelli™ Seizure Monitoring System meets the cost criterion and therefore proposed to approve the Nelli™ Seizure Monitoring System for new technology add-on payments for FY 2027, for the FDA-cleared indication covered by the Breakthrough Device designation listed in the table. We stated we considered the beginning of the newness period to commence on January 20, 2026, the date on which the Nelli™ Seizure Monitoring System became commercially available.

As previously noted, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (86 FR 45145). As noted, the applicant included capital costs of $89 for the PRU in the total technology cost. Therefore, we stated it appeared that these costs are not eligible for new technology add-on payment, and we noted that any new technology add-on payment for the Nelli™ Seizure Monitoring System would be based on only the operating costs of $1,500 for the analysis during inpatient hospital stay. As a result, based on preliminary information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of the Nelli™ Seizure Monitoring System would be $975 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether the Nelli™ Seizure Monitoring System meets the cost criterion and our proposal to approve new technology add-on payments for the Nelli™ Seizure Monitoring System for FY 2027.

Comment: The applicant submitted a public comment supporting CMS's proposal to approve new technology add-on payments for the Nelli™ Seizure Monitoring System. The applicant provided assertions regarding the clinical impact of the technology and the expected impact of approval for new technology add-on payments. The applicant stated that the cost for the Nelli System remains $1,500. The applicant also stated that ICD–10–PCS code XXE0X48 (Measurement of brain electrical activity, computer-aided semiologic analysis, new technology group 8), effective October 1, 2022, may be used to identify use of the technology.

Response: We thank the applicant for its comment. As previously noted, clinical performance is not within the scope of CMS's evaluation for new technology add-on payment under the alternative pathway.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comment we received, we continue to believe the Nelli™ Seizure Monitoring System meets the cost criterion. The technology received marketing authorization from FDA as a Breakthrough Device on November 21, 2025 for the indication covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the Nelli™ Seizure Monitoring System for FY 2027. We consider the beginning of the newness period to commence on January 20, 2026, the date on which the technology became commercially available for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the Nelli™ Seizure Monitoring System is $1,500. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the Nelli™ Seizure Monitoring System is $975 for FY 2027 (that is, 65 percent of the average cost of the technology).

Cases involving the use of the Nelli™ Seizure Monitoring System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code: XXE0X48 (Measurement of brain electrical activity, computer-aided semiologic analysis, new technology group 8).

10. NEXUS® Aortic Arch Stent Graft System

ENDOSPAN submitted a FY 2027 application for new technology add-on payments for the NEXUS® Aortic Arch Stent Graft System. According to the applicant, the NEXUS® Aortic Arch Stent Graft System is a branched endovascular stent graft system designed specifically for repair of aortic arch pathologies (including aneurysms, chronic dissections, penetrating ulcers, and intramural hematoma) involving Zone 0 ascending aorta and the arch.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for the NEXUS® Aortic Arch Stent Graft System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251006114Y0.*

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	Request submitted.	N/A
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** The NEXUS™ Aortic Arch Stent Graft System is indicated for the endovascular treatment of thoracic aortic lesions involving the aortic arch including chronic dissections, aneurysms, penetrating aortic ulcers and intramural hematoma, with a proximal landing zone in the ascending aorta and in the brachiocephalic artery. The NEXUS™ Aortic Arch Stent Graft System is indicated for exclusion of the aneurysm or the false lumen and the restoration of blood flow through the stent graft lumen. Patients should have appropriate anatomy to accommodate the NEXUS System in an endovascular procedure. **FDA Indication:** Pending.	Pending FDA marketing authorization.
Newness Period	FDA decision anticipated by May 1, 2026, consistent with its Breakthrough Device designation. No commercial availability delay expected.	Pending FDA marketing authorization.
Cost Criterion	1,219 claims mapping to 16 MS-DRGs, with 33.72 percent of claims mapping to MS-DRG 220 (Cardiac Valve and Other Major Cardiothoracic Procedure with and without Cardiac Catheterization with CC). Final inflated average case-weighted standardized charge per case ($513,444) exceeded the average case-weighted threshold amount ($257,842).	Meets cost criterion.
Technology Cost	The total anticipated cost to the hospital is $55,200 per patient. Per the applicant, the arch stent graft and ascending curve aorta stent graft are $45,000 per patient and will be used in every procedure. The descending extension stent graft is $17,000 per patient but is only used in 60 percent of the procedures based on clinical trial data ($17,000 x .60 = $10,200).	Maximum new technology add-on payment: $35,880

Cost Criterion

In the proposed rule, we stated that after review of the information provided by the applicant, we agreed with the applicant that the NEXUS® Aortic Arch Stent Graft System meets the cost criterion and therefore proposed to approve the NEXUS® Aortic Arch Stent Graft System for new technology add-on payments for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

Based on preliminary cost information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use

of the NEXUS® Aortic Arch Stent Graft System would be $35,880 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether the NEXUS® Aortic Arch Stent Graft System meets the cost criterion and our proposal to approve new technology add-on payments for the NEXUS® Aortic Arch Stent Graft System for FY 2027, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2026.

Comment: The applicant submitted a public comment in support of the NEXUS® Aortic Arch Stent Graft System, including a copy of the FDA PMA approval letter. The applicant stated that FDA marketing authorization was received prior to the May 1, 2026 deadline and requested CMS confirm that the NEXUS® Aortic Arch Stent Graft System satisfies the FDA marketing authorization criterion. The applicant stated FDA approval was supported by the one-year results of the TRIOMPHE Investigational Device Exemption (IDE) clinical study and provided its assertions regarding the clinical outcomes demonstrated by the trial.

Other commenters also expressed support for the approval of the NEXUS® Aortic Arch Stent Graft System, stating that the technology meets the new technology add-on payment requirements and offers a minimally invasive treatment option for patients with complex aortic arch disease—including aneurysms, chronic dissections, penetrating ulcers, and intramural hematoma—who often face high operative risk and limited alternatives with conventional open arch surgery. The commenters stated that temporary add-on payment is appropriate to facilitate access to this innovative therapy while utilization patterns and MS–DRG relative weights for these cases continue to evolve.

Response: We thank the applicant and other commenters for their comments. As previously noted, clinical performance is not within the scope of CMS's evaluation for new technology add-on payment under the alternative pathway. We agree with the applicant that the NEXUS® Aortic Arch Stent Graft System meets the marketing authorization requirement because the NEXUS® Aortic Arch Stent Graft System received PMA approval as a Breakthrough Device prior to May 1, 2026.

Comment: A commentor submitted a public comment related to the cost criterion analysis for the NEXUS® Aortic Arch Stent Graft System stating that MS–DRG 209 was not active until FY 2026 as it was created to recognize the complexity and resource use for procedures utilizing several new technologies in complex aortic arch procedures, including the GORE® TAG® Thoracic Branch Endoprosthesis. The commenter stated that the cost threshold is significantly higher for MS–DRG 209 and requested CMS clarify whether the cost analysis should rank MS–DRG 209 higher related to the payment thresholds for FY 2027 new technology add-on payment applications. The commenter also stated that if the applicant's cost analysis were used as submitted, the new ICD–10–PCS section X codes for this technology (which it referred to as X2VJ3HC and X2VJ3JC) should be included in MS–DRGs 219–221 only, which the commenter stated appeared to be the dominant MS–DRGs per the analysis.

Response: We thank the commenter for its comment. We are unclear on the commenter's suggestion that the cost analysis should be reconfigured to rank MS–DRG 209 higher, as MS–DRGs in a cost analysis are not ranked. We note that even if only the FY 2027 new technology add-on payment threshold for MS–DRG 209 was used for all identified cases in the cost criterion analysis, the NEXUS® Aortic Arch Stent Graft System would still meet the cost criterion because the final inflated average case-weighted standardized charge per case ($513,444) would exceed the threshold amount for MS–DRG 209 ($402,058). We also note that the process to request MS–DRG classification changes is separate and distinct from the new technology add-on payment application process. We refer the commenter to the MS–DRG classification change request process that is discussed in section II.C.1.b of the preamble of this final rule for further information.

We further note that the applicant was granted approval for unique ICD–10–PCS procedure codes that are different from one of the codes discussed in the comment, and which are discussed later in this section.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the NEXUS® Aortic Arch Stent Graft System meets the cost criterion. The technology received PMA approval from FDA as a Breakthrough Device on April 2, 2026 with an indication for the endovascular treatment of chronic dissections involving the aortic arch in patients who are at high risk for open surgical repair and who have appropriate anatomy,[97] which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the NEXUS® Aortic Arch Stent Graft System for FY 2027. We consider the beginning of the newness period to commence on April 2, 2026, the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the NEXUS® Aortic Arch Stent Graft System is $55,200. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the NEXUS® Aortic Arch Stent Graft System is $35,880 for FY 2027 (that is, 65 percent of the average cost of the technology).

The applicant was granted approval for unique ICD–10–PCS procedure codes for the NEXUS® Aortic Arch Stent Graft System beginning in FY 2027. Therefore, cases involving the use of the NEXUS® Aortic Arch Stent Graft System that are eligible for new technology add-on payments will be identified by either ICD–10–PCS procedure code X2VJ3HC (Restriction of thoracic aorta, ascending and arch using branched intraluminal device, integrated system with innominate branch, percutaneous approach, new technology group 12), or X2VJ3HC in combination with X2VW3JC (Restriction of thoracic aorta, descending using branched intraluminal device, integrated system extension, percutaneous approach, new technology group 12).

11. OmniaSecure™ MRI SureScan™ Lead Model 3930M

Medtronic submitted a FY 2027 application for new technology add-on payments for the OmniaSecure™ MRI SureScan™ Lead Model 3930M (OmniaSecure™ defibrillation lead). According to the applicant, the OmniaSecure™ defibrillation lead is an implantable defibrillation lead designed to deliver pacing, sensing, cardioversion, and defibrillation therapy

[97] *https://www.accessdata.fda.gov/cdrh_docs/pdf25/P250033A.pdf.*

for patients at risk of life-threatening ventricular arrhythmias.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for the OmniaSecure™ defibrillation lead and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP250930Q7TFH.*

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	Request submitted.	N/A
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** The Model 3930M lead is intended for use in the right ventricle for sensing, pacing, cardioversion, and defibrillation when a cardiac implantable electronic device is indicated to treat patients who have experienced, or are at significant risk of developing, life-threatening tachyarrhythmias. This includes adolescent pediatric patients who are at least 30 kg and are also at least 12 years of age, and whose cardiac anatomy is conducive to RV coil placement. **FDA Indication:** This device is indicated for single use in the right ventricle for pacing, sensing, cardioversion, and defibrillation when a cardiac implantable electronic device is indicated to treat patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias. This includes adolescent pediatric patients who are at least 30 kg and are also at least 12 years of age, and whose cardiac anatomy is conducive to RV coil placement.	FDA indication is appropriate for consideration under the alternative pathway.
Newness Period	PMA approved on 4/22/2025 Commercial availability delay until 1/7/2026, due to field sales training and contracting with hospitals prior to market availability in the U.S.	Newness date: 1/7/2026.
Cost Criterion	9,809 claims mapping to 4 MS-DRGs, with 35.80 percent of claims mapping to MS-DRG 277 (Cardiac Defibrillator Implant without MCC) Final inflated average case-weighted standardized charge per case ($256,251) exceeded the average case-weighted threshold amount ($238,636).	Meets cost criterion.
Technology Cost	The total anticipated cost to the hospital is $11,995 per patient, for one OmniaSecure™ defibrillation lead.	Maximum new technology add-on payment: $7,796.75

Cost Criterion

In the proposed rule, we stated that after review of the information provided by the applicant, we agreed with the applicant that the OmniaSecure™ defibrillation lead meets the cost criterion and therefore proposed to approve the OmniaSecure™ defibrillation lead for new technology add-on payments for FY 2027, for the FDA-approved indication covered by the Breakthrough Device designation listed in the table. We stated we considered the beginning of the newness period to commence on January 7, 2026, the date on which the OmniaSecure™ defibrillation lead became commercially available.

Based on preliminary information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of the OmniaSecure™ defibrillation lead would be $7,796.75 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether the OmniaSecure™ defibrillation lead meets the cost criterion and our proposal to approve new technology add-on payments for the OmniaSecure™ MRI SureScan™ Lead Model 3930M for FY 2027.

Comment: A few commenters, including the applicant expressed support for our proposal to approve new technology add-on payment for the OmniaSecure™ MRI SureScan™ Lead Model 3930M. The applicant stated that it agreed with the assessment provided in the proposed rule and stated that two new ICD–10–PCS codes, X2HV3GB (Insertion of lumenless small-diameter defibrillator lead into right ventricle, percutaneous approach, new technology group 11) and X2HM3GB (Insertion of lumenless small-diameter defibrillator lead into ventricular septum, percutaneous approach, new technology group 11) became effective April 1, 2026, to describe procedures involving insertion of the OmniaSecure™ defibrillation lead. The applicant requested that CMS finalize approval at the proposed maximum payment amount of $7,796.75 per case.

Response: We thank the commenters for their comments and support.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the OmniaSecure™ defibrillation lead meets the cost criterion. The technology received marketing authorization from FDA as a Breakthrough Device on April 22, 2025 for the indication covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the OmniaSecure™ defibrillation lead for FY 2027 for single use in the right ventricle for pacing, sensing, cardioversion, and defibrillation when a cardiac implantable electronic device is indicated to treat patients who have experienced, or are at significant risk of

developing, life-threatening ventricular tachyarrhythmias. We consider the beginning of the newness period to commence on January 7, 2026, the date on which the technology became commercially available for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the OmniaSecure™ defibrillation lead is $11,995. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the OmniaSecure™ defibrillation lead is $7,796.75 for FY 2027 (that is, 65 percent of the average cost of the technology).

The applicant was granted approval for unique ICD–10–PCS procedure codes for the OmniaSecure™ defibrillation lead beginning in FY 2026. However, we disagree that cases involving the use of OmniaSecure™ defibrillation lead that are identified by X2HM3GB (Insertion of lumenless small-diameter defibrillator lead into ventricular septum, percutaneous approach, new technology group 11) should be eligible for new technology add-on payment as the FDA Breakthrough Device-designated indication only covers the OmniaSecure™ defibrillation lead when intended for use in the right ventricle. The use of the OmniaSecure™ defibrillation lead for placement at the left bundle branch area in the ventricular septum is not covered by its Breakthrough Device-designated indication. Therefore, cases involving the use of the OmniaSecure™ defibrillation lead that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code X2HV3GB (Insertion of lumenless small-diameter defibrillator lead into right ventricle, percutaneous approach, new technology group 11).

12. PearlMatrix™ P–15 Peptide Enhanced Bone Graft

Cerapedics, Inc. submitted a FY 2027 application for new technology add-on payments for PearlMatrix™ P–15 Peptide Enhanced Bone Graft. According to the applicant, PearlMatrix™ P–15 Peptide Enhanced Bone Graft is a composite bone graft material consisting of a synthetic peptide, found naturally occurring in human Type I collagen (P–15), adsorbed onto calcium phosphate particles, which are incorporated into a fibrous collagen matrix putty as an inert carrier. We note that the applicant submitted an application for new technology add-on payments for this technology for FY 2026 (90 FR 18193 through 18195; 90 FR 36770).

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for PearlMatrix™ P–15 Peptide Enhanced Bone Graft and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251001VFM4K.*

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	XW0U0XB, XW0U3XB, or XW0U4XB	See following discussion.
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** The P-15L Bone Graft is indicated for intervertebral body fusion of the spine in skeletally mature patients. The P-15L Bone Graft is intended to be used in conjunction with a TLIF Fusion Device and supplemental internal spinal fixation systems cleared by the FDA for use in the lumbosacral spine. The system is to be used in patients who have had at least six months of non-operative treatment. The P-15L Bone Graft is intended for use at one level in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. **FDA Indication:** This device is indicated for intervertebral body fusion of the spine in skeletally mature patients. PearlMatrix™ Bone Graft is intended to be used in conjunction with a PEEK TLIF Fusion Device and supplemental internal spinal fixation systems cleared by the FDA for use in the lumbosacral spine. The system is to be used in patients who have had at least six months of non-operative treatment. PearlMatrix™ Bone Graft is intended for use at one level in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back and/or radicular pain of discogenic origin with degeneration of the disc confirmed by history, physical exam, and radiographic studies. Per the applicant, the P-15L Bone Graft named in the Breakthrough Device designation letter is the same device as PearlMatrix™ P-15 Peptide Enhanced Bone Graft.	FDA indication is appropriate for consideration under the alternative pathway. See following discussion.
Newness Period	PMA approval on 6/18/2025	Newness date: 6/18/2025.
Cost Criterion	6,211 claims mapping to 2 MS-DRGs, with 94.85 percent of claims mapping to MS-DRG 451 (Single Level Spinal Fusion Except Cervical without MCC). Final inflated average case-weighted standardized charge per case ($158,116) exceeded the average case-weighted threshold amount ($135,408).	Meets cost criterion.
Technology Cost	An average of one (10 cc) kit is used per inpatient stay, based on the average number of units per inpatient stay (8.2) in clinical trial. The total anticipated cost to the hospital is $6,500 per patient, per kit. The applicant provided the following cost breakdown of each component: bone graft peptide ($3,120 operating cost and $780 capital cost), porcine anorganic bone mineral ($780 operating cost and $195 capital cost), and fibrous collagen matrix ($1,300 operating cost and $325 capital cost).	Maximum new technology add-on payment: $3,380 See following discussion.

ICD–10–CM Coding:

In the proposed rule, we stated that after review of the information provided by the applicant, we noted that subsequent to the June 18, 2025 PMA as listed in the table, a supplemental PMA for PearlMatrix™ P–15 Peptide Enhanced Bone Graft was approved on December 11, 2025,[98] expanding the indication to allow implantation of the product using additional surgical approaches. We noted that, as previously stated, under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment for FY 2027. Therefore, we stated it appeared that only the use of the PearlMatrix™ P–15 Peptide Enhanced Bone Graft in conjunction with a TLIF device, and the FDA Breakthrough Device designation it received for that use, would be relevant for purposes of the new technology add-on payment application for FY 2027. We noted that the applicant stated that effective October 1, 2025, the following ICD–10–PCS codes could be used to uniquely describe procedures involving the use of the technology: XW0U0XB (Introduction of peptide enhanced bone void filler into joints, open approach, new technology group 11), XW0U3XB (Introduction of peptide enhanced bone void filler into joints, percutaneous approach, new technology group 11), or XW0U4XB (Introduction of peptide enhanced bone void filler into joints, percutaneous endoscopic approach, new technology group 11). We stated we believed the relevant ICD–10–PCS procedure codes that would be appropriate to report in combination with the PearlMatrix™ P–15 Peptide Enhanced Bone Graft's unique ICD–10–PCS codes to identify use of the technology for the Breakthrough Device-designated indication would be the following:

[98] *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P240001S001.*

ICD-10-PCS Code	Description
0SG00AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG03AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG04AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG30AJ	Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG33AJ	Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG34AJ	Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach

We invited public comments on the use of these ICD–10–PCS procedure codes to identify use of the technology for the Breakthrough Device-designated indication for purposes of the new technology add-on payment, if approved, and did not receive any comments.

Cost Criterion

In the proposed rule we stated we agreed with the applicant that PearlMatrix™ P–15 Peptide Enhanced Bone Graft meets the cost criterion and therefore proposed to approve PearlMatrix™ P–15 Peptide Enhanced Bone Graft for new technology add-on payments for FY 2027, for the FDA-approved indication covered by the Breakthrough Device designation listed in the table and as described previously. We stated we considered the beginning of the newness period to commence on June 18, 2025, the date on which PearlMatrix™ P–15 Peptide Enhanced Bone Graft received FDA marketing authorization.

Based on preliminary cost information from the applicant at the time of the proposed rule, we stated that the applicant anticipated the total cost of PearlMatrix™ P–15 Peptide Enhanced Bone Graft to the hospital to be $6,500 per patient, for one 10 cc kit used per inpatient stay. We noted that the applicant stated there were capital costs of $1,300 for the bone graft peptide, porcine anorganic bone mineral, and fibrous collagen matrix, and that, as we had previously discussed, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (86 FR 45145). Therefore, we stated it appeared that the $1,300 capital costs were not eligible for new technology add-on payment, and we noted that any new technology add-on payment for PearlMatrix P–15 Peptide Enhanced Bone Graft would be based on only the operating costs of $5,200 for the bone graft peptide, porcine anorganic bone mineral, and fibrous collagen matrix. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of PearlMatrix™ P–15 Peptide Enhanced Bone Graft would be $3,380 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether PearlMatrix™ P–15 Peptide Enhanced Bone Graft meets the cost criterion and our proposal to approve new technology add-on payments for PearlMatrix™ P–15 Peptide Enhanced Bone Graft for FY 2027.

We did not receive any comments related to PearlMatrix™ P–15 Peptide Enhanced Bone Graft.

Based on the information provided in the application for new technology add-on payments, we believe PearlMatrix™ P–15 Peptide Enhanced Bone Graft meets the cost criterion. The technology received marketing authorization from FDA as a Breakthrough Device on June 18, 2025 for the indication covered by its Breakthrough Device designation, as described previously. Therefore, we are finalizing our proposal to approve new technology add-on payments for PearlMatrix™ P–15 Peptide Enhanced Bone Graft for FY 2027. We consider the beginning of the newness period to commence on June 18, 2025, the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of PearlMatrix™ P–15 Peptide Enhanced Bone Graft meets is $5,200. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of PearlMatrix™ P–15 Peptide Enhanced Bone Graft is $3,380 for FY 2027 (that is, 65 percent of the average cost of the technology).

As noted earlier in this section, PearlMatrix™ P–15 Peptide Enhanced Bone Graft has received FDA marketing authorization for multiple indications, and only the use of the PearlMatrix™ P–15 Peptide Enhanced Bone Graft in conjunction with a TLIF device, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2027. Therefore, cases involving the use of PearlMatrix™ P–15 Peptide Enhanced Bone Graft that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW0U0XB (Introduction of peptide enhanced bone void filler into joints, open approach, new technology group 11), XW0U3XB (Introduction of peptide enhanced bone void filler into joints, percutaneous approach, new technology group 11), or XW0U4XB (Introduction of peptide enhanced bone void filler into joints, percutaneous endoscopic approach, new technology group 11), in combination with any of the following ICD–10–PCS procedure codes:

ICD-10-PCS Code	Description
0SG00AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG03AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG04AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG30AJ	Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG33AJ	Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG34AJ	Fusion of lumbosacral vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach

13. SAPIEN M3 Transcatheter Mitral Valve Replacement System

Edwards LifeSciences, LLC submitted a FY 2027 application for new technology add-on payments for the SAPIEN M3 Transcatheter Mitral Valve Replacement System (the SAPIEN M3 TMVR System). According to the applicant, the SAPIEN M3 TMVR System is a transcatheter system designed to allow for replacement of the native mitral valve in patients with symptomatic mitral valve regurgitation or symptomatic mitral stenosis.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for the SAPIEN M3 TMVR System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251003XXUEG.*

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	Request submitted.	N/A
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** Indications for use include (1) the treatment of symptomatic, moderate-to-severe or severe primary or secondary mitral regurgitation in patients deemed refractory to guideline directed medical therapy (for patients with secondary mitral regurgitation only) and unsuited for surgery or transcatheter edge-to-edge repair by a multidisciplinary heart team experienced in mitral valve therapies, and (2) the treatment of symptomatic severe mitral valve dysfunction (moderate-to-severe or severe mitral regurgitation, severe mitral stenosis, or moderate mitral regurgitation with moderate or greater mitral stenosis) associated with severe mitral annular calcification in patients who are deemed unsuited for mitral valve surgery. **FDA Indication:** This device is indicated for the treatment of symptomatic moderate-to-severe or severe mitral regurgitation (MR) in patients who are deemed unsuitable for surgery or transcatheter edge-to-edge repair (TEER) therapy by a multidisciplinary heart team. It is also indicated for the treatment of symptomatic mitral valve dysfunction (moderate-to-severe or severe MR, severe mitral stenosis (MS), or moderate MR with moderate MS) associated with mitral annular calcification (MAC) in patients who are deemed unsuitable for surgery or TEER therapy by a multidisciplinary heart team.	FDA indication is appropriate for consideration under the alternative pathway.
Newness Period	PMA approval on 12/22/2025	Newness date: 12/22/2025.
Cost Criterion	Scenario 1: 634 claims mapping to 11 MS-DRGs, with 43.85 percent of claims mapping to MS-DRG 266 (Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC). Scenario 2: 11,523 claims mapping to 2 MS-DRGs, with 54.16 percent of claims mapping to MS-DRG 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC). Final inflated average case-weighted standardized charge per case (Scenario 1– $434,734; Scenario 2– $344,193) exceeded the average case-weighted threshold amount (Scenario 1– $234,166; Scenario 2 – $206,449).	Meets cost criterion.
Technology Cost	The total anticipated cost to the hospital is $54,000 per patient. Per the applicant, while the system has multiple components (e.g., valve, docking station, etc.), they are all single-patient use and cannot be sold or used separately.	Maximum new technology add-on payment: $35,100

Cost Criterion

In the proposed rule, we stated that after review of the information provided by the applicant, we agreed with the applicant that the SAPIEN M3 TMVR System meets the cost criterion and therefore proposed to approve the SAPIEN M3 TMVR System for new technology add-on payments for FY 2027, for the FDA-approved indication covered by the Breakthrough Device designation listed in the table. We stated we considered the beginning of the newness period to commence on December 22, 2025, the date on which the SAPIEN M3 TMVR System received FDA marketing authorization.

Based on preliminary information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of the SAPIEN M3 TMVR System would be $35,100 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether the SAPIEN M3 TMVR System meets the cost criterion and our proposal to approve new technology add-on payments for the SAPIEN M3 Transcatheter Mitral Valve Replacement System for FY 2027.

Comment: Multiple commenters, including the applicant, expressed support for our proposal to approve new technology add-on payment for the SAPIEN M3 TMVR System. The applicant stated that the cost criterion is met and urged CMS to finalize the proposal.

Response: We thank the applicant and commenters for their comments and support.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the SAPIEN M3 TMVR System meets the cost criterion. The technology received marketing authorization from FDA as a Breakthrough Device on December 22, 2025 for the indication covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the SAPIEN M3 TMVR System for FY 2027. We consider the beginning of the newness period to commence on December 22, 2025, the date on which the technology received

FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the SAPIEN M3 TMVR System is $54,000. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the SAPIEN M3 TMVR System is $35,100 for FY 2027 (that is, 65 percent of the average cost of the technology).

The applicant was granted approval for a unique ICD–10–PCS procedure code for the SAPIEN M3 TMVR System beginning in FY 2027. Therefore, cases involving the use of the SAPIEN M3 TMVR System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code: X2RG3FC (Replacement of mitral valve with balloon-expandable bioprosthetic valve with dock, percutaneous approach, new technology group 12).

14. SetPoint System®

SetPoint Medical Corporation submitted a FY 2027 application for new technology add-on payments for the SetPoint System®. According to the applicant, the SetPoint System® is a fully integrated, rechargeable, implantable vagus nerve stimulation system used to treat individuals with moderate to severe rheumatoid arthritis (RA) who have experienced a loss of efficacy, inadequate response, or intolerance to one or more biologic or targeted synthetic disease modifying antirheumatic drugs (DMARDs).

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for the SetPoint System® and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251006Y987F.*

:	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	Request submitted.	N/A
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** The SetPoint system is indicated for the treatment of adult patients with moderately to severely active RA who have had an inadequate response, loss of response or intolerance to one (1) or more biological or targeted synthetic DMARDs. **FDA Indication:** This device is indicated for use in the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response, loss of response, or intolerance to one or more biological or targeted synthetic disease modifying antirheumatic drugs (b/tsDMARDs).	FDA indication is appropriate for consideration under the alternative pathway.
Newness Period	PMA approval on 7/30/2025 Commercial availability delay to 8/21/2025 due to a delay in manufacturing.	Newness date: 8/21/2025.
Cost Criterion	6,563 claims mapping to 2 MS-DRGs, with 76.84 percent of claims mapping to MS-DRG 041 (Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator). Final inflated average case-weighted standardized charge per case ($292,843) exceeded the average case-weighted threshold amount ($100,081).	Meets cost criterion.
Technology Cost	The total anticipated cost to the hospital is $59,500 per patient, for one complete SetPoint System®. The SetPoint System® includes an implantable Neuroimmune Modulator ($56,500), a Silicone Pod ($300), and a Charger and Docking Station ($2,700) packaged into a single SKU/system package. The Charger and Docking Station is provided to the patient at the time of surgery and it is only usable by one patient.	Maximum new technology add-on payment: $38,675

Cost Criterion

In the proposed rule, we stated that after review of the information provided by the applicant, we agreed with the applicant that the SetPoint System® meets the cost criterion and therefore proposed to approve the SetPoint System® for new technology add-on payments for FY 2027, for the FDA approved indication covered by the Breakthrough Device designation listed in the table. We stated we considered the beginning of the newness period to commence on August 21, 2025, the date on which the SetPoint System® became commercially available.

Based on preliminary information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of the SetPoint System® would be $38,675 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether the SetPoint System® meets the cost criterion and our proposal to approve new technology add-on payments for the SetPoint System® for FY 2027.

Comment: A few commenters, including the applicant, submitted public comments that expressed support for our proposal to approve the SetPoint System® with a maximum payment amount of $38,675. The applicant described its assertions regarding the clinical impact of the technology and

the importance of approving it for new technology add-on payments.

Response: We thank the applicant and commenters for their comments and support.

We note that clinical performance is not within the scope of CMS's evaluation for new technology add-on payment under the alternative pathway, as previously stated.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the SetPoint System® meets the cost criterion. The technology received marketing authorization from FDA as a Breakthrough Device on July 30, 2025 for the indication covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the SetPoint System® for FY 2027. We consider the beginning of the newness period to commence on August 21, 2025, the date on which the technology became commercially available for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the SetPoint System® is $59,500. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the SetPoint System® is $38,675 for FY 2027 (that is, 65 percent of the average cost of the technology).

The applicant was granted approval for a unique ICD–10–PCS procedure code for the SetPoint System® beginning in FY 2027. Therefore, cases involving the use of the SetPoint System® that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code: X0HQ05C (Insertion of leadless neurostimulator generator into vagus nerve, open approach, new technology group 12).

15. Spur® Peripheral Retrievable Stent System

Reflow Medical, Inc. submitted a FY 2027 application for new technology add-on payments for the Spur® Peripheral Retrievable Stent System. According to the applicant, the Spur® Peripheral Retrievable Stent System is used as an adjunct to percutaneous transluminal angioplasty (PTA) to dilate stenoses in infrapopliteal arteries ranging in diameter from 2.5 mm to 4.5 mm. We note that the applicant submitted an application for new technology add-on payments for this technology for FY 2026 (90 FR 18203 through 18205; 90 FR 36770).

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for the Spur® Peripheral Retrievable Stent System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251001G2LL6.*

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	X2HP38B, X2HQ38B, X2HR38B, X2HS38B, X2HT38B, and X2HU38B.	No concerns.
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** The Bare Temporary Spur Stent System is intended for the treatment of de novo or restenotic lesions of the infrapopliteal arteries to increase luminal gain. **FDA Indication:** The Spur® Peripheral Retrievable Stent System is intended as an adjunct to percutaneous transluminal angioplasty (PTA) to dilate stenoses in infrapopliteal arteries ranging in diameter from 2.5 mm to 4.5 mm. Per the applicant, the Bare Temporary Spur Stent System named in the Breakthrough Device designation letter is the same device as the Spur® Peripheral Retrievable Stent System.	FDA indication is appropriate for consideration.
Newness Period	De Novo classification granted on 5/29/2025.	Newness date: 5/29/2025.
Cost Criterion	Scenario 1: 2,665 claims mapping to 75 MS-DRGs, with 17 percent of claims mapping to MS-DRG 271 (Other Major Cardiovascular Procedures with CC). Scenario 2: 12,708 claims mapping to 133 MS-DRGs, with 30.93 percent of claims mapping to MS-DRG 253 (Other Vascular Procedures with CC) and MS-DRG 271 (Other Major Cardiovascular Procedures with CC). Final inflated average case-weighted standardized charge per case (Scenario 1 – $261,797; Scenario 2 – $238,193) exceeded the average case-weighted threshold amount (Scenario 1 – $140,905; Scenario 2 – $140,008).	Meets cost criterion.
Technology Cost	The average total cost of the system to the hospital is $3,995 per patient, based on one system used per inpatient stay. Internal sales data was used to calculate the price received. The system costs include $3,994 for the Spur Stent, and $1 for the Spur Stent System Delivery Catheter.	Maximum new technology add-on payment: $2,596.75

Cost Criterion

In the proposed rule, we stated that after review of the information provided by the applicant, we agreed with the applicant that the Spur® Peripheral Retrievable Stent System meets the cost criterion and therefore proposed to approve the Spur® Peripheral Retrievable Stent System for new technology add-on payments for FY 2027, for the FDA-approved indication

covered by the Breakthrough Device designation listed in the table. We stated we considered the beginning of the newness period to commence on May 29, 2025, the date on which the Spur® Peripheral Retrievable Stent System received FDA marketing authorization.

Based on preliminary cost information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of the Spur® Peripheral Retrievable Stent System would be $2,596.75 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether the Spur® Peripheral Retrievable Stent System meets the cost criterion and our proposal to approve new technology add-on payments for the Spur® Peripheral Retrievable Stent System for FY 2027.

Comment: The applicant and other commenters submitted comments in support of new technology add-on payments for the Spur® Peripheral Retrievable Stent System. The applicant's comment confirmed that the final per-patient price of the technology is $3,995, and agreed with the proposed maximum new technology add-on payment of $2,596.75 for FY 2027. The applicant requested that CMS finalize the proposal to approve new technology add-on payments.

Response: We thank the applicant and other commenters for their comments.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we continue to believe the Spur® Peripheral Retrievable Stent System meets the cost criterion. The technology received marketing authorization from FDA as a Breakthrough Device on May 29, 2025 for the indication covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the Spur® Peripheral Retrievable Stent System for FY 2027. We consider the beginning of the newness period to commence on May 29, 2025, the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the Spur® Peripheral Retrievable Stent System is $3,995. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the Spur® Peripheral Retrievable Stent System is $2,596.75 for FY 2027 (that is, 65 percent of the average cost of the technology).

Cases involving the use of the Spur® Peripheral Retrievable Stent System that are eligible for new technology add-on payments will be identified by any of the following ICD–10–PCS procedure codes:

ICD-10-PCS Code	Description
X2HP38B	Insertion of temporary intraluminal device into right anterior tibial artery, percutaneous approach, new technology group 11
X2HQ38B	Insertion of temporary intraluminal device into left anterior tibial artery, percutaneous approach, new technology group 11
X2HR38B	Insertion of temporary intraluminal device into right posterior tibial artery, percutaneous approach, new technology group 11
X2HS38B	Insertion of temporary intraluminal device into left posterior tibial artery, percutaneous approach, new technology group 11
X2HT38B	Insertion of temporary intraluminal device into right peroneal artery, percutaneous approach, new technology group 11
X2HU38B	Insertion of temporary intraluminal device into left peroneal artery, percutaneous approach, new technology group 11

16. Trilogy™ Transcatheter Aortic Valve Regurgitation System

JenaValve submitted a FY 2027 application for new technology add-on payments for the Trilogy™ Transcatheter Aortic Valve Regurgitation System. According to the applicant, the Trilogy™ Transcatheter Aortic Valve Regurgitation System for transcatheter aortic valve implantation is deployed so that the Transcatheter Heart Valve (THV) expands radially at the native annulus and clips onto the native aortic leaflets to anchor the THV. Per the applicant, the THV is designed to anchor in the diseased regurgitant aortic valve.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for the Trilogy™ Transcatheter Aortic Valve Regurgitation System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP25100691E86.*

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	Request submitted.	N/A
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** Indications for use include aortic valve replacement for the relief of aortic regurgitation (AR) and AR-dominant mixed aortic valve disease, in eligible patients with severe native aortic valve regurgitation who are judged by a heart team (including at least one cardiac surgeon) to be eligible for the device and to be at high risk for open surgical aortic valve replacement (defined as STS-PROM score ≥8%, or if <8%, a documented heart team agreement determines that significant co-morbidities are not captured by the STS-PROM score. **FDA Indication:** This device is indicated for the treatment of symptomatic, severe native tricuspid aortic valve regurgitation (not due to acute endocarditis, rheumatic heart disease, or acute aortic dissection) in patients who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for surgical aortic valve replacement (i.e., predicted risk of surgical mortality ≥8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).	FDA indication is appropriate for consideration.
Newness Period	PMA approval on 3/17/2026.	Newness date: 3/17/2026.
Cost Criterion	408 claims mapping to 9 MS-DRGs, with 41.67 percent of claims mapping to MS-DRG 266 (Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC). Final inflated average case-weighted standardized charge per case ($362,565) exceeded the average case-weighted threshold amount ($245,485).	Meets cost criterion.
Technology Cost	The total anticipated cost to the hospital is $39,500 per patient. The technology is a single device application and system, designed for single patient use only.	Maximum new technology add-on payment: $25,675

Cost Criterion

In the proposed rule, we stated that after review of the information provided by the applicant, we agreed with the applicant that the Trilogy™ Transcatheter Aortic Valve Regurgitation System meets the cost criterion and therefore proposed to approve the Trilogy™ Transcatheter Aortic Valve Regurgitation System for new technology add-on payments for FY 2027, for the FDA-approved indication covered by the Breakthrough Device designation listed in the table. We stated we considered the beginning of the newness period to commence on March 17, 2026, the date on which the Trilogy™ Transcatheter Aortic Valve Regurgitation System received FDA marketing authorization.

Based on preliminary information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of the Trilogy™ Transcatheter Aortic Valve Regurgitation System would be $25,675 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether the Trilogy™ Transcatheter Aortic Valve Regurgitation System meets the cost criterion and our proposal to approve new technology add-on payments for the Trilogy™ Transcatheter Aortic Valve Regurgitation System for FY 2027.

Comment: We received several comments that expressed support for our proposal to approve new technology add-on payment for the Trilogy™ Transcatheter Aortic Valve Regurgitation System. The commenters stated that without an add-on payment, the standard MS–DRG payment will not adequately compensate hospitals for the cost of the device during this early adoption period, and speculated on the potential for slow adoption of the technology and resulting issues with Medicare beneficiary access. Multiple commenters described their assertions regarding the clinical need for this technology for Medicare beneficiaries. Several commenters also asserted that the Trilogy™ Transcatheter Aortic Valve Regurgitation System is different from conventional TAVR systems. The applicant and other commenters stated that the technology meets eligibility requirements and requested that CMS finalize its proposal to approve the new technology add-on payments for FY 2027 at the proposed maximum add-on payment of $25,675 per case, with the applicant confirming the cost analysis values reflected in the proposed rule. Another commenter expressed concerns about the high cost of the technology when considering shelf life and lack of consignment options, within a broader context of concern about new technology add-on payments creating incentivization for higher costs and charges.

Response: We thank the commenters for their comments. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, the Trilogy™ Transcatheter Aortic Valve Regurgitation System meets the cost criterion. We note that assessment of clinical improvement and substantial similarity is not within the scope of CMS's evaluation for new technology add-on payment under the alternative pathway as previously described.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we

believe the Trilogy™ Transcatheter Aortic Valve Regurgitation System meets the cost criterion. The technology received marketing authorization from FDA as a Breakthrough Device on March 17, 2026 for the indication covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the Trilogy™ Transcatheter Aortic Valve Regurgitation System for FY 2027. We consider the beginning of the newness period to commence on March 17, 2026, the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the Trilogy™ Transcatheter Aortic Valve Regurgitation System is $39,500. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the Trilogy™ Transcatheter Aortic Valve Regurgitation System is $25,675 for FY 2027 (that is, 65 percent of the average cost of the technology).

The applicant was granted approval for a unique ICD–10–PCS procedure code for the Trilogy™ Transcatheter Aortic Valve Regurgitation System beginning in FY 2027. Therefore, cases involving the use of the Trilogy™ Transcatheter Aortic Valve Regurgitation System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code: X2RF3LC (Replacement of aortic valve using zooplastic tissue, with integrated native leaflet clipping locators, percutaneous approach, new technology group 12).

17. ViaOne™ Epicardial Access System

CardioVia Ltd. submitted a FY 2027 application for new technology add-on payments for the ViaOne™ Epicardial Access System (ViaOne™). According to the applicant, ViaOne™ is a sterile, single use device, designed to allow safe pericardial access utilizing a proprietary mechanism of entry into the pericardial sac with a blunt tip and a concealed needle.

In the proposed rule, we provided the following table containing an overview of the new technology add-on payment application for ViaOne™ and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting at *https://mearis.cms.gov/public/publications/ntap/NTP251001MFBVW.*

	Applicant Statements	Preliminary CMS Assessment
Unique ICD-10-PCS Code(s)?	Request submitted.	N/A
Breakthrough Device Requirement	**Breakthrough Device Designation Indication:** The ViaOne device is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate placement of devices into the pericardial space for the diagnosis and treatment of Ventricular Tachycardia. **FDA Indication:** The ViaOne Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach to deliver diagnostic and therapeutic interventions for ventricular tachycardia. Per the applicant, the ViaOne™ device named in the Breakthrough Device designation letter is the same device as the ViaOne™ Epicardial Access System.	FDA indication is appropriate for consideration under the alternative pathway.
Newness Period	510(k) clearance on 3/20/2025. Commercial availability delay expected until 4/27/2026.	See following discussion.
Cost Criterion	4,517 claims mapping to 90 MS-DRGs, with 30.68 percent of claims mapping to MS-DRG 274 (Percutaneous and Other Intracardiac Procedures with MCC). Final inflated average case-weighted standardized charge per case ($303,361) exceeded the average case-weighted threshold amount ($180,573).	Meets cost criterion.
Technology Cost	The total anticipated cost to the hospital for the ViaOne™ Device is $2,000 per patient. It is expected that one device will be utilized per inpatient hospital stay.	Maximum new technology add-on payment: $1,300

Newness Period

In the proposed rule, we stated that after review of the information provided by the applicant, regarding commercial availability, we noted that the applicant stated that the technology would not be available for sale until April 27, 2026. We noted that the applicant stated that the original manufacturing partner permanently ceased operations, requiring the applicant to engage a new qualified manufacturer and conduct full verification and validation testing. We noted that the applicant also stated that delays in completion of the required FDA establishment registration and device listing process, and current aviation and international shipping constraints related to regional security developments are expected to further delay initial U.S. availability. We stated we were interested in confirmation regarding the first date of availability for sale of ViaOne™ on the U.S. market (irrespective of purchase volume or when the first sale occurred).

Comment: In response to CMS's request for additional information regarding the technology's market availability, the applicant submitted a public comment reiterating that its manufacturing partner permanently ceased operations unexpectedly, requiring the applicant to restart the process of identifying and qualifying a new manufacturing partner that met all

FDA requirements. The applicant further reiterated that it experienced substantial delays in aviation and international shipping caused by regional security developments, which significantly delayed product shipment and commercial availability. The applicant stated that these circumstances were outside its control and that the product is expected to be available for purchase in June 2026. The applicant requested that CMS use June 2026 as the beginning of the newness period for the ViaOne™ Epicardial Access System, rather than the initial expected commercial date of April 27, 2026. The applicant stated its recognition that if further delays in market availability were to occur, the newness period would begin no later than September 30, 2026, consistent with CMS's proposed policy to ensure the newness period begins prior to the new technology add-on payment effective date.

Response: We thank the applicant for its comment, including the additional information regarding the commercial availability of ViaOne™. Because the applicant stated that it anticipates first commercial use and launch beginning June 2026, but the exact date has yet to be established at this time, there is not sufficient information to determine a specific newness date based on the documented delay in the technology's availability on the U.S. market. Absent additional information, we therefore consider the newness date for this technology to be March 20, 2025, the date on which the technology received 510(k) clearance. We welcome updates from the applicant once the technology becomes commercially available for future rulemaking.

Cost Criterion

In the proposed rule, we stated we agreed with the applicant that ViaOne™ meets the cost criterion and therefore proposed to approve ViaOne™ for new technology add-on payments for FY 2027, for the FDA-cleared indication covered by the Breakthrough Device designation listed in the table.

Based on preliminary information from the applicant at the time of the proposed rule, we proposed that the maximum new technology add-on payment for a case involving the use of ViaOne™ would be $1,300 for FY 2027 (that is, 65 percent of the average cost of the technology). We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We invited public comments on whether ViaOne™ meets the cost criterion and our proposal to approve new technology add-on payments for the ViaOne™ Epicardial Access System for FY 2027.

Comment: Multiple commenters, including the applicant, expressed support for approval of new technology add-on payments for ViaOne™. The applicant stated ViaOne™ met the new technology add-on payment requirements for Breakthrough-designated devices under the alternative pathway having received Breakthrough Device designation from FDA on August 2, 2022, and FDA market authorization on March 30, 2025, prior to May 1, 2026. The applicant confirmed that the per-patient hospital operating cost of ViaOne™ is $2,000, consistent with the amount provided in its application.

Response: We thank the commenters for their comments. We note that while the applicant stated in its comment that FDA market authorization was received on March 30, 2025, the application for new technology add-on payment and the supporting documentation provided by the applicant indicate an FDA market authorization date of March 20, 2025.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe ViaOne™ meets the cost criterion. The technology received marketing authorization from FDA as a Breakthrough Device on March 20, 2025 for the indication covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for ViaOne™ for FY 2027. We consider the beginning of the newness period to commence on March 20, 2025, the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of ViaOne™ is $2,000. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of ViaOne™ is $1,300 for FY 2027 (that is, 65 percent of the average cost of the technology).

The applicant was granted approval for a unique ICD–10–PCS procedure code for ViaOne™ beginning in FY 2027. Therefore, cases involving the use of ViaOne™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code: XEZD3QC (Pericardial cavity access using blunt-tip concealed needle with mechanical gripping mechanism, percutaneous approach, new technology group 12).

7. Alternative Pathway Repeal for New Technology Add-On Payment and Outpatient Prospective Payment System (OPPS) Device Pass-Through

As discussed previously, in the FY 2020 and FY 2021 IPPS/LTCH PPS final rules (84 FR 42292 through 42297; 85 FR 58737 through 58739), we finalized a policy to establish an alternative inpatient new technology add-on payment pathway for certain transformative new devices and certain antimicrobial products. Under this pathway, FDA-designated Breakthrough Devices and QIDPs, and drugs approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway (sometimes collectively referred to in this section as ''alternative pathway designations'') are considered to be not substantially similar to existing technology for purposes of the new technology add-on payment, and do not need to meet the requirement under § 412.87(b)(1) that the technology represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. We also finalized a policy in the CY 2020 OPPS/ASC final rule to establish an alternative transitional pass-through payment pathway for devices that are part of the FDA's Breakthrough Devices Program and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation (84 FR 61295 through 61296). Under this alternative pathway, FDA-designated Breakthrough Devices are not evaluated for substantial clinical improvement under § 419.66(c)(2) for the purposes of determining device pass-through payment status. We refer readers to the CY 2026 OPPS/ASC final rule (90 FR 53632 through 53636) for additional background on the OPPS Pass-Through Payment for Devices.

In the proposed rule, we noted that the Breakthrough Devices Program is intended to help patients have more timely access to designated medical devices by expediting their development, assessment, and review.[99] The Breakthrough Device designation criteria are defined in section 515B(b) of

[99] Breakthrough Devices Program Guidance for Industry and Food and Drug Administration Staff (September 15, 2023) *https://www.fda.gov/media/162413/download.*

the FD&C Act (21 U.S.C. 360e–3(b)), which provides for a Program for devices that: ''(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and (2)(A) that represent breakthrough technologies; (B) for which no approved or cleared alternatives exist; (C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or (D) the availability of which is in the best interest of patients.'' [100] Per FDA guidance, a sponsor should demonstrate a reasonable expectation that the device could provide for more effective treatment or diagnosis of the disease or condition identified in the proposed indications for use.[101] FDA defines a QIDP as ''an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by—(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or (2) qualifying pathogens listed by the Secretary under'' section 505E(f) of the FD&C Act.[102] FDA believed the LPAD pathway would facilitate development and approval of certain antibacterial and antifungal drugs to treat serious or life-threatening infections in limited populations of patients with unmet needs. FDA may approve an antibacterial or antifungal drug, alone or in combination with one or more other drugs, under the LPAD pathway, if: The drug is intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs; The drug meets the standards for approval under section 505(c) and (d) of the FD&C Act or the standards for licensure under section 351 of the Public Health Service Act; and FDA receives a written request from the sponsor to approve the drug as a LPAD pathway drug.[103]

We noted in the proposed rule that, as discussed in the FY 2020 IPPS/LTCH PPS rulemaking (84 FR 42292 through 42297) and in the CY 2020 OPPS/ASC rulemaking (84 FR 61295 through 61296), we stated that we believed that the benefits of addressing barriers to healthcare innovation and ensuring Medicare beneficiaries have access to critical and life-saving new cures and technologies that improve beneficiary health outcomes supported establishing the alternative pathway for new technology add-on payments and OPPS device pass-through payments. We also stated that we believed it was prudent to gain experience under this new alternative pathway for certain transformative new devices before expanding it to other special designations to allow us to evaluate the benefits of this proposed alternative pathway to facilitate beneficiary access to transformative new medical devices as well as any other considerations that may come to light after application of this new pathway (84 FR 42296).

We further stated that as we have gained experience, we had concerns with the limited evaluation process for alternative pathway applications for new technology add-on and OPPS device pass-through payments, and after further consideration, we believed it would be in the best interest of Medicare patients to refine our approach to ensure that all new technologies approved for new technology add-on payment have demonstrated that the technology is not substantially similar to existing technologies and represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Similarly, we thought it in the best interest of Medicare patients that new technologies approved for OPPS device pass-through payment status have demonstrated a substantial clinical improvement; that is, the devices substantially improved the diagnosis or treatment of an illness or injury or improved the functioning of a malformed body part, compared to the benefits of a device or devices in a previously established category or other available treatment. Therefore, we proposed to repeal the alternative pathway for new technology add-on payment and OPPS device pass-through applications, and require all applicants for new technology add-on payments and OPPS device pass-through payments to demonstrate that they met the same eligibility requirements to receive add-on payments and/or pass-through payments. We stated our belief that this proposed requirement would better align spending and value and ultimately support providers in delivering the best, data-driven care possible. We also stated that by requiring all technologies to demonstrate that they offered a substantial clinical improvement as part of our evaluation process, we would be better able to make evidence-based decisions on which technologies should receive these additional payments. We also stated that holding all applicants to the same standards and requiring all applicants to demonstrate that their technologies meet the same criteria would maintain our focus on new and innovative technologies that improve beneficiary health outcomes while strengthening the evidence base supporting our approval decisions for new technology add-on payment and OPPS device pass-through payment, ensuring value for American taxpayers and Medicare beneficiaries.

Therefore, we proposed that for all applications received for new technology add-on payments for FY 2028 and subsequent fiscal years, including applications for FDA-designated Breakthrough Devices and QIDPs, or drugs approved under FDA's LPAD pathway, we would evaluate whether the technology is new and not substantially similar to an existing technology, and the technology must demonstrate that it meets the requirements under § 412.87(b) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. That is, we proposed that beginning with applications received for new technology add-on payments for FY 2028 and subsequent fiscal years, all applicants would need to meet all three of the criteria as specified at § 412.87(b) and described earlier in this section in order to receive the additional payment: (1) the medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. We stated that technologies that are currently under review for FY 2027 new technology add-on payments under the alternative pathway would remain eligible for consideration for add-on payment under the alternative pathway. Technologies that have previously been approved for add-on payments under

[100] *Ibid.*

[101] *Ibid.*

[102] Qualified Infectious Disease Product Designation Questions and Answers Guidance for Industry (May 2021) *https://www.fda.gov/media/148480/download.*

[103] Limited Population Pathway for Antibacterial and Antifungal Drugs—the LPAD Pathway (Content current as of: 03/24/2025) *https://www.fda.gov/drugs/development-resources/limited-population-pathway-antibacterial-and-antifungal-drugs-lpad-pathway.*

the alternative pathway would remain eligible for add-on payment under the alternative pathway. Consistent with our proposal to remove the alternative pathway for certain antimicrobial products currently at § 412.87(d), we also proposed removal of the conditional approval process for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products that does not receive FDA marketing authorization by July 1 prior to the fiscal year for which the applicant applied for new technology add-on payments, as currently reflected at § 412.87(f)(3). Accordingly, we stated that beginning with the FY 2028 new technology add-on payment applications, in order to be eligible for consideration for the new technology add on payment for the upcoming fiscal year, all applicants would need to receive FDA marketing authorization by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered, as reflected at § 412.87(f)(2).

We proposed to amend § 412.87 to reflect these proposals by revising paragraphs § 412.87(c) and (d) and removing subparagraph 412.87(f)(3). We also proposed related revisions to the title of paragraph (f) and subparagraphs (1) and (2) of paragraph (f) to reflect the proposed policy. We also proposed to make a technical correction to the introductory text at § 412.87(d) to restore language that was previously removed in error, with additional revisions to reflect the proposed repeal. We also proposed to make a technical correction to the introductory text at § 412.88(a)(2)(ii)(A) to reference § 412.88(a)(2)(ii)(C), consistent with our policy as finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69245 through 69252).

Similarly, we proposed that all applications received for OPPS device pass-through payment status on or after October 1, 2026, including all applications received through the remainder of the CY 2028 OPPS application cycle ending on March 1, 2027, and applications received for subsequent calendar years would be required to demonstrate that the technology met the requirements currently reflected at § 419.66(c)(2)(i). We stated that OPPS device pass-through payment applications submitted as of September 30, 2026, for devices that were part of the FDA's Breakthrough Devices Program and received FDA marketing authorization for the indication covered by the Breakthrough Device designation would be evaluated and could be approved under the alternative pathway, provided that all other criteria had been met. Existing device category codes established based on the approval, either preliminary or via a final determination made in an OPPS/ASC final rule, including any device category codes established for approved alternative pathway applications received as of September 30, 2026, would continue to be eligible for device pass-through payment status and would remain in effect for at least 2 years, but no more than 3 years, consistent with § 419.66(g). Previously existing device category codes that were no longer eligible for device pass-through payment status would remain unchanged. We proposed to revise paragraph § 419.66(c)(2)(ii) to reflect the proposed policy, effective October 1, 2026.

We stated that we believed these changes would be the most prudent and transparent method to allow us to improve our focus on facilitating payment for innovative, high-value technologies that improve care for Medicare beneficiaries. As we stated in the September 7, 2001 final rule (66 FR 46913), we believed the special payments for new technology should be limited to those new technologies that have been demonstrated to represent a substantial improvement in caring for Medicare beneficiaries, such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology. We also stated that where such an improvement was not demonstrated, we continued to believe the incentives of the DRG system would provide a useful balance to the introduction of new technologies. As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36672), even if a technology does not receive new technology add-on payments, CMS continues to pay for new technologies through the regular payment mechanism established by the DRG payment methodology. Similarly, as we stated in the CY 2026 OPPS/ASC final rule (90 FR 53635), if a technology does not obtain OPPS device pass-through payment status, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate Ambulatory Payment Classifications (APC) payment. Whether a technology receives new technology add-on payments or OPPS device pass-through payments does not affect coverage of the technology or the ability for Medicare providers to provide such technology to patients where appropriate.

In addition, we stated that we believe holding all applicants to the same standards by requiring all applicants to demonstrate that their technologies meet the same criteria would ensure that all applications undergo the same review process by CMS. For new technology add-on payment, this includes the opportunity to present at the New Technology Town Hall Meeting on the substantial clinical improvement criterion with regard to pending new technology add-on payment applications, and to have applications considered as part of the annual IPPS rulemaking. Furthermore, we noted that because the application and approval timelines for new technology add-on payments are the same for traditional and alternative application pathways, the proposal would not change the time to approval, except for technologies submitted under the alternative pathway for certain antimicrobial products, for which the conditional approval process would no longer be available. Likewise, for OPPS device pass-through, applications are submitted to CMS through the quarterly process, and all applications are subject to notice and comment rulemaking in the next applicable OPPS/ASC annual rulemaking cycle (80 FR 70417 through 70418). We stated that applications, regardless of the pathway under which they apply, that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process may receive pass-through payment status prior to the final determination in the OPPS/ASC final rule. We noted that the proposal would not change the time to approval. Technologies that demonstrate they meet the criteria during the quarterly process may receive pass-through payment status prior to the final determination in the OPPS/ASC final rule. Technologies that demonstrate they meet the criteria during notice and comment rulemaking would receive pass-through payment status via a final determination in the OPPS/ASC final rule.

We stated we would also be interested in information on alternate methods that stakeholders believe would more effectively or efficiently accomplish the goal of aligning payment with value by facilitating payment for innovative, high-value technologies that have demonstrated improved Medicare beneficiary health outcomes, such as alternative strategies for leveraging FDA designations.

We invited public comment on our proposal to require all applicants for new technology add-on payments and OPPS device pass-through payments to demonstrate that they meet the same requirements for eligibility.

We received numerous comments, which we summarize and address in this section.

Comment: Commenters stated their support of CMS's proposal to rescind the alternative pathways and agreed that all technologies seeking additional payment should be required to meet the same statutory and regulatory eligibility criteria. Commenters agreed that this approach would better align spending and value for Medicare and its beneficiaries. A commenter appreciated CMS's clarification that this change will not affect coverage of the technology or the ability for Medicare providers to choose a technology where appropriate. The commenter stated that holding all technologies to comparable evidentiary standards is critical to ensuring consistent and equitable determinations of whether existing diagnosis-related group or ambulatory payment classification rates are inadequate and warrant additional payment. The commenter stated that absent uniform requirements, the alternative pathways risk undermining payment accuracy and creating inequitable incentives across technologies. The commenter also stated that ensuring that all applicants demonstrate comparable clinical benefit and resource impact supports the integrity of both the IPPS and the OPPS.

Another commenter, MedPAC, stated that it recognized the need to maintain financial rewards for innovation while preserving the incentives within the IPPS and OPPS for efficiency. MedPAC stated that including the substantial clinical improvement requirement in the evaluation ensures that additional Medicare payments are used to support Medicare beneficiaries' access to innovations that are demonstrated to improve outcomes compared to the currently available treatment. MedPAC further stated that CMS's proposal is consistent with its comment letter submitted in response to the IPPS proposed rule for FY 2020, in which it indicated its lack of support for the use of the FDA's Breakthrough Device Program for qualification for new technology add-on payment unless the drug or device in question also meets the current substantial clinical improvement criterion—that is, unless there is evidence that the new technology results in improved care for beneficiaries. Specifically, MedPAC pointed to language in its comment letter that stated that it maintained that the Medicare program, not FDA, should adjudicate spending determinations based on the specific needs of the Medicare population.[104] In addition, MedPAC highlighted that, it had also noted that it has long held that Medicare should pay similar rates for similar care, and that to protect the well-being of beneficiaries and ensure good value for the Medicare program and thus the taxpayers, Medicare should not pay more for technologies that have not yet been proven to provide better outcomes for beneficiaries. Therefore, drugs or devices should not qualify for new technology add-on payment if there is no evidence that the drug or device is an improvement relative to existing care.[105] Likewise, MedPAC noted that it did not support CMS's proposal to use the FDA's Breakthrough Device Program for qualification for OPPS device pass-through payment, or FDA's LPAD for qualification for new technology add-on payment, unless the technologies in question also meet the substantial clinical improvement requirement, as MedPAC stated in its comment letters on the CY 2020 OPPS and FY 2021 IPPS proposed rules, respectively.[106] [107] MedPAC further noted that it has also supported a clinical superiority requirement being included in two other contexts, including its June 2021 report to the Congress where MedPAC recommended that the Secretary modify the pass-through drug policy in the OPPS so that it applies only to drugs and biologics that are clinically superior to their packaged analogs and in its comment letters on the CY 2022 and 2025 ESRD proposed rules stating that CMS should use a clinical superiority requirement for transitional drug add-on payment adjustment (TDAPA) and post-TDAPA for end-stage renal disease drugs.[108] [109] [110] Finally, MedPAC further noted that it continued to have general concerns about how Medicare pays for new costly technology, including drugs and biologicals, and had previously commented that the cost criteria used to determine payment for new technology provide an incentive for manufacturers and hospitals to increase their prices and charges.[111]

Another commenter stated that it strongly agreed that the qualifications for new technology add-on payment and OPPS device pass-through payments should be demonstrated, and not assumed, for FDA-designated Breakthrough Devices. The commenter stated that the FDA Breakthrough Device designation does not necessarily ensure that a device is ''not substantially similar to existing technology.'' The commenter stated that while the first three of the four elements of the designation's second criterion are related to the device's novelty, the fourth element is that the device's availability ''is in the best interest of patients,'' and only one of the elements of the second criterion must be met. The commenter asserted that as the designation's first criterion is concerned with the potential for more effective treatment, not necessarily the device's novelty, FDA-designated Breakthrough Device technologies that meet the second criterion based only on its fourth element may not be sufficiently evaluated for similarity to existing alternatives. The commenter also noted that receiving an FDA Breakthrough Device designation and earning authorization from the FDA does not mean that a device demonstrates substantial clinical improvement, as the commenter stated was required for both new technology add-on payment and OPPS pass-through payment. The commenter stated that FDA Breakthrough Device designation is based on ''a reasonable expectation that a device could provide for more effective treatment or diagnosis,'' and FDA market authorization does not require that this expectation is sufficiently substantiated. Instead, the commenter stated that when considering whether to authorize an FDA-designated Breakthrough Device, the FDA ''may accept a greater extent of uncertainty of the benefit-risk profile'' and allow for more flexibility in the design of the study supporting authorization, including the use of surrogate endpoints, shorter duration of follow-up, and increased reliance on postmarket data.[112] The commenter referenced an analysis of the data

[104] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/06212019_medpac_2020_ipps_ltch_comment_v3_sec.pdf.*

[105] Ibid.

[106] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/09132019_opps_asc_2020_medpac_comment_v2_sec.pdf.*

[107] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/07072020_fy2021_ipps_medpac_comment_v2_sec.pdf.*

[108] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/default-document-library/jun21_ch8_medpac_report_to_congress_sec.pdf.*

[109] Ibid.

[110] *https://www.medpac.gov/wp-content/uploads/2022/08/08192022_ESRD_CY2023_MedPAC_COMMENT_SEC.pdf.*

[111] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/06252021_fy_2022_ipps_ltch_medpac_comment_sec.pdf.*

[112] *Breakthrough Devices Program: Guidance for Industry and Food and Drug Administration Staff.* U.S. Food and Drug Administration; 2023. Accessed June 8, 2026. *https://www.fda.gov/media/162413/download.*

supporting FDA-designated Breakthrough Devices, which found that about half of primary effectiveness endpoints were surrogate measures and almost 20 percent were not evaluated with statistical tests.[113] Similarly, the commenter stated that in an examination of the studies supporting FDA-designated Breakthrough Devices approved for OPPS device pass-through payments between 2017 and 2023, less than two-thirds of the studies met any primary effectiveness endpoint and half of the primary effectiveness endpoints were surrogate measures.[114] Furthermore, the commenter asserted the evidence supporting FDA-designated Breakthrough Devices may not be generalizable to Medicare beneficiaries, as this is not required for FDA authorization. As an example, the commenter shared an examination of three cardiovascular FDA-designated Breakthrough Devices, which found that the study participants were younger and more likely to be male than would be expected for a Medicare beneficiary population.[115] The commenter stated that while the repeal of the alternative pathways is an important step, analyses of devices receiving new technology add-on payment and pass-through payments that are not FDA-designated Breakthrough Devices have found that these devices may not be supported by high-quality data and may not have been studied sufficiently in the Medicare population.[116] The commenter suggested that to strengthen the new technology add-on payment and OPPS device pass-through payment, CMS should consider specifying data quality requirements for the demonstration of substantial improvement, such as the use of randomized, controlled trials with blinding, when possible, that evaluate clinical benefit and have participant populations representative of the Medicare beneficiary population.[117]

Another commenter stated that the new technology add-on payment alternative pathway for FDA-designated Breakthrough Devices may result in unintended consequences that misalign Medicare spending with value. The commenter stated that first, as Breakthrough Device designation is often issued before product development and clinical trial protocols are finalized, the alternative pathway may create a disincentive to generate evidence of improved outcomes for Medicare beneficiaries, which could lead to safety concerns, as well as unjustified excess spending. Second, the commenter stated that the alternative pathway may create a disincentive for providers to adopt FDA-designated Breakthrough Devices that receive new technology add-on payment because they have not been evaluated for substantial clinical improvement, as providers may be less willing to adopt costly new FDA-designated Breakthrough Devices without an assurance of substantial clinical improvement relative to existing treatments. The commenter asserted that the substantial clinical improvement criterion is an indicator of the benefit of an FDA-designated Breakthrough Device to the Medicare population and ensures the intended effect of the new technology add-on payment program by promoting uptake of novel products that can ensure better alignment between Medicare spending and value.

The commenter also stated its belief that new technology add-on payment is critical to promote uptake and evidence generation that supports other determinants of patient access like Medicare coverage. This commenter stated that this was particularly relevant for FDA-designated Breakthrough Devices that may not have sufficient evidence to meet the ''reasonable and necessary'' threshold for Medicare coverage but do have evidence to demonstrate substantial clinical improvement. For example, the commenter stated that of the 13 eligible devices with active Coverage with Evidence Development (CED) policies, six have received new technology add-on payment. The commenter asserted that new technology add-on payment thus supports evidence generation for ''reasonable and necessary'' Medicare coverage. The commenter also stated that there was an opportunity to consider how the new technology add-on payment supports efforts to streamline Medicare coverage for FDA-designated Breakthrough Devices. The commenter stated that premarket evidence generation under the Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway would inform both FDA authorization and CMS coverage assessments. The commenter believed that although this premarket evidence generation may not always meet the ''reasonable and necessary''' standard for Medicare coverage, meeting the new technology add-on payment criteria, particularly the substantial clinical improvement criterion, would be a very effective indicator of not just the potential value of the product, but the effectiveness of the RAPID coverage pathway in evidence generation relevant to Medicare beneficiaries. The commenter stated that when critical postmarket evidence gaps remain, CMS could consider employing key elements of the Transitional Coverage of Emerging Technologies (TCET) pathway such as the Evidence Development Plan (EDP), and CED policy to ensure predictable and robust evidence generation. The commenter also recommended that CMS preserve the technology add-on payment alternative pathway for antimicrobials as the commenter believed that greater use of these products could drastically reduce Medicare costs, thereby aligning spending with value.

Response: We appreciate the commenters' feedback and their support of the proposal. We agree with the commenters that requiring all technologies seeking additional payment under IPPS or OPPS meet the same statutory and regulatory eligibility criteria for each pathway would better align spending and value for Medicare and its beneficiaries and would ensure consistent and equitable determinations while maintaining the integrity of both the IPPS and the OPPS. Further, we agree with the commenter that the qualifications for new technology add-on payment and OPPS device pass-through payments should be demonstrated, and not assumed, for FDA-designated technologies seeking add-on payments. With respect to comments on the RAPID coverage pathway, we refer commenters to the CMS press release which notes that a proposed procedural notice regarding the RAPID coverage pathway is expected to be issued for additional information.[118]

[113] Kadakia KT, Dhruva SS, Ross JS, et al. FDA Authorization of Therapeutic Devices Under the Breakthrough Devices Program. *JAMA Intern Med.* 2025;185(8):996. doi:10.1001/jamainternmed.2025.2235.

[114] Moneer O, Johnston JL, Rathi VK, Ross JS, Dhruva SS. Medical Devices Applying for Outpatient Medicare Supplemental Payments. *JAMA Health Forum.* 2024;5(11):e244016. doi:10.1001/jamahealthforum.2024.4016.

[115] Moneer O, Rathi VK, Johnston JL, Ross JS, Dhruva SS. Aligning US Agency Policies for Cardiovascular Devices Through the Breakthrough Devices Program. *JAMA Cardiol.* 2023;8(12):1174. doi:10.1001/jamacardio.2023.3819.

[116] Moneer O, Johnston JL, Rathi VK, Ross JS, Dhruva SS. Medical Devices Applying for Outpatient Medicare Supplemental Payments. *JAMA Health Forum.* 2024;5(11):e244016. doi:10.1001/jamahealthforum.2024.4016.

[117] Judson TJ, Dhruva SS, Redberg RF. Evaluation of technologies approved for supplemental payments in the United States. *BMJ.* Published online June 17, 2019:l2190. doi:10.1136/bmj.l2190.

[118] CMS and FDA Announce RAPID Coverage Pathway to Accelerate Patient Access to Life-Changing Medical Devices *https://www.cms.gov/newsroom/press-releases/cms-fda-announce-rapid-coverage-pathway-accelerate-patient-access-life-changing-medical-devices.*

We agree that absent uniform requirements, continuing the alternative pathways may create challenges for payment accuracy or inequitable incentives across technologies. We agree with MedPAC that including the substantial clinical improvement requirement in the evaluation ensures that additional Medicare payments are used to support Medicare beneficiaries' access to innovations that are demonstrated to improve outcomes compared to the currently available treatment. Further, we agree with the commenter that receiving an FDA designation and earning FDA market authorization does not mean that a device demonstrates substantial clinical improvement, as required under the traditional pathway for both new technology add-on payment and OPPS pass-through payment. As we noted in the proposed rule, FDA Breakthrough Device designation is based on ''a reasonable expectation that the device could provide for more effective treatment or diagnosis of the disease or condition identified in the proposed indications for use,'' and FDA market authorization does not evaluate whether this expectation is substantiated. Moreover, FDA guidance [119] provides that a complete set of clinical data is not required for Breakthrough Device designation, and mechanisms for demonstrating a reasonable expectation of technical and clinical success could include literature or preliminary data (bench, animal, or clinical). The guidance provides examples, where a sponsor might provide preliminary bench data to support the potential for technical success and literature to support that a given principle of operation could more effectively treat or diagnose the identified disease or condition. We believe that the FDA Breakthrough Device and QIDP designation criteria are distinct from the CMS new technology add-on payment and OPPS device pass-through payment status program requirements. New technology add-on payment and OPPS device pass-through payment status criteria require that the technology demonstrate a substantial clinical improvement for Medicare beneficiaries, which is not a requirement for the FDA designations. As approvals under the alternative pathway do not require the assessment of available data or comparison to other technologies used by Medicare patients, CMS would not be able to ensure that technologies receiving add-on payments under this pathway truly add value. CMS has continuously stated that FDA and CMS act under different statutes that have different standards, and has noted in recent years that FDA marketing authorization alone is often insufficient to support Medicare decision making.[120] [121] We also believe it may be relevant to consider whether, as stated by another commenter, that as Breakthrough Device designation is often issued before product development and clinical trial protocols are finalized, the alternative pathway may reduce incentives to generate evidence of improved outcomes for Medicare beneficiaries.

Our concerns are exacerbated by the timing gap between FDA Breakthrough Device and QIDP designation and marketing authorization, or when technologies begin to be eligible to apply for add-on payments. As mentioned by a commenter, these FDA designations are early designations that generally occur years before the manufacturer applies for marketing authorization. Therefore, even the expectation of benefit under these designations is generally assessed years before CMS would evaluate technologies for the purposes of new technology add-on payment and OPPS device pass-through payment status, in many cases more than four years prior. During the time between when a technology receives FDA Breakthrough Device or QIDP designation and when the technology may apply for new technology add-on payment and OPPS device pass-through payment status, other meaningful comparator technologies may receive FDA market authorization such that a technology with a FDA designation that may have had the potential to demonstrate substantial clinical improvement over technologies existing at the time of FDA designation may no longer offer substantial clinical improvements over the currently available treatments. New developments in the treatment landscape in the years following the FDA designations remain an important consideration for CMS under our statute and regulations.

We also agree with the commenter that FDA designation does not necessarily ensure that a device is not substantially similar to existing technology. For a Breakthrough Device designation, FDA does not necessarily have to consider whether the device represents a novel technology. We also note that before issuing a marketing authorization, FDA generally cannot publicly disclose whether FDA has granted a Breakthrough Device designation request, unless the sponsor decides to make that information available to the public, and that while FDA's website includes a list of Breakthrough Devices that have obtained marketing authorization for an indication consistent with its Breakthrough Designation, FDA does not identify there the particular criteria under which the Breakthrough Device designation was granted. We further note that even when the device represents a novel technology, as previously stated, FDA considers whether there is a reasonable expectation that a device could provide for more effective treatment or diagnosis, but FDA market authorization does not provide a determination that this expectation was substantiated, and with a time lag between this assessment and eligibility for add-on payment, the treatment landscape may have changed. Finally, FDA may grant Breakthrough Device designation to multiple devices with the same intended use, and a Breakthrough Device designation will not be revoked solely on the basis of another FDA-designated Breakthrough device obtaining marketing authorization.[122] Similarly, FDA may grant QIDP designation to multiple products with the same active ingredient with the same use, because the designation applies to a specific drug product from a specific sponsor for a specific use for which it is being studied.[123] As such, we do not believe that FDA Breakthrough Device or QIDP designations ensure that a technology is not substantially similar nor a substantial clinical improvement relative to existing technology, especially when the time lag is considered. Accordingly, we do not believe a technology should be considered to have demonstrated that it is not substantially similar to existing technology or to have met the substantial clinical improvement criterion strictly on the basis of having FDA Breakthrough Device or QIDP designation.

[119] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program.*

[120] Final rule to repeal the ''Medicare Coverage of Innovative Technology (MCIT) and Definition of ''Reasonable and Necessary'' final rule (86 FR 62945–62946).

[121] Transitional Coverage for Emerging Technologies (TCET) pathway final notice (89 FR 65725, 65727).

[122] Breakthrough Devices Program—Guidance for Industry and Food and Drug Administration Staff—Document issued on September 15, 2023. *https://www.fda.gov/files/guidance%20documents/published/Breakthrough-Devices-Program.pdf.*

[123] Qualified Infectious Disease Product Designation—Questions and Answers Guidance for Industry—May 2021 *https://www.fda.gov/media/148480/download.*

Regarding the commenter's concern that the alternative pathway may create a disincentive for providers to adopt FDA-designated Breakthrough Devices that receive new technology add-on payment because they have not been evaluated for substantial clinical improvement, we agree that CMS's determination that a technology demonstrates substantial clinical improvement may be a factor for providers when they are faced with the decision to adopt a new technology. In addition, we are concerned that providers may assume that CMS's approval of a technology indicates that the technology has demonstrated that it offers a substantial clinical improvement over other products or treatments on the market, when in fact, no such demonstration has been made. In fact, we are aware of instances where manufacturers suggest that technologies approved for the alternative pathway can be said to have met the substantial clinical improvement criterion by virtue of being approved for add-on payments through the alternative pathways. We believe it would be beneficial to providers to require that all technologies that receive add-on payments have demonstrated that they have met all of the CMS criteria, as this may further support providers in making informed decisions regarding the technologies available to them and their beneficiaries. We concur with MedPAC's statement that Medicare should not pay more for these technologies when they have not yet been proven to provide better outcomes for beneficiaries. As such, we continue to believe it is in the best interest of Medicare patients to refine our approach to ensure that all applicants for new technology add-on payment or OPPS device pass-through payment status have demonstrated that they meet the same eligibility requirements, including that they improve the diagnosis or treatment of Medicare beneficiaries. We further agree that CMS, not FDA, should adjudicate spending determinations based on the specific needs of the Medicare population, as these add-on payments are governed by CMS's statutory and regulatory authority.

For these reasons, we continue to believe that ensuring that all applicants for new technology add-on payment or OPPS device pass-through payment status have demonstrated that they meet the same eligibility requirements is the better policy.

With respect to a commenter's belief that new technology add-on payment supports other determinants of patient access like Medicare coverage, as discussed further in this section, and as stated in the September 7, 2001 final rule and CY 2003 OPPS final rule (66 FR 46914, 67 FR 66783), the criteria for determining whether a technology is eligible for new technology add-on payment and OPPS device pass-through payments are not intended for use in making coverage decisions under section 1862(a)(1)(A) of the Act.

Regarding the commenter who described concerns that even devices applying under the traditional pathway and which have been determined to have met the substantial clinical improvement criterion may not be supported by the highest-quality data, and they may not necessarily have been studied in the Medicare population, we agree that higher quality data with generalizability to Medicare beneficiaries is ideal. However, the regulations at § 412.87 are intentionally broad in order to provide flexibility for applicants in what they can provide to demonstrate substantial clinical improvement, and we have aimed to strike a balance in accepting a broad range of available evidence for consideration. In addition, we do not agree that CMS should preserve the alternative pathway for antimicrobials, which we discuss in greater detail later in this section.

Comment: Many commenters stated they shared CMS's commitment to ensuring that Medicare beneficiaries receive the best, evidence-based care; however, they opposed the proposal to repeal the alternative pathways for new technology add-on payment and OPPS device pass-through. Commenters who were non-supportive of the proposal stated that the alternative pathways facilitate the early adoption of promising technologies while additional evidence is developed, and that removing the alternative pathways may limit the generation of clinically meaningful data and real-world evidence to inform future coverage and payment policy. Commenters believed that the alternative pathways have played a critical role in supporting early adoption of breakthrough technologies in both the inpatient and outpatient setting by mitigating the payment lag that often follows FDA market authorization, improving the timeliness of Medicare beneficiary access to FDA-designated Breakthrough Devices, and easing the burden on innovators to meet the Agency's evidentiary requirements. Some of the commenters stated their belief that devices that have received FDA Breakthrough Device designation have cleared a meaningful, evidence-based, and rigorous threshold, as FDA has determined the technologies address an unmet need and warrant expedited development and review. A commenter stated that by aligning new technology add-on payment and OPPS device pass-through eligibility with FDA's Breakthrough Device designation, CMS had created a more predictable and efficient route for technologies that meet a high evidentiary bar. Some commenters stated that in CMS's rationale from prior rulemaking to establish the alternative pathways, CMS had recognized that FDA provides marketing authorization under the FDA Breakthrough Devices Program to technologies that are still developing their evidence base and had concluded that FDA's assessment could serve as a reasonable proxy for the substantial clinical improvement criterion, which reduced duplicative evidentiary burdens. A commenter stated that CMS and stakeholders had accumulated meaningful experience with FDA Breakthrough Device-related OPPS device pass-through payments and that the alternative pathway had functioned as intended. The commenter provided a cross-sectional analysis of 43 OPPS device pass-through applications (2017–2023) and found that CMS approved 17 (40 percent) overall, including all 8 (100 percent) applications submitted under the alternative pathway for FDA-designated Breakthrough Devices, with most denials due to failure to demonstrate substantial clinical improvement, highlighting that this was the principal access barrier. The commenter further stated that CMS had also increased transparency by publicly posting OPPS device pass-through public application summaries, illustrating continued reliance on the OPPS device pass-through framework by innovators. Commenters provided examples from prior rulemaking, including applications for FY 2027, stating that 32 of 47 (68 percent) new technology add-on payment applicants utilized the alternative pathway, reflecting that the pathway is a central mechanism by which genuinely novel, high-need technologies access the add-on payment, and that overall, total new technology add-on payment applications have increased 161 percent from FY 2020 to FY 2027, reflecting the pathway working as intended.

Commenters stated their belief that requiring proof of substantial clinical improvement at the time of new technology add-on payment application imposes a standard that does not fully account for the different FDA and CMS evidence timelines. Commenters further stated that demonstration of substantial clinical improvement at the time of new

technology add-on payment application may be difficult for many technologies to meet or may be constrained by ethical, methodological, or practical considerations. A commenter explained that when a device treats a population for whom no comparable standard of care exists, or for whom the counterfactual is high-risk surgery or no treatment at all, randomized comparative trials are frequently ethically and practically impossible within the new technology add-on payment timeframe. Another commenter asserted that for patients without a single, defined comparable therapy against which improvement can be measured, such as patients with drug-resistant epilepsy that have failed multiple antiseizure medications and have varying comorbidities and prior treatment history, technologies may offer profound clinical value that is not captured by the framework that CMS has historically applied in the substantial clinical improvement criterion evaluation process. Some commenters asserted that the traditional pathway is not available to pre-commercial FDA-designated Breakthrough Devices by nature of the designation, not by choice or for lack of clinical merit, and that the alternative pathway fills a genuine structural gap in the new technology add-on payment evaluation. Other commenters noted that devices cleared through the FDA 510(k) clearance pathway, such as those used in spine surgery, do not require pre-market clinical trial data as they are only required to be substantially equivalent to a predicate device. A commenter stated that for technologies cleared through the 510(k) pathway, the window available to accumulate the peer-reviewed, comparative outcome literature CMS expects under the substantial clinical improvement criterion often overlaps the technology's same three-year new technology add-on payment eligibility window, and usually cannot be satisfied simultaneously. Another commenter stated that evidence of substantial clinical improvement is not typically available during the initial period of commercialization of a novel technology because the evidence is beyond the scope of FDA's determination of safety and effectiveness, which would disproportionately affect FDA 510(k) cleared devices that require limited or no clinical evidence for marketing authorization, but would also impact devices reviewed through the Premarket Approval (PMA) process. Other commenters stated that for FDA PMA products in particular, the FDA Breakthrough Device designation reflects technologies that address serious or life-threatening conditions and meet rigorous FDA criteria. A commenter stated its agreement that Breakthrough Device designation alone is not a sufficient proxy for robust clinical evidence demonstrating safety, effectiveness, and meaningful clinical benefit because the designation is granted early in development, typically before such evidence has been fully generated. The commenter cited a recent peer-reviewed analysis [124] that examined the 26 FDA-designated Breakthrough Devices cleared through the 510(k) pathway as of July 2023 and found that, among the 16 therapeutic devices, 6 (37.5 percent) had no clinical studies referenced in their FDA decision letters. However, the commenter believed that the appropriate response was targeted reform, as it stated that technologies FDA market authorized through FDA De Novo and PMA pathways based on completed IDE studies are already required to have the clinical evidence sought by CMS.

Commenters also shared their concerns that CMS was increasingly holding applicants to excessively stringent standards, particularly with respect to the substantial clinical improvement criterion. A few commenters further believed this stringency disproportionately impacted certain classes of technologies, including cell and gene therapies, particularly those that treat rare or ultra-rare conditions. The commenter stated that these therapies often serve very small patient populations, making traditional clinical trial designs and data accumulation challenging, despite profound clinical benefit, and that without new technology add-on payment, hospitals may delay or altogether forgo adopting technologies that could improve outcomes for patients with limited or no existing treatment options. Another commenter stated its concerns about CMS inappropriately considering newer generation CAR T-cell therapies as ''substantially similar'' to first generation therapies despite differences in their methods of action. The commenter urged CMS to recognize innovations in the newer generation of CAR T-cell therapies and how they differentiate these from previous generations, including recognizing when the CAR construct of a CAR T-cell therapy is differentiated in a manner that leads to improvements in treatment that are supported by clinical evidence. Other commenters also asserted that the evidentiary standard CMS applies to substantial clinical improvement for medical devices raises concerns about alignment with the Agency's position that new technology add-on payment and OPPS device pass-through determinations are payment decisions, not coverage determinations. Commenters stated that in practice, the substantial clinical improvement threshold increasingly requires comparative, peer-reviewed evidence demonstrating improved outcomes in the Medicare population, a level of rigor similar to, or exceeding, that typically used for Medicare coverage under the ''reasonable and necessary'' standard. Commenters stated that once CMS determines a technology meets this threshold, it becomes difficult to reconcile how coverage could subsequently be denied for clinically appropriate patients. A commenter further stated that such an illogical result demonstrates the unreasonably high burden of the evidentiary showing required to demonstrate substantial clinical improvement. The commenter stated that CMS's escalating substantial clinical improvement evidence demands have, in practice, converted what the Agency characterizes as a circumscribed payment inquiry into a de facto coverage adjudication. The commenter stated that the substantial clinical improvement standard was never intended for this purpose, but current evidence requirements created what it described as a clear contradiction—either (i) new technology add-on payment and OPPS device pass-through determinations are genuinely ''only payment decisions,'' with evidentiary standards that reflect that limited scope, or (ii) CMS should recognize that the substantial clinical improvement criterion as applied is expansive such that it encompasses and exceeds the bar for a ''reasonable and necessary'' coverage determination and treat it as such. A commenter stated that the statutory text reflects that Congress intended new technology add-on payment to be available for innovative new technologies with costs not yet reflected in applicable MS–DRG rates, not that Congress intended technology add-on payment to have such strict evidentiary requirements that it would be only very rarely available.

Response: We appreciate commenters' feedback on our proposal to require all applicants for new technology add-on payments and OPPS device pass-

[124] FDA Breakthrough Device Designation: Clinical Evidence And Medicare Payment Policies *https://www.healthaffairs.org/content/forefront/fda-breakthrough-device-designation-clinical-evidence-and-medicare-payment-policies.*

through payments to meet the same eligibility criteria. We recognize the role of the alternative pathways in supporting early adoption of technologies in both the inpatient and outpatient setting by mitigating the payment lag that often follows FDA market authorization. However, both new technology add-on payment and OPPS device pass-through payment are intended to collect cost data for the purposes of payment, not to facilitate the collection of clinical data. For new technology add-on payment, this is reflected in the general provisions at § 412.87(a). OPPS device pass-through payment, as implemented at § 419.66, is intended to facilitate access for beneficiaries to the advantages of new, innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861).

With respect to comments arguing that devices that have received FDA Breakthrough Device designation have cleared a rigorous, evidence-based threshold, we note, as we have before, that FDA Breakthrough Device designation is based on, among other things, a reasonable expectation that a device could provide for more effective treatment or diagnosis.[125] FDA market authorization does not provide a determination that this expectation was substantiated, and mechanisms for demonstrating a reasonable expectation of technical and clinical success could include literature or preliminary data (bench, animal, or clinical). We further note that FDA-designated Breakthrough Devices that have obtained premarket authorization through the 510(k) pathway are sometimes cleared without evaluation of clinical safety or effectiveness data and instead are authorized on the basis of substantial equivalence to a legally marketed predicate device. Accordingly, we do not believe a device should be considered to have met CMS's substantial clinical improvement criterion strictly on the basis of having FDA Breakthrough Device designation. We further note with respect to the comments regarding therapies that serve small patient populations and provide profound clinical benefit, or improve outcomes for patients without existing treatment options, if they in fact do have evidence to support improved outcomes, we do not believe these therapies would be negatively impacted as the regulations describing requirements for substantial clinical improvement specifically describe these scenarios as potentially representative of substantial clinical improvement. In fact, many of these types of technologies have been approved for new technology add-on payments after providing evidence that meets the requirements for approval.

Regarding the commenters who stated that we had previously believed, at the time of implementation of the alternative pathway, that it was appropriate to facilitate beneficiary access to transformative new medical devices without requiring substantial clinical improvement, we note that we have continued to accumulate experience with this pathway and worked collaboratively with the FDA and FDA's expedited programs, including the Breakthrough Devices Program, over the past years. We believe it may be relevant to consider whether the pathways may unintentionally reduce incentives to generate evidence of improved outcomes for Medicare beneficiaries because evidence submission became unnecessary to receive these additional payments under the alternative pathway, as suggested by a commenter. Furthermore, we disagree that requiring a demonstration of substantial clinical improvement for new technology add-on payment and OPPS device pass-through payment would systematically disadvantage novel and innovative technologies. Rather, these technologies would instead be subject to the same criteria as all other novel and innovative technologies that apply under the traditional pathways. We believe CMS should incentivize the use of technologies that have demonstrated evidence of substantial clinical improvement. As we stated in the September 7, 2001 final rule (66 FR 46913), we believed the special payments for new technology should be limited to those new technologies that have been demonstrated to represent a substantial improvement in caring for Medicare beneficiaries, such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology. Following our continued experience with the alternative pathway and for the reasons discussed in this final rule, we believe it is most appropriate for CMS to return to providing additional payment and facilitating beneficiary access under these special payment programs for those technologies that have demonstrated a substantial improvement for Medicare beneficiaries.

We disagree that our evaluations of substantial similarity and substantial clinical improvement have gotten increasingly stringent. We note, as previously summarized, that other commenters have suggested that we are not stringent enough, as they asserted recent approvals for new technology add-on payments and OPPS device pass-through payment are not based on high-quality data. We believe that commenters who assert our evaluations have become increasingly stringent may instead be seeing a positive reflection of the improvement in treatment landscapes for a diversity of patient populations and diseases since the inception of new technology add-on payment and OPPS device pass-through payment, which has increased the standard-of-care options available to patients. Because our evaluations for the additional payments compare against existing technologies used for Medicare beneficiaries, an increase in relevant comparator technologies may have the appearance of stricter standards because more information may be necessary to demonstrate that a technology meets our criteria. We believe that this inherent scaling relative to the availability of treatment options in a particular clinical area also appropriately supports innovation in areas with true unmet needs where there are little to no meaningful standard-of-care options. We also believe there is a misunderstanding of what CMS requires to establish substantial clinical improvement. In fact, we discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292) how we may evaluate substantial clinical improvement for purposes of new technology add-on payments and OPPS device pass-through payments to allow for greater clarity and predictability. The regulations under § 412.87(b)(1)(iii), as codified in the FY 2020 IPPS/LTCH PPS final rule, provide a non-exhaustive list of published or unpublished information sources from within the United States or elsewhere that may be sufficient to establish substantial clinical improvement. Direct comparative, peer-reviewed evidence is not a requirement under the regulations. As previously stated, the regulations are intentionally broad to provide flexibility for applicants in the evidence required to demonstrate substantial clinical improvement.

We also disagree with commenters asserting that the evidentiary standard CMS applies to substantial clinical improvement raises concerns about alignment with the Agency's position that new technology add-on payment and OPPS device pass-through payment determinations are payment decisions, not coverage determinations. As stated

[125] *https://www.fda.gov/media/162413/download.*

in the September 7, 2001 final rule (66 FR 46914) and the CY 2003 OPPS final rule (67 FR 66783), the criteria for determining whether a technology is eligible for new technology add-on payment and OPPS device pass-through payments are not intended for use in making coverage decisions under section 1862(a)(1)(A) of the Act. While a technology can be covered under Medicare and not receive new technology add-on payment or OPPS device pass-through payment, the reverse is generally not true. When a new technology add-on or pass-through payment is established for a technology, it would not be covered and no payment would be made if it is furnished to a patient for which it is not reasonable and necessary. Moreover, we note that the substantial clinical improvement criterion requires that new technologies demonstrate that the technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Section 1862(a)(1)(A) of the Act, the standard for Medicare coverage, requires (absent a specific statutory exception) a determination that items and services are ''reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.'' This does not establish that to be reasonable and necessary that an item or service offer substantial clinical improvement over other appropriate options. These two determinations serve different purposes, as one allows for payment under Medicare, while the other provides extra payment for specific technologies that meet additional criteria. Setting a standard for substantial clinical improvement for additional payments exceeds what is required for Medicare coverage and standardized payment; therefore, there is no misalignment.

We also disagree that our evaluation of substantial clinical improvement conflicts with statutory text. Sections 1886(d)(5)(K)(vi) and Section 1833(t)(6) of the Act specify that a medical service or technology will be considered ''new'' if it meets criteria established by the Secretary (after notice and opportunity for public comment). When we subsequently established the substantial clinical improvement criterion in the September 7, 2001 final rule (66 FR 46913), we explained that we had proposed the ''substantial improvement'' criterion to limit these special payments for those technologies that afford clear improvements over the use of previously available technologies. Similarly, when we finalized the substantial clinical improvement criterion in the November 2, 2001, OPPS interim final rule with comment period (66 FR 55852 to 55853), we explained that we believed it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, the need for additional payments for devices that offer little or no clinical improvement over a previously existing device is less apparent.

Comment: Commenters expressed concern that this proposal may limit hospital willingness to adopt newer technologies and slow the availability of innovative technologies, including those intended to address serious or life-threatening conditions for Medicare beneficiaries, which would particularly affect underserved patient populations or those with unmet needs. A commenter stated that CMS has historically played an important role in supporting responsible adoption of breakthrough technologies that improve patient outcomes. Commenters stated that the alternative pathways have allowed providers to gain earlier access to innovative therapies during the period before payment systems fully reflect the costs associated with new technologies. Commenters provided examples of technologies that they each believed would not have been offered or will not be available to Medicare beneficiaries in the absence of the alternative pathways. Commenters spoke to their experiences with hospital decisions to adopt new technologies while facing thin to nonexistent hospital margins. The commenters stated that financial considerations were a prerequisite to bringing a new device into the formulary, and a technology that was not adequately reimbursed would be a financial liability and would not be adopted by the hospital. Commenters believed that this would have a significant impact on patients, listing different groups such as those treated by safety-net institutions, community hospitals, health systems serving rural and underserved populations, or academic medical centers. Commenters asserted that rather than creating better stewardship of CMS/Medicare dollars, this would instead exacerbate disparities between the care available in well-resourced settings and the care available elsewhere. Commenters also shared examples of patients they each believed would be particularly affected by the proposal, such as those requiring dialysis access, with drug-resistant epilepsy, or with severe therapy-refractory diabetic foot ulcers. Commenters stated that predictability matters as much as the payment itself, and that what they described as the abrupt proposal would make responsible institutions more hesitant to invest in the next generation of tools. A commenter also stated from the provider's perspective, an add-on payment never dictates care, and that whether a given technology is used for a given patient remains a clinical judgment made by physicians and care teams at the point of care, and that they took seriously their dual responsibility for both patient care and the prudent use of resources. Commenters stated that as new technology add-on payment eligibility is determined post-claim, it is unknown at the point of patient admission whether the case will ultimately receive an add-on payment. Commenters noted that although CMS stated technologies may still be paid through the regular MS–DRG or APC payment mechanisms, the current MS–DRG or APC payment rates would not yet account for the costs of the new technologies. Another commenter stated that many FDA-designated Breakthrough Devices are adjunctive technologies used within existing inpatient procedures already reimbursed under existing coding and payment frameworks, and do not seek a separate inpatient procedure payment.

Commenters emphasized the uncertainty for device manufacturers if the pathway is repealed because investment, clinical, and commercialization decisions for devices currently in development typically span 5 to 7 years or longer, with antimicrobial resistance product development spanning 10 to 15 years, and which they stated were made based on the existing alternative pathways. Another commenter stated that the new technology add-on payment alternative pathway was specifically designed to address the period between FDA approval and sustainable reimbursement. Commenters stated their belief that the proposed, abrupt changes to the requirements could disrupt development and reimbursement planning, ultimately limiting Medicare beneficiary access to promising, innovative technologies. Commenters stated that the inadequate transition time would be particularly damaging for startups, small, emerging, or mid-size manufacturers across the country, who lacked the resources to absorb a sudden shift in the

reimbursement landscape. Some commenters shared the negative impacts that the proposed repeal would have on their technologies in development, and explained the difficulties they would face pivoting to or starting over clinical trials to potentially meet the substantial clinical improvement criterion. Another commenter stated that the repeal would disproportionately disadvantage novel technologies that, for example, address rare diseases or small patient populations or rely on non-traditional or adaptive evidence generation approaches, as well as undermining FDA programs expressly designed to accelerate patient access to novel therapies. A commenter further stated that it would be fundamentally unfair, and contrary to the settled expectations CMS created, to foreclose technologies already in the commercialization pipeline because of a change in program timing that manufacturers could not have anticipated or controlled. In addition, commenters stated that the proposal introduced regulatory unpredictability that risks deterring future investment in these technologies. A commenter noted that over time, this could shift investment away from complex inpatient technologies and toward areas with more predictable reimbursement, impacting Medicare beneficiaries that require the most complex care. Commenters stated that the early-market uncertainty would be particularly acute for technologies that depend on newly established CPT codes or ICD–10–PCS procedure codes and lack viable legacy coding alternatives to achieve meaningful hospital adoption. A commenter further asserted that in such cases, absence of timely OPPS device pass-through payment would not merely slow adoption, it could effectively prevent hospitals from offering the technology at launch, irrespective of clinical need. Another commenter asserted that without a strong national payment anchor, Medicare Administrative Contractor-level coverage variability will create inequitable access for Medicare beneficiaries whose hospitals fall into lower-reimbursement jurisdictions, effectively stratifying access to a technology designed to benefit a broader Medicare population.

Commenters also described the impact the proposed repeal would have on technologies under specific FDA marketing authorization pathways. A commenter provided its analysis on the FY 2026 new technology add-on payment applications, stating that CMS received more than twice as many applications through the alternative pathway for devices as through the traditional pathway (34, compared to 13), at least 10 of which were based on FDA 510(k)-cleared technologies, suggesting that the alternative pathway has become the primary route through which innovative technologies, including those following a FDA 510(k) pathway, access new technology add-on payment since its inception. Another commenter asserted that the unstated implication of the proposal is that, if finalized, no FDA-designated Breakthrough Device would qualify for new technology add-on payment or OPPS device pass-through ever again, and as a result, developers may choose not to develop these devices at all. A commenter further asserted that repealing the pathway would not reduce the pipeline of innovative technologies seeking Medicare payment recognition; it simply would foreclose the pathway best suited to evaluate them, returning the burden of demonstrating substantial clinical improvement to technologies cleared via the 510(k) FDA regulatory pathway, for which it asserted that standard was previously structurally inaccessible. Commenters stated that the practical consequences for Medicare beneficiaries are predictable as manufacturers of 510(k)-cleared FDA-designated Breakthrough Devices may deliberately slow their path to market to preserve newness eligibility under the traditional pathway once sufficient post-market clinical data can be assembled; or hospitals may be unable to support the premium price of these new technologies introduced without add-on payment support.

Other commenters expressed their concerns about the impact of the proposed repeal of the alternative pathway specifically on QIDPs and LPAD products, due to the impact of antimicrobial resistance on Medicare beneficiaries along with the challenges presented by the current antibiotic development landscape. Commenters stated the proposed repeal was inconsistent with the Administration's stated commitments on antimicrobial resistance. Commenters also asserted that the proposal contradicted CMS's rationale from FY 2020 IPPS rulemaking, where CMS stated its belief that Medicare beneficiaries may be disproportionately impacted by antimicrobial resistance and that the alternative pathway for QIDPs would be a means of addressing some of the regulatory barriers and disincentives for manufacturers to invest in innovation. The commenter noted that stewardship programs appropriately encourage the restricted use of novel antibiotics to preserve their effectiveness and slow the emergence of resistance, but that this necessary public health practice simultaneously limits commercial utilization and undermines the economic viability of antibiotic innovation. However, commenters stated that antibiotic registration programs are typically conducted using non-inferiority trial designs, which are considered the ethical and regulatory standard for serious bacterial infections where placebo-controlled studies are not feasible, and requiring demonstration of significant clinical improvement creates a substantial disconnect between the realities of antimicrobial development under established FDA regulatory pathways and CMS reimbursement policy. Commenters stated that these trial designs cannot generate the head-to-head superiority data required for a substantial clinical improvement criterion determination under the new technology add-on payment. A commenter further stated that the new technology add-on payment substantial similarity criterion may also not adequately capture the nature of antimicrobial innovation, where products may share similar classes or mechanisms of action but still provide clinically meaningful benefits through improved activity against resistant pathogens. Therefore, commenters asserted that antimicrobial drugs are uniquely disadvantaged from qualifying for new technology add-on payment in the absence of the alternative pathway. Another commenter asserted that CMS failed to confront the fact that these technologies have already essentially proven that they represent a substantial clinical improvement and are not ''substantially similar'' to existing products, and cited § 506(h)(1) of the FD&C Act, stating that specifically, to be approved under the LPAD, a drug must be intended for use by patients with unmet needs. The commenter, citing FDA guidance issued in 2014, stated that an unmet need means ''a condition whose treatment or diagnosis is not addressed adequately by available therapy,'' including ''an immediate need for a defined population . . . or a longer-term need for society (*e.g.,* to address the development of resistance to antibacterial drugs).'' [126] Commenters believed that the proposed policy change would further weaken incentives for antibiotic research and development at a time when antimicrobial resistance

[126] FDA. (May 2014). Guidance for Industry Expedited Programs for Serious Conditions—Drugs and Biologics, at 4. Available at: *https://www.fda.gov/media/86377/download.*

remains a national security and growing global threat and the antibiotic pipeline is already fragile, which would negatively impact patients, public health, and innovation. Commenters believed it was also important to recognize that relatively few QIDP products utilize the new technology add-on payment pathway. A commenter further stated that the overall cost to Medicare associated with new technology add-on payment for QIDPs was limited due to the small number of products that seek (and therefore get approved for) add-on payment and the limited payment period. The commenter also provided an analysis of claims data from FY 2021 to FY 2025 that showed that actual new technology add-on payment utilization for QIDP and LPAD products was only 1.3 percent of CMS estimates in rulemaking (about $9.4 million versus $721.2 million). Therefore, the commenter asserted that the impact to CMS and on the Medicare budget associated with this pathway for QIDPs was simply not considerable enough to supersede the importance of maintaining innovation in this space. The commenter also further urged CMS not to finalize the proposal to remove the conditional approval process for QIDPs because it would impose further hurdles on manufacturers that worsen delays in availability that are driven by these external dynamics, which would negatively impact utilization and market access. Another commenter stated that new technology add-on payment remains one of the few practical and functioning policy tools available to help mitigate the distinctive economic challenges associated with anti-infective development, while broader reimbursement reform, such as establishing a subscription-based reimbursement model for qualifying antibiotics, has not been enacted. A commenter stated that between 2020 and 2024, only four systemic antibacterial new molecular entities were approved by FDA, and global assessments by the World Health Organization have found that few candidates in development represent meaningful advances against priority pathogens.[127]

Response: We share commenters' interest in ensuring that new and innovative technologies, including those intended to address serious or life-threatening conditions, remain available to Medicare beneficiaries. We also appreciate commenters' perspectives based on their experiences as manufacturers and investors developing these new technologies and as providers and hospitals caring for these beneficiaries.

Applicants retain the ability to pursue new technology add-on payment and OPPS device pass-through payment under the traditional pathway. In addition, as we have previously noted, there are existing mechanisms to pay for new technologies under the IPPS and OPPS. As we stated in the proposed rule (91 FR 19458), and as discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36672), even if a technology does not receive new technology add-on payments, CMS continues to pay for new technologies through the regular payment mechanism established by the DRG payment methodology. Similarly, as we stated in the CY 2026 OPPS/ASC final rule (90 FR 53635), if a technology does not obtain OPPS device pass-through payment status, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Whether a technology receives new technology add-on payments or OPPS device pass-through payments does not affect coverage of the technology or the ability for Medicare providers to provide such technology to patients where appropriate. Although commenters have noted that the MS–DRG or APC payment rates would not yet account for the costs of these new technologies, we continue to believe that the existing payment mechanisms provide a useful balance to the introduction of new technologies, especially when substantial clinical improvement is not demonstrated. We continue to believe it is in the best interest of Medicare beneficiaries to proceed very carefully with respect to the incentives created to quickly adopt new technology. As also discussed in the September 7, 2001 final rule, in deciding which treatment is most appropriate for any particular patient, it is expected that physicians would balance the clinical needs of patients with the efficacy and costliness of particular treatments (66 FR 46919). We also note that there are other mechanisms, beyond additional payments from Medicare, that hospitals may be able to consider to support any premium price of new technologies, including negotiation with manufacturers, or taking advantage of rebates offered by manufacturers.

We also disagree that this proposal is an abrupt shift that disrupts settled expectations. When we initially finalized the policy that established the alternative pathways in the FY 2020 IPPS/LTCH PPS final rule, we indicated that we would be evaluating the benefits of the alternative pathways and any considerations that may come to light. Specifically, we stated that we believed it was prudent to gain experience under this new alternative pathway for certain transformative new devices before expanding it to other special designations to allow us to evaluate the benefits of this proposed alternative pathway to facilitate beneficiary access to transformative new medical devices as well as any other considerations that may come to light after application of this new pathway (84 FR 42296). CMS has continually emphasized FDA and CMS act under different statutes that have different standards and has noted in recent years that FDA designation or marketing authorization alone is often insufficient to support Medicare decision making.[128] [129] For example, FDA and CMS must consider different legal authorities and apply different statutory standards when making marketing authorization and payment decisions, respectively. We believe that requiring all applicants to demonstrate that they meet the same eligibility requirements to receive add-on payments and/or pass-through payments is consistent with the determinations that CMS has continued to make over the past few years and is a regulatory change to align with Agency understanding and ongoing experience with these technologies, rather than a drastic, unexpected reversal. We also disagree with commenter assertions that there was a settled expectation that their technologies would be approved for new technology add-on payment or OPPS device pass-through payment because CMS must review all applications and make an approval determination through annual notice-and-comment rulemaking, regardless of a technology's eligibility under the alternative pathways. With respect to commenters' belief that the lack of legacy coding options could effectively prevent hospitals from offering the technology at launch, we note that new CPT codes or ICD–10–PCS codes may be established in advance of FDA market

[127] World Health Organization. (June 2022). Lack of innovation set to undermine antibiotic performance and health gains. Available at: *https://www.who.int/news/item/22-06-2022-22-06-2022-lack-of-innovation-set-to-undermine-antibiotic-performance-and-health-gains.*

World Health Organization. (October 2025). Analysis of Antibacterial Agents in Clinical and Preclinical Development: Overview and Analysis 2025. Available at: *https://www.who.int/publications/i/item/9789240113091.*

[128] Final rule to repeal the ''Medicare Coverage of Innovative Technology (MCIT) and Definition of ''Reasonable and Necessary'' final rule (86 FR 62944–62958).

[129] Transitional Coverage for Emerging Technologies (TCET) pathway final notice (89 FR 65724–65754).

authorization, and that, in general OPPS and IPPS are bundled payment systems, so while it may be not be possible to actually identify when a particular product was used when there is no unique code to identify it amongst other products in the category, the product is nonetheless used and paid for. We also disagree that new technology add-on payment or OPPS device pass-through payments would be considered a strong national payment anchor, as these are additional payments provided for a limited period of time for certain new technologies that meet the criteria.

We recognize that changes to the alternative pathways for new technology add-on payment and OPPS device pass-through payment may have implications for manufacturers' launch planning and evidence development strategies, particularly for technologies that anticipated additional payment to support early adoption. We also recognize that the implications may change depending on the availability of clinical evidence required under the type of FDA marketing authorization pathway relevant to a technology. However, we believe that these additional payments are appropriately reserved for technologies that demonstrate substantial clinical improvement for Medicare beneficiaries. The proposed repeal reflects our interest in maintaining a consistent, evidence-based standard for additional payment eligibility, rather than reliance on external designations that may be based on different evidentiary thresholds or policy objectives. CMS continues to support timely beneficiary access to innovative technologies, and we believe that aligning payment with demonstrated clinical value is essential to ensuring appropriate resource use. Importantly, manufacturers retain the ability to pursue new technology add-on payment and OPPS device pass-through payment under the traditional pathway and may consider how their evidence development strategies can best address CMS's criteria, including generating data relevant to the Medicare population and demonstrating meaningful clinical improvement over existing alternatives. We also disagree that an implication of this proposal was that FDA-designated Breakthrough Devices would no longer qualify for new technology add-on payment or OPPS device pass-through payment, because we have approved devices through the traditional pathway, including those without an FDA Breakthrough Device designation, who also receive marketing authorization under FDA's standard 510(k), De Novo, or PMA pathways.

With respect to commenters' concerns about the impact of the proposed repeal specifically on QIDPs and LPAD products, we note that commenters primarily focused on the need to support the development of these products. While we continue to recognize the concerns related to antimicrobial resistance and its impact on Medicare beneficiaries, it is unclear to us whether new technology add-on payment is the appropriate vehicle to support these goals in lieu of broader reimbursement reforms. For example, a commenter highlighted that some products may share similar classes or mechanisms of action but still provide clinically meaningful benefits through improved activity against resistant pathogens. However, we note that having additional options to choose from related to public health concerns would not necessarily indicate that those options are dissimilar from existing technologies that have already been incorporated into the MS–DRG payment rates. In addition, although commenters describe the difficulties of demonstrating substantial clinical improvement through placebo-controlled studies and head-to-head superiority data, as discussed earlier, such evidence is not required under the regulations at § 412.87(b)(1)(iii). We encourage applicants for QIDPs and LPAD products to review the available options for demonstrating substantial clinical improvement to determine which approach would best align with the outcomes demonstrated by their technology. We also disagree with commenters that these products have already proven that they represent a substantial clinical improvement and are not ''substantially similar'' to existing products. Although a commenter stated that to be approved under the LPAD, a drug must be intended for use by patients with unmet needs, we note that under the FDA guidance shared by the commenter, FDA provides additional definitions of unmet needs that do not align with the new technology add-on payment criteria. For example, FDA states: ''When available therapy exists for a condition, a new treatment generally would be considered to address an unmet medical need if the treatment [. . .] addresses an emerging or anticipated public health need, such as a drug shortage.'' Or ''where the only available therapy was approved under the accelerated approval program based on a surrogate endpoint or an intermediate clinical endpoint and clinical benefit has not yet been verified.'' [130] We also note that FDA's requirement to address an unmet need does not apply to QIDPs. In addition, with respect to commenters' request to maintain conditional approval, we note that it is procedurally infeasible to maintain conditional approval under the traditional pathway because, as discussed previously in this rule and in prior rulemaking, we do not believe it is appropriate for CMS to determine whether a medical service or technology represents a substantial clinical improvement over existing technologies before FDA makes a determination as to whether the medical service or technology is safe and effective (86 FR 45047).

Comment: Commenters asserted that this proposal contradicted with the Administration's views on reducing regulatory burdens, ensuring American leadership in healthcare and life sciences, innovation, or the power of the private sector to drive meaningful clinical change. Commenters further stated that the proposed changes appear incongruent with FDA and CMS's goals as proposed under the RAPID coverage pathway to accelerate patient access to certain innovative technologies. A commenter quoted CMS's stated objectives in the recent RAPID announcement that noted the Agency's goal of, ''cutting red tape for innovators, and helping beneficiaries access new, life-changing health technology faster.'' [131] Commenters stated that manufacturers would need to demonstrate substantial clinical improvement even after they provided sufficient evidence for FDA market authorization and Medicare national coverage. Commenters asserted that the proposed repeal may undermine the broader Agency objectives by creating additional barriers to hospital adoption of new therapies, and risks creating a situation where technologies are technically covered but practically unavailable at many hospitals.

Commenters also stated their belief that the proposed repeal did not align with congressional intent for the Breakthrough Device Program or QIDP pathway, with a commenter further asserting that CMS may be exceeding its statutory authority. A commenter stated that requiring that a 510(k)-cleared FDA-designated Breakthrough Device also satisfy the CMS substantial clinical improvement criterion at the time of

[130] *https://www.fda.gov/media/86377/download.*

[131] CMS and FDA Announce RAPID Coverage Pathway to Accelerate Patient Access to Life-Changing Medical Devices *https://www.cms.gov/newsroom/press-releases/cms-fda-announce-rapid-coverage-pathway-accelerate-patient-access-life-changing-medical-devices.*

new technology add-on payment application imposes a third evidentiary requirement that neither FDA nor Congress designed for FDA 510(k) devices. The commenter also stated that any suggestion that FDA 510(k) clearance, by virtue of its predicate-comparison framework, is inherently inconsistent with newness for new technology add-on payment eligibility conflates two standards that Congress and the agencies themselves have kept separate. Commenters stated their concern that the proposed repeal would create a structural bias, as the FDA 510(k) pathway exists because Congress and FDA determined that lower-risk devices do not require clinical trials as a condition of market clearance. Commenters believed that the proposal could reduce Medicare beneficiary access to the types of innovative breakthrough devices the program was designed to reach, including technologies that FDA has authorized to enter the commercial market, which, by FDA's own regulatory design, do not require pre-market clinical trial data. Commenters stated that such devices have no clinical trial data because their risk profile and substantial equivalence to a predicate device satisfy FDA's clearance standard under the 510(k) pathway. Commenters believed that recognition by FDA's Breakthrough Device designation indicated the potential for more effective treatment or diagnosis of life-threatening or irreversibly debilitating disease or conditions. The commenter further stated that the proposed repeal was inconsistent with the aims of the 21st Century Cures Act, as it stated Congress enacted the 21st Century Cures Act specifically to reduce barriers to patient access to breakthrough medical innovations by accelerating FDA review timelines. The commenter asserted that CMS's proposed repeal effectively offsets that acceleration by reinstating what it described as the most significant payment-side barrier to early adoption of FDA 510(k) technologies: the requirement to demonstrate substantial clinical review through post-market literature, before MS–DRG rates have adjusted to reflect a technology's cost. Other commenters stated their belief that eliminating the alternative pathways tells researchers, hospitals, and innovators that the FDA's scientific judgment and Breakthrough Device designation no longer translates into a meaningful reimbursement advantage. Commenters believed that this messaging would be contrary to congressional intent, would deter investment in these technologies, and would undermine United States's global competitiveness in medical innovation.

A commenter expressed its concern that current proposals and policy changes from prior rulemaking, taken in their totality, reflect an increasingly restrictive approach toward new technology add-on payments. The commenter stated that new technology add-on payments were created in response to an express directive by Congress for CMS to ''establish a mechanism to recognize the costs of new medical services and technologies,'' that ''adequately reflects the estimated average cost of such service or technology'' during a statutorily prescribed newness period. The commenter stated that in enacting the new technology add-on payments statute, Congress recognized the need for CMS to address an inherent limitation in the IPPS's rate-setting methodology: due to the time-lag inherent in the retrospective claims data used to set rates under the IPPS, truly novel technologies are not adequately reimbursed under the MS–DRG system unless a special additional payment mechanism is available to account for the costs of such new technologies. The commenter stated it did not believe Congress intended improper restrictions on new technology add-on payment that could either prevent its availability or unreasonably limit its effective duration, thereby undermining the purpose of the statutorily-mandated mechanism. The commenter stated its concern that CMS's proposals reflect an increasing hostility to new technology add-on payment that is at odds with both its statutory intent and sound public policy.

Response: We disagree that requiring all applicants for new technology add-on payments and OPPS device pass-through payments to meet the same eligibility criteria would be contrary to the Administration's views on reducing federal regulatory burden. We believe that this proposal would create more homogeneity and consistency in the administration of the new technology add-on payment process, and result in the removal of certain regulations related to the alternative pathway and associated costs that do not necessarily deliver value to Medicare beneficiaries.

We also do not agree that this proposal is incongruent with FDA and CMS's stated goals under the RAPID coverage pathway to accelerate patient access to certain innovative technologies. Requiring all applicants for new technology add-on payments and OPPS device pass-through payments to meet the same eligibility criteria is not indicative of any change in CMS's goals for the RAPID coverage pathway. We remind commenters that coverage and additional payments for new technologies are separate processes with different standards and purposes, as previously discussed. The traditional pathway for new technology add-on payment applications will continue. We do not believe that Medicare should financially incentivize new technologies for hospitals and manufacturers without evidence of substantial clinical improvement over existing services or technologies, to benefit Medicare beneficiaries.

We further disagree that CMS is exceeding its statutory authority or is implementing these programs in a way that is contrary to congressional intent for the FDA Breakthrough Device Program and QIDP pathway. We note that FDA and CMS must consider different legal authorities and apply different statutory standards in implementing their respective programs. While FDA must consider the applicable authorities for the Breakthrough Device Program under the FD&C Act, as created by the 21st Century Cures Act, among other statutes, QIDP pathway, and FDA marketing authorization pathways as outlined in its statute, CMS is not bound by the same statutory authorities. Instead, CMS implements its payment programs in accordance with section 1886(d)(5)(K)(i) of the Act, which required the Secretary to establish a mechanism to recognize the costs of new medical services and technologies, and section 1833(t)(6), which establishes transitional pass-through payment. As previously noted, sections 1886(d)(5)(K)(vi) and section 1833(t)(6) of the Act further specify that a medical service or technology will be considered ''new'' if it meets criteria established by the Secretary (after notice and opportunity for public comment). In addition, we disagree with the concerns that our proposal represented a structural bias against the FDA 510(k) clearance pathway or suggests it is inherently inconsistent with newness, as such technologies may also demonstrate that they meet the newness and substantial clinical improvement criteria, as applicable.[132]

We also disagree that our proposals reflect an increasing hostility toward new technology add-on payment and that they are at odds with both its

[132] For example, the following FDA 510(k) devices have received new technology add-on payment and/or OPPS device pass-through payments: T2Bacteria® Panel (84 FR 42278 through 42288); SpineJack® Expansion Kit (85 FR 58689 through 58701; 85 FR 86003 through 86011); FLEX Vessel Prep™ System (88 FR 81749 through 81755).

statutory intent and sound public policy. Although the commenter stated that it did not believe Congress intended what it described as improper restrictions on new technology add-on payments that could either prevent its availability or unreasonably limit its effective duration, we note that section 1886(d)(5)(K)(i) and section 1833(t)(6) of the Act authorized the Secretary to establish a mechanism to recognize the costs of new medical services and technologies, after notice and opportunity for public comment. When CMS first established this mechanism in the September 7, 2001 final rule (66 FR 46912 to 46921) and in the November 2, 2001, OPPS interim final rule with comment period (66 FR 55852 to 55853), we finalized the requirement that a new technology must represent a substantial improvement. In these final rules, we explained our belief that the special payments for new technology established by the final rule should be limited to those new technologies that have been demonstrated to represent a substantial improvement in caring for Medicare beneficiaries, such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology. As previously discussed, we subsequently adopted the alternative pathway for certain transformative medical devices and antimicrobials. However, at this time, following our further experience with and consideration of the application of this alternative pathway, we believe it is most appropriate to return to applying this standard consistently across all applications.

Comment: Commenters stated that CMS had not presented data demonstrating that the alternative pathways have failed to deliver clinical benefit to Medicare beneficiaries, or resulted in inappropriate approvals, excess spending, adverse outcomes, program integrity concerns, or systematic abuse that would warrant a repeal. Commenters also stated that CMS did not explain why the proposed repeal serves Medicare patients' best interests nor analyze how it would impact Medicare patients' timely access to these technologies. Commenters stated that CMS did not appear to analyze the cost to industry related to practice development and evidence-generation associated with transitioning to the traditional pathway, which may particularly affect small single-product companies. Commenters requested that CMS provide data behind its proposal to eliminate the alternative pathways and stated that without this information, the proposal was premature and stakeholders would be unable to offer meaningful input on alternative options.

Commenters stated that CMS did not explain how FDA's determinations are now insufficient to demonstrate that a new technology confers a substantial clinical advantage despite the alignment between the FDA statute and CMS regulations, and that CMS should transparently identify exactly why FDA's evaluation is (or has become) insufficient. Commenters further stated that if CMS feels FDA's Breakthrough Device evaluation is in fact sufficient, CMS should provide its basis for proposing to repeal the policy that allowed the Agency to waive the 'substantial clinical improvement' requirement under 42 CFR 412.87(b)(1). Another commenter believed that CMS's statements in the proposed rule contradicted statements in prior rulemaking about working towards a broader alternative pathway over time and that it was prudent to gain experience under this new alternative pathway before expanding it to other special designations, and which the commenter stated had resulted in reliance interests (84 FR 42044, 42296). Another commenter stated that the Agency's own actions in this rulemaking are difficult to reconcile with its position that the alternative pathways produce insufficiently justified spending, as in the same proposed rule, CMS proposed to approve a substantial number of FDA-designated Breakthrough Devices under the alternative pathways.

A commenter stated that CMS failed to adequately consider less drastic reform alternatives. Commenters also asserted that CMS failed to address reliance interest of stakeholders during every stage of the product lifecycle, including early-stage clinical development, multi-year planning cycles and pipelines, and post-market evidence collection. A commenter provided examples of multicenter randomized controlled trials, large-scale claims analyses, and prospective registries collected during the early commercialization period. Commenters asserted that under the Administrative Procedure Act, a change in agency position requires a more detailed justification when prior policy has engendered serious reliance interests. Commenters provided prior Supreme Court case law, including *Encino Motorcars, LLC* v. *Navarro* [133] and *Department of Homeland Security* v. *Regents of the University of California,* [134] stating when an agency is not writing on a blank slate, it must identify whether reliance interests exist, determine their significance, and weigh them against competing policy concerns. Another commenter further stated that under *Motor Vehicle Manufacturers Ass'n* v. *State Farm Mutual Automobile Insurance Co.,* [135] an Agency acts arbitrarily and capriciously when it fails to consider an important aspect of the problem. Commenters stated that the Supreme Court held in *FCC* v. *Fox Television Stations, Inc.* [136] that an agency must give a ''reasoned explanation'' when it changes a policy. The commenters stated that the decision stated that the agency must have ''good reasons'' for the new policy, and in certain situations, must ''provide a more detailed justification than what would suffice for a new policy created on a blank slate,'' which includes situations where ''its new policy rests upon factual findings that contradict those which underlay its prior policy.'' Commenters argued that the reasoning provided by CMS to support the proposal failed to meet the standard set forth by the Supreme Court. Commenters asserted that, therefore, for procedural reasons alone, the proposal must not be finalized.

A commenter also disagreed that the proposed repeal would achieve CMS's goal to better align spending and value and ultimately support providers in delivering the best, data-driven care possible. The commenter asserted that a hospital's receipt of incremental payments for the adoption of new technologies does not mandate the use of the technology and would not lead to less than optimal care. The commenter stated that decisions on the appropriate care pathway belong with providers and established coverage determination processes and that the new technology add-on payment eliminates the financial disincentive that hospitals have for adopting new and innovative technologies that may benefit patient care.

A commenter stated that CMS has expressed concern with the increasing volume and complexity of new technology add-on payment applications and finalized policies intended to reduce agency burden associated with evaluating them, and stated it was not clear why these challenges would warrant repealing a pathway that, by design, reduced CMS's evaluative burden. Commenters believed that evaluating FY 2028

[133] 579 U.S. 211 (2016).

[134] 591 U.S. 1 (2020).

[135] 463 U.S. 29 (1983)12.

[136] 556 U.S. 502, 514 (2009).

applications under the traditional pathways would likely consume more time and resources for CMS. Commenters stated their belief that the alternative pathways had also reduced administrative burden at the Agency by streamlining aspects of the new technology add-on payment and OPPS device pass-through review process without lowering standards. Commenters stated that eliminating the alternative pathways risked duplicative review and longer timelines without a clear policy benefit. A commenter stated that CMS retained multiple safeguards that already provided the flexibility to ensure that new technology add-on payment and OPPS device pass-through payments remain targeted, time-limited, and value-conscious, including: the newness criterion, with a defined 2 to 3 year newness window and policies clarifying how commercial availability delays are treated; a rigorous cost criterion to ensure that new technology add-on payment is reserved for cases where IPPS payment is demonstrably inadequate; and caps on new technology add-on payment percentage, which preserves financial risk under the prospective payment system and prevents full cost-shifting to Medicare. The commenter further stated that recent CMS rulemaking demonstrates that the Agency is willing to use new technology add-on payment policy to support access to transformative, high-cost therapies while at the same time refining financial safeguards, such as when CMS increased the new technology add-on payment percentage to 75 percent for certain gene therapies for sickle cell disease, or when CMS clarified how delays in commercial availability should affect the newness period to emphasize that new technology add-on payments remain focused on the true introductory period of a technology. The commenter stated that the examples suggest that targeted refinements, rather than repeal, are the appropriate policy tool if CMS believes additional guardrails are needed.

Commenters stated that the proposed changes appear to be focused on cost reductions, and stated their belief that CMS needed to provide an evidentiary basis to repeal the alternative pathways, such as a cost-benefit analysis demonstrating that costs of the alternative pathways outweigh the patient benefits. A few commenters described their analyses of CMS spending on new technology add-on payment. The commenters stated that their claims analyses for technologies approved for new technology add-on payment under the alternative pathway found that actual utilization was significantly lower than CMS estimates. A commenter shared its empirical analysis of new technology add-on payment utilization and payment data spanning FY 2011 through FY 2024 and compared actual new technology add-on payment expenditures to CMS estimates provided during annual rulemaking. The commenter stated that the data showed that actual new technology add-on payment expenditures under the alternative pathway represented only 13.3 percent of CMS's estimates across all product types, compared to 45.2 percent for the traditional pathway, which it stated suggested that CMS's methodology for projecting new technology add-on payment expenditures may not adequately account for the utilization dynamics of alternative pathway technologies. The commenter also found that new technology add-on payments for devices under the alternative pathway represented a small fraction of both estimated expenditures and overall inpatient hospital spending. The commenter also reviewed year-by-year patterns for new technology add-on payments for devices under the alternative pathway and found that actual expenditures had declined since FY 2022. A few commenters stated that a claims analysis for FY 2021 to FY 2024 found that 38 percent of eligible claims under the alternative pathway triggered new technology add-on payment (22 percent of the estimated expenditure), and under the traditional pathway, those values were 46 percent and 28 percent respectively. The commenters noted that critically, add-on payments are not automatic; they are triggered only when a hospital's costs for a particular case exceed the applicable payment threshold, and, as a result, lower hospital acquisition costs reduce both the likelihood and magnitude of any add-on payment. Additional commenters stated an analysis of FY 2021 to FY 2025 claims data showed that hospitals only received less than 20 percent (17.3 percent) of an estimated spend of $1.5 billion over the five-year period. Commenters stated that new technology add-on payments and OPPS device pass-through payments are temporary and limited in scope and help support appropriate reimbursement and incentivize technology adoption for a short time before the costs of new technologies are incorporated into the applicable payment rates. A commenter stated that deferring a final decision on the proposed repeal would carry comparatively low fiscal risk for several reasons: (1) actual expenditures have consistently been a fraction of estimated expenditures and have declined; (2) the new technology add-on payment is time-limited by statute and does not capture the full incremental cost of a new device; and (3) the total new technology add-on payment for devices was only a small fraction of overall Medicare inpatient spending.

Response: We disagree with commenters' assertions that the repeal would be arbitrary and capricious, or that the proposal should not be finalized because we failed to consider less drastic alternatives or reliance interests or provide data to demonstrate the proposal is warranted. We believe we have adequately assessed whether there were reliance interests, determined whether those interests were significant, and weighed any such interests against competing policy concerns in accordance with requirements under law, including court decisions cited by the commenters. We further believe that our new policy is permissible under the statute, that there are good reasons for it, and—for the reasons set forth in this preamble—we believe it to be better than continuing the existing alternative pathways policy.

For example, we recognize that there may be potential reliance interests of industry, including manufacturers and investors, throughout the product lifecycle when considering evidence development and commercialization strategies for their technologies, and providers and facilities that may be interested in using these technologies. However, we do not believe that the existence of the alternative pathways would have given rise to serious or significant reliance interests that would be affected by our proposal. At the time of FY 2020 IPPS/LTCH PPS and CY 2020 OPPS/ASC final rules, the FDA's Breakthrough Device program was still relatively new. We indicated in the FY 2020 IPPS/LTCH PPS final rule that we believed it was prudent to gain experience under the new alternative pathway, in order to allow us to evaluate the benefits of this proposed alternative pathway to facilitate beneficiary access to transformative new medical devices as well as any other considerations that may come to light after application of this new pathway. As previously described, since then, CMS has indicated our concern with relying solely on an FDA designation to support Medicare decision-making as FDA and CMS operate under different statutory authorities.[137] We believe that

[137] Final rule to repeal the ''Medicare Coverage of Innovative Technology (MCIT) and Definition of

any reliance on the availability of the alternative pathways would have been neither significant nor reasonable in light of CMS's stated openness to reassess the alternative pathways as it gained more information, and our continued concern that FDA and CMS must consider different legal authorities and apply different statutory standards. We also believe that any asserted reliance interests that may have stemmed from an expectation that technologies would be eligible to apply under the alternative pathways and would all be approved for new technology add-on payment or OPPS device pass-through payment would be unjustified because CMS reviews all applications and makes determinations through annual notice-and-comment rulemaking. While, as noted, we recognize that there may be potential reliance interests of industry, providers, and facilities, even taking those interests into account, we do not believe those interests outweigh CMS's obligations to American taxpayers and Medicare beneficiaries, including the obligation to make sure that in creating a payment incentive for the use of new technology, such technology represents a substantial improvement in care provided for Medicare beneficiaries. With respect to commenters' statements that CMS did not explain how FDA's determinations are now insufficient, as discussed in greater detail earlier, we do not consider technologies applying under the alternative pathways to have demonstrated that they are not substantially similar to existing technology or to have met the substantial clinical improvement criterion strictly on the basis of having an FDA Breakthrough Device or QIDP designation, or being approved under the LPAD pathway, and we refer readers to our prior discussion regarding the differences between the FDA and CMS criteria. Moreover, as noted, in recent years, CMS has continually emphasized that FDA marketing authorization alone is often insufficient to support Medicare decision making. As we explained in the proposed rule, we believe that holding all applicants to the same standards and requiring all applicants to demonstrate that their technologies meet the same criteria maintains our focus on new and innovative technologies that improve beneficiary health outcomes while strengthening the evidence base supporting our approval decisions for new technology add-on payment and OPPS device pass-through payment, ensuring value for American taxpayers and Medicare beneficiaries. With respect to the commenter stating that our actions in this rulemaking are difficult to reconcile because CMS proposed to approve applications under the alternative pathway, we clarify that while we had proposed to continue to make available the alternative pathway for those technologies for which an application had previously been submitted under the alternative pathway for FY 2027, we continue to believe that it is appropriate to change our policy going forward for the reasons discussed.

While evaluation of applications under the traditional pathway would not necessarily reduce agency review, we believe that any change in agency burden associated with reviewing all applications under the same criteria would also be outweighed by CMS's obligations to ensure value for current and future beneficiaries of the Medicare Trust Fund. With respect to the analyses shared by commenters showing that the overall utilization of all new technology add-on payments including technologies approved under the alternative pathways were lower than CMS estimates, we note that this both aligns with our experience and was not a relevant consideration in our development of this proposal. As mentioned by commenters, our cost estimates are based on the applicant's estimated cases at the time they submitted their original application and the increase in new technology add-on payments as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment, which would typically result in an overestimation. The estimated financial impact of a technology does not influence our evaluation of new technology add-on payment applications. We believe that any payment incentive that may be made for the use of new technologies should be limited to those technologies that improve outcomes for Medicare beneficiaries, regardless of whether actual Medicare expenditures reach estimated spending. Although commenters pointed out these additional payments are temporary and limited in scope, this would not mitigate the limitations in evaluation of technologies under the alternative pathways that we are addressing.

Comment: Many commenters requested that CMS consider alternatives to the proposal to preserve predictable reimbursement pathways that support early hospital adoption of transformative technologies. Commenters provided suggestions that CMS withdraw the proposal or spend additional time to evaluate its impact and explore modifications. Commenters requested that CMS evaluate the access implications for rural, safety-net, teaching, and specialty hospitals before finalizing any changes that could slow adoption. A commenter recommended that CMS conduct and publish a comprehensive evaluation of the alternative pathways' impact on FDA-designated Breakthrough Devices, including: the number and type of FDA-designated Breakthrough Devices that have received new technology add-on payment or OPPS device pass-through under the alternative pathway; the aggregate spending associated with these devices relative to total IPPS and OPPS expenditures; and patterns of adoption and affordability challenges across hospital types (rural vs. urban, teaching vs. non-teaching, safety-net vs. non-safety-net), and corresponding changes in access for Medicare beneficiaries. Commenters suggested that CMS improve cross-agency coordination (with CDC and FDA) and pursue additional stakeholder engagement through a Request for Information (RFI), such as to understand how the alternative pathways influenced clinical practice, patient outcomes, and investment decisions in healthcare. A commenter further requested that CMS directly conduct outreach to affected companies before finalizing any changes. Commenters believed that subsequent refinements should be proposed through future notice-and-comment rulemaking before finalizing any changes. Commenters stated their belief that this was especially important given ongoing changes to CMS coverage programs, including the recently announced RAPID coverage pathway.

Some commenters requested additional clarity and details on the new RAPID coverage program and how it would interact with new technology add-on payment eligibility. Commenters further asked that CMS explicitly clarify that participation in the RAPID coverage pathway does not increase the evidentiary burden for simultaneous or subsequent new technology add-on payment participation, and that RAPID coverage determinations are independent of and do not substitute for new technology add-on payment eligibility determinations. A commenter urged CMS to delay finalization of the proposed alternative pathways repeal until the RAPID coverage program has published its final **Federal Register** procedural notice and has demonstrably completed at least three national coverage determinations within the

''Reasonable and Necessary'' final rule (86 FR 62945).

Agency's target timelines. The commenter believed that finalizing the proposed alternative pathways repeal would be defensible once the RAPID coverage program was demonstrably operational. Another commented believed that the RAPID coverage pathway could not substitute for the alternative pathways, as its eligibility requirements, including an Investigational Device Exemption (''IDE'') study enrolling Medicare beneficiaries and, for Class II devices, enrollment in FDA's Total Product Lifecycle Advisory Program (''TAP'') pilot, may render the program structurally unavailable to many 510(k)-cleared FDA-designated Breakthrough Devices.

Some commenters also requested that CMS provide additional clarity on the substantial clinical improvement criterion, including methods, standards, or evidentiary expectations for assessing whether a new technology meets the substantial clinical improvement criterion. Commenters were interested in additional published guidance on the types of evidence necessary to prove that the substantial clinical improvement is met, taking into consideration the differing types of evidence used to support FDA market authorization and the time-based restrictions for the additional payments. Commenters requested formal guidance clarifying how substantial clinical improvement would be evaluated for epilepsy-specific indications, including for implantable monitoring, neuromodulation, and precision therapeutics. A commenter requested that for computer-aided triage and notification software, CMS adopt evidentiary endpoints appropriate to that class of technology, such as demonstrated reductions in time-to-notification and in missed or delayed identification of target findings, rather than therapeutic-outcome endpoints designed for drugs and therapeutic devices. Commenters recommended that CMS treat an FDA Breakthrough Device designation, together with subsequent FDA marketing authorization, as establishing a rebuttable presumption that the substantial clinical improvement criterion is satisfied, and expressly recognize real-world evidence, patient registry data, and peer-reviewed clinical studies as acceptable forms of evidence. A commenter believed that CMS should confirm that pre-market single-arm trial data and real-world evidence may satisfy the substantial clinical improvement criterion where comparative head-to-head data against existing alternatives is unavailable at the time of application, and that the absence of published peer-reviewed comparative data does not constitute a failure per se. Another commenter stated that CMS could enhance evidence requirements by requiring alternative pathway applicants to submit: human factors or real-world performance data from clinical deployments; a cost-benefit analysis demonstrating that the incremental cost of the technology is offset by downstream savings; and a structured data collection plan that would generate utilization and outcomes data usable for future MS–DRG recalibration. A commenter encouraged CMS to consider National Comprehensive Cancer Network Guidelines as a resource in determining clinical appropriateness. Commenters requested that CMS continue to enable engagement and build on opportunities for applicants to meet with CMS throughout the application cycle, including prior to submission of applications. The commenter believed that as manufacturers are contemplating evidence generation to support determination of substantial clinical improvement, both CMS and applicants would benefit from earlier engagement to discuss availability of evidence and anticipated outcomes to support new technology add-on payment and OPPS device pass-through. Commenters believed that CMS should work with stakeholders to establish substantial clinical improvement evidentiary standards that meet the Agency's pledge to consider the totality of the circumstances, including reasonable expectations regarding the type and extent of comparative effectiveness data that may be available at the time of FDA marketing authorization, and that reflect the objectives of new technology add-on payment and OPPS device pass-through as well as the limited ''payment only'' scope of positive determinations. Another commenter further stated that until then, it would be inappropriate and damaging to both beneficiary access and the U.S. medical innovation ecosystem for CMS to proceed with eliminating the alternative pathways.

Commenters also requested that CMS delay or provide a transition period of up to a few years before any potential repeal of the alternative pathways to allow companies to adjust their technology development to potentially meet the eligibility requirements under the traditional pathways, and provide clear guidance and protection for technologies already in the application pipeline. Other commenters requested that CMS grandfather technologies that have received FDA Breakthrough Device or QIDP designations and allow them continued access to the existing alternative pathways, with a commenter further suggesting that to ensure the program does not remain open-ended, there could be a defined window, such as 7 to 10 years from the date of the FDA Breakthrough Device designation, for applicants to apply for additional payments for their technology. A commenter stated that it was confident that its FY 2028 new technology add-on payment application would meet the traditional pathway criteria, but would appreciate being grandfathered into the alternative pathway. Other commenters provided targeted suggestions that select technologies could be grandfathered into existing policy if they: had previously applied for new technology add-on payment under the alternative pathways; were developed in reliance on the existing policy framework; were far along the development and/or clinical validation cycle; had established clinical performance profiles, or were in the process of establishing such performance profiles through Category A and B IDE pivotal trials with endpoints reviewed and approved by both FDA and CMS; were class II or III technology that were actively enrolling Medicare beneficiaries and/or Medicare-aged subjects in an IDE study generating relevant clinical evidence for Medicare beneficiaries; or had data demonstrating a reasonable likelihood of substantial clinical improvement in a Medicare beneficiary population. A commenter suggested that any new restrictions or eliminations would apply only to designations granted after the policy change takes effect.

A commenter stated that although the proposed repeal is described as applying to FY 2028 applications and beyond, in practical effect, this proposal would be retroactive for any Breakthrough Device company currently in an IDE trial. A commenter stated that when CMS finalized the new technology add-on payment FDA marketing authorization deadline change from July 1 to May 1, it applied the new deadline prospectively beginning with FY 2025 applications, allowing manufacturers a full year to adjust, and that applying the same principle here (at a minimum, delaying the effective date of any repeal) would preserve both the integrity of CMS's regulatory framework and the confidence of future innovators that Breakthrough Device development has stable and predictable reimbursement, without representing new obligations for CMS staff reviewing applications. A

commenter stated its belief that the proposed September 30, 2026, eligibility cutoff for the alternative pathway under the new technology add-on payment created a practical problem, as applications for the upcoming fiscal year were historically not available until August, and therefore may not open before the cutoff date. The commenter requested that CMS either open the FY 2028 new technology add-on payment application before September 30, 2026, or extend the alternative pathway eligibility to the actual application deadline, so that manufacturers currently in the pipeline can complete the process under the existing framework.

Commenters also provided alternate methods that they believed would more effectively or efficiently accomplish the goal of aligning payment with value by facilitating payment for innovative, high-value technologies that have demonstrated improved Medicare beneficiary health outcomes. Alternatives suggested by commenters included: requiring applicants to provide outcomes through post-market evaluation before consideration for future ratesetting changes; requiring structured continued evidence development and reporting; requiring transparency guardrails; setting defined points for reassessment; focusing on a subset of FDA-designated Breakthrough Devices addressing the most serious conditions with the highest unmet need; incorporating claims-based tracking; including FDA-designated Regenerative Medicine Advanced Therapies (RMATs) and Breakthrough Therapies in the alternative pathways; establishing an enhanced new technology add-on payment pathway specific to gene therapies that would pay 100 percent of the cost of the therapy for greater than three years; or establishing a MS–DRG for each FDA-approved gene therapy, which would also be budget neutral. A commenter believed that CMS should work with stakeholders to establish clearer, more consistent, and more predictable evidentiary standards that appropriately reflect the types of evidence used to support FDA market authorization, including data generated through investigational device exemption (IDE) studies and other FDA-reviewed evidence development pathways. Another commenter believed that CMS could address concerns through targeted refinements, such as enhanced documentation standards or additional cost substantiation requirements. A commenter recommended that CMS consider the FDA National Evaluation System for Health Technology (NEST) initiative, which it stated had facilitated FDA's acceptance of real-world evidence to demonstrate safety, effectiveness and improvement through industry partnerships. Commenters encouraged CMS to establish a provisional substantial clinical improvement standard for alternative pathway applicants, accepting observational studies, registry data, surgeon expert testimony, or published case series as sufficient to demonstrate substantial clinical improvement for OPPS device pass-through and under the totality-of-circumstances standard for new technology add-on payment. A commenter asked that CMS recognize that early payment is often essential to evidence development itself, and that developing a modernized transitional payment pathway could support both patient access and evidence generation. A few commenters asked CMS to state that FDA Breakthrough Device or QIDP designation remained a relevant factor in coverage and quality framework decisions. Commenters suggested that retaining the alternative pathways could serve as safeguard to help ensure that hospitals and Medicare beneficiaries continue to have timely access to breakthrough technologies during periods of regulatory transition or uncertainty, with one stating that federal policy surrounding FDA accelerated review pathways continues to evolve. A commenter encouraged CMS to simplify operational and documentation requirements, and explore supplemental pathways that improve equitable access to innovative therapies and technologies. An additional commenter suggested that CMS could implement tiered or cost-adjusted payment structures that preserve innovation incentives while addressing fiscal considerations.

Commenters recommended that CMS establish a phased approach or a conditional pathway that would permit evidence generation where substantial clinical improvement could not yet be demonstrated. A commenter explained that an applicant with a CMS-approved study protocol designed to produce the evidence necessary to demonstrate substantial clinical improvement could be eligible to receive new technology add-on payment while that evidence was collected, with continued payment subject to a final, up-or-down determination by CMS on the substantial clinical improvement criterion at the conclusion of the study. The commenter stated that this mechanism reflects the same evidence development principles embodied in CMS's existing Coverage with Evidence Development framework: it allows clinically promising technologies to reach Medicare beneficiaries while ensuring that payment remained tied to the timely production of robust clinical evidence and that add-on payment would cease if the technology ultimately failed to demonstrate substantial clinical improvement. Another commenter recommended that CMS establish an explicit evidence maturity framework that would account for differences in evidence development at the time of application, where technologies would be evaluated based on the level of clinical evidence available, with payment aligned accordingly. A commenter also provided another consideration that CMS decouple the duration of the add-on payment from the newness window, as a technology that requires additional time to generate the evidence necessary to demonstrate substantial clinical improvement may exhaust much of its newness window before it is able to qualify. The commenter recommended that CMS retain the newness period for eligibility, but provide approved technologies three years of payment as measured from the date of new technology add-on payment approval. The commenter asserted that where a technology saw limited adoption during the early portion of its newness window precisely because it lacked adequate reimbursement, the corresponding claims data will not reflect the technology's cost, and the rationale for terminating payment at the original newness date—that the MS–DRG weights have been recalibrated to capture that cost—does not hold. Another commenter suggested that CMS could extend new technology add-on payment eligibility windows commensurate with the evidence generation timelines that early-stage clearance necessitates.

A commenter stated that stakeholders have disagreed over whether a new device category is merited or if the mechanism of action and/or composition of the underlying materials demonstrates ''newness.'' A few commenters suggested that CMS should instead require that FDA-designated Breakthrough Device applicants demonstrate that their devices meet the newness criterion in rulemaking, with a commenter further suggesting that applicants could present on this requirement during the new technology add-on payment Town Hall.

Commenters also recommended limiting eligibility to the alternative pathways for specific categories of technologies. For example, a commenter

believed that the alternative pathways should be maintained for FDA-designated Breakthrough Devices in high-acuity areas such as stroke and neurovascular disease. Some commenters believed that the alternative pathways should be maintained for FDA 510(k) cleared technologies because these devices reach the market without pre-market clinical trial data by regulatory design, and the alternative pathways allowed early hospital adoption to generate post-market evidence. Other commenters asserted that the alternative pathways should be maintained for technologies that have received FDA Premarket Approval (PMA) because PMA-approved technologies have undergone FDA's rigorous review process and are supported by substantial clinical evidence demonstrating safety and effectiveness. These commenters believed that prioritizing FDA PMA products would support truly innovative technologies that provide meaningful clinical benefit to create a more clinically grounded and sustainable alternative pathway framework while continuing to support meaningful medical innovation. Another commenter further believed that devices granted an FDA De Novo classification request based on completed IDE studies generating Medicare-relevant clinical evidence of safety and effectiveness, including clinical health outcomes agreed upon by CMS and FDA and relevant to Medicare coverage decision-making, should remain eligible under the alternative pathways. The commenter stated that such considerations would also align with the eligibility criteria CMS and FDA articulated for the RAPID coverage pathway. Some commenters stated that FDA-designated Breakthrough Devices authorized through pathways not commonly supported by Medicare-relevant clinical evidence of safety and effectiveness, most notably the FDA 510(k) pathway, should be required to demonstrate substantial clinical improvement through a controlled clinical study, consistent with CMS's criterion. Another commenter supported CMS's proposal to repeal the alternative pathway for FDA 510(k)-cleared devices and device-led combination products, which it stated are often authorized without clinical evaluations of safety or effectiveness and instead rely on predicate devices. The commenter stated that it was not appropriate to use Medicare funds to provide additional reimbursement for therapies that lack robust evidence of clinical benefit.

Commenters requested that CMS not move forward with the proposal to repeal the alternative pathway and conditional approvals for QIDP and LPAD products. Commenters stated that conditional approvals expedited patient access to new products and would address the access gaps created by the Agency's prior decision to move the FDA marketing authorization deadline from July 1 to May 1 of the new technology add-on payment application year. A commenter stated that the case for expanding the conditional approval policy to FDA-designated Breakthrough Devices has garnered bipartisan support in Congress. A commenter cautioned that eliminating the alternative pathway could create additional barriers and timing misalignments for urgently needed antibacterial and antifungal agents that target multidrug resistant organisms and other high consequence infections, as well as for other high priority infectious diseases technologies. The commenter urged CMS to either maintain an appropriately structured alternative pathway for infectious diseases products or, at minimum, develop a modified framework that preserves an expedited, conditional approval process for qualifying infectious diseases technologies, allowing them to receive time-limited new technology add-on payments while additional evidence is generated, with the expectation that these products ultimately meet the criteria for the traditional pathway through annual notice-and-comment-rulemaking. The commenter believed this approach would preserve streamlined access to high priority infectious diseases diagnostics, therapeutics, and devices while still incorporating safeguards to ensure clinical benefit and prudent use of Medicare resources, and would avoid inadvertently slowing access to important FDA-designated QIDP, LPAD, and other critical infectious disease products that previously relied on the alternative pathway for timely support. A commenter suggested that CMS could refine eligibility criteria to maintain alternative pathways for multidrug-resistant organisms where clinical need is unquestionable, create tiered review processes with expedited pathways for designated priority pathogens identified by CDC, and establish clear clinical criteria that define specific infectious disease scenarios while maintaining rigorous scientific standards. The commenter stated that value-based innovation approaches could implement outcome-based payment adjustments that link new technology add-on payments to demonstrated resistance prevention benefits, establish shared savings programs for antimicrobials that demonstrate stewardship benefits and reduced healthcare utilization, and create population health incentives that significantly reduce healthcare-associated infections or improve antimicrobial stewardship outcomes.

Response: We thank commenters for sharing their recommendations and alternatives to our proposal for our consideration. With respect to comments regarding the potential impact of our proposal, it appears that commenters' concerns may be predicated on the assumption that interested parties would no longer have access to apply for additional payments for these technologies. However, technologies that meet the traditional new technology add-on payment application pathway or OPPS device pass-through payment requirements will still be appropriately considered and approved for additional payments under these pathways.

Comments requesting additional details and clarification on the RAPID coverage pathway are outside of scope of the proposed rule, as a separate proposed procedural notice outlining the RAPID coverage pathway will be published in the **Federal Register**. We refer commenters to the CMS press release announcing the RAPID coverage pathway for additional information.[138]

With respect to comments requesting additional clarity and guidance on the substantial clinical improvement criterion, as previously discussed, we currently make determinations on an application-by-application basis based on clinical factors relevant to a specific technology. As previously stated, the regulations are intentionally broad to provide flexibility for applicants in the evidence required to demonstrate substantial clinical improvement. Commenters have described unique challenges specific to certain categories of technologies, which are taken into consideration during our reviews and during the public notice-and-comment rulemaking. The regulations under § 412.87(b)(1)(iii) provide a non-exhaustive list of published or unpublished information sources from within the United States or elsewhere that may be sufficient to establish substantial clinical improvement. In practice, this has included the various information sources that commenters

[138] CMS and FDA Announce RAPID Coverage Pathway to Accelerate Patient Access to Life-Changing Medical Devices *https://www.cms.gov/newsroom/press-releases/cms-fda-announce-rapid-coverage-pathway-accelerate-patient-access-life-changing-medical-devices.*

have requested we take into consideration, including clinical guidelines, single-arm trial data, case studies, and real-world evidence. As discussed in greater detail earlier in this section, we disagree with commenter recommendations that CMS treat the FDA designations with subsequent FDA marketing authorization as a presumption that the technologies meet the substantial clinical improvement criterion. FDA and CMS reviews are separate and are conducted independently by the two agencies under different statutory and regulatory standards. While earlier engagement with manufacturers may be beneficial, we note that any determinations as to whether the criteria for additional payment are met for any particular technology continue to be subject to CMS's evaluation of the application and the rulemaking process. As discussed earlier, interested parties with further questions regarding Medicare's coverage, coding, and payment processes, and how they can navigate these processes, whether for new technology add-on payments or otherwise, should review the updated resource guide available at: *https://www.cms.gov/medicare/coding-billing/guide-medical-technology-companies-other-interested-parties.* Parties that would like to further discuss questions or concerns with CMS should contact the Pharmaceutical & Technology Ombudsman at *PharmTechOmbud@cms.hhs.gov.*

We also appreciate the alternate methods shared by commenters that they believed would more effectively or efficiently accomplish the goal of aligning payment with value by facilitating payment for innovative, high-value technologies that have demonstrated improved Medicare beneficiary health outcomes. Commenters provided a variety of suggestions as to how the new technology add-on payment and OPPS device pass-through payment programs could be modified to allow for the generation of evidence to support improved outcomes for Medicare beneficiaries through a conditional evidence generation pathway. However, we believe the special payments for new technology should be limited to those new technologies that have been demonstrated to represent a substantial improvement in caring for Medicare beneficiaries, such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology. In addition, we are concerned that providing these additional payments during a conditional evidence generation period could result in Medicare having incentivized the use of technology for which later evidence generated demonstrates that the technology had been less effective than initially thought, or even potentially harmful. There are also practical limitations to developing a conditional evidence generation pathway, as for example, applicable rulemaking for a second year of payment would commence during the first year of additional payment for a technology. As commenters have noted, both new technology add-on payment and OPPS device pass-through payments are time limited, which is required under statute. In addition, consistent with the prospective nature of the IPPS and OPPS, we do not make mid-year changes to payment amounts, and any changes to payment amounts are considered in future rulemaking. We note that commenters also suggested alternatives that were either outside the scope of the statute or our proposal, such as decoupling the newness period from payment for new technology add-on payment, further expanding the alternative pathways, increasing new technology add-on payment percentages, or establishing new MS–DRGs.

While we agree with commenters that suggested that CMS evaluate the substantial similarity criteria under the newness criterion, we do not believe that implementing this suggestion alone as an alternative to our proposal addresses our concerns about the lack of evaluation of the substantial clinical improvement criterion.

Regarding the suggestions to limit eligibility to the alternative pathways for specific categories of technologies, such as those addressing specific conditions or those under specific FDA marketing authorization pathways, we note that while commenters were supportive of their technology of interest, they raised concerns about other technologies that they believed should not be eligible. Taken in their entirety, we believe that these concerns further support that repealing the alternative pathways is the appropriate policy to ensure that CMS is only providing an additional payment for technologies that have evidence of clinical benefit. Furthermore, as we discussed in greater detail earlier, while we understand the importance of facilitating innovation in antimicrobial products, we do not believe that CMS should continue to provide an additional payment for technologies that may not offer substantial clinical improvement over currently available treatments.

We also disagree with commenters that have asserted that a substantial blanket delay is needed to allow companies to adjust their technology development, or that the effect of the proposal would be retroactive. As previously described, when we initially finalized the alternative pathways, we indicated that we would be evaluating the benefits of the alternative pathways and any considerations that may come to light. Since that time, as previously discussed, CMS has also described our concerns with the use of FDA Breakthrough Device designation alone to support Medicare decision-making.[139] [140] We would hope that manufacturers would have been considering the clinical impacts of their technologies with respect to Medicare beneficiaries regardless of the available pathways for additional Medicare payment. However, while we continue to believe that it is appropriate to finalize our policy in this final rule for the reasons discussed, after consideration of the public comments received, we also agree that it would be appropriate to adopt a transitional approach to support the technologies already in advanced stages of commercial development or that may already be commercially available. Therefore, we are finalizing our proposal, with modifications, to grandfather eligibility under the alternative pathway for certain technologies for a limited period of time. Specifically, a new technology that is (1) designated by FDA as a Breakthrough Device or QIDP as of September 30, 2026, and has received marketing authorization for the indication covered by the Breakthrough Device or QIDP designation by May 1, 2028, or (2) approved under FDA's LPAD pathway and used for the indication approved under the LPAD pathway by May 1, 2028, will remain eligible to apply for new technology add-on payment under the alternative pathways for FY 2028 and FY 2029. In addition, a new device that is part of FDA's Breakthrough Devices Program and has received Breakthrough Device designation as of September 30, 2026, and has received marketing authorization as a Breakthrough Device for the indication covered by the Breakthrough Device designation, will remain eligible to apply for OPPS device pass-through payment under the

[139] Final rule to repeal the ''Medicare Coverage of Innovative Technology (MCIT) and Definition of ''Reasonable and Necessary'' final rule (86 FR 62944–62958).

[140] Transitional Coverage for Emerging Technologies (TCET) pathway final notice (89 FR 65724–65754).

alternative pathway for CY 2028 and CY 2029.

Similar to other policy changes made to the new technology add-on payment in prior rulemaking (for example, to move the deadline for FDA marketing authorization from July 1 to May 1 (88 FR 58948 through 58958)), this finalized policy applies prospectively as described. With respect to the commenter that requested that CMS open the FY 2028 new technology add-on payment application before September 30, 2026, we note that regardless of the duration of the application window, any application for FY 2028 new technology add-on payment will be considered under the policy finalized in this final rule.

After consideration of the public comments received, for the reasons discussed previously and in the FY 2027 IPPS/LTCH PPS proposed rule, we are finalizing our proposed policy, with modification to grandfather eligibility under the alternative pathway for certain technologies for a limited period of time.

Specifically, we are finalizing a policy that, unless specifically excepted as described in this section, for all applications received for new technology add-on payments for FY 2028 and subsequent fiscal years, including applications for FDA-designated Breakthrough Devices and QIDPs, or drugs approved under FDA's LPAD pathway, we will evaluate whether the technology is new and not substantially similar to an existing technology, and the technology must demonstrate that it meets the requirements under § 412.87(b) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. That is, beginning with applications received for new technology add-on payments for FY 2028 and subsequent fiscal years, all applicants will need to demonstrate that the technology meets all three of the criteria as specified at § 412.87(b) and described earlier in this section in order to receive the additional payment: (1) the medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. In addition, we are finalizing a limited exception such that the following technologies will remain eligible to apply for new technology add-on payment under the alternative pathway through FY 2029: (1) a new medical device that is part of FDA's Breakthrough Devices Program and has received Breakthrough Device designation as of September 30, 2026, and has received marketing authorization as a Breakthrough Device for the indication covered by the Breakthrough Device designation by May 1, 2028; (2) new medical product that is designated by FDA as a QIDP as of September 30, 2026, and has received marketing authorization for the indication covered by the QIDP designation by May 1, 2028; and (3) a new medical product that is approved under FDA's LPAD pathway and used for the indication approved under the LPAD pathway by May 1, 2028.

Technologies that have previously been approved for new technology add-on payments under the alternative pathway, as well as technologies that have been approved for FY 2027 new technology add-on payments under the alternative pathway in this final rule, will remain eligible for add-on payment under the alternative pathway, subject to the requirements for continued payment, as previously discussed in section II.E.4. of the preamble of this final rule. Consistent with our finalized policy to remove the alternative pathway for certain antimicrobial products currently at § 412.87(d), we are also finalizing the removal of the conditional approval process for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products that does not receive FDA marketing authorization by July 1 prior to the fiscal year for which the applicant applied for new technology add-on payments, as currently reflected at § 412.87(f)(3). Accordingly, beginning with the FY 2028 new technology add-on payment applications, in order to be eligible for consideration for the new technology add on payment for the upcoming fiscal year, all applicants will need to receive FDA marketing authorization by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered, as reflected at § 412.87(f)(2). This includes QIDPs and LPADs that meet the criteria for exception and are eligible to apply under the alternative pathway through FY 2029 as described above.

We are finalizing our amendments to § 412.87, with modifications, to reflect the finalized policy by revising paragraphs § 412.87(c) and (d) and removing subparagraph 412.87(f)(3). We are also finalizing the proposed revisions to the title of paragraph (f) to reflect the modified policy. In connection with these changes, we are also making a technical correction to subparagraph (c)(1) for clarity and consistent with our existing policy, to reflect that the new medical device must receive marketing authorization as a Breakthrough Device for the indication covered by the Breakthrough Device designation by May 1, 2028. We are not finalizing our proposed revisions to subparagraphs (1) and (2) of paragraph (f) due to the modified policy. We are also finalizing the proposed technical correction to the introductory text at § 412.87(d) to restore language that was previously removed in error, with additional revisions to reflect the finalized policy. We are also finalizing as proposed the technical correction to the introductory text at § 412.88(a)(2)(ii)(A) to reference § 412.88(a)(2)(ii)(C), consistent with our policy as finalized in the FY 2025 IPPS/LTCH PPS final rule (*89 FR 69245* through *69252*). We note that we did not receive any public comments with respect to these technical corrections.

Similarly, we are finalizing our policy, with modification, that, unless specifically exempted, all applications received for OPPS device pass-through payment status on or after October 1, 2026, including all applications received through the remainder of the CY 2028 OPPS application cycle ending on March 1, 2027, and applications received for subsequent calendar years will have to demonstrate that the technology met the requirements currently reflected at § 419.66(c)(2)(i).

OPPS device pass-through payment applications submitted as of September 30, 2026, for devices that are part of the FDA's Breakthrough Devices Program and received FDA marketing authorization for the indication covered by the Breakthrough Device designation will be evaluated and could be approved under the alternative pathway, provided that all other criteria have been met. In addition, we are finalizing a limited exception such that the following devices will remain eligible to apply for OPPS device pass-through payment under the alternative pathway through CY 2029: a new device that is part of FDA's Breakthrough Devices Program and has received Breakthrough Device designation as of September 30, 2026, and has received marketing authorization as a Breakthrough Device for the indication covered by the Breakthrough Device designation.

Existing device category codes established based on the approval, either preliminary or via a final determination made in an OPPS/ASC

final rule, including any device category codes established for approved alternative pathway applications received as of September 30, 2026, will continue to be eligible for OPPS device pass-through payment status and would remain in effect for at least 2 years, but no more than 3 years, consistent with § 419.66(g). Previously existing device category codes that were no longer eligible for OPPS device pass-through payment status would remain unchanged.

We are finalizing revisions, with modifications, to paragraph § 419.66(c)(2)(ii) to reflect the finalized policy, effective October 1, 2026. We note that we are making these modifications to address the many comments we received regarding the need for support for technologies already in advanced stages of commercial development or that may already be commercially available.

8. Other Comments

We received several public comments requesting changes to the new technology add-on payment policies such as, but not limited to: changing the payment length or payment methodology, rescinding the requirement for a complete and active FDA marketing authorization request, providing a remedy for technologies impacted by the requirement for a complete and active FDA marketing authorization request, developing a more frequent application cycle, adding guidance regarding the reporting of inpatient drug acquisition costs for products furnished from single-use vials, and creating a new pathway for FDA 510(k)-exempt Class I products to be eligible for new technology add-on payment. We also received comments on technologies that are not under consideration for new technology add-on payments for FY 2027. These comments were outside the scope of the proposals included in the FY 2027 IPPS/LTCH PPS proposed rule and we are therefore not addressing them in this final rule.

III. Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We refer to this factor as the wage index. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the FY 2027 hospital wage index based on the statistical areas appears under section III.B of the preamble of this final rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. CMS collects these data on the Medicare cost report titled ''Hospital and Hospital Health Care Complex Cost Report'', Form CMS–2552–10, Worksheet S–3, Parts II, III, and IV. The information collection is currently approved under OMB control number 0938–0050 and has a September 30, 2028, expiration date. Section 1886(d)(3)(E) of the Act also generally requires that updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The adjustment for FY 2027 is discussed in section II.B of the Addendum to this final rule.

As discussed in section III.I of the preamble of this final rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The budget neutrality adjustment for FY 2027 is discussed in section II.A.4.b of the Addendum to this final rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program to construct an occupational mix adjustment to the wage index. The information collection is currently approved under OMB control number is 0938–0907 and expires on December 31, 2028. A discussion of the occupational mix adjustment that we are applying to the FY 2027 wage index appears under section III.E of the preamble of this final rule.

2. Core-Based Statistical Areas (CBSAs) for the FY 2027 Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. In accordance with section 1886(d)(3)(E) of the Act, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs) (FY 2005 IPPS final rule, 69 FR 49026 through 49032). In the July 16, 2021, **Federal Register** (86 FR 37777), OMB finalized a schedule for future updates based on results of the decennial Census updates to commuting patterns from the American Community Survey (ACS). In accordance with that schedule, on July 21, 2023, OMB released Bulletin No. 23–01. The current statistical areas (which were implemented beginning with FY 2025) are based on revised OMB delineations issued on July 21, 2023, in OMB Bulletin No. 23–01. According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (''the 2020 Standards''), which appeared in the **Federal Register** on July 16, 2021 (86 FR 37770 through 37778), and the application of those standards to Census Bureau population and journey-to-work data (that is, 2020 Decennial Census, ACS, and Census Population Estimates Program data) (we refer to these revised OMB delineations as the ''new OMB delineations'' in this final rule). A copy of OMB Bulletin No. 23–01 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*. We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69253 through 69266) for a full discussion of our adoption of the new OMB delineations for the FY 2025 wage index. For FY 2027, we are continuing to use the new OMB delineations that we adopted beginning with FY 2025 to calculate the area wage indexes and the transition periods, as we discuss below.

3. Codes for Constituent Counties in CBSAs

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying code, a Federal Information Processing Standard (FIPS) county code. The FIPS county codes are maintained by the U.S. Census Bureau. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we adopted a policy to use the FIPS county codes for purposes of crosswalking counties to CBSAs. In addition, in the same rule, we implemented the latest FIPS code updates, which were effective October 1, 2017, beginning with the FY 2018

wage indexes. These updates have been used to calculate the wage indexes in a manner generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963). We refer the reader to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130) for a complete discussion of our adoption of FIPS county codes. For FY 2027, we are continuing to use the FIPS county codes for purposes of crosswalking counties to CBSAs. For FY 2027, Tables 2 and 3 associated with this final rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS website reflect the latest FIPS county code updates.

B. Worksheet S–3 Wage Data for the FY 2027 Wage Index

1. Cost Reporting Periods Beginning in FY 2023 for FY 2027 Wage Index

The FY 2027 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2023 (cost reports with a begin date on or after October 1, 2022 and before October 1, 2023). The FY 2026 wage indexes were based on data from cost reporting periods beginning during FY 2022.

The FY 2027 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty).
- Home office costs and hours.
- Certain contract labor costs and hours including direct patient care (which includes nursing), certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 IPPS final rule with comment period (72 FR 47315 through 47317)).
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590) and modified in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49505 through 49508)) and other deferred compensation costs.

Consistent with the wage index methodology for FY 2026, the wage index for FY 2027 excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to Graduate Medical Education (GME) (teaching physicians and residents), certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The FY 2027 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally Qualified Health Centers (FQHCs), because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, as explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398), salaries, hours, and wage-related costs of Critical Access Hospitals (CAHs) are excluded from the wage index as we believe that removing CAHs from the wage index is prudent policy, given the substantial negative impact these hospitals have on the wage indexes in the areas where they are located and the minimal impact they have on the wage indexes of other areas. We refer the reader to the FY 2004 IPPS final rule (68 FR 45397 through 45398) for a complete discussion regarding the exclusion of CAHs from the wage index. Similar to our treatment of CAHs, as discussed later in this section, we exclude Rural Emergency Hospitals (REHs) from the wage index.

For FY 2020 and subsequent years, other wage-related costs are also excluded from the calculation of the wage index. As discussed in the FY 2019 IPPS/LTCH final rule (83 FR 41365 through 41369), other wage-related costs reported on Worksheet S–3, Part II, Line 18 and Worksheet S–3, Part IV, Line 25 and subscripts, as well as all other wage-related costs, such as contract labor costs, are excluded from the calculation of the wage index.

2. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to Inpatient Rehabilitation Facilities (IRFs), Inpatient Psychiatric Facilities (IPFs), Long-Term Care Hospitals (LTCHs), and for hospital outpatient services. We note, in the calendar year (CY) 2025 End-Stage Renal Disease (ESRD) PPS final rule (89 FR 89097–89116), CMS finalized a new ESRD PPS-specific wage index that is used to adjust ESRD PPS payments for geographic differences in area wages. We refer the reader to the CY 2025 ESRD PPS final rule for complete details regarding ESRD wage index. We further note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

3. Verification of Worksheet S–3 Wage Data

The wage data for the FY 2027 wage index were obtained from Worksheet S–3, Parts II, III and IV of the Medicare cost report, CMS Form 2552–10 (OMB Control Number 0938–0050 with an expiration date September 30, 2028) for cost reporting periods beginning on or after October 1, 2022, and before October 1, 2023. For wage index purposes, we refer to cost reports beginning on or after October 1, 2022, and before October 1, 2023, as the ''FY 2023 cost report,'' the ''FY 2023 wage data,'' or the ''FY 2023 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the FY 2027 wage index includes FY 2023 data submitted to us as of January 21, 2026. For FY 2027, the wage data was not subject to a desk review by the Medicare Administrative Contractors (MACs). CMS performed a review of the wage data to identify and resolve aberrant data, such as analyzing the data from a regional and national level.

We note, in previous fiscal years, we reviewed and evaluated the audited wage data, and the impacts of the COVID–19 PHE on such data. For FY 2027, we have not identified any significant issues with the FY 2023 wage data itself in terms of our review of this data.

For the proposed FY 2027 wage index, we identified and excluded 66 providers with aberrant data that should not be included in the wage index. (We note, in the proposed rule we inadvertently stated that 68 hospitals were identified and excluded with aberrant data instead of 66 hospitals). However, we stated that if data elements for some of these providers are corrected, we intended to include data from those providers in the final FY 2027 wage index. We also adjusted certain aberrant data and included these data in the wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in

accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to transmit any changes to the wage data no later than March 21, 2026. After we issued the proposed rule, for the final FY 2027 wage index, we restored the data of 8 hospitals to the wage index, because their data was either verified or improved, and removed the data of 1 hospital with aberrant data. Thus, 59 hospitals with aberrant data remain excluded from the FY 2027 wage index.

In constructing the proposed FY 2027 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2023, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We stated in the proposed rule (91 FR 19461) that we believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages.

As discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398) and FY 2025 IPPS/LTCH final rule (89 FR 69268), any hospital that is designated as a CAH or REH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation of the wage index.

For the proposed FY 2027 wage index, we removed 7 hospitals that converted to CAH status and 2 hospitals that converted to REH status on or after January 24, 2025, the cut-off date for CAH and REH exclusion from the FY 2026 wage index, and through and including January 23, 2026, the cut-off date for CAH and REH exclusion from the FY 2027 wage index. We did not receive any comments with regard to this proposal, and we are finalizing as proposed to exclude hospitals that converted to CAH and/or REH on or after January 24, 2025 and through and including January 23, 2026 from the wage index calculation. Since we issued the proposed rule, we learned of 7 more hospitals that converted to CAH and/or REH status on or after January 24, 2025, and through and including January 23, 2026. We removed these additional hospitals from the FY 2027 wage index due to their conversion to CAH and/or REH status. In summary, we calculated the FY 2027 wage index using the Worksheet S–3, Parts II and III wage data of 3,006 hospitals.

For the FY 2027 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located using campus full-time equivalent (FTE) percentages as originally finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51591). Table 2, which contains the FY 2027 wage index associated with this final rule (available via the internet on the CMS website), includes separate wage data for the campuses of 26 multicampus hospitals. The following chart lists the multicampus hospitals by CMS certification number (CCN) and the FTE percentages on which the wages and hours of each campus were allotted to their respective labor market areas:

CCN of Main Campus of Multicampus Hospital	Full-Time Equivalent Percentage of Main Campus	CCN of Sub Campus of Multicampus Hospital	Full-Time Equivalent Percentage of Sub Campus	CCN of Second Sub Campus of Multicampus Hospital	Full-Time Equivalent Percentage of Second Sub Campus
050121	0.86	05B121	0.14		
070010	0.85	07B010	0.15		
070022	0.99	07B022	0.01		
100029	0.54	10B029	0.46		
140010	0.81	14B010	0.19		
220074	0.9	22B074	0.1		
310069	0.19	31B069	0.81		
330103	0.71	33B103	0.29		
330195	0.89	33B195	0.11		
330214	0.77	33B214	0.23		
330234	0.8	33B234	0.2		
340040	0.93	34B040	0.07		
340115	0.81	34B115	0.06	34C115	0.13
360020	0.97	36B020	0.03		
390115	0.82	39B115	0.18		
390142	0.83	39B142	0.17		
390307	0.91	39B307	0.09		
420004	0.89	42B004	0.11		
450033	0.96	45B033	0.04		
450330	0.96	45B330	0.04		
460051	0.78	46B051	0.22		
510022	0.94	51B022	0.06		
520009	0.74	52B009	0.26		
520030	0.99	52B030	0.01		
670062	0.87	67B062	0.13		
670116	0.64	67B116	0.36		

We note that, in past years, in Table 2, we have placed a ''B'' to designate the subordinate campus in the fourth position of the hospital CCN. However, for the FY 2019 IPPS/LTCH PPS proposed and final rules and subsequent rules, we have moved the ''B'' to the third position of the CCN. Because all IPPS hospitals have a ''0'' in the third position of the CCN, we believe that placement of the ''B'' in this third position, instead of the ''0'' for the subordinate campus, is the most efficient method of identification and interferes the least with the other variable digits in the CCN. We also note that providers can have an additional second sub campus located in a

different CBSA then the main campus and its other sub campus(es). Therefore, to uniquely identify a second sub campus, we place a ''C'' in the third position of the CCN.

Comment: A commenter urged CMS to consider policies to mitigate abrupt year-to-year wage index reductions when they are driven by historical wage data that may not reflect current labor market conditions. The commenter suggested that such policies could include additional transition protections, smoothing methodologies, or other approaches that better align Medicare payment adjustments with contemporary labor costs. The commenter expressed concern that the FY 2027 wage index methodology does not adequately reflect current labor market conditions and could result in significant payment reductions despite continued growth in hospital workforce costs. Although the commenter acknowledged that CMS's existing 5-percent cap on annual hospital-level wage index decreases provides important protection against abrupt payment disruptions, the commenter asserted that additional refinements are warranted to ensure that Medicare payments more accurately reflect hospitals' actual labor expenses and workforce challenges. Specifically, the commenter recommended that CMS do all of the following:

- Adopt a multi-year rolling average of wage data to reduce year-to-year volatility.
- Incorporate more current wage data into the wage index calculation.
- Provide additional transition relief for states experiencing unusually large aggregate wage index declines.
- Evaluate whether rapid population growth and resulting workforce demand should be reflected in the wage index methodology.
- Review the effects of occupational mix adjustments and other wage index policies to ensure they accurately reflect regional labor costs.

The commenter stated that these changes would improve the stability, predictability, and accuracy of the wage index while preserving budget neutrality and better aligning Medicare payments with hospitals' actual workforce costs.

Response: We thank the commenter for their comments. Under the current annual wage index timeline, consistent with the IPPS rate-setting processes, our policy has generally been to use the most current data and information available, which typically reflects a 4-year lag (for example, the FY 2027 wage index is based on FY 2023 cost report data). Since the inception of the IPPS, the wage index has been subject to this annual review process. As noted above, for development of the FY 2027 wage index, the wage data were not subject to a desk review by the MACs. However, CMS conducted its own review of the data for the development of the FY 2027 wage index.

With regard to the use a multi year rolling average and states experiencing unusually large aggregate wage index declines, as discussed in the FY 2023 IPPS/LTCH PPS Final Rule discussion (87 FR 49018 through 49019), we believe a 5 percent annual cap on wage index decreases effectively addresses instability.

With regard to the use of more recent wage data and to evaluate whether rapid population growth and resulting workforce demand should be reflected in the wage index methodology, as discussed below, we have a multistep, 15-month process for the review and correction of the hospital wage data used to develop the IPPS wage index for the upcoming fiscal year. We will consider, through future rulemaking, modifications to the 15-month process that may allow for the use of more recent wage data. We also note that the commenter did not provide any data or evaluation of potential effects of rapid population growth and resulting workforce demand on the wage index methodology or how such factors could be reflected in the wage index methodology.

With regard to the effects of the occupational mix data and other wage index policies, the commenter did not provide any evidence or data to demonstrate the effects of these adjustments and their effect on year-to-year changes to the wage index. We welcome additional data from the commenter to demonstrate the effects of these adjustments and their effect on year to year changes to the wage index.

4. Process for Requests for Wage Index Data Corrections

a. Process for Hospitals To Request Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files for the proposed FY 2027 wage index were made available on May 23, 2025, through the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/fy-2027-wage-index-home-page.*

On January 30, 2026, we posted a public use file (PUF) at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/fy-2027-wage-index-home-page* containing FY 2027 wage index data available as of January 30, 2026. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October 1, 2022, through September 30, 2023; that is, FY 2023 wage data), a tab with the occupational mix data (which includes data from the CY 2022 occupational mix survey, Form CMS–10079), a tab containing the Worksheet S–3 wage data of hospitals deleted from the January 30, 2026 wage data PUF, and a tab containing the CY 2022 occupational mix data of the hospitals deleted from the January 30, 2026 occupational mix PUF. In a memorandum dated January 22, 2026, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 30, 2026, wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2027 Hospital Wage Index Development Timetable available at *https://www.cms.gov/files/document/fy-2027-hospital-wage-index-development-time-table.pdf.*

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on the CMS website that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule.

In a memorandum dated April 16, 2025, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the preliminary wage index data files and the CY 2022 occupational mix survey data files posted on May 23, 2025, and the process and timeframe for requesting revisions.

If a hospital wished to request a change to its data as shown in the May 23, 2025, preliminary wage data files and occupational mix data files, the hospital had to submit corrections along with complete, detailed supporting documentation to its MAC so that the MAC received them by September 2, 2025. Hospitals were notified of these deadlines and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the internet, through the letters sent to them by their MACs.

November 14, 2025, was the date by when MACs were required to transmit revised wage index data files and occupational mix data files to CMS. CMS published the wage index PUFs that included hospitals' revised wage index data on January 30, 2026. Hospitals had until February 17, 2026,

to submit requests to the MACs to correct errors in the January 30, 2026, PUF due to CMS or MAC mishandling of the wage index data, or to revise adjustments to their wage index data as included in the January 30, 2026, PUF. Hospitals also were required to submit sufficient documentation to support their requests. Hospitals' requests and supporting documentation must have been received by the MAC by the February deadline (that is, by February 17, 2026, for the FY 2027 wage index).

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 20, 2026. Under our current policy as adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38153), the deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's handling of wage data on any basis (including a policy, factual, or other dispute) was April 3, 2026. Data that were incorrect in the preliminary or January 30, 2026, wage index data PUFs, but for which no correction request was received by the February 17, 2026, deadline, are not considered for correction at this stage. In addition, April 3, 2026, was the deadline for hospitals to dispute data corrections made by CMS of which the hospital was notified after the January 30, 2026, PUF and at least 14 calendar days prior to April 3, 2026 (that is, by March 20, 2026), that do not arise from a hospital's request for revisions. The hospital's request and supporting documentation must be received by CMS (and a copy received by the MAC) by the April deadline (that is, by April 3, 2026, for the FY 2027 wage index). We refer readers to the FY 2027 Hospital Wage Index Development Timetable for complete details.

Hospitals were given the opportunity to examine Table 2 associated with the proposed rule, which is listed in section VI of the Addendum to the proposed rule and available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/fy-2027-wage-index-home-page.* Table 2 associated with the proposed rule contained each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the proposed FY 2027 wage index, which was constructed from FY 2023 data. We noted in the proposed rule that the proposed hospital average hourly wages shown in Table 2 only reflected changes made to a hospital's data that were transmitted to CMS by late January 2026.

We posted the final wage index data PUFs on April 30, 2026, on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/fy-2027-wage-index-home-page.* The April 2026 PUFs are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process (the process for disputing revisions submitted to CMS by the MACs by March 20, 2026, and the process for disputing data corrections made by CMS that did not arise from a hospital's request for wage data revisions as discussed earlier), as previously described.

After the release of the April 2026 wage index data PUFs, changes to the wage and occupational mix data can only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 20, 2026.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 30, 2026, wage index PUFs.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2026 final wage index data PUFs, a hospital believes that its wage or occupational mix data are incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital is given the opportunity to notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital was required to send its request to CMS and to the MAC so that it was received no later than May 29, 2026. May 29, 2026, was also the deadline for hospitals to dispute data corrections made by CMS of which the hospital was notified on or after 13 calendar days prior to April 3, 2026 (that is, March 21, 2026), and at least 14 calendar days prior to May 29, 2026 (that is, May 15, 2026), that did not arise from a hospital's request for revisions. (Data corrections made by CMS of which a hospital is notified on or after 13 calendar days prior to May 29, 2026 (that is, May 16, 2026), may be appealed to the Provider Reimbursement Review Board (PRRB)). In accordance with the FY 2027 Hospital Wage Index Development Timetable posted on the CMS website at *https://www.cms.gov/files/document/fy-2027-hospital-wage-index-development-time-table.pdf,* the May appeals were required to be submitted to CMS through an online submission process. We refer readers to the FY 2027 Hospital Wage Index Development Timetable for complete details.

Verified corrections to the wage index data received timely (that is, by May 29, 2026) by CMS and the MACs were incorporated into the final FY 2027 wage index, which will be effective October 1, 2026.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2027 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines as previously set forth (requiring requests to MACs by the specified date in February and, where such requests are unsuccessful, requests for intervention by CMS by the specified date in April) will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections. As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156), this policy also applies to a hospital disputing corrections made by CMS that do not arise from a hospital's request for a wage index data revision. That is, a hospital disputing an adjustment made by CMS that did not arise from a hospital's request for a wage index data revision is required to request a correction by the first applicable deadline. Hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to changes.

Again, we believe the wage index data correction process described earlier

provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals had access to the final wage index data PUFs by late April 2026, they had an opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2027 wage index by August 2026, and the implementation of the FY 2027 wage index on October 1, 2026. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 29, 2026, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with § 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) the MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 29, 2026, for the FY 2027 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS website prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised § 412.64(k)(2) to specify that, effective October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) the MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 29, 2026, deadline for the FY 2027 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 29, 2026 deadline for the FY 2027 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; it can only be used for the current Federal fiscal year. In situations where our policies will allow midyear corrections other than those specified in § 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

b. Process for Data Corrections by CMS After the January 30, 2026, Public Use File (PUF)

The process set forth with the wage index timetable discussed in section III.B.4 of the preamble of this final rule allows hospitals to request corrections to their wage index data within prescribed timeframes. In addition to hospitals' opportunity to request corrections of wage index data errors or MACs' mishandling of data, CMS has the authority under section 1886(d)(3)(E) of the Act to make corrections to hospital wage index and occupational mix data to ensure the accuracy of the wage index. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56914), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. We believe that, under section 1886(d)(3)(E) of the Act, we have discretion to make corrections to hospitals' data to help ensure that the costs attributable to wages and wage-related costs in fact accurately reflect the relative hospital wage level in the hospitals' geographic areas.

We have a multistep, 15-month process for the review and correction of the hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year. Since the origin of the IPPS, the wage index has been subject to its own annual review process. As noted above, for the development of the FY 2027 wage index, the wage data was not subject to a desk review by the MACs. As in past years, CMS conducted its own review of the data and, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. This ongoing communication with hospitals about their wage data may result in the discovery by CMS of additional items that were reported incorrectly or other data errors, even after the posting of the January 30, 2026, PUF, and throughout the remainder of the wage index development process. In addition, the fact that CMS analyzes the data from a regional and even national level, can facilitate additional editing of the data. In these occasional instances, an error may be of sufficient magnitude that the wage index of an entire CBSA is affected. Accordingly, CMS uses its authority to ensure that the wage index accurately reflects the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, by continuing to make corrections to hospital wage data upon discovering incorrect wage data, distinct from instances in which hospitals request data revisions.

We note that CMS corrects errors to hospital wage data as appropriate, regardless of whether that correction will raise or lower a hospital's average hourly wage. For example, as discussed in section III.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41364), in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with

policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). Furthermore, for example, if a positive adjustment resulting from a prior year's wage index appeal of a hospital's wage-related costs such as pension costs was not incorporated in the data, CMS can correct the data error, and the hospital's average hourly wage will likely increase as a result.

While we maintain CMS' authority to conduct additional review and make resulting corrections at any time during the wage index development process, in accordance with the policy finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156) and as first implemented with the FY 2019 wage index (83 FR 41389), hospitals are able to request further review of a correction made by CMS that did not arise from a hospital's request for a wage index data correction. Instances where CMS makes a correction to a hospital's data after the January 30, 2026, PUF based on a different understanding than the hospital about certain reported costs, for example, could potentially be resolved using this process before the final wage index is calculated. We believe this process and the timeline for requesting review of such corrections (as described earlier and in the FY 2018 IPPS/LTCH PPS final rule) promote additional transparency in instances where CMS makes data corrections after the January 30, 2026 PUF and provide opportunities for hospitals to request further review of CMS changes in time for the most accurate data to be reflected in the final wage index calculations. These additional appeals opportunities are described earlier and in the FY 2027 Hospital Wage Index Development Timetable, as well as in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156).

C. Method for Computing the FY 2027 Unadjusted Wage Index

The method used to compute the FY 2027 wage index without an occupational mix adjustment follows the same methodology that we used to compute the wage indexes without an occupational mix adjustment in the FY 2021 IPPS/LTCH PPS final rule (see 85 FR 58758 through 58761), and we did not propose any changes to this methodology. We have restated our methodology in this preamble section of this final rule.

Step 1.—We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period relevant to the wage index (in this case, for FY 2027, these were data from cost reports for cost reporting periods beginning on or after October 1, 2022, and before October 1, 2023). In addition, we included data from hospitals that had cost reporting periods beginning prior to the October 1, 2022, begin date and extending into FY 2023 but that did not have any cost report with a begin date on or after October 1, 2022, and before October 1, 2023. We include this data because no other data from these hospitals will be available for the cost reporting period as previously described, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as data applicable to the fiscal year wage data being used to compute the wage index for those hospitals. We note that, if a hospital had more than one cost reporting period beginning during FY 2023 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2022, and before October 1, 2023), we include wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2.—Salaries.—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. (We note that, beginning with FY 2008 (72 FR 47315), we included what were then Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II of CMS Form 2552–96 for overhead services in the wage index. Currently, these lines are lines 28, 33, and 35 on CMS Form 2552–10. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation is to compute a ''revised'' Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 28, 33, and 35. In calculating a hospital's Net Salaries (we note that we previously used the term ''average'' salaries in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), but we now use the term ''net'' salaries) plus wage-related costs, we first compute the following: Subtract from Line 1 (total salaries) the GME and CRNA costs reported on CMS Form 2552–10, Lines 2, 4.01, 7, and 7.01, the Part B salaries reported on Lines 3, 5 and 6, home office salaries reported on Line 8, and exclude salaries reported on Lines 9 and 10 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. Therefore, the formula for Net Salaries (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)).

To determine Total Salaries plus Wage-Related Costs, we add to the Net Salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 11, 12 and 13), home office salaries and wage-related costs reported by the hospital on Lines 14.01, 14.02, 15.01 and 15.02, and nonexcluded area wage-related costs (Lines 17, 22, 25.50, 25.51, and 25.52). We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 22) are excluded if no corresponding salaries are reported for those employees on Line 4.

As noted above, the FY 2027 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2023 (cost reports with a begin date on or after October 1, 2022 and before October 1, 2023). Per the instructions in Section 4005.2, Part II, Hospital Wage Index Information, of the Provider Reimbursement Manual, for cost reporting periods on or after October 1, 2015 and before October 1, 2022, hospitals reported salaries and hours for Home Office (and related organizations) Physician Part A—Administrative direct employees and employees under contract on Worksheet S3, Part II, Line 15.

Per the instructions in Section 4005.2, Part II, Hospital Wage Index Information, of the Provider Reimbursement Manual, for cost reporting periods on or after October 1, 2022, line 15 has been split into two lines with hospitals reporting salaries and hours for Home Office (and related organizations) Physician Part A—Administrative direct employees on Line 15.01 and salaries and hours for Home Office (and related organizations) Physicians Part A—Administrative under contract on Line 15.02. Since the FY 2027 wage index uses cost reports with a begin date in FY 2023, we

proposed to include Lines 15.01 and 15.02 in the calculation of the FY 2027 wage index and future fiscal years.

In reviewing the wage data used for FY 2027, approximately 61 hospitals reported salaries and hours on Line 15 instead of Lines 15.01 and 15.02. Because this is the first year we are using Lines 15.01 and 15.02 and hospitals are still adjusting to this reporting change, for FY 2027, we proposed to use Line 15 in the wage index calculation in addition to lines 15.01 and 15.02. We stated in the proposed rule that we believe using Line 15 for the FY 2027 wage index will minimize disparities in the FY 2027 wage index by ensuring that the data informing the calculation are applied uniformly. We further proposed to use Lines 15.01 and 15.02 instead of Line 15 for future fiscal years.

We did not receive any comments on these proposals, and we are finalizing as proposed for FY 2027 to use Line 15 in the wage index calculation in addition to lines 15.01 and 15.02. We also are finalizing as proposed to use Lines 15.01 and 15.02 instead of Line 15 for future fiscal years.

The formula for Total Salaries plus Wage-Related Costs (from Worksheet S–3, Part II) for FY 2027 is the following: ((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + Line 14.02 + Line 15 + Line 15.01 + Line 15.02) + (Line 17 + Line 22 + Line 25.50 + Line 25.51 + Line 25.52).

Step 3.—Hours.—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2. As noted above, for FY 2027 we are finalizing as proposed to include Lines 15, 15.01 and Line 15.02 in this calculation. We also are finalizing as proposed to use Lines 15.01 and 15.02 instead of Line 15 for future fiscal years.

The formula for Total Hours (from Worksheet S–3, Part II) for FY 2027 is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15 + Line 15.01 + Line 15.02).

Step 4.—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the ''excluded rate'', which is the ratio of excluded area hours to Revised Total Hours (from Worksheet S–3, Part II) with the following formula: (Line 9 + Line 10)/(Line 1 + Line 28 + Line 33 + Line 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, and 8 and Lines 26 through 43). We then compute the amounts of overhead salaries and hours to be allocated to the excluded areas by multiplying the previously discussed ratio by the total overhead salaries and hours reported on Lines 26 through 43 of Worksheet S–3, Part II. Next, we compute the amounts of overhead wage-related costs to be allocated to the excluded areas using three steps:

- We determine the ''overhead rate'' (from Worksheet S–3, Part II), which is the ratio of overhead hours (Lines 26 through 43 minus the sum of Lines 28, 33, and 35) to revised hours excluding the sum of lines 28, 33, and 35 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, 9, 10, 28, 33, and 35). We note that, for the FY 2008 and subsequent wage index calculations, we have been excluding the overhead contract labor (Lines 28, 33, and 35) from the determination of the ratio of overhead hours to revised hours because hospitals typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 28, 33, and 35 require that associated wage-related costs be combined with wages on the respective contract labor lines. The formula for the Overhead Rate (from Worksheet S–3, Part II) is the following: (Lines 26 through 43 − Lines 28, 33 and 35)/ ((((Line 1 + Lines 28, 33, 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, and 26 through 43)) − (Lines 9 and 10)) + (Lines 26 through 43 − Lines 28, 33, and 35)).
- We compute overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 17, 22, 25.50, 25.51, and 25.52.
- We multiply the computed overhead wage-related costs by the previously described excluded area hours ratio.

Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5.—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2022, through April 15, 2024, for private industry hospital workers from data obtained from the Bureau of Labor Statistics' (BLS') Office of Compensation and Working Conditions. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringe benefits) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we did not propose to make any changes to the usage of the ECI for FY 2027. The factors used to adjust the hospital's data are based on the midpoint of the cost reporting period, as indicated in this final rule.

Step 6.—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B), 1886(d)(8)(E), or 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7.—We divide the total adjusted salaries plus wage-related costs obtained under Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8.—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the Nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage.

Step 9.—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10.—For each urban labor market area for which we do not have any hospital wage data (either because there are no IPPS hospitals in that labor market area, or there are IPPS hospitals in that area but their data are either too new to be reflected in the current year's wage index calculation, or their data are aberrant and are deleted from the wage

index), we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42305) that, for FY 2020 and subsequent years' wage index calculations, such CBSAs' wage index will be equal to total urban salaries plus wage-related costs (from Step 5) in the State, divided by the total urban hours (from Step 4) in the State, divided by the national average hourly wage from Step 8 (see 84 FR 42305 and 42306). We believe that, in the absence of wage data for an urban labor market area, it is reasonable to use a statewide urban average, which is based on actual, acceptable wage data of hospitals in that State, rather than impute some other type of value using a different methodology. For calculation of the FY 2027 wage index, we note there is one urban CBSA for which we do not have IPPS hospital wage data. In Table 3 (which is available via the internet on the CMS website and contains the area wage indexes), we include a footnote to indicate to which CBSA this policy applies. This CBSA's wage index is calculated as described, based on the FY 2020 IPPS/LTCH PPS final rule methodology (84 FR 42305). Under this step, we also apply our policy with regard to how dollar amounts, hours, and other numerical values in the wage index calculations are rounded.

We refer readers to section II of Appendix B of this final rule for the policy regarding rural areas that do not have IPPS hospitals.

Step 11.—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. The areas affected by this provision are identified in Table 2 listed in section VI of the Addendum to this final rule and available via the internet on the CMS website.

The following is our policy with regard to rounding of the wage data (dollar amounts, hours, and other numerical values) in the calculation of the unadjusted and adjusted wage index, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42306). For data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we use such data ''as is,'' and do not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round the dollar amounts to 2 decimals. For any hour amounts within the wage index calculations, we round such hour amounts to the nearest whole number. For any numbers not expressed as dollars or hours within the wage index calculations, which could include ratios, percentages, or inflation factors, we round such numbers to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the ECI for compensation for each 30-day increment from October 14, 2022, through April 15, 2024, for private industry hospital workers from the BLS' Office of Compensation and Working Conditions data. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we did not propose to make any changes to the usage of the ECI for FY 2027. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment Factor
10/14/2022	11/15/2022	**1.06254**
11/14/2022	12/15/2022	**1.05809**
12/14/2022	01/15/2023	**1.05376**
01/14/2023	02/15/2023	**1.04954**
02/14/2023	03/15/2023	**1.04543**
03/14/2023	04/15/2023	**1.04142**
04/14/2023	05/15/2023	**1.03752**
05/14/2023	06/15/2023	**1.03371**
06/14/2023	07/15/2023	**1.02991**
07/14/2023	08/15/2023	**1.02603**
08/14/2023	09/15/2023	**1.02206**
09/14/2023	10/15/2023	**1.01813**
10/14/2023	11/15/2023	**1.01436**
11/14/2023	12/15/2023	**1.01076**
12/14/2023	01/15/2024	**1.00721**
01/14/2024	02/15/2024	**1.00363**
02/14/2024	03/15/2024	**1.00000**
03/14/2024	04/15/2024	**0.99641**

For example, the midpoint of a cost reporting period beginning January 1, 2023, and ending December 31, 2023, is June 30, 2023. An adjustment factor of 1.02991 was applied to the wages of a hospital with such a cost reporting period.

Previously, we would also provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR

56915), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico specific wage index that was applied to the labor-related share of the Puerto Rico-specific standardized amount. Section 601 of Division O, Title VI (section 601) of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915 through 56916), because Puerto Rico hospitals are no longer paid with a Puerto Rico specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) and the national wage index, which is applied to the national labor-related share of the national standardized amount. Therefore, for FY 2027, there is no Puerto Rico-specific overall average hourly wage or wage index.

Based on the previously described methodology, the final FY 2027 unadjusted national average hourly wage is the following:

Final FY 2027 Unadjusted National Average Hourly Wage	$58.89

D. Occupational Mix Adjustment to the FY 2027 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Use of 2022 Medicare Wage Index Occupational Mix Survey for the FY 2027 Wage Index

Section 304(c) of Appendix F, Title III of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program and to measure the earnings and paid hours of employment for such hospitals by occupational category. As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69275 through 69278), we collected data in 2022 to compute the occupational mix adjustment for the FY 2025, FY 2026, and FY 2027 wage indexes.

The FY 2027 occupational mix adjustment is based on a calendar year (CY) 2022 survey. Hospitals were required to submit their completed 2022 surveys (Form CMS–10079, OMB Control Number 0938–0907, expiration date December 31, 2028) to their MACs by July 1, 2023. The preliminary, unaudited CY 2022 survey data were posted on the CMS website on July 12, 2023.

2. Calculation of the Occupational Mix Adjustment for FY 2027

For FY 2027, we proposed to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the FY 2027 wage index. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308), we modified our methodology with regard to how dollar amounts, hours, and other numerical values in the unadjusted and adjusted wage index calculation are rounded, to ensure consistency in the calculation. According to the policy finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308 and 42309), for data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we continue to use these data ''as is'', and not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round such dollar amounts to 2 decimals. We round any hour amounts within the wage index calculations to the nearest whole number. We round any numbers not expressed as dollars or hours in the wage index calculations, which could include ratios, percentages, or inflation factors, to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

Similar to the method we use for the calculation of the wage index without occupational mix, salaries and hours for a multicampus hospital are allotted among the different labor market areas where its campuses are located. Table 2 associated with this final rule (which is available via the internet on the CMS website), which contains the FY 2027 occupational mix adjusted wage index, includes separate wage data for the campuses of multicampus hospitals. We refer readers to section III.C of the preamble of this final rule for a chart listing the multicampus hospitals and the FTE percentages used to allot their occupational mix data.

Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that will be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the FY 2027 wage index. For the proposed FY 2027 wage index, we used the Worksheet S–3, Parts II and III wage data of 3,006 hospitals, and we used the occupational mix surveys of 2,922 hospitals for which we also had Worksheet S–3 wage data, which represented a ''response'' rate of 97 percent (2,922/3,006). For the proposed FY 2027 wage index, we applied proxy

data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the proposed FY 2027 occupational mix adjusted national average hourly wage was $58.82.

We did not receive any comments on our proposed calculation of the occupational mix adjustment to the FY 2027 wage index. Thus, for the reasons discussed in this final rule and in the FY 2027 IPPS/LTCH PPS proposed rule, we are finalizing our proposal without modification to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index and to apply the occupational mix adjustment to 100 percent of the FY 2027 wage index.

For the final FY 2027 wage index, we are using the Worksheet S–3, Parts II and III wage data of 3,006 hospitals and the occupational mix surveys of 2,921 hospitals of those hospitals for which we also had Worksheet S–3 wage data, or 97 percent (2,921/3,006). For the final FY 2027 wage index, we are applying proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the final FY 2027 occupational mix adjusted national average hourly wage is the following:

Final FY 2027 Occupational Mix Adjusted National Average Hourly Wage	$58.83

3. Occupational Mix Adjustment and the FY 2027 Occupational Mix Adjusted Wage Index

As discussed in section III.E of the preamble of this final rule, for FY 2027, we are applying the occupational mix adjustment to 100 percent of the FY 2027 wage index. We calculated the occupational mix adjustment using data from the 2022 occupational mix survey, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582–51586).

Based on the 2022 occupational mix survey data, the FY 2027 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

OCCUPATIONAL MIX NURSING SUBCATEGORY	AVERAGE HOURLY WAGE
National RN	$60.42
National LPN and Surgical Technician	$35.01
National Nurse Aide, Orderly, and Attendant	$23.54
National Medical Assistant	$23.13
National Nurse Category	$50.06

The national average hourly wage for the entire nurse category is computed in Step 5 of the occupational mix calculation. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2022 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) the following:

National Percentage of Hospital Employees in the Nurse Category	45%
National Percentage of Hospital Employees in the All Other Occupations Category	55%

4. 2025 Medicare Wage Index Occupational Mix Survey Data for Use Beginning With the FY 2028 Wage Index

A new measurement of occupational mix is required for FY 2028. As such, the FY 2028 occupational mix adjustment is based on a new calendar year (CY) 2025 survey. The CY 2025 survey (Form CMS–10079, OMB Control Number 0938–0907, expiration date December 31, 2028) received OMB approval on December 30, 2025. The final CY 2025 Occupational Mix Survey Hospital Reporting Form is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/2025-occupational-mix-survey-hospital-reporting-form-cms-10079-wage-index-beginning-fy-2028.* Hospitals were required to submit their completed 2025 surveys to their MACs by June 30, 2026. The preliminary, unaudited CY 2025 survey data was posted on the CMS website in mid-July 2026. As with the Worksheet S–3, Parts II and III cost report wage data, CMS and the MACs may revise or verify data elements in hospitals' occupational mix surveys as part of the FY 2028 wage index development process.

E. Hospital Redesignations and Reclassifications

The following sections III.E.1 through III.E.4 discuss revisions to the wage index based on hospital redesignations and reclassifications. Specifically, hospitals may have their geographic area changed for wage index payment by applying for urban to rural reclassification under section 1886(d)(8)(E) of the Act (implemented at § 412.103), reclassification by the Medicare Geographic Classification Review Board (MGCRB) under section 1886(d)(10) of the Act, Lugar status redesignations under section

1886(d)(8)(B) of the Act, or a combination of the foregoing.

1. Urban to Rural Reclassification Under Section 1886(d)(8)(E) of the Act, Implemented at § 412.103

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at § 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act (such hospitals are referred to herein as ''§ 412.103 hospitals''). The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals. We refer readers to the FY 2024 IPPS/LTCH final rule (88 FR 58971 through 58977) for a review of our policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49004) to calculate the rural floor with the wage data of urban hospitals reclassifying to rural areas under § 412.103, and discussion of our modification to the calculation of the rural wage index and its implications for the rural floor.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41369 through 41374), we codified certain policies regarding multicampus hospitals in the regulations at §§ 412.92, 412.96, 412.103, and 412.108. We stated that reclassifications from urban to rural under § 412.103 apply to the entire hospital (that is, the main campus and its remote location(s)). We also stated that a main campus of a hospital cannot obtain Sole Community Hospital (SCH), Rural Referral Center (RRC), or Medicare Dependent Hospital (MDH) status, or rural reclassification under § 412.103, independently or separately from its remote location(s), and vice versa. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49012 and 49013), we added § 412.103(a)(8) to clarify that for a multicampus hospital, approved rural reclassification status applies to the main campus and any remote location located in an urban area, including a main campus or any remote location deemed urban under section 1886(d)(8)(B) of the Act. If a remote location of a hospital is located in a different CBSA than the main campus of the hospital, it is CMS' longstanding policy to assign that remote location a wage index based on its own geographic area to comply with the statutory requirement to adjust for geographic differences in hospital wage levels (section 1886(d)(3)(E) of the Act). Hospitals are required to identify and allocate wages and hours based on FTEs for remote locations located in different CBSAs on Worksheet S–2, Part I, Lines 165 and 166 of form CMS–2552–10. In calculating wage index values, CMS identifies the allocated wage data for these remote locations in Table 2 with a ''B'' in the 3rd position of the CCN. These remote locations of hospitals with § 412.103 rural reclassification status in a different CBSA are identified in Table 2, and hospitals should evaluate potential wage index outcomes for their remote location(s) when terminating MGCRB reclassification, or canceling § 412.103 rural reclassification status.

As discussed at § 412.103(f), the duration of an approved rural reclassification remains in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved. If a hospital located in an urban area was approved for a rural reclassification under § 412.103(a)(1), that reclassification will no longer be valid if the hospital is no longer located within a rural census tract of an MSA as determined by the Federal Office of Rural Health Policy (FORHP) of the Health Resources and Services Administration (HRSA). Therefore, we encourage all hospitals and CAHs with active rural reclassifications under section 1886(d)(8)(E) of the Act to review their original reclassification application and determine whether the reclassification status will still apply.

Finally, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69280), CMS finalized a policy regarding terminated or ''tied-out'' hospitals, to address our concerns regarding the impacts these hospitals would have on rural wage index values. Specifically, we finalized a policy that § 412.103 reclassifications would be considered cancelled for the purposes of calculating the area wage index for any hospital with a CCN listed as terminated or ''tied-out'' as of the date that the hospital ceased to operate with an active CCN. We stated that we will obtain and review the best available CCN termination status lists as of the § 412.103(b)(6) ''lock-in'' date (60 days after the proposed rule for the FY is displayed in the **Federal Register**), consistent with the wage index development timeline. The lock-in date is used to determine whether a hospital has been approved for § 412.103 reclassification in time for that status to be included in the upcoming year's wage index development.

We noted that our policy to consider § 412.103 reclassifications cancelled for the purposes of calculating area wage index for any hospital with a CCN listed as terminated or ''tied-out'' is not intended to alter or affect the qualification for Critical Access Hospital (CAH), Sole Community Hospital (SCH), or Rural Emergency Hospital (REH) statuses or to have other effects unrelated to hospital wage index calculations. The rural reclassification status will remain in effect for any period that the original PPS hospital remains in operation with an active CCN. For REH qualification requirement purposes, this will include the date of enactment of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), which was December 27, 2020.

2. General Policies and Effects of MGCRB Reclassification and Treatment of Dual Reclassified Hospitals

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions not later than the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in § 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations and the policies for the effects of hospitals' reclassifications and redesignations on the wage index are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596).

In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under § 412.103. In the FY 2020 IPPS/

LTCH PPS final rule (84 FR 42332 through 42336), we finalized a policy to exclude the wage data of urban hospitals reclassifying to rural areas under § 412.103 from the calculation of the rural floor, but we reverted to the pre-FY 2020 policy in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49002 through 49004). Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of § 412.103.

On April 21, 2016, we published an interim final rule with comment period (IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 urban to rural and MGCRB reclassifications. Prior to this amendment to the regulations, hospitals had to choose between a § 412.103 urban to rural reclassification which confers other rural benefits (Medicare provisions such as payments to disproportionate share hospitals (DSHs), and non-Medicare payment provisions, such as the 340B Drug Pricing Program administered by HRSA) besides the wage index under section 1886(d) of the Act or a reclassification under the MGCRB to solely increase its wage index. Under the amended regulations, a hospital that has an active MGCRB reclassification and is then approved for an urban to rural reclassification under § 412.103 will not lose its MGCRB reclassification. Additionally, a hospital is no longer required to cancel its § 412.103 reclassification in order to be approved for an MGCRB reclassification. By amending the regulations and allowing a hospital to pursue reclassification under the MGCRB while also maintaining a rural reclassification under § 412.103, hospitals are accorded the benefits of a § 412.103 urban to rural reclassification and the ability to use distance and average hourly wage criteria designated for rural hospitals to obtain a higher wage index value through an MGCRB reclassification. We note, for wage index calculation and payment purposes, when there is both a § 412.103 reclassification and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes.

Prior to FY 2024, we excluded hospitals with § 412.103 urban to rural redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. That is, if an application for urban reclassification through the MGCRB is approved and is not terminated by the hospital within the established timelines, we considered the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We refer readers to the April 21, 2016, IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922 through 56930), in which we finalized the April 21, 2016, IFC, for a full discussion of the effect of simultaneous reclassifications under both the § 412.103 and the MGCRB processes on wage index calculations. For FY 2024 and subsequent years, we refer readers to the FY 2024 IPPS/LTCH PPS final rule for discussion of our policy to include hospitals with a § 412.103 reclassification that also have an active MGCRB reclassification to another area in the calculation of the reclassified rural wage index (88 FR 58971 through 58977).

3. MGCRB Reclassification Issues for FY 2027

a. FY 2027 Reclassification Application Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through § 412.280. There are 501 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2027. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2027, hospitals reclassified beginning in FY 2025 or FY 2026 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 284 hospitals approved for wage index reclassifications in FY 2025 that will continue for FY 2027, and 333 hospitals approved for wage index reclassifications in FY 2026 that will continue for FY 2027. Of all the hospitals approved for reclassification for FY 2025, FY 2026, and FY 2027, 1,118 hospitals (approximately 35 percent of IPPS hospitals) are in a MGCRB reclassification status for FY 2027 (with 302 of these hospitals reclassified back to their urban geographic location). We refer readers to section III.F.3.b of the preamble of this final rule for information on the effects of adopting the new OMB delineations on reclassified hospitals.

Under the regulations at § 412.273, hospitals that have applied to be reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB any time before the MGCRB issues a decision on the application. Hospitals are also permitted to terminate an approved reclassification after the MGCRB issues a decision, provided the request for termination is received by the MGCRB within 45 days of the date of filing for public inspection of the proposed rule at the website of the Office of the Federal Register, or within 7 calendar days of receiving a decision of the Administrator's in accordance with § 412.273, whichever is later.

For information about the current process for withdrawing a 3-year MGCRB reclassification application, terminating an approved 3-year MGCRB reclassification, or canceling a previous termination of a 3-year reclassification for wage index purposes, we refer readers to § 412.273, as well as section III.E.3.b of the preamble of this final rule, the FY 2002 IPPS final rule (66 FR 39887 through 39888), and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations was included in the FY 2008 IPPS final rule (72 FR 47333), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148 through 38150), and the FY 2026 IPPS/LTCH PPS final rule (90 FR 36847 through 36848).

Applications for FY 2028 reclassifications are due to the MGCRB by September 1, 2026. This is also the current deadline for canceling a previous wage index reclassification termination (reinstating a reclassification) under § 412.273(d) for FY 2028.

Applications and other information about MGCRB reclassifications may be obtained beginning in mid-July 2026 via the internet on the CMS website at *https://www.cms.gov/medicare/regulations-guidance/geographic-classification-review-board.* This collection of information is approved under OMB Control Number 0938–0573 and expires on February 28, 2029.

Comment: Several commenters stated that reclassification was intended to ensure fair reimbursement for hospitals in CBSAs that exhibited the characteristics of another CBSA but now serves as a tool to manipulate wage indexes, leading to uncertainty. They requested CMS revise its termination, cancellation, and withdrawal rules and restrict hospitals' ability to reclassify annually or between the proposed and final rule, to stabilize reclassification changes and improve the predictability

of final wage indexes based on the proposed rule.

Response: We acknowledge that hospitals' reclassification decisions can create wage index fluctuations annually or between the proposed and final rules. However, we note that we did not propose any changes to the regulations at § 412.273 for withdrawing an application, terminating an approved 3-year reclassification, or cancelling a previous termination in the FY 2027 IPPS/LTCH PPS proposed rule.

b. Revisions to § 412.230(c)(1) To Address Ferry Routes

The regulation at § 412.230(c)(1) requires that hospitals seeking reclassification to an area must submit appropriate data relating to its proximity to the area, including evidence of the shortest route over improved roads to the area and the distance of that route as proximity data. The MGCRB has denied reclassification requests using ferry routes, but these decisions were overturned via administrative appeal.

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69281), commenters suggested revising the proximity data regulations to include waterways traveled by ferry boats as equivalent to travel over improved roads. CMS agreed that a modification to § 412.230(c)(1) could reduce unnecessary appeals.

Therefore, we proposed to modify § 412.230(c)(1) to include ferry routes when mapping the shortest route. This change would minimize appeals of MGCRB decisions and reduce administrative burden for both CMS and hospitals. This proposal is consistent with our definition of mileage for purposes of proximity in the FY 2002 IPPS Final Rule (66 FR 39874–39875), where we stated that we believe that mileage should continue to be measured by the shortest route over improved roads maintained by any local, State, or Federal government entity for public use. Since most ferry routes are maintained by local, State, or Federal government entities for public transportation over water, similar to bridges, we consider it appropriate to treat them as improved roads.

We stated that we would apply the same measurement method for miles traveled on land to those traveled by ferry boat over water. That is, the MGCRB requires providers to submit map evidence from nationally recognized electronic mapping services (*e.g.,* Google Maps, Bing Maps, MapQuest) showing the shortest route over improved roads from the front entrance of the hospital to the county line of the requested area and the distance of that route.[141] Miles traveled by ferry boat would also need to be mapped using a nationally recognized electronic mapping service and included as evidence of the shortest route.

We proposed to revise the regulations at § 412.230(c)(1) to state: ''To demonstrate proximity to the area, the hospital must submit evidence from a nationally recognized electronic mapping service of the shortest route from the front entrance of the hospital over improved roads or waterways traveled by ferry boats to the county line of the requested area and the distance of that route.'' We sought comment on this proposal.

Comment: A commenter supported CMS's proposal to recognize ferry routes for MGCRB proximity requirements, stating that this revision will ease administrative burden for hospitals with unique transportation circumstances.

Response: After consideration of the comment we received in support of our proposal, we are finalizing this policy and corresponding revision of the regulation at 412.230(c)(1) as proposed without modification.

c. Clarification Regarding the Data Used for Reclassifying to an Area With a Lower Wage Index (§ 412.230(a)(5)(i))

MGCRB reclassifications are approved for a 3-year period, and when evaluating a hospital's request for reclassification, effective with reclassifications for FY 2003, section 1886(d)(10)(D)(vi)(II) of the Act requires that the MGCRB must use the average of the most recent hospital wage survey data and the data from each of the two immediately preceding surveys. These data requirements are described in regulation at § 412.230(d)(2). CMS publishes this data in a ''Three Year MGCRB Reclassification Data Applications'' file during each application cycle on the CMS website.[142] We believe that using 3-year data improves wage index consistency, and reduces the likelihood that a single year of aberrant wage data in given area would impact the ability of hospitals to obtain geographic reclassification.

To be approved for an MGCRB reclassification, hospitals, in general, must demonstrate that their average hourly wage data is, on average, greater than their geographic area, and is similar to the area to which they seek to be reclassified. As described at § 412.230(a)(5)(i), hospitals also must demonstrate that the area to which they are reclassifying has a higher pre-reclassification wage index than the area they are geographically located. It has come to our attention that some view the data requirement of § 412.230(a)(5)(i) to be ambiguous and believe using only a single year of wage data is acceptable. It is CMS' longstanding position that, for all average hourly wage criteria described under § 412.230, the three-year weighted average data is required for approval by the MGCRB. To remove any ambiguity, we therefore proposed to revise § 412.230(a)(5)(i) to explicitly state that the data submitted must comply with the requirements of § 412.230(d)(2). That is, for purposes of meeting the criterion at § 412.230(a)(5)(i), we are affirming that the most recent three-year average hourly wage data must be submitted for hospitals located in both the area the applicant is located, and hospitals in the area to which reclassification is sought. This clarification is consistent with prior decisions made by the MGCRB, and the required usage of published 3-year data has been upheld on appeal through the Administrator's review process.

We did not receive any comments on this proposal, and we are finalizing the revision to § 412.230(a)(5)(i) to clarify the appropriate wage data to be used by hospitals seeking reclassification as proposed.

d. Revisions to § 412.230 To Waive Wage Data Comparisons for Hospitals Reclassifying to Home

As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45188–45190), urban hospitals with § 412.103 rural reclassifications are eligible to obtain MGCRB reclassifications to receive the wage index of another area. In that rulemaking, CMS also discussed the option of such a hospital reclassifying to its geographic labor market area, or its ''home'' area. When approved for a home area reclassification, the hospital may obtain the benefits of rural status, while receiving the wage index applied to other hospitals in its geographic urban area. These home area reclassifications have become significantly more common since FY 2022 rule, with nearly a quarter of all MGCRB approvals being to the hospital's geographic home area in FY 2026. Under current regulations, obtaining a home area reclassification is a relatively simple process. There would be no proximity requirement, as the hospital is physically located in the labor market to

[141] MGCRB Rules 5.2(A)(1), available at *https://www.cms.gov/medicare/regulations-guidance/geographic-classification-review-board/mgcrb-rules.*

[142] *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files.*

which it is seeking reclassification. As discussed in the May 10, 2021 Interim final rule with comment period (86 FR 24736–24738) and in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45188–45190), CMS described several options to obtain MGCRB reclassification for hospitals with § 412.103 reclassification. For example, in meeting the criterion at § 412.230(a)(5)(i), restricting MGCRB reclassifications to labor market areas with lower pre-reclassified wages than the area the hospital is located, CMS allowed an urban hospital with a § 412.103 rural reclassification to be considered located either in its geographic area or in the rural area of the State. Regarding the criteria at § 412.230(d)(1)(iii)(C), confirming that the hospital's wages are above average for its area (the 106/108 percent criterion), § 412.103 hospitals are permitted to compare their average hourly wage data to either the other hospitals in its geographic area, or to the hospitals in the state's rural labor market area. Additionally, many § 412.103 hospitals also have obtained rural referral center status. The provision at § 412.230(d)(3)(i) waives the average hourly wage comparison requirement at § 412.230(d)(1)(iii)(C) for rural referral centers.

The only criterion that most home area reclassification applicants are required to meet is at § 412.230(d)(1)(iv). That is, if a hospital with a rural reclassification demonstrates that its 3-year average hourly wage is at least 82 percent of the average hourly wage of its own geographic labor market area (the area to which it is seeking a home area MGCRB reclassification), the MGCRB application would be approved. The 82 percent criterion was initially determined to cover more than two standard deviations of wage variance within any given labor market area. Given these factors, it would be exceptionally rare for any hospital with a rural reclassification to be denied a home area MGCRB reclassification.

However, we are aware of a circumstance in which a home area MGCRB reclassification would be denied. The published wage data used for MGCRB reclassification is based on cost report data that could be up to three years old. Newly established hospitals (or remote locations of hospitals located in a different labor market area than the main campus of the hospital) would not yet have a cost report included in the current fiscal year wage index development process, and no average hourly wage data would be published. In this case, these hospitals and remote locations would not be eligible for individual MGCRB reclassification due to their inability to meet the § 412.230(d)(1)(iv) average hourly wage comparison.

Individual hospitals are required to have at least one year of published average hourly wage data in order to receive a wage index reclassification. Newly established hospitals or remote locations without published wage data that are included in a county group reclassification (§ 412.232 and § 412.234) with other hospitals are eligible for approval. However, individual reclassification requests would be denied. We believe this is the appropriate policy, as the MGCRB is required to review wage data to determine whether it is appropriate to grant an individual hospital the wage index of another labor market area. However, given the unique nature of a home area reclassification, it is difficult to see what policy objective would be achieved by denying a hospital a wage index based on its own geographic area. Therefore, we proposed to waive the application of § 412.230(d)(1)(iv) for a hospital requesting reclassification to its geographic home area. Specifically, we proposed to add an exception at § 412.230(d)(6) to waive the application of requirements of § 412.230(d)(1)(iv) for hospitals with § 412.103 rural reclassification seeking MGCRB reclassification to their geographic labor market area. While CMS continues to have concerns with hospitals using § 412.103 in order to enhance the state's rural floor, the scenario we are addressing would only affect situations where the inability to obtain a home area reclassification could lead to lower wage index value for the hospital. In such a case, a hospital would have the option to cancel its rural reclassification per the provision at § 412.103(g), and receive the wage index of its geographic urban area. However, there are situations where canceling rural reclassification would have significant financial impacts on the hospital, particularly in scenarios where a hospital operates in multiple urban labor market areas. For example, if a hospital with a § 412.103 reclassification opens or acquires a remote location in a different urban labor market area, we apply a separate wage index to that remote location based on its location and reclassification status. That remote location would be ineligible for individual MGCRB reclassification until CMS reviewed a cost report that allocates wages between the inpatient locations. In this case, the new remote location would be assigned its state's rural wage index based on the main campus' rural status, not the urban wage index for its geographic area.

Given that the large majority of hospitals with § 412.103 rural reclassifications can obtain home area MGCRB reclassification, we see no compelling policy justification to restrict reclassification in such a narrow circumstance. The few hospitals potentially affected by this proposed policy would not have published wage data for at least first year of any MGCRB reclassification and, therefore, would have a negligible impact on the accuracy or consistency of overall wage index values. We believe this proposal to waive the application of § 412.230(d)(1)(iv) for hospitals requesting reclassification to its geographic home area would provide an equitable opportunity to obtain a competitive wage index for affected hospitals. We sought comment on this proposal.

We did not receive any comments on this proposal, and we are finalizing as proposed to add an exception § 412.230(d)(6) to waive the application of requirements of § 412.230(d)(1)(iv) for hospitals with § 412.103 rural reclassification seeking MGCRB reclassification to their geographic labor market area.

Comment: Many commenters asked CMS to waive the wage data comparison requirement for low wage index hospitals seeking any MGCRB reclassification, similar to the exception for hospitals reclassifying to home proposed at § 412.230(d)(6). In addition, commenters requested regulatory changes to § 412.230(d) to permit low wage hospitals to reclassify to an area within 50 miles and to receive the unblended wage index that is paid to hospitals in that area. Several commenters requested a common 50-mile standard for proximity criteria for all hospitals, to better account for current commuting patterns.

Response: We note that we did not propose any changes to § 412.230 in the FY 2027 IPPS/LTCH PPS proposed rule beyond the narrow exception for hospitals reclassifying to their geographic labor market, and as such, are not finalizing other changes to § 412.230 in this final rule.

4. Redesignations Under Section 1886(d)(8)(B) of the Act

a. Lugar Status Determinations

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status to receive the out-migration adjustment has effectively

waived its deemed urban status and, thus, is rural for all purposes under the IPPS effective for the fiscal year in which the hospital receives the outmigration adjustment. In addition, in that rule, we adopted a minor procedural change that will allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the issuance of the proposed rule in the **Federal Register**) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital will no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930), we further clarified that if a hospital wishes to reinstate its urban status for any fiscal year within this 3-year period, it must send a request to CMS within 45 days of the issuance of the proposed rule in the **Federal Register** for that particular fiscal year. We indicated that such reinstatement requests may be sent electronically to *wageindex@cms.hhs.gov.* In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38147 through 38148), we finalized a policy revision to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, to notify CMS within 45 days from the date of public display of the proposed rule at the Office of the Federal Register. These revised notification timeframes were effective beginning October 1, 2017. In addition, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148), we clarified that both requests to waive and to reinstate Lugar status may be sent to *wageindex@cms.hhs.gov.* To ensure proper accounting, we request hospitals to include their CCN, and either ''waive Lugar'' or ''reinstate Lugar'', in the subject line of these requests. When applicable, this election will result in a cancelation of a hospital's rural reclassification status under § 412.103, effective October 1, 2026. We also inform hospitals that for the request to be approved, the hospital must terminate any active MGCRB reclassification. All requests, once approved, will remain in effect for the remainder of the 3-year out-migration adjustment period.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42314 and 42315), we clarified that in circumstances where an eligible hospital elects to receive the outmigration adjustment within 45 days of the public display date of the proposed rule at the Office of the Federal Register in lieu of its Lugar wage index reclassification, and the county in which the hospital is located will no longer qualify for an outmigration adjustment when the final rule (or a subsequent correction notice) wage index calculations are completed, the hospital's request to accept the outmigration adjustment will be denied, and the hospital will be automatically assigned to its deemed urban status under section 1886(d)(8)(B) of the Act. We stated that final rule wage index values will be recalculated to reflect this reclassification, and in some instances, after taking into account this reclassification, the out-migration adjustment for the county in question could be restored in the final rule. However, as the hospital is assigned a Lugar reclassification under section 1886(d)(8)(B) of the Act, it will be ineligible to receive the county outmigration adjustment under section 1886(d)(13)(G) of the Act.

We did not receive any requests from hospitals to waive or reinstate its Lugar redesignation this cycle.

F. Wage Index Adjustments: Rural Floor, Imputed Floor, State Frontier Floor, Out-Migration Adjustment, Cap on Wage Index Decrease Policies, and Continuation of Transition for the Discontinuation of the Low Wage Index Hospital Policy

The following adjustments to the wage index are listed in the order that they are generally applied. First, the rural floor, imputed floor, and state frontier floor provide a minimum wage index. The rural floor at section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that the wage index for hospitals in urban areas of a State may not be less than the wage index applicable to hospitals located in rural areas in that State. The imputed floor at section 1886(d)(3)(E)(iv) of the Act provides a wage index minimum for all-urban states. The state frontier floor at section 1886(d)(3)(E)(iii) of the Act generally requires that hospitals in frontier states cannot be assigned a wage index of less than 1.00. Next, the out-migration adjustment at section 1886(d)(13)(A) of the Act is applied, potentially increasing the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county or counties with a higher wage index. Finally, all hospital wage index decreases are capped at 5 percent of the hospital's final wage index in the prior fiscal year, such that a hospital's wage index would not be less than 95 percent of its final wage index for the prior fiscal year, according to the policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021).

1. Rural Floor

Section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the rural floor. Section 3141 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) also requires that a national budget neutrality adjustment be applied in implementing the rural floor. Based on the FY 2027 wage index associated with this final rule (which is available on the CMS website), and based on the calculation of the rural floor including the wage data of hospitals that have reclassified as rural under § 412.103, we estimate that 991 hospitals would receive the rural floor in FY 2027. The budget neutrality impact of the proposed application of the rural floor is discussed in section II.A.4.e of Addendum A of this final rule.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 48784), CMS finalized a policy change to calculate the rural floor in the same manner as we did prior to the FY 2020 IPPS/LTCH PPS final rule, in which the rural wage index sets the rural floor. We stated that for FY 2023 and subsequent years, we would include the wage data of § 412.103 hospitals that have no Medicare Geographic Classification Review Board (MGCRB) or Lugar reclassification in the calculation of the rural floor, and include the wage data of such hospitals in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

In the FY 2024 IPPS/LTCH final rule (88 FR 58971 through 58977), we finalized a policy change beginning that year to include the data of *all* § 412.103 hospitals, even those that have an MGCRB reclassification, in the calculation process for the rural floor and the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. We explained that after revisiting the case law, prior public comments, and the

relevant statutory language, we agreed that the best reading of section 1886(d)(8)(E)'s text that CMS ''shall treat the [§ 412.103] hospital as being located in the rural area'' is that it instructs CMS to treat § 412.103 hospitals the same as geographically rural hospitals for the wage index calculation.

Accordingly, in the FY 2024 IPPS/LTCH PPS final rule, we finalized a policy to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) that are implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. For additional information on these changes, we refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 58971 through 58977).

Comment: A commenter expressed continued support for treating urban hospitals reclassified as rural under § 412.103 the same as geographically rural hospitals for wage index purposes.

Response: We appreciate the commenter's support of our current policy. We note that we did not propose any changes to the treatment of hospitals with § 412.103 urban to rural reclassifications for wage index purposes in the FY 2027 IPPS/LTCH PPS proposed rule.

Comment: Several commenters asked CMS not to apply the rural floor budget neutrality adjustment to hospitals receiving the rural floor. The commenters asserted that Section 4410(b) of the Balanced Budget Act of 1997 exempts urban and reclassified rural hospitals receiving the rural floor from wage index reductions due to application of the budget neutrality factor.

Response: We disagree with the commenters' argument that hospitals receiving the rural floor should be excluded from the application of the rural floor budget neutrality factor. We direct the reader to responses to similar comments in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69299) and the FY 2026 IPPS/LTCH PPS final rule (90 FR 36850 through 36851) for a full explanation of why we disagree with the commenters' approach. We believe we have applied the rural floor budget neutrality adjustment in a manner consistent with the statute.

Comment: Several commenters expressed concern over rural floor manipulation, particularly by large urban hospitals reclassifying as rural to raise their state's rural floor. Commenters encouraged CMS to evaluate the redistributive impacts of the rural floor and other wage index policies, with some commenters specifically noting the impact on Medicare Advantage reimbursement. Commenters asked CMS to increase predictability by changing the methodology for including wage data of reclassified hospitals and by limiting wage index changes annually and between the proposed and final rules.

Response: While we note that we did not propose any changes to the rural floor policy in the FY 2027 IPPS/LTCH PPS proposed rule, we understand the commenters' concerns regarding hospitals taking advantage of the rural floor policy and the effect on all hospitals due to the budget neutrality adjustment. As we have noted in previous rules in response to similar comments (88 FR 58975 through 58976, 89 FR 69299, and 90 FR 36850), we expect this trend to continue such that the majority of hospitals (if not all) will be assigned identical wage index values within their states. We also understand that the IPPS wage index has effects beyond the IPPS, including on Medicare Advantage reimbursement. However, as we stated in the previous rules, we believe this result would be unavoidable given the requirement of section 1886(d)(8)(E) of the Act to treat § 412.103 hospitals ''as being located in the rural area'' of the State, as well as the requirement at sections 4410(b) of the BBA 1997 and 3141 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) that a uniform, national budget neutrality adjustment be applied in implementing the rural floor. While we note that we did not propose any limits on reclassification decisions hospitals can make annually or between the proposed and final rules, we believe that our 5% cap policy helps increase predictability by limiting annual wage index decreases.

2. Imputed Floor

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the imputed floor policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that had stated that they were disadvantaged by the absence of rural hospitals to set a wage index floor for those States. We extended the imputed floor policy eight times since its initial implementation, the last of which was adopted in the FY 2018 IPPS/LTCH PPS final rule and expired on September 30, 2018. We refer readers to further discussions of the imputed floor in the IPPS/LTCH PPS final rules from FYs 2014 through 2019 (78 FR 50589 through 50590, 79 FR 49969 through 49971, 80 FR 49497 through 49498, 81 FR 56921 through 56922, 82 FR 38138 through 38142, and 83 FR 41376 through 41380, respectively) and to the regulations at § 412.64(h)(4). For FYs 2019, 2020, and 2021, hospitals in all-urban states received a wage index that was calculated without applying an imputed floor, and we no longer included the imputed floor as a factor in the national budget neutrality adjustment.

Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), enacted on March 11, 2021, amended section 1886(d)(3)(E)(i) of the Act and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Specifically, section 1886(d)(3)(E)(iv)(I) and (II) of the Act provides that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. Unlike the imputed floor that was in effect from FYs 2005 through 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Section 1886(d)(3)(E)(iv)(IV) of the Act provides that, for purposes of the imputed floor wage index under clause (iv), the term all-urban State means a State in which there are no rural areas (as defined in section 1886(d)(2)(D) of the Act) or a State in which there are no hospitals classified as rural under section 1886 of the Act. Under this definition, given that it applies for purposes of the imputed floor wage index, we consider a hospital to be classified as rural under section 1886 of the Act if it is assigned the State's rural area wage index value.

Effective beginning October 1, 2021 (FY 2022), section 1886(d)(3)(E)(iv) of the Act reinstated the imputed floor wage index policy for all-urban States, with no expiration date, using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45176 through 45178) for further discussion of the original imputed floor calculation methodology implemented in FY 2005 and the alternative methodology implemented in FY 2013.

Based on data available for this final rule, States that would be all-urban States as defined in section 1886(d)(3)(E)(iv)(IV) of the Act, and thus hospitals in such States that would be

eligible to receive an increase in their wage index due to application of the imputed floor for FY 2027, are identified in Table 3 (which is available on the CMS website) associated with this final rule. States with a value in the column titled ''State Imputed Floor'' are eligible for the imputed floor.

The regulations at § 412.64(e)(1) and (4) and (h)(4) and (5) implement the imputed floor required by section 1886(d)(3)(E)(iv) of the Act for discharges occurring on or after October 1, 2021. The imputed floor would continue to be applied for FY 2027 in accordance with the policies adopted in the FY 2022 IPPS/LTCH PPS final rule. For more information regarding our implementation of the imputed floor required by section 1886(d)(3)(E)(iv) of the Act, we refer readers to the discussion in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45176 through 45178).

Comment: We received comments supporting the application of the imputed floor.

Response: We thank the commenters for their input. As discussed earlier, the imputed floor is a statutory requirement under section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) which requires the Secretary to establish a minimum area wage index for hospitals in all-urban States for discharges occurring on or after October 1, 2021. We note that we did not propose any changes to the methodology for calculating the imputed floor as set forth in § 412.64(e)(1) and (4) and (h)(4) and (5). Therefore, in accordance with the statute and existing regulations, we are applying the imputed floor for hospitals in all-urban States for FY 2027.

3. State Frontier Floor for FY 2027

Section 10324 of Public Law 111–148 amended Section 1886(d)(3)(E) of the Act and added section 1886(d)(3)(E)(iii) of the Act to require that hospitals in frontier States cannot be assigned a wage index of less than 1.00. We refer readers to the regulations at § 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161). We note that in the FY 2027 IPPS/LTCH PPS proposed rule, we did not propose any changes to the frontier floor policy for FY 2027. In the proposed rule, we stated 40 hospitals would receive the frontier floor value of 1.00 for their FY 2027 proposed wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming.

We did not receive any public comments on the application of the State frontier floor for FY 2027. In this final rule, 31 hospitals will receive the frontier floor value of 1.00 for their FY 2027 wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming. We note that while Nevada meets the criteria of a frontier State, all hospitals within the State currently receive a wage index value greater than 1.00.

The areas affected by the rural and frontier floor policies for the FY 2027 wage index are identified in Table 3 associated with this final rule, which is available via the internet on the CMS website.

4. Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When section 1886(d)(13) was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census Bureau used at that time, and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative data set based on the latest available data on where residents in each county worked in 2010, for use in developing a new out-migration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in prior IPPS/LTCH PPS final rules, we have applied the same policies, procedures, and computations since FY 2012. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source. We also stated that we will consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate.

As discussed previously in section III.A.2, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69253 through 69266), CMS adopted revised Core-Based Statistical Area (CBSA) delineations from the OMB Bulletin No. 23–01, published July 21, 2023. The revised delineations incorporated population estimates based on the 2020 decennial census, as well as updated journey-to-work commuting data. The Census Bureau once again worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked, for use in developing a new out-migration adjustment based on new commuting patterns. We analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the ACS, utilizing 2016 through 2020 data. The Census Bureau produces county level commuting flow tables every 5 years using non-overlapping 5-year ACS estimates. The data includes demographic characteristics, home and work locations, and journey-to-work travel flows. The custom tabulation requested by CMS was specific to general medical and surgical hospital and specialty (except psychiatric and substance use disorder treatment) hospital employees (hospital sector Census code 8191/NAICS code 6221 and 6223) who worked in the 50 States, Washington, DC, and Puerto Rico and, therefore, provided information about commuting patterns of workers at the county level for residents of the 50 States, Washington, DC, and Puerto Rico.

For the ACS, the Census Bureau selects a random sample of addresses where workers reside to be included in the survey, and the sample is designed to ensure good geographic coverage. The ACS samples approximately 3.5 million

resident addresses per year.[143] The results of the ACS are used to formulate descriptive population estimates, and, as such, the sample on which the dataset is based represents the figures that would be obtained from a complete count.

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69301), we finalized that for FY 2025 and subsequent years, the out-migration adjustment will be based on the data derived from the previously discussed custom tabulation of the ACS utilizing 2016 through 2020 (5-year) Microdata. We believe that these data are the most appropriate to establish qualifying counties, because they are the most accurate and up-to-date data that are available to us. For FY 2027, we are not proposing any changes to the methodology or data source for calculating the out-migration adjustment. Specifically, we proposed that the FY 2027 out-migration adjustments continue to be based on the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment.

Comment: We received a comment stating that Middlesex County, NJ narrowly missed the eligibility thresholds required to qualify for the out-migration adjustment despite having previously qualified in prior years. Given that the underlying data used to calculate these thresholds is not fully audited, the commenter argues that such a marginal shortfall should not be sufficient grounds for withholding the adjustment.

The commenter also raised a broader policy concern, arguing that the current eligibility structure is inequitable, as counties with nearly identical labor market conditions can receive different treatment based on negligible differences. The commenter suggested that CMS should reassess whether the current OMA eligibility criteria reflect labor market realities; and to consider refining the standards in future rulemaking, specifically by eliminating the average hourly wage comparison requirement.

Response: Section 1886(d)(13)(B)(iii) of the Act requires that, to qualify for the out-migration adjustment, the average hourly wage for all hospitals in the county must be equal to or exceed the average hourly wage for all hospitals in its labor market area. We believe we have implemented this policy consistent with the statute (69 FR 49061–49067). With regard to the commenter stating that a marginal shortfall should not be sufficient grounds for not qualifying for the adjustment when the underlying data used to calculate the qualifying thresholds is not fully audited, as stated earlier, CMS uses actual wage data submitted by the hospitals to calculate the wage index. Specifically, the wage data for the FY 2027 wage index were obtained from Worksheet S–3, Parts II, III and IV of the Medicare cost report, CMS Form 2552–10 (OMB Control Number 0938–0050 with an expiration date September 30, 2028) for cost reporting periods beginning on or after October 1, 2022, and before October 1, 2023. Hospitals submit wage data to CMS through the Medicare cost report and should ensure accuracy when submitting their own wage data. In addition, as noted above, for the development of the FY 2027 wage index, CMS conducted its own review of the data. For these reasons, we disagree with the commenter that the adjustments be provided when the eligibility thresholds are narrowly missed based on the data used for the FY 2027 rulemaking.

After consideration of the comments, we are finalizing as proposed that the FY 2027 out-migration adjustments continue to be based on the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment. We have applied these same policies, procedures, and computations since FY 2012, and we believe they continue to be appropriate for FY 2027. We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602). Table 2 of this final rule (which is available on the CMS website) lists the out-migration adjustments for the FY 2027 wage index. In addition, Table 4A associated with this final rule, ''List of Counties Eligible for the Out Migration Adjustment under Section 1886(d)(13) of the Act'' (also available on the CMS website), consists of the following: A list of counties that are eligible for the outmigration adjustment for FY 2027 identified by FIPS county code, the FY 2027 out-migration adjustment, and the number of years the adjustment would be in effect. We refer readers to section V.I of the Addendum of this final rule for instructions on accessing IPPS tables that are posted on the CMS websites identified in this final rule.

[143] According to the Census Bureau, the effects of the public health emergency (PHE) on ACS activities in 2020 resulted in a lower number of addresses (~2.9 million) in the sample, as well as fewer interviews than a typical year.

5. Cap on Wage Index Decreases and Budget Neutrality Adjustment

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), we finalized a wage index cap policy and associated budget neutrality adjustment for FY 2023 and subsequent fiscal years. Under this policy, we apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. A hospital's wage index will not be less than 95 percent of its final wage index for the prior FY. We note, as discussed below, that for FY 2027 we proposed to continue the transitional payment exception that addresses the effects of the removal of the low wage index hospital policy. This proposed transitional payment exception would be applied after the application of the 5-percent cap.

Except for newly opened hospitals, we apply the cap for a fiscal year using the final wage index applicable to the hospital on the last day of the prior fiscal year. A newly opened hospital will be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year, and it will not receive a cap for that first year, because it will not have been assigned a wage index in the prior year. The wage index cap policy is reflected at § 412.64(h)(7). We apply the cap in a budget neutral manner through a national adjustment to the standardized amount each fiscal year. For more information about the wage index cap policy and associated budget neutrality adjustment, we refer readers to the discussion in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021).

For FY 2027, we will apply the wage index cap and associated budget neutrality adjustment in accordance with the policies adopted in the FY 2023 IPPS/LTCH PPS final rule. We refer readers to the Addendum of this final rule for further information regarding the budget neutrality calculations.

Comment: We received many comments in support of our proposed cap on wage index decreases for FY 2027. Some of these commenters urged CMS to apply this policy in a non-budget neutral manner. A commenter asked CMS to consider a smaller percentage point cap, stating that even a 5 percent decrease could impact the financial stability of hospitals operating on narrow margins.

Response: We thank the commenters for their support. With regard to the commenters requesting that CMS apply this policy in a non-budget neutral

manner, we refer readers to our response to similar comments in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58981). In response to the commenter asking for a smaller percentage point cap, we refer readers to the FY 2023 IPPS/LTCH PPS Final Rule discussion (87 FR 49018 through 49019) explaining why we believe a 5 percent annual cap on wage index decreases effectively addresses instability.

6. Continued Transition for the Discontinuation of the Low Wage Index Hospital Policy

In the FY 2025 interim final action with comment period (IFC) (89 FR 80405 through 80421), we recalculated the FY 2025 IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. We also removed the low wage index budget neutrality factor from the FY 2025 standardized amounts. For FY 2026 and subsequent fiscal years, consistent with the FY 2025 IFC, after considering the D.C. Circuit's decision in *Bridgeport Hospital* v. *Becerra,* we discontinued the low wage index hospital policy and the application of the low wage index budget neutrality factor to the standardized amounts (90 FR 36854).

For FY 2025 and FY 2026, consistent with our past practice to establish temporary transition policies to mitigate short-term instability and payment fluctuations, we established transition policies for hospitals significantly impacted by the discontinuation of the low wage index hospital policy using our authority under section 1886(d)(5)(I) of the Act. The transitional payment exception for FY 2025 for those hospitals was equal to the additional FY 2025 amount a hospital would have been paid under the IPPS if its FY 2025 wage index were equal to 95 percent of its FY 2024 wage index. The transitional payment exception for FY 2026 was equal to the additional FY 2026 amount the hospital would be paid under the IPPS if its FY 2026 wage index were equal to 90.25 percent of its FY 2024 wage index.[144] For FY 2025, we opted not to budget neutralize the interim transition policy given the timing of the *Bridgeport Hospital* v. *Becerra* decision. However, for FY 2026, we finalized a payment transition with a budget neutrality adjustment through notice-and-comment rulemaking for hospitals facing significant reductions over two years that would not be sufficiently mitigated by the wage index cap policy at 42 CFR 412.64(h)(7). We refer readers to the FY 2025 IFC (89 FR 80405 through 80421) and to the FY 2026 IPPS/LTCH PPS Final Rule (90 FR 36855 through 36857) for a full discussion of these transitional payment policies.

Some hospitals that previously benefitted from the low wage index hospital policy would continue to experience decreases of approximately 5 percent or more per year from their FY 2024 wage index (with the low wage index hospital policy applied). For example, these hospitals may experience a decrease of 15 percent or more over the three years from their FY 2024 wage index to their proposed FY 2027 wage index (that is, approximately 5 percent or more per year over that time period). Therefore, we proposed to extend the transitional exception to the calculation payments for FY 2027 for these hospitals in the same manner as we did for the FY 2026 wage index.

Similar to the FY 2026 transition, the transitional exception policy we proposed for FY 2027 would continue to apply only to hospitals that benefited from the FY 2024 low wage index hospital policy. For FY 2027, for example, we would compare the hospital's proposed FY 2027 wage index to the hospital's FY 2024 wage index if the hospital benefited from the low wage index hospital policy in FY 2024. If the hospital is significantly impacted by the discontinuation of the low wage index hospital policy, meaning the hospital's proposed FY 2027 wage index is decreasing by more than 14.2625 percent[145] from the hospital's FY 2024 wage index, then the transitional payment exception for FY 2027 for that hospital would be equal to the additional FY 2027 amount the hospital would be paid under the IPPS if its FY 2027 wage index were equal to 85.7375 percent[146] of its FY 2024 wage index.[147] We note this proposed transitional payment exception would be applied after the application of the 5-percent cap described at 42 CFR 412.64(h)(7).

For example: assume the FY 2024 wage index for a hospital that benefitted from the low wage index hospital policy is 0.7600, and the hospital's proposed FY 2027 wage index is 0.6500. (If applicable, this proposed FY 2027 wage index value would include the 5-percent cap based on a comparison of the hospital's FY 2027 wage index prior to application of the 5-percent cap, to the hospital's FY 2026 wage index. We note that the FY 2026 wage index that will be used in this comparison is generally the FY 2026 wage index listed in Table 2 from the FY 2026 Final Rule in the column labeled ''FY 2026 Wage Index With Cap''. We note that all hospitals, regardless of whether the cap was applied to their FY 2026 wage index, have a value in the column ''FY 2026 Wage Index With Cap''. Hospitals that did not have a cap applied to their FY 2026 wage index will display a wage index in this column without the cap.) The hospital's proposed FY 2027 wage index is decreasing by more than 14.2625 percent from the hospital's FY 2024 wage index [that is, 0.6500 < 0.6516 where 0.6516 = (0.857375 times 0.7600)]. The proposed transitional payment exception for FY 2027 for this hospital is equal to the additional amount the hospital would be paid under the IPPS if its FY 2027 wage index were equal to 0.6516, which is 85.7375 percent of 0.7600, its FY 2024 wage index. We note that the hospital in this example would not qualify for the transitional payment exception in FY 2028 should the policy be extended if its 2028 wage index is more than 0.6190, which is 81.450625 percent (or 0.95^4) of its FY 2024 wage index of 0.7600.

Similar to the FY 2026 transition, we proposed to make this policy budget neutral for FY 2027 through an adjustment applied to the standardized amount for all hospitals because: (1) the wage index cap policy at 42 CFR 412.64(h)(7) would have mitigated these FY 2027 wage index decreases had the combined payment effect of the FY 2025 and FY 2026 wage index and the transitional payment exception been reflected solely in the FY 2025 and FY 2026 wage index, and it would have done so in a budget neutral manner under our current regulations; and (2) the circumstances described in the FY 2025 IFC (89 FR 80405 through 80421) that caused us to decline to budget neutralize the interim FY 2025 transition policy are not applicable to subsequent years. In addition,

[144] 90.25 percent = 95 percent for FY 2025 * 95 percent for FY 2026. This can also be expressed as .95^2.

[145] Under the wage index cap policy at 42 CFR 412.64(h)(7), a hospital's wage index for a FY cannot be lower than 0.95 * its wage index from the prior FY. Over a 3-year period if its wage index were decreasing by more than 5 percent each year, this will mean a hospital's wage index for a FY cannot be lower than (0.95 * 0.95 * 0.95) times its wage index from three years earlier. Similarly for our proposed FY 2027 transitional exception policy, we proposed that a hospital is significantly impacted by the discontinuation of the low wage index hospital policy if its FY 2027 wage index is less than (0.95 * 0.95 * 0.95) of its FY 2024 wage index, which equates to a decrease of more than 14.2625 percent.

[146] 85.7375 percent = 95 percent for FY 2025 * 95 percent for FY 2026 * 95 percent for FY 2027. This can also be expressed as .95^3.

[147] We note that we are not proposing to change the FY 2027 wage index values under section 1886(d)(3)(E) for hospitals eligible for the proposed FY 2027 transitional exception policy on the basis of the exception; the proposed change will be applied as a separate step only for purposes of determining the hospitals' FY 2027 IPPS payments.

implementing the proposed transition policy for FY 2027 in a budget neutral manner would be consistent with past practice. For example, we budget neutralized the FY 2015 wage index transition budget neutrality policy discussed earlier (79 FR 49956 through 49962). As we have discussed in other instances (89 FR 19398), we believed, and continue to believe, that transition policies should not increase estimated aggregate Medicare payments beyond the payments that would be made had we never proposed these transition policies. Therefore, we proposed to use our authority under section 1886(d)(5)(I)(i) of the Act twice. First, we proposed to adopt a narrow transitional exception to the calculation of FY 2027 IPPS for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy. Second, we proposed to exercise our authority again to do so in a budget neutral manner.[148] [149] We refer the reader to section II.A.4.g of the Addendum of this final rule for complete details regarding the application of the transition for the discontinuation of the low wage index hospital policy budget neutrality factor.

We also proposed to make a budget neutral equivalent exception under the capital IPPS. Under the capital IPPS, the adjustment for local cost variation is based on the hospital wage index value that is applicable to the hospital under the operating IPPS. We adjust the capital standard Federal rate so that the effects of the annual changes in the geographic adjustment factor (GAF) are budget neutral. As discussed in the FY 2025 IFC (89 FR 80408), since FY 2023, the GAFs reflect the wage index cap policy that limits any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline, to 95 percent of its prior year value. As described previously, some hospitals that previously benefitted from the low wage index hospital policy will experience decreases of 15 percent or more over the three years from their FY 2024 wage index (with the low wage index hospital policy applied) to their proposed FY 2027 wage index, at approximately 5 percent or more per year over that time period and for subsequent years. As such, similar to the FY 2025 and FY 2026 transition policies, we proposed for FY 2027 to make a budget neutral equivalent exception under the capital IPPS.

Comment: Many commenters supported the proposed transition but urged CMS not to budget neutralize the policy. Several challenged CMS's authority under subsection (d)(5)(I)(i) to budget neutralize the policy, and a commenter urged CMS to allow the policy to sunset to end the associated budget neutrality adjustment.

Conversely, some commenters asked CMS to extend the transition beyond FY 2027 to provide payment stability to affected hospitals, particularly in Puerto Rico. Many commenters encouraged CMS to continue developing policies to support low wage hospitals that do not adversely affect other hospitals. These commenters expressed that a temporary transition is inadequate, since the need for the discontinued low wage policy remains. Suggested alternatives included: working with Congress on permanent wage index reform or legislation to assist low wage hospitals; a Cost of Living Adjustment (COLA) for Puerto Rico; and a more permissive reclassification mechanism for low wage hospitals.

Response: We thank the commenters for their support for the policy in general. In response to the commenters opposing the budget neutrality adjustment, we believe that the reasons we stated in the proposed rule for budget neutralizing the transition continue to apply. Consistent with our response to similar comments about the authority for budget neutrality in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58767), we believe that we have authority under section 1886(d)(5)(I)(i) of the Act to promulgate a budget neutrality adjustment to the national standardized amount and that this authority is not limited to transfer cases. We disagree with the commenters that we are not permitted to make budget neutral exceptions under section 1886(d)(5)(I)(i) of the Act.

With regard to extending the transition for additional years, we may consider this in future rulemaking. We thank the commenters for the suggested alternatives to assist low wage hospitals in the absence of the low wage hospital policy, some of which would require legislation. Finally, regarding the suggested reclassification changes for low wage hospitals, we have addressed those comments in Section IV.E.III.d. of this final rule.

After consideration of the public comments we received, we are finalizing as proposed without modification to use our authority under section 1886(d)(5)(I)(i) of the Act twice. First, to adopt a narrow transitional exception to the calculation of FY 2027 IPPS payments for low wage index hospitals that benefitted from the FY 2024 low wage index hospital policy and are significantly impacted by the discontinuation of the low wage index hospital policy. Second, we are exercising our authority again to do so in a budget neutral manner through an adjustment applied to the standardized amount for all hospitals. We are also finalizing our proposal to make a budget neutral equivalent exception under the capital IPPS.

G. FY 2027 Wage Index Tables

In this FY 2027 IPPS/LTCH PPS final rule, we have included the following wage index tables: Table 2 titled ''Case-Mix Index and Wage Index Table by CCN''; Table 3 titled ''Wage Index Table by CBSA''; Table 4A titled ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act''; and Table 4B titled ''Counties redesignated under section 1886(d)(8)(B) of the Act (Lugar Counties).'' We refer readers to section VI of the Addendum to this final rule for a discussion of the wage index tables for FY 2027.

H. Labor-Related Share for the FY 2027 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs that are attributable to wages and wage-related costs of the diagnosis related group (DRG) prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

[148] We note that even more so than was the case for the FY 2025 and FY 2026 interim transition policy, the scope and magnitude of the FY 2027 transitional policy are much smaller than the low wage index hospital policy, and we expect this trend to continue as effects of discontinuing the low wage hospital policy diminish. As discussed in section VI of the preamble of this final rule, we estimate only 54 hospitals, out of the over 3,000 hospitals paid under the IPPS will receive FY 2027 transitional exception payments. Also, as discussed in section II. A 4 of the addendum to this final rule, as proposed, we applied a budget neutrality factor to the standardized amount.

[149] We note that because creating an exception to the calculation of the FY 2027 payments is in this circumstance functionally equivalent to adjusting the FY 2027 payments, the transitional exception can be alternatively considered a transitional adjustment.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share results in a higher payment.

In the FY 2026 IPPS/LTCH PPS final rule (90 FR 36869 through 36873), we rebased and revised the hospital market basket to a 2023-based IPPS hospital market basket, which replaced the 2018-based IPPS hospital market basket, effective beginning October 1, 2025. Using the 2023-based IPPS market basket, we finalized a labor-related share of 66.0 percent for discharges occurring on or after October 1, 2025. In addition, in FY 2026, we implemented this rebased labor-related share in a budget neutral manner (90 FR 36857 through 36858, 90 FR 37216 through 37217). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. In the FY 2026 IPPS/LTCH PPS final rule, we included in the labor-related share the national average proportion of operating costs that are attributable to the following cost categories in the 2023-based IPPS market basket: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; and All Other: Labor-Related Services as measured in the 2023-based IPPS market basket. We note that in the proposed rule for FY 2027, we did not propose to make any further changes to the labor-related share. For FY 2027, we are finalizing the policy to continue to use a labor-related share of 66.0 percent for discharges occurring on or after October 1, 2026.

As discussed in section VI.B of the preamble of this final rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2027, we are not proposing a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Tables 1A and 1B, which are published in section VI of the Addendum to this FY 2027 IPPS/LTCH PPS final rule and available via the internet on the CMS website, reflect the national labor-related share. Table 1C, in section VI of the Addendum to this FY 2027 IPPS/LTCH PPS final rule and available via the internet on the CMS website, reflects the national labor-related share for hospitals located in Puerto Rico. For FY 2027, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2027, we are applying the wage index to a labor-related share of 66.0 percent of the national standardized amount.

Comment: A commenter stated that CMS's labor-related share methodology understates the labor-related share by excluding the ''universe'' of labor-related costs, regardless of whether those costs vary by the local market. The commenter urged CMS to include these costs in the labor-related share.

Response: We note that we did not propose to make any further changes to the labor-related share for FY 2027. As discussed earlier, for FY 2027, we are continuing to use a labor-related share of 66.0 percent for discharges occurring on or after October 1, 2026.

We also disagree with the commenter's claim that the labor-related share should include the universe of labor-related costs, including those costs that do not vary with the local labor market. The labor-related share of the IPPS standardized amount is adjusted to account for geographic differences in area wage levels by applying the applicable IPPS wage index. The purpose of the labor-related share is to reflect the proportion of the national IPPS standardized amount that is adjusted by the hospital's wage index (representing the relative costs of their local labor market to the national average). Therefore, we include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. Currently this would include all wages and salaries and employee benefits for any worker employed by the hospital, and any contract worker providing direct patient care. Additionally, it includes a proportion of costs for professional services (such as legal and accounting) and home office/related organization costs based on Medicare cost report data submitted by IPPS hospitals, and purchased costs associated with services that would generally be conducted in the location of the hospital (such as maintenance and repair, etc.). We note that for the 2023-based IPPS market basket (90 FR 36869 through 36873), we finalized the use of the Medicare cost report data for IPPS hospitals to determine the proportion of expenses classified as professional fees that meet our definition of labor-related services while the 2018-based IPPS market basket (86 FR 45204 through 45205) used a survey of hospitals conducted by CMS in 2008. Both the Medicare cost report data and survey indicated that only a portion of these costs are purchased in the local labor market.

IV. Payment Adjustment for Medicare Disproportionate Share Hospitals for FY 2027 (§ 412.106)

A. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals [150] that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, the more commonly used method, is based on the hospital's disproportionate patient percentage (DPP), described below, under which the DSH payment adjustment is based on a complex statutory formula that includes the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's DPP.

A hospital's DPP is the sum of two fractions: the ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

DSH Eligibility	Qualifying Criteria
Statutory Formula	A hospital that has a disproportionate patient percentage equal to or exceeding 15 percent may qualify for the Medicare DSH adjustment. We refer readers to 42 CFR 412.106 for the specific eligibility criteria and payment formulas.
"Pickle Method"	A hospital that is located in an urban area and has 100 or more beds may qualify to receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during the cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes.

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated and how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (ACA), as amended by section 10316 of the ACA and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. We refer to these provisions collectively as section 3133 of the ACA. Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments on the basis of the hospital's DPP under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

Since FY 2014, section 1886(r) of the Act has required that hospitals that are eligible under section 1886(d)(5)(F) of the Act receive two separately calculated payments:

Medicare DSH Payment	An empirically justified DSH payment equal to 25% of the amount determined under the statutory formula in section 1886(d)(5)(F) of the Act.
Medicare DSH Uncompensated Care Payment	An uncompensated care payment determined as the product of 3 factors discussed in this section.

Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC

[150] See section 1886(d)(1)(B) of the Act for the definition of a ''subsection (d) hospital''.

in its March 2007 Report to Congress.[151] We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospitals an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. In other words, the first factor of the uncompensated care payment calculation is 75 percent of the payments that would otherwise be made as Medicare DSH payments under section 1886(d)(5)(F) of the Act.

Section 1886(r)(2)(B) of the Act provides that the second factor is, for FY 2018 and subsequent fiscal years, 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified). As discussed in a later section, we note that the second factor is computed based on estimates of the total U.S. population.

Section 1886(r)(2)(C) of the Act provides that the third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments for the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment amount determined by these factors as the ''uncompensated care payment.'' In brief, the uncompensated care payment for an individual hospital is the product of the following 3 factors:

Factor 1	75% of the total amount of DSH payments that would otherwise be made under section 1886(d)(5)(F) of the Act.
Factor 2	1 minus the percent change in the percent of individuals who are uninsured.
Factor 3	The hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that receive DSH payments, expressed as a percentage.

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the ACA for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which was established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or of the periods selected to develop such estimates.

B. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

The payment methodology under section 3133 of the ACA applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year to receive a Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the empirically justified Medicare DSH payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to ''such subsection (d) hospitals'' the uncompensated care payment. Section 1886(r)(2)'s reference to ''such subsection (d) hospitals'' refers to hospitals that receive empirically justified Medicare DSH payments under section 1886(r)(1) for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we explained that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status (that is, a hospital's eligibility to receive empirically justified Medicare DSH payments) for the applicable fiscal year (using the most recent data available). For this final rule, we estimated DSH status for all hospitals using the most recent available SSI ratios and information from the most recent available Provider Specific File. We note that FY 2023 SSI ratios available on the CMS website were the most recent

[151] *https://www.medpac.gov/document/march-2007-report-to-the-congress-medicare-payment-policy/.*

available SSI ratios at the time of developing this final rule.[152] If more recent data on DSH eligibility becomes available before the final rule, we would use such data in the final rule. Our final determinations of a hospital's eligibility for empirically justified Medicare DSH and uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for FY 2027.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and in the rulemakings for subsequent fiscal years, we have specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. Eligible hospitals include the following:

- Subsection (d) Puerto Rico hospitals are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act (78 FR 50623) and FY 2015 IPPS/LTCH PPS final rule (79 FR 50006).
- Sole community hospitals (SCHs) that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the fiscal year (based on the best available data at that time) subject to settlement through the cost report. If they receive interim empirically justified Medicare DSH payments in a fiscal year, they will also be eligible to receive interim uncompensated care payments for that fiscal year on a per discharge basis. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).
- Medicare-dependent, small rural hospitals (MDHs) are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (FY 2012 IPPS/LTCH PPS final rule, 76 FR 51684). The IPPS Federal rate that is used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Because MDHs are paid based on the IPPS Federal rate, they continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent, and we apply the same process to determine MDHs' eligibility for interim empirically justified Medicare DSH and interim uncompensated care payments as we do for all other IPPS hospitals. Recently enacted legislation has extended the MDH program through December 31, 2026. We refer readers to section V.E. of the preamble of this final rule for further discussion of the MDH program. We will continue to make a determination concerning an MDH's eligibility for interim empirically justified Medicare DSH and uncompensated care payments based on the hospital's estimated DSH status for the applicable fiscal year.
- Transforming Episode Accountability Model (TEAM) is a new episode-based payment model (89 FR 68986). Hospitals participating in TEAM continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. The model started January 1, 2026.
- IPPS hospitals that participate in the Comprehensive Care for Joint Replacement Expanded (CJR–X) Model would continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. We refer readers to section X.C. of this final rule for further discussion on the CJR–X Model.

Ineligible hospitals include the following:

- Maryland hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1866(r) of the Act because they are not paid under the IPPS. CMS and the State have entered into an agreement to govern payments to Maryland hospitals under a new payment model, the Achieving Healthcare Efficiency through Accountable Design (AHEAD) Model, beginning January 1, 2026. Maryland hospitals are not paid under the IPPS and are ineligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act. Further information is available on the CMS website at *https://www.cms.gov/priorities/innovation/innovation-models/ahead.*
- SCHs that are paid under their hospital-specific rate are not eligible for Medicare DSH and uncompensated care payments (78 FR 50623 and 50624).
- Hospitals participating in the Rural Community Hospital Demonstration Program are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173).[153] The period of participation for the last hospital in the demonstration under the most recent legislative authorization (Pub. L. 116–260) will end on June 30, 2028. Under the payment methodology that applies during this most recent extension of the demonstration program, participating hospitals do not receive empirically justified Medicare DSH payments, and they are excluded from receiving interim and final uncompensated care payments. At the time of development of this final rule, we believe 22 hospitals may participate in the demonstration program at the start of FY 2027. In the FY2027 IPPS/LTCH PPS proposed rule (91 FR 19482), we noted that if at the time of developing the final rule there is a different number of hospitals projected to participate in the demonstration program during FY 2027, we would use updated information in the FY 2027 final rule.

C. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the Secretary to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to

[152] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.*

[153] The Rural Community Hospital Demonstration Program was extended for a subsequent 5-year period by sections 3123 and 10313 of the ACA. The period of performance for this 5-year extension period ended on December 31, 2016. Section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the ACA), therefore requiring an additional 5-year participation period for the demonstration program. Section 15003 of Public Law 114–255 also required a solicitation for applications for additional hospitals to participate in the demonstration program. The period of performance for this 5-year extension period ended December 31, 2021. The Consolidated Appropriations Act, 2021 (Pub. L. 116–260) amended section 410A of Public Law 108–173 to extend the demonstration program for an additional 5-year period.

develop any new operational mechanisms for making such payments.

Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising Medicare Administrative Contractors (MACs) to simply adjust subsection (d) hospitals' interim claim payments to an amount equal to 25 percent of what would have been paid if section 1886(r) of the Act did not apply. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments could be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html.*

Comment: We received several comments outside the scope of the proposed rule.

Response: While the comments were outside the scope of this rulemaking, we will consider issues and concerns raised by the commenters for future rulemaking.

D. Supplemental Payment for Indian Health Service (IHS) and Tribal Hospitals and Puerto Rico Hospitals

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051), we established a supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico for FY 2023 and subsequent fiscal years. This payment was established to help to mitigate the impact of the decision to discontinue the use of low-income insured days as a proxy for uncompensated care costs for these hospitals and to prevent undue long-term financial disruption for these providers. The regulations located at 42 CFR 412.106(h) govern the supplemental payment. In brief, the supplemental payment for a fiscal year is the difference between the hospital's base year amount and its uncompensated care payment for the applicable fiscal year as determined under § 412.106(g)(1). The base year amount is the hospital's FY 2022 uncompensated care payment adjusted by one plus the percent change in the total uncompensated care amount between the applicable fiscal year (that is, FY 2027 for purposes of this rulemaking) and FY 2022, where the total uncompensated care amount for a fiscal year is the product of Factor 1 and Factor 2 for that year. If the base year amount is equal to or lower than the hospital's uncompensated care payment for the current fiscal year, then the hospital would not receive a supplemental payment because the hospital would not be experiencing financial disruption in that year as a result of the use of uncompensated care data from the Worksheet S–10 in determining Factor 3 of the uncompensated care payment methodology.

For FY 2027, we did not propose any changes to the methodology for determining the supplemental payments, and we will calculate the supplemental payments to eligible IHS/Tribal and Puerto Rico hospitals consistent with the methodology finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051) and § 412.106(h).

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49048 and 49049), the eligibility and payment processes for the supplemental payment are consistent with the processes for determining eligibility to receive interim and final uncompensated care payments adopted in FY 2014 IPPS/LTCH PPS final rule. The MAC will make a final determination with respect to a hospital's eligibility to receive the supplemental payment for a fiscal year, in conjunction with its final determination of the hospital's eligibility for DSH payments and uncompensated care payments for that fiscal year.

Comment: Several commenters discussed the supplemental payment for Puerto Rico hospitals. A commenter thanked CMS for continuing to recognize that Puerto Rico hospitals face unique challenges with respect to Medicare DSH payments. However, this commenter stated that Puerto Rico hospitals' delivery system is operating on margins that cannot absorb further payment reductions. Another commenter thanked CMS for continuing to recognize that Worksheet S–10 data alone does not fully reflect the level of uncompensated care provided by Puerto Rico hospitals.

Several commenters expressed concern that the supplemental payment for Puerto Rico hospitals has declined in recent years and remains vulnerable to year-to-year fluctuations. The commenters requested that CMS confirm the FY 2027 supplemental payment at a level no lower than the FY 2026 level and disclose the data and methodology used to calculate the supplemental payment in the final rule. The commenters also recommended that CMS commit to a stable, transparent, multi-year DSH supplemental payment methodology, rather than deriving the payment amount annually, to support hospital financial planning. Additionally, both commenters requested that CMS evaluate whether the Worksheet S–10 can be refined to reflect Puerto Rico's distinct payer mix and disproportionate share of uncompensated and undercompensated care.

A commenter reiterated similar recommendations that they submitted in response to the proposal to establish these supplemental payments in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 49049). The commenter recommended that CMS calculate the supplemental payment for Puerto Rico hospitals using a base year amount determined using a Medicare SSI days proxy of at least 43 percent of the hospital's Medicaid days, to reflect the local poverty level instead of the current base year amount, which incorporates the proxy that was applied from FYs 2017 through 2022 of 14 percent of the hospital's Medicaid days and that was based on national data on the relationship between Medicare SSI days and Medicaid days.

Response: We thank the commenters for their input. We refer commenters to the FY 2023 IPPS/LTCH PPS final rule (*87 FR 49047* through *49051*) for a detailed discussion of the methodology for calculating the supplemental payment for Puerto Rico hospitals. In response to commenters suggesting other approaches to calculating the supplemental payment for Puerto Rico hospitals, we note that we did not propose any changes to our methodology in the proposed rule and therefore consider these comments to be outside the scope. However, we refer readers to our responses to substantially similar comments in the FY 2023 IPPS/LTCH PPS final rule (*87 FR* 49047 through 49051, FY 2024 IPPS/LTCH PPS final rule (*88 FR* 58992 and 58993), and FY 2025 IPPS/LTCH PPS final rule (89 FR 69313 through 69315) for fulsome discussion on these issues.

E. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors, which are discussed in the next sections.

1. Calculation of Factor 1 for FY 2027

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. The regulations located at 42 CFR 412.106(g)(1)(i) govern the Factor 1 calculation. Under a prospective payment system, we would not know

the precise aggregate Medicare DSH payment amounts that would be paid for a fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, we would not know the precise aggregate empirically justified Medicare DSH payment amounts that would be paid for a fiscal year until cost report settlement for all IPPS hospitals is completed. Thus, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount. In brief, Factor 1 is the difference between the Secretary's estimates of: (1) the amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of section 1886(r) of the Act; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act.

In the FY 2027 IPPS/LTCH PPS proposed rule, consistent with the policy that has applied since the FY 2014 final rule (78 FR 50627 through 50631), we determined Factor 1 from the most recently available estimates of the aggregate amount of Medicare DSH payments that would be made for FY 2027 in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments that would be made for FY 2027, both as calculated by CMS' Office of the Actuary (OACT). We stated that consistent with the policy that has applied in previous years, these estimates will not be revised or updated subsequent to publication of our final projections in the FY 2027 IPPS/LTCH PPS final rule.

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19482 through 19484), to calculate both estimates, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by OACT using the most recently filed Medicare hospital cost reports with Medicare DSH payment information and the most recent DPPs and Medicare DSH payment adjustments provided in the IPPS Impact File. The projection of Medicare DSH payments for the fiscal year is also partially based on OACT's Part A benefits projection model, which projects, among other things, inpatient hospital spending. Projections of DSH payments additionally require projections of expected increases in utilization and case-mix. The assumptions that were used in making these inpatient hospital spending, utilization, and case-mix projections and the resulting estimates of DSH payments for FY 2024 through FY 2027 are discussed later in this section and in the table titled ''Factors Applied for FY 2024 through FY 2027 to Estimate Medicare DSH Expenditures Using FY 2023 Baseline.''

For purposes of calculating Factor 1 and modeling the impact of the FY 2027 IPPS/LTCH PPS proposed rule, we used OACT's January 2026 Medicare DSH estimates, which were based on data from the December 2025 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2026 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2026 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are ineligible for empirically justified Medicare DSH payments and uncompensated care payments, they were excluded from the January 2026 Medicare DSH estimates. Because Maryland hospitals are not paid under the IPPS, they are also ineligible for empirically justified Medicare DSH payments and uncompensated care payments and were also excluded from OACT's January 2026 Medicare DSH estimates.

The 22 hospitals that CMS expects will participate in the Rural Community Hospital Demonstration Program in FY 2027 were also excluded from OACT's January 2026 Medicare DSH estimates because under the payment methodology that applies during the demonstration, these hospitals are not eligible to receive empirically justified Medicare DSH payments or uncompensated care payments.

In the FY 2027 IPPS/LTCH proposed rule, using the data sources previously discussed, OACT's January 2026 estimate of Medicare DSH payments for FY 2027 without regard to the application of section 1886(r)(1) of the Act, is approximately $15.303 billion. Therefore, also based on OACT's January 2026 Medicare DSH estimates, the estimate of empirically justified Medicare DSH payments for FY 2027, with the application of section 1886(r)(1) of the Act, is approximately $3.826 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2027). Under § 412.106(g)(1)(i), Factor 1 is the difference between these two OACT estimates. Therefore, in the FY 2027 IPPS/LTCH PPS proposed rule, we determined that Factor 1 for FY 2027 would be $11.477 billion, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2027 ($15.303 billion minus $3.826 billion). We noted that consistent with our approach in previous rulemakings, OACT intended to use more recent data that may become available for purposes of projecting the final Factor 1 estimates for the FY 2027 IPPS/LTCH PPS final rule.

In the FY 2027 IPPS/LTCH proposed rule (91 FR 19483), we stated that the Factor 1 estimates for IPPS/LTCH PPS proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and Factor 1 estimates for IPPS/LTCH PPS final rules are generally consistent with those used for the Midsession Review of the President's Budget. We explained that consistent with historical practice, we expected the Midsession Review would have updated economic assumptions and actuarial analysis, which would be used for the development of Factor 1 estimates in the FY 2027 IPPS/LTCH PPS final rule.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2025 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds,'' available on the CMS website at *https://www.cms.gov/oact/tr/2025*. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

In the FY 2027 IPPS/LTCH proposed rule (91 FR 19482 through 19484), we included information regarding the data sources, methods, and assumptions employed by OACT's actuaries in determining our estimate of Factor 1. In summary, we indicated the historical HCRIS data update OACT used to estimate Medicare DSH payments. We also explained that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provided the components of all the update factors that were applied to the historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the

associated rationale and assumptions. The discussion also includes descriptions of the ''Other'' and ''Discharges'' assumptions.

We invited public comments on our proposed Factor 1 for FY 2027.

Comment: A few commenters expressed concern regarding CMS' proposed reduction to the Factor 1 amount for FY 2027 while others requested that CMS ensure that the proposed Factor 1 amount accurately reflects DSH payments. As in prior years, commenters encouraged CMS to provide greater transparency regarding the assumptions and data used by CMS OACT to estimate Factor 1. A few commenters asserted that hospitals' lack of opportunity to review the data used in rulemaking is inconsistent with the Administrative Procedure Act. These commenters expressed concern regarding the lack of transparency in the Factor 1 calculation and asserted that hospitals cannot meaningfully comment on the methodology without additional detail. Specifically, these commenters stated that the proposed rule provided neither sufficient detail nor an explanation regarding the treatment of Medicaid expansions in the Factor 1 calculation.

Several commenters urged CMS to provide additional detail regarding how the ''Other'' factor is calculated, including the assumptions and adjustments reflected in the estimate. Specifically, a commenter stated the FY 2027 IPPS/LTCH PPS proposed rule omitted a statement included in prior rulemaking explaining that the ''Other'' factor accounts for estimated changes in Medicaid enrollment through FY 2023. Another commenter stated that CMS did not clearly explain how it used Medicaid expansion levels in calculating Factors 1 and 2, whether it considered those levels consistently across both factors, or how it adjusted Factor 1 for the assumed Medicaid expansion level in FY 2027. Several commenters stated that CMS estimates a $900 million, or 9 percent, decrease in Factor 1 attributable to the ''Other'' factor for FY 2027 and requested additional explanation on CMS' assumptions and data that resulted in the decline. A commenter requested that CMS publish a detailed methodology for its ''Other'' calculation, including how each component contributes to changes in the estimate from year to year, while a couple of commenters also requested that CMS clarify why the ''Other'' factor frequently varies across successive rulemaking cycles.

Response: We thank the commenters for their input.

Regarding the commenters that express concern with the proposed decrease in Factor 1, as discussed further in this section, we have used the best available data to estimate DSH payments for this final rule, consistent with the statutory requirements for Factor 1.

We disagree with commenters' assertions regarding a lack of transparency with respect to the methodology and assumptions used in the calculation of Factor 1. As explained in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19312) and in this section of this final rule, we have been and continue to be transparent about the methodology and data used to estimate Factor 1. Regarding the commenters who reference the Administrative Procedure Act, we note that under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In this case, the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19482 through 19484) included a detailed discussion of our proposed Factor 1 methodology and the data sources that would be used in making our final estimate. Accordingly, we believe commenters were able to meaningfully comment on our proposed estimate of Factor 1.

To provide additional context, and as we have explained in prior rulemakings (see example, 90 FR 36536), Factor 1 is not estimated in isolation from other projections made by OACT. As stated in the FY 2027 IPPS/LTCH proposed rule (91 FR 19483) the Factor 1 estimates for the proposed rules are generally consistent with the economic assumptions and actuarial analyses used to develop the President's Budget estimates under current law, and the Factor 1 estimates for this final rule are the latest estimates from OACT at the time of development of this final rule. We recognize that our reliance on the economic assumptions and actuarial analyses used to develop the President's Budget in estimating Factor 1 has an impact on hospitals, health systems, and other impacted parties that wish to replicate the Factor 1 calculation by, for example, modeling the relevant Medicare Part A portion of the President's Budget. Yet, we continue to believe commenters are able to meaningfully comment on our proposed estimate of Factor 1 without replicating the budget.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2026 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds,'' available under ''Downloads'' on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html.* The annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization, and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, given that the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

Additionally, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19482 through19484) and described in more detail later in this section, we included information regarding the data sources, methods, and assumptions employed by the actuaries to determine the OACT's estimate of Factor 1. We explained that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used to calculate Factor 1, and we provided the components of all update factors that were applied to historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the associated rationale and assumptions. This discussion also included a description of the ''Other,'' ''Discharges,'' and ''Case-Mix'' factors and their underlying assumptions.

Regarding the commenter's concern that the FY 2027 proposed rule did not include a prior statement that the ''Other'' factor accounts for estimated changes in Medicaid enrollment through FY 2023, we refer readers to OACT's FY 2027 Memorandum ''Estimate of Medicare DSH Payments Used in Development of Factor 1.'' (Available on the CMS website at: *https://www.cms.gov/files/document/fy-2027-final-rule-oact-memo-dsh-factor-1.pdf*).

In that memorandum, OACT explains that the ''Other'' factor includes an adjustment for the change in Medicaid enrollment in 2023 and that, after examining estimated changes in Medicaid enrollment over the past few years, OACT is making no further explicit adjustments for Medicaid enrollment beyond 2023. As we described in the proposed rule (91 FR

19483), OACT's estimates for FY 2027 for the proposed rule began with baseline Medicare DSH expenditures for FY 2023 and as such make no further adjustments for Medicaid enrollment.

Comment: Commenters requested that CMS provide additional detail regarding the calculations and assumptions associated with the ''Discharge'' component used in the Factor 1 formula, with some urging CMS to publish discharge estimates annually in the IPPS proposed rule. These commenters stated that the additional detail would allow commenters to evaluate whether CMS is accurately capturing the impact of Medicare Advantage (MA) enrollment growth on Medicare Fee for Service (FFS) inpatient hospital payments. One of the commenters stated that the continued expansion of MA has raised concerns, especially around prior authorization requirements imposed by plans, which often create burdens for both patients and providers, prompting broader conversations about the sustainability of MA growth and its implications for inpatient hospital payments, especially for hospitals serving a disproportionate share of low-income beneficiaries. The same commenter welcomed the opportunity to work with CMS in examining the impacts of MA enrollment on FFS inpatient hospital payments—particularly with respect to this impact on the ''Discharge'' component of Factor 1. Another commenter urged CMS to clarify how it uses MA data to inform Factor 1 and stated that MA penetration varies significantly by state, community, and provider, and that DSH status meaningfully affects hospitals' relationships with MA plans, as some hospitals report that MA plans frequently exclude essential hospitals with higher DSH adjustments from their networks.

Several other commenters stated that CMS' discharge projections for FY 2026 and FY 2027 are based on assumptions rather than actual data. Another commenter requested that CMS establish a formal process, such as a technical workgroup or a dedicated public comment period on DSH methodology, through which these issues could be examined in a structured and transparent manner.

Further, a commenter urged CMS to update its proposed ''Case-Mix'' update factor to more accurately reflect the increasing acuity and resource intensity of inpatient encounters. The commenter stated that the shift of healthcare services from inpatient to outpatient settings, as further reflected by the elimination of the inpatient-only list for the Outpatient Prospective Payment System, has resulted in increasingly complex care being furnished in the inpatient setting. The commenter also cited CMS projections that Medicare Part A per capita spending will grow at an average annual rate of 4.5 percent between 2020 and 2030, while CMS proposes a 13 percent decline in the proposed ''Case-Mix'' factor from 1.0075 in FY 2026 to 1.0050 in FY 2027.

Another commenter stated that CMS had not adequately explained why assumptions from a 2012 Technical Review Panel report remain appropriate for estimating the FY 2027 Case-Mix update factor, given changes in Medicare beneficiary demographics, MA enrollment trends, and post-COVID–19 PHE utilization patterns since 2012.

Response: We thank the commenters for their input. We continue to disagree with commenters' assertions regarding a lack of transparency with respect to the methodology and assumptions used in the calculation of Factor 1. Regarding commenters' requests for additional detail on the calculations and assumptions underlying the ''Discharges'' and ''Case-Mix'' factors, we refer the commenters to the discussion elsewhere in this section of this final rule and the relevant discussion in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19483–19484), which detail the calculations and assumptions we used to calculate the FY 2027 ''Discharges'' and ''Case-Mix'' factors. We also note that in updating our estimate of Factor 1 for this final rule, we considered, as appropriate, the same set of factors that we used in the FY 2026 IPPS/LTCH PPS proposed rule and in prior rulemakings (for example, FY 2026 IPPS/LTCH final rule 90 FR 36536, 36880 through 36894). As we stated we would do in the FY 2027 IPPS/LTCH PPS proposed rule, we then updated our estimates for the FY 2027 ''Discharges,'' ''Case-Mix'' component, and other Factor 1 components, to incorporate the latest available data based on more recent economic assumptions and actuarial analyses. Regarding the comment on the changes to the inpatient only procedures list, we refer readers to the CY2026 OPPS final rule. (90 FR 53450).

Regarding the comments on the impacts of MA enrollment on the Medicare FFS discharge volume and the ''Discharges'' component of Factor 1, we refer commenters to the actuarial projections and assumptions regarding future trends in Medicare FFS and MA program enrollment, utilization, and costs of health care services covered by Medicare, as well as other factors affecting Medicare FFS and MA program expenditures, contained in the ''2026 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds,'' available under ''Downloads'' on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html.* We considered these projections, assumptions, and other factors when developing our estimate of the ''Discharges'' factor for FY 2027. We also note that in this final rule, consistent with prior years (see example, 90 FR 36536), our estimate of the ''Discharges'' component for FY 2027 incorporates only claims from the Medicare FFS program rather than claims from the MA program. Accordingly, we believe that the FY 2027 ''Discharges'' factor in this final rule accurately reflects trends in Medicare FFS discharges. We welcome input from commenters on the MA program and the Factor 1 methodology during the comment period.

Regarding the comments about CMS discharge projections, we note that we believe the use of discharge trend assumptions and projections for Factor 1 is consistent with the statute and long-standing methodology of Factor 1. OACT's Factor 1 estimate is based on the most recent available data and uses reasonable assumptions for recent discharge trends.

Regarding the commenter's comparison of the projected growth in Medicare Part A per capita spending and the case-mix changes in FY 2027, we refer the commenters to the actuarial projections and assumptions regarding future trends outlined in the ''2026 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds''. We considered those projections and assumptions in calculating the Case-Mix factor component of Factor 1. As discussed later in this section, we continue to believe it is a reasonable assumption that the growth in case-mix will slow gradually until reaching 0.5 percent annually in fiscal year 2027. The projections for case-mix growth are discussed later in this section.

After consideration of the public comments received, we are finalizing, as proposed, the methodology for calculating Factor 1 for FY 2027. Consistent with prior rulemakings, for this final rule, OACT used the most recently submitted Medicare cost report data from the March 31, 2026, update of HCRIS to identify Medicare DSH payments and the most recent Medicare

DSH payment adjustments provided in the Impact File and applied update factors and assumptions for projected changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year.

The June 2026 OACT estimate for Medicare DSH payments for FY 2027, without regard to application of section 1886(r)(1) of the Act, is approximately $15.767 billion. This estimate excluded Maryland hospitals, which participate in the Maryland Total Cost of Care Model and are not paid under the IPPS, hospitals participating in the Rural Community Hospital Demonstration, and SCHs paid under their hospital-specific payment rate. Therefore, based on this June 2026 estimate, the estimate of empirically justified Medicare DSH payments for FY 2027, with application of section 1886(r)(1) of the Act, is approximately $3.94 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2027). Under § 412.106(g)(1)(i), Factor 1 is the difference between these two OACT estimates. Therefore, the final Factor 1 for FY 2027 is $11,825,250,000, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2027 ($15,767,000,000 minus $3,941,750,000). OACT's estimates for FY 2027 for this final rule began with a baseline of $12.898 billion in Medicare DSH expenditures for FY 2023. The following table shows the factors applied to update this baseline through the current estimate for FY 2027.

FACTORS APPLIED FOR FY 2024 THROUGH FY 2027 TO ESTIMATE MEDICARE DSH EXPENDITURES USING FY 2023 BASELINE

FY	IPPS Hospital Market Basket Update Factor	Discharges	Case-Mix	Other	Total	Estimated DSH Payment (in billions)*
2024	1.031	1.002	1.0000	1.0279	1.0619	13.696
2025	1.029	1.027	1.0090	0.9936	1.0593	14.508
2026	1.026	1.014	1.0075	0.9674	1.0137	14.707
2027**	1.023	1.021	1.0050	1.0215	1.0721	15.767

*Rounded.

** The FY 2027 figures reflect the inpatient hospital market basket percentage increase and productivity adjustment and are based on the 2nd quarter 2026 IHS Global Inc. (IGI) forecast, the most recent forecast available at the time of development of this final rule.

In this table, the discharges factor column shows the changes in the number of Medicare FFS inpatient hospital discharges. The discharge figures for FY 2024 and FY 2025 are based on Medicare claims data that have been adjusted by a completion factor to account for incomplete claims data. The discharge figures for FY 2026 and FY 2027 are assumptions based on recent historical experience and assumptions related to how many beneficiaries will be enrolled in MA plans.

The case-mix factorcolumn shows the estimated change in case-mix for IPPS hospitals. The case-mix figures for FY 2024 and FY 2025 are based on actual claims data adjusted by a completion factor to account for incomplete claims data. The case-mix figure for FY 2026 reflects an expected transition to the case-mix figure for FY 2027. In other words, the FY 2026 factor value of 1.0075 is a midpoint transition to the expected ultimate trend of 1.005. The FY 2026 and the FY 2027 case-mix figures are based on assumptions from the 2012 ''Review of Assumptions and Methods of the Medicare Trustees' Financial Projections'' report by the 2010–2011 Medicare Technical Review Panel.[154]

The ''Other'' column reflects the change in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and IPPS discharges and various adjustments (*e.g.,* budget neutrality adjustments) to the IPPS payment rates that have been finalized and applied over the years but are not reflected in the other columns.

The following table shows the factors that are included in the ''IPPS Hospital Market Basket Update Factor'' column of the previous table:

FY	IPPS Hospital Market Basket Percentage Increase	Productivity Adjustment	Documentation and Coding	Total Update Percentage
2024	3.3	0.2	0.0	3.1
2025	3.4	0.5	0.0	2.9
2026	3.3	0.7	0.0	2.6
2027	3.2	0.9	0.0	2.3

Note: All figures in this table are the final inpatient hospital updates for the applicable fiscal year. The FY 2027 figures reflect the inpatient hospital market basket percentage increase and productivity adjustment and are based on the 2nd quarter 2026 IGI forecast, the most recent forecast available at the time of development of this final rule. We refer to section VI.B. of the preamble of this final rule for a complete discussion of the inpatient hospital market basket update for FY 2027.

Note: All figures in this table are the final inpatient hospital updates for the applicable fiscal year. The FY 2027 figures reflect the inpatient hospital market basket percentage increase and productivity adjustment and are based on the 2nd quarter 2026 IGI forecast, the most recent forecast available at the time of development of this final rule. We refer to section VI.B. of the preamble of this final rule for a complete discussion of the inpatient hospital market basket update for FY 2027.

2. Calculation of Factor 2 for FY 2027

a. Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Section 1886(r)(2)(B)(ii) of the Act

[154] *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/downloads/technicalpanelreport2010-2011.pdf.*

provides that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified).

We are continuing to use the methodology that was used in fiscal years (FYs) 2018 through 2026 to determine Factor 2 for FY 2027—to use the National Health Expenditure Accounts (NHEA) data to determine the percentage point change in the percent of individuals who are uninsured. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 and 38198) for a complete discussion of the NHEA and why we determined, and continue to believe, that it is the data source for the rate of uninsurance that best meets all our considerations and is consistent with the statutory requirement that the estimate of the rate of uninsurance be based on data from the Census Bureau or other sources the Secretary determines appropriate.

In brief, the NHEA represents the government's official estimates of economic activity (*that is,* spending) within the health sector. The NHEA includes comprehensive enrollment estimates for total private health insurance (PHI) (including direct-purchase and employer-sponsored plans), Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. The NHEA data are publicly available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html.*

To compute Factor 2 for FY 2027, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. For a complete discussion of the approach OACT used to prepare the NHEA's estimate of the rate of uninsurance in 2013, including the data sources used, we refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 58998–58999).

The next metrics needed to compute Factor 2 for FY 2027 are projections of the rate of uninsurance in calendar years (CYs) 2026 and 2027 for the total U.S. population. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. The most recent projections are for 2025 through 2034 and were published on June 24, 2026. Those projections used the latest NHEA historical data that were available at the time of their construction (that is, all NHEA historical data through 2024). The NHEA projection methodology accounts for expected changes in enrollment across all of the categories of insurance coverage previously noted. For a complete discussion of how the NHEA data account for expected changes in enrollment across all the categories of insurance coverage previously noted, we refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 58999).

b. Factor 2 for FY 2027

Using these data sources and the previously described methodologies, at the time of developing the proposed rule, OACT had estimated that the uninsured rate for the historical baseline year of 2013 was 14.0 percent, and that the uninsured rates for CYs 2026 and 2027 were projected to be 9.0 and 9.1 percent, respectively (FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19484)). As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS certified these estimates. We refer readers to OACT's Memorandum on Certification of Rates of Uninsured prepared for the FY 2027 IPPS/LTCH PPS proposed rule for further details on the methodology and assumptions that were used in the projection of these rates of uninsurance.[155]

As with the CBO estimates on which we based Factor 2 for fiscal years before FY 2018, the NHEA estimates are for a calendar year. Under the approach originally adopted in the FY 2014 IPPS/LTCH PPS final rule (79 FR 50014), we have used a weighted average approach to project the rate of uninsurance for each fiscal year. We continue to believe that, in order to estimate the rate of uninsurance during a fiscal year accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather than the rate of uninsurance during only one of the calendar years the fiscal year spans. Accordingly, in the FY 2027 IPPS/LTCH PPS proposed rule, we proposed to continue to apply the weighted average approach used in past fiscal years to estimate this final rule's rate of uninsurance for FY 2027.

[155] *See https://www.cms.gov/files/document/certification-rates-uninsured-fy-2027-proposed-rule.pdf.*

OACT certified the estimate of the rate of uninsurance for FY 2027 determined using this weighted average approach to be reasonable and appropriate for purposes of section 1886(r)(2)(B)(ii) of the Act.[1] In the proposed rule (91 FR 19485), we noted that we may also consider the use of more recent data that may become available before publication of the final rule, for purposes of estimating the rates of uninsurance used in the calculation of the final Factor 2 for FY 2027.

In the proposed rule, we outlined the calculation of the proposed Factor 2 for FY 2027 as follows:

- Percent of individuals without insurance for CY 2013: 14.0 percent.
- Percent of individuals without insurance for CY 2026: 9.0 percent.
- Percent of individuals without insurance for CY 2027: 9.1 percent.
- Percent of individuals without insurance for FY 2027: (0.25 times 0.090) + (0.75 times 0.091) = 9.1 percent.
- FY 2027's proposed Factor 2 is calculated as 1 minus the percent change in the percent of individuals without insurance between CY 2013 and FY 2027.
- Proposed Factor 2 is as follows: $1 - |((0.14 - 0.091)/0.14)| = 1 - 0.3500 = 0.6500$

We proposed that Factor 2 for FY 2027 would be 65.00 percent.

The proposed FY 2027 uncompensated care amount was equivalent to proposed Factor 1 multiplied by proposed Factor 2, which was $7,460,212,500.

We invited public comments on our proposed Factor 2 for FY 2027.

Comment: Most commenters that discussed Factor 2 expressed concern that the proposed rule's FY 2027 uninsured rate is underestimated. Commenters stated that the proposed Factor 2 amount does not account for several finalized and proposed federal policy changes that could dramatically increase the uninsured rate in FY 2027. These commenters referenced policy changes such as the expiration of the American Rescue Plan's Marketplace enhanced premium tax credits, the implementation of Medicaid work requirements, the projected impact of the One Big Beautiful Bill Act (H.R.1), the Working Families Tax Cut legislation, and other pending or proposed federal policy changes that may restrict Medicaid enrollment and impact the uninsured population in FY 2027. Other commenters voiced concerns that the proposed reduction to Factor 2 coincides with increased operating costs for hospitals that provide uncompensated care.

Several commenters also referenced data sources and analyses estimating the impact of proposed federal policies on the uninsured rate. Some commenters cited the Congressional Budget Office (CBO) projection of the uninsured rate, which estimates that the number of uninsured individuals will increase by 5.2 million in 2027, and 10 million by 2034, due to the passage of the One Big Beautiful Bill Act. Other commenters cited the CBO projection that 2.2 million individuals will lose their health insurance in 2026 and that 16 million will become uninsured from 2027 to 2034 due to the expiration of the American Rescue Plan's Marketplace enhanced premium tax credits. A few commenters referenced the CBO estimate that by 2034, about 4.8 to 5.3 million individuals will lose their insurance due to the Medicaid work requirements, and 10 million individuals will become uninsured. A commenter also referred to the CMS Marketplace Integrity and Affordability Final Rule regarding estimates that Marketplace enrollment would decrease by 725,000, to 1.8 million enrollees in 2026 (90 FR 27213). A commenter referenced a Kaiser Family Foundation analysis, which showed that 28 percent of enrollees in Louisiana were disenrolled from Medicaid and the Children's Health Insurance Program (CHIP) between 2023 and 2026. Another commenter referenced a Robert Wood Johnson Foundation report, which showed that 4.9 to 10.1 million individuals, and 25 to 50 percent of enrollees in Ohio, are at risk of losing their Medicaid coverage by 2028 because of the new Medicaid work requirements.

Citing CMS' statement in the proposed rule that the agency could consider more recent data that may become available for the calculation of final Factor 2 for FY 2027, many commenters urged CMS to use more recent and ''accurate'' data sources to account for the anticipated increase in the uninsured rate for FY 2027. Some commenters urged CMS to consider utilizing alternative, more comprehensive, and real-world data sources and calculations from interested parties and researchers or supplementing the NHEA data with other data sources to ensure that the Factor 2 estimate appropriately reflects the current coverage landscape and accurately estimates uninsured projections.

Additionally, a few commenters stated that the current Factor 2 methodology may have been appropriate during periods of stable insurance coverage but may no longer be adequate given the above-referenced recent and proposed federal policy shifts that may impact the uninsured rate. As such, these commenters urged CMS to reevaluate the current data sources and methodologies used to estimate Factor 2. Another commenter requested that CMS update the proposed rule's estimate of the uninsured rate for the upcoming fiscal year earlier in each rulemaking cycle to enhance the reliability of the proposed rule in projecting changes to uncompensated care payments for upcoming fiscal years. Other commenters urged CMS to ensure that the NHEA estimates are accurate and up to date, while others questioned the NHEA's conclusion that Medicaid enrollment will continue to grow in 2026 and 2027, given CBO estimates of an increase in the uninsured rate. A couple of commenters also questioned the reliability of the NHEA projections, noting that they were published in June 2025, rely on historical data through 2023, and do not fully account for recent changes in the coverage landscape due to the above-referenced, recently enacted and proposed federal policy changes.

Response: We thank the commenters for their input regarding the estimate of Factor 2 included in the proposed rule. In response to comments concerning the NHEA data source used for calculating Factor 2 for FY 2027, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 through 38198) for a complete discussion of why we continue to believe the NHEA remains the data source that best meets all considerations for ensuring reasonable estimates of the uninsured rate throughout the IPPS rulemaking cycle. Importantly, the NHEA's projected estimates of the rate of uninsurance are based on an established methodology, they account for expected enrollment changes across all coverage categories (including public and private coverage), and they incorporate the latest available data for use in the respective proposed and final rules. Regarding the comments requesting that CMS update the Factor 2 methodology and data sources and increase Factor 2, we continue to believe that estimating Factor 2 based on the best available data is appropriate and consistent with the requirements of Section 1886(r)(2)(B)(ii) of the Act, as discussed in prior rulemaking (*see, e.g.,* 82 FR 38197 and 38198).

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19484 and 19485), we explained that we used the most recent available estimates from the NHEA at that time, and we refer readers to the relevant discussion in the proposed rule and OACT's memorandum on ''*Certification of Rates of Uninsured*'' prepared for the proposed rule for further details on the methodology and assumptions used in the proposed rule's calculation of the projected uninsured rate.[1] In brief, we indicated that our projection of the rates of uninsurance for CYs 2026 and 2027 were from the latest NHEA historical data available and accounted for expected changes in enrollment across all categories of insurance coverage. We remind readers that OACT's estimates in the proposed rule considered the expiration of the American Rescue Plan's Marketplace enhanced premium tax credits and the latest Medicaid projections publicly available at that time (90 FR 36889).

In response to commenters who requested that we update the Factor 2 estimates in the FY 2027 IPPS/LTCH PPS proposed rule to account for any anticipated changes in the uninsured rate using more recent or alternative data sources, we stated in the proposed rule that we may consider the use of more recent data that may become available for purposes of estimating the rates of uninsurance used in the calculation of the final Factor 2 for FY 2027. This final rule uses the most recent NHEA estimates, available as of June 24, 2026. These projections were finalized in April 2026 and reflect current law (including the expiration of the Inflation Reduction Act's temporary extension of enhanced premium tax credits and the enactment of the One Big Beautiful Bill Act). Consistent with the FY 2026 IPPS/LTCH PPS final rule (90 FR 36887), and for the reasons stated earlier in this section of this final rule, we are using the updated NHEA data for the final Factor 2 calculation as we believe that it is the most appropriate measure of changes in the rate of uninsurance.

Regarding the request that CMS issue an earlier estimate of the uninsured rate for the upcoming FY during each annual IPPS rulemaking cycle, we believe the proposed rule and final rule's estimates are appropriate and timely as they reflect projections that are developed in each calendar year and released in June of each calendar year. We will continue to use the most recently available data during the development of the proposed and final rule.

Comment: Several commenters urged CMS to provide additional details on how Factor 2 is calculated and how it accounts for the current coverage landscape, while others urged CMS to be more transparent regarding the data sources used for calculating Factor 2, the assumptions behind the uninsured

rate, and the ''hospital-specific uncompensated care factors.'' A couple of commenters asserted that the proposed rule did not provide sufficient details, nor an explanation of the treatment of Medicaid expansions in the calculation for Factor 2. A few commenters requested that CMS publish a detailed methodology on the calculation of Factor 2 and how the NHEA projections are incorporated into the estimate.

Finally, a commenter requested that CMS publish the relevant OACT information involved in the calculation of Factor 2 in advance of the final rule publication and in the IPPS proposed rule each year going forward to ensure that hospitals can verify the underlying data and understand the fluctuations in DSH payments before the end of the proposed rule's comment period.

Response: In response to the comments concerning transparency, we note that OACT's updated memorandum, ''Certification of Rates of Uninsured,'' contains additional methodological detail describing the methods used to derive the FY 2027 rate of uninsured for this final rule. Section 1886(r)(2)(B)(ii) of the Act permits us to use a data source other than CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. (Available on the CMS website at: *https://www.cms.gov/files/document/certification-rates-uninsured-2027-final-rule.pdf.*) As explained elsewhere in this section of this final rule, the NHEA data and methodology that were used to estimate Factor 2 for this final rule are transparent and best meet all our considerations for ensuring reasonable estimates for the rate of uninsurance that are available for each IPPS rulemaking cycle. We continue to believe it is appropriate to update the projection of the FY 2027 rate of uninsurance using the most recent NHEA data, as it properly accounts for all recent, relevant legislative actions. For additional information on the NHEA's projection of the uninsured rate, see the projection's methodology documentation. (Available on the CMS website at: *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/downloads/projectionsmethodology.pdf.*)

While we appreciate the commenter's request for earlier publication of the OACT data used to calculate Factor 2, the publication timeframe of that NHEA data is beyond the scope of this rulemaking's Factor 2 calculation. The projected national uninsured rates and underlying methodologies were available for public review by the display and publication dates of the IPPS proposed rule, and we stated that if more timely estimates became available, they would be used for the final rule. Updated projections became publicly available in June 2026 and included supporting methodology material. (Available on the CMS website at: *https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/projected*). We believe our established process allows hospitals adequate opportunity to analyze the proposed rule's estimate and supporting methodology material (see, *e.g.,* 90 FR 36888 and 36889).

After consideration of the public comments we received, we are updating the calculation of Factor 2 for FY 2027 to incorporate the most recent NHEA data. The final estimates of the percentage of uninsured individuals have been certified by the Chief Actuary of CMS.

The calculation of the final Factor 2 for FY 2027 using a weighted average of OACT's updated projections for CY 2026 and CY 2027 is as follows:

- Percent of individuals without insurance for CY 2013: 14.0 percent.
- Percent of individuals without insurance for CY 2026: 9.2 percent.
- Percent of individuals without insurance for CY 2027: 9.5 percent.
- Percent of individuals without insurance for FY 2027: (0.25 times 0.092) + (0.75 times 0.095) = 9.4 percent.
- FY 2027's Factor 2 is calculated as 1 minus the percent change in the percent of individuals without insurance between CY 2013 and FY 2027.
- Factor 2 is as follows: $1 - |((0.14 - 0.094)/0.14)| = 1 - 0.3286 = 0.6714$

Therefore, Factor 2 for FY 2027 is 67.14 percent.

The final FY 2027 uncompensated care amount is equivalent to Factor 1 multiplied by Factor 2, which is $7,939,472,850.

3. Calculation of Factor 3 for FY 2027

a. General Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of: (1) the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. To implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary for us to determine: (1) the definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (the estimated uncompensated care amount for an individual hospital) and the denominator (the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. For a discussion of the methodology we used to calculate Factor 3 for fiscal years (FYs) 2014 through 2022, we refer readers to the FY 2024 IPPS/LTCH final rule (88 FR 59001 and 59002).

b. Background on the Methodology Used To Calculate Factor 3 for FY 2024 and Subsequent Years

Section 1886(r)(2)(C) of the Act governs the selection of the data to be

used in calculating Factor 3 and allows the Secretary the discretion to determine the time periods from which we derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for a subsection (d) hospital for a period selected by the Secretary. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50634 through 50647), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments for a fiscal year and for those hospitals that we do not estimate will qualify for Medicare DSH payments for that fiscal year but that may ultimately qualify for Medicare DSH payments for that fiscal year at the time of cost report settlement.

As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45237), commenters expressed concerns that the use of only 1 year of data to determine Factor 3 would lead to significant variations in year-to-year uncompensated care payments. Some stakeholders recommended the use of 2 years of historical data from Worksheet S–10 data of the Medicare cost report. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45237), we stated that we would consider using multiple years of data when the vast majority of providers had been audited for more than 1 fiscal year under the revised reporting instructions. Audited FY 2020 cost reports were available for the development of the FY 2024 IPPS/LTCH PPS proposed and final rules. Feedback from previous audits and lessons learned were incorporated into the audit process for the FY 2020 reports.

In consideration of the comments discussed in the FY 2022 IPPS/LTCH PPS final rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49036 through 49047), we finalized a policy of using a multi-year average of audited Worksheet S–10 data to determine Factor 3 for FY 2023 and subsequent fiscal years. We explained our belief that this approach would be generally consistent with our past practice of using the most recent single year of audited data from the Worksheet S–10, while also addressing commenters' concerns regarding year-to-year fluctuations in uncompensated care payments. Under this policy, we used a 2-year average of audited FYs 2018 and 2019 Worksheet S–10 data to calculate Factor 3 for FY 2023. We also indicated that we expected FY 2024 would be the first year that 3 years of audited data would be available at the time of rulemaking.

For FY 2024 and subsequent fiscal years, we finalized a policy of using a 3-year average of the uncompensated care data from the 3 most recent fiscal years for which audited data are available to determine Factor 3. Consistent with the approach that we followed when multiple years of data were previously used in the Factor 3 methodology, if a hospital does not have data for all 3 years used in the Factor 3 calculation, we will determine Factor 3 based on an average of the hospital's available data. For IHS and Tribal hospitals and Puerto Rico hospitals, we use the same multi-year average of Worksheet S–10 data to determine Factor 3 for FY 2024 and subsequent fiscal years as is used to determine Factor 3 for all other DSH-eligible hospitals (in other words, hospitals eligible to receive empirically justified Medicare DSH payments for a fiscal year) to determine Factor 3.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49033 through 49047), we also modified our policy regarding cost reports that start in one fiscal year and span the entirety of the following fiscal year. Specifically, in the rare cases when we use a cost report that starts in one fiscal year and spans the entirety of the subsequent fiscal year to determine uncompensated care costs for the subsequent fiscal year, we would not use the same cost report to determine the hospital's uncompensated care costs for the earlier fiscal year. We explained that using the same cost report to determine uncompensated care costs for both fiscal years would not be consistent with our intent to smooth year-to-year variation in uncompensated care costs. As an alternative, we finalized our proposal to use the hospital's most recent prior cost report, if that cost report spans the applicable period.[156]

[156] For example, in determining Factor 3 for FY 2023, we did not use the same cost report to determine a hospital's uncompensated care costs for both FY 2018 and FY 2019. Rather, we used the cost report that spanned the entirety of FY 2019 to determine uncompensated care costs for FY 2019 and used the hospital's most recent prior cost report to determine its uncompensated care costs for FY 2018, provided that cost report spanned some portion of FY 2018.

(1) Scaling Factor

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69323), we continued the policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042) to address the effects of calculating Factor 3 using data from multiple fiscal years by applying a scaling factor to the Factor 3 values calculated for all DSH-eligible hospitals. As a result, the total uncompensated care payments to hospitals that are projected to be DSH-eligible for a fiscal year will be consistent with the estimated amount available to make uncompensated care payments for that fiscal year. Pursuant to that policy, we divide 1 (the expected sum of all DSH-eligible hospitals' Factor 3 values) by the actual sum of all DSH-eligible hospitals' Factor 3 values and then multiply the quotient by the uncompensated care payment determined for each DSH-eligible hospital to obtain a scaled uncompensated care payment amount for each hospital. This process is designed to ensure that the sum of the scaled uncompensated care payments for all hospitals that are projected to be DSH-eligible is consistent with the estimate of the total amount available to make uncompensated care payments for the applicable fiscal year.

(2) New Hospital Policy

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69323), we continued our new hospital policy that was modified in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042) and initially adopted in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42370 through 42371) to determine Factor 3 for new hospitals. Consistent with our policy of using multiple years of cost reports to determine Factor 3, we defined new hospitals as hospitals that do not have cost report data for the most recent year of data being used in the Factor 3 calculation. Under this definition, the cut-off date for the new hospital policy is the beginning of the fiscal year after the most recent year for which audits of the Worksheet S–10 data have been conducted. For FY 2027, FY 2023 cost reports are the most recent year of cost reports for which audits of Worksheet S–10 data have been conducted. Thus, hospitals with CMS Certification Numbers (CCNs) established on or after October 1, 2023, would be subject to the new hospital policy for FY 2027.

Under our modified new hospital policy, if a new hospital has a preliminary projection of being DSH-eligible based on its most recent available disproportionate patient percentage, it may receive interim empirically justified DSH payments. However, new hospitals will not receive interim uncompensated care payments because we would have no uncompensated care data on which to determine what those interim payments should be. The MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement. In FY 2025, while we continued to determine the numerator of the Factor 3 calculation using the new hospital's uncompensated care costs reported on Worksheet S–10 of the hospital's cost report for the current fiscal year, we determined Factor 3 for new hospitals using a denominator based solely on uncompensated care costs from cost reports for the most recent fiscal year for which audits have been conducted. In addition, we applied a scaling factor to the Factor 3 calculation for a new hospital.[157]

(3) Newly Merged Hospital Policy

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 690323 through 690324), we continued our policy of treating hospitals that merge after the development of the final rule for the applicable fiscal year similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50021), for these newly merged hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50021 and 50022), we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year will be recalculated similar to new hospitals.

Consistent with the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 690323 through 690324), we stated that we would continue to treat newly merged hospitals in a similar manner to new hospitals, such that the newly merged hospital's final uncompensated care payment will be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 will be based on the cost report of only the surviving hospital (that is, the newly merged hospital's cost report) for the current fiscal year. However, if the hospital's cost reporting period includes less than 12 months of data, the data from the newly merged hospital's cost report will be annualized for purposes of the Factor 3 calculation. Consistent with the methodology used to determine Factor 3 for new hospitals described in section IV.E.3. of the preamble of this final rule, we continued our policy for determining Factor 3 for newly merged hospitals using a denominator that is the sum of the uncompensated care costs for all DSH-eligible hospitals, as reported on Worksheet S–10 of their cost reports for the most recent fiscal year for which audits have been conducted. In addition, we apply a scaling factor, as discussed in section IV.E.3. of the preamble of this final rule, to the Factor 3 calculation for a newly merged hospital. In the FY 2025 IPPS/LTCH PPS final rule, we explained that consistent with past policy, interim uncompensated care payments for the newly merged hospital would be based only on the data for the surviving hospital's CCN available at the time of the development of the final rule.

Comment: A commenter supported for the policy currently in place for newly merged and new hospitals, while another commenter suggested that CMS verify the proper attribution of merger data to a surviving hospital's CCN to avoid any potential underpayment to hospitals that will not be resolved until cost report settlement.

Response: We thank commenters for their input. We refer commenters to the FY 2027 IPPS/LTCH PPS proposed rule (*91 FR 19312*), where we state that each year, along with the proposed rule, we publish a supplemental data file containing a list of the mergers of which we are aware and the computed uncompensated care payment for each merged hospital. We generally believe that publishing the supplemental data file in conjunction with the proposed rule and the 60-day window from the proposed rule date of public display allows hospitals adequate time to review the data and notify CMS of any discrepancies. We note that we do not include pending mergers for purposes of the final rule's calculations.

(4) CCR Trim Methodology

The calculation of a hospital's total uncompensated care costs on Worksheet S–10 requires the use of the hospital's cost to charge ratio (CCR). In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69324), we continued the policy of trimming CCRs, which we adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49043), for FY 2025. Under this policy, we apply the following steps to determine the applicable CCR separately for each fiscal year that is included as part of the multi-year average used to determine Factor 3:

Step 1: Remove Maryland hospitals. In addition, we will remove all-inclusive rate providers because their CCRs are not comparable to the CCRs calculated for other IPPS hospitals.

Step 2: Calculate a CCR ''ceiling'' for the applicable fiscal year with the following data: for each IPPS hospital that was not removed in Step 1 (including hospitals that are not DSH-eligible), we use cost report data to calculate a CCR by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. (Combining data from multiple cost reports from the same fiscal year is not necessary, as the longer cost report will be selected.) The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. This approach is consistent with the methodology for calculating the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR.

Step 3: Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for the applicable fiscal year for hospitals within each State (including hospitals that are not DSH-eligible), weighted by the sum of total hospital discharges from Worksheet S–3, Part I, Line 14, Column 15.

Step 4: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals, excluding all-inclusive rate providers, with a CCR for the applicable fiscal year greater than 3 standard deviations above the national geometric mean for that fiscal year (that is, the CCR ''ceiling'').

Step 5: For hospitals that did not report a CCR on Worksheet S–10, Line 1, we assign them the statewide average CCR for the applicable fiscal year as determined in step 3.

After completing these steps, we re-calculate the hospital's uncompensated care costs (Line 30) for the applicable fiscal year using the trimmed CCR (the statewide average CCR (urban or rural, as applicable)).

[157] In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042), we explained our belief that applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new hospitals, to improve consistency and predictability across all hospitals.

(5) Uncompensated Care Data Trim Methodology

After applying the CCR trim methodology, there are rare situations where a hospital has potentially aberrant uncompensated care data for a fiscal year that are unrelated to its CCR. Therefore, under the trim methodology for potentially aberrant uncompensated care costs (UCC) that was included as part of the methodology for purposes of determining Factor 3 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58832), if the hospital's uncompensated care costs for any fiscal year that is included as a part of the multi-year average are an extremely high ratio (greater than 50 percent) of its total operating costs in the applicable fiscal year, we will determine the ratio of uncompensated care costs to the hospital's total operating costs from another available cost report, and apply that ratio to the total operating expenses for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs for the applicable fiscal year.[158]

However, we note that we have audited the Worksheet S–10 data that will be used in the Factor 3 calculation for a number of hospitals. Because the UCC data for these hospitals have been subject to audit, we believe that there is increased confidence that if high uncompensated care costs are reported by these audited hospitals, the information is accurate. Therefore, as we explained in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58832), we determined it is unnecessary to apply the UCC trim methodology for a fiscal year for which a hospital's UCC data have been audited.

In rare cases, hospitals that are not currently projected to be DSH-eligible and that do not have audited Worksheet S–10 data may have a potentially aberrant amount of insured patients' charity care costs (line 23 column 2). In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69324 through 69325), we stated that in addition to the UCC trim methodology, we will continue to apply an alternative trim specific to certain hospitals that do not have audited Worksheet S–10 data for one or more of the fiscal years that are used in the Factor 3 calculation. For FY 2023 and subsequent fiscal years, in the rare case that a hospital's insured patients' charity care costs for a fiscal year are greater than $7 million and the ratio of the hospital's cost of insured patient charity care (line 23 column 2) to total uncompensated care costs (line 30) is greater than 60 percent, we will not calculate a Factor 3 for the hospital at the time of proposed or final rulemaking. This trim will only impact hospitals that are not currently projected to be DSH-eligible; and therefore, are not part of the calculation of the denominator of Factor 3, which includes only uncompensated care costs for hospitals projected to be DSH-eligible. Consistent with the approach adopted in the FY 2022 IPPS/LTCH PPS final rule, if a hospital would be trimmed under both the UCC trim methodology and this alternative trim, we apply this trim in place of the existing UCC trim methodology. We continue to believe this alternative trim more appropriately addresses potentially aberrant insured patient charity care costs compared to the UCC trim methodology, because the UCC trim is based solely on the ratio of total uncompensated care costs to total operating costs and does not consider the level of insured patients' charity care costs.

Similar to the approach initially adopted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45245 and 45246), in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69324), we also stated that we would continue to use a threshold of 3 standard deviations from the mean ratio of insured patients' charity care costs to total uncompensated care costs (line 23 column 2 divided by line 30) and a dollar threshold that is the median total uncompensated care cost reported on most recent audited cost reports for hospitals that are projected to be DSH-eligible. We stated that we continued to believe these thresholds are appropriate to address potentially aberrant data. We also continued to include Worksheet S–10 data from IHS/Tribal hospitals and Puerto Rico hospitals consistent with our policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051). In addition, we continued our policy adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49044) of applying the same threshold amounts originally calculated for the FY 2019 reports to identify potentially aberrant data for FY 2025 and subsequent fiscal years to facilitate transparency and predictability. If a hospital subject to this trim is determined to be DSH-eligible at cost report settlement, the MAC will calculate the hospital's Factor 3 using the same methodology used to calculate Factor 3 for new hospitals.

c. Methodology for Calculating Factor 3 for FY 2027

For FY 2027, consistent with § 412.106(g)(1)(iii)(C)(*11*), we are following the same methodology as applied in FY 2024 and described in the previous section of the preamble of this final rule, to determine Factor 3 using the most recent 3 years of audited cost reports, from FYs 2021, 2022, and 2023. Consistent with our approach for FY 2025, for FY 2027, we are also applying the scaling factor, new hospital, newly merged hospital, CCR trim methodology, UCC trim, and alternative trim methodology policies discussed in the previous section of the preamble of this final rule. For purposes of the proposed rule, we used reports from the December 2025 Healthcare Provider Cost Reporting Information System (HCRIS) extract to calculate Factor 3. In the proposed rule, we noted that we intended to use the March 2026 update of HCRIS to calculate the final Factor 3 for the FY 2027 IPPS/LTCH PPS final rule.

Thus, for FY 2027, we will use 3 years of audited Worksheet S–10 Part 1 data to calculate Factor 3 for all eligible hospitals, including IHS and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013, following steps. We note that these steps use Worksheet S–10, Part I, rather than Worksheet S–10, Part II, to calculate Factor 3.

Step 1: Select the hospital's longest cost report for each of the most recent 3 years of FY audited cost reports (FYs 2021, 2022, and 2023). Alternatively, in the rare case when the hospital has no cost report for a particular year because the cost report for the previous fiscal year spanned the more recent fiscal year, the previous fiscal year cost report will be used in this step. In the rare case that using a previous fiscal year cost report results in a period without a report, we would use the prior year report, if that cost report spanned the applicable period.[159] In general, we note that, for purposes of the Factor 3 methodology, references to a fiscal year cost report are to the cost report that spans the relevant fiscal year.

Step 2: Annualize the UCC from Worksheet S–10, Part I, Line 30, if a cost

[158] For example, if a hospital's FY 2018 cost report is determined to include potentially aberrant data, data from its FY 2019 cost report would be used for the ratio calculation.

[159] For example, if a hospital does not have a FY 2021 cost report because the hospital's FY 2020 cost report spanned the FY 2021 time period, we will use the FY 2020 cost report that spanned the FY 2021 time period for this step. Using the same example, where the hospital's FY 2020 report is used for the FY 2021 time period, we will use the hospital's FY 2019 report if it spans some of the FY 2020 time period. We will not use the same cost report for both the FY 2021 and the FY 2020 time periods.

report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combine adjusted and/or annualized uncompensated care costs for hospitals that merged using the merger policy.

Step 4: Calculate Factor 3 for all DSH-eligible hospitals using annualized uncompensated care costs (Worksheet S–10, Part I, Line 30) based on cost report data from the most recent 3 years of audited cost reports (from Step 1, 2 or 3). New hospitals and other hospitals that are treated as if they are new hospitals for purposes of Factor 3 are excluded from this calculation.

Step 5: Average the Factor 3 values from Step 4; that is, add the Factor 3 values, and divide that amount by the number of cost reporting periods with data to compute an average Factor 3 for the hospital. Multiply by a scaling factor, as discussed in the previous section of the preamble of this final rule.

We received comments regarding the Factor 3 calculation, including Worksheet S–10 cost report audits and uncompensated care cost report instructions.

Comment: Several commenters expressed their support for CMS's proposal to calculate Factor 3 for FY 2027 based on a three-year average of audited FYs 2021, 2022, and 2023 Worksheet S–10 data. Commenters who supported this proposal specified that the use of a multi-year average of Worksheet S–10 data minimizes year-to-year volatility in uncompensated care payments and provides greater transparency.

Response: We are grateful to the commenters who expressed their support for our policy of using a three-year average of audited FYs 2021, 2022, and 2023 Worksheet S–10 data to determine each hospital's share of uncompensated care costs in FY 2027. As explained in the FY 2023 IPPS/LTCH PPS final rule (*87 FR 49037*), we believe that using a multi-year average of Worksheet S–10 data will provide assurance that hospitals' uncompensated care payments remain stable and predictable, while mitigating unpredictable swings and anomalies in a hospital's uncompensated care costs.

Comment: Other commenters expressed opposition to using a three-year average of Worksheet S–10 data to calculate uncompensated care payments for FY 2027. Commenters raised concerns that CMS's reliance on an average of three years of dated Medicare cost report Worksheet S–10 data does not adequately account for recent and expected changes in insurance coverage. Specifically, they stated that CMS estimates of the FY2027 uninsured rate projections from the FY 2027 IPPS/LTCH PPS proposed rule show an increase from FY 2026 uninsured rate to FY 2027 uninsured rate. Commenters stated that the agency's approach may not reflect the current coverage landscape or the substantial coverage losses that occurred following the end of the COVID–19 PHE continuous enrollment protections and impacts from recent legislation, such as H.R.1. Other commenters expressed their concern that the multi-year averaging approach does not adequately acknowledge emerging uncompensated care pressures, particularly those faced by rural hospitals, and may understate rural providers' uncompensated care burden.

Response: For the reasons explained in the FY 2023 IPPS/LTCH PPS final rule (*87* FR 49038), we continue to believe that using a multi-year average of Worksheet S–10 data will provide assurance that hospitals' uncompensated care payments remain stable and predictable, while mitigating unpredictable swings and anomalies in a hospital's uncompensated care costs. For those commenters who expressed concern regarding the three-year average due to the significant policy changes introduced by H.R.1, we continue to believe the three-year average methodology will smooth data fluctuations over time.

Comment: We received comments recommending alternative approaches to consider when distributing uncompensated care (UC) payments, the vast majority of which we consider outside the scope of methodological concepts concerning the blending of historical Worksheet S–10 data to calculate Factor 3 discussed in the proposed rule (91 FR 19486) and earlier in this section of this final rule. These recommendations included maintaining the same uncompensated care pool in FY 2027 as in FY 2026, incorporating alternative or additional data sources to more accurately estimate total uncompensated care costs and each hospital's share, publishing interim Factor 3 calculations earlier in each IPPS rulemaking cycle, creating temporary adjustments for states with significant coverage losses, and establishing a supplemental uncompensated care payment for hospitals with large increases in the number of uninsured patients or uncompensated care costs. Another commenter recommended that CMS distribute existing DSH and UC payments based on each hospital's share of the Medicare Safety-Net Index (MSNI) and add $4 billion to the MSNI pool. The commenter also recommended that CMS make similar MSNI payments to hospitals for services furnished to Medicare Advantage (MA) enrollees and exclude those payments from MA benchmarks.

Response: We thank commenters for their feedback, concerns, and suggestions related to incorporating alternative and additional data sources to validate total uncompensated care costs. However, for the reasons stated earlier in this section of this final rule and in earlier rulemaking (*see also 83 FR 41144; 84 FR 42044; 85 FR 58432; 86 FR 44774; 87 FR 48780; 88 FR 58640; 89 FR 68986;* and *90 FR 36536*), we continue to believe that utilizing Worksheet S–10 data to generate the best estimates of the uncompensated care payments is most conducive to administrative efficiency, finality, and predictability in payments.

In response to the commenter who suggested we publish interim Factor 3 calculations earlier in the rulemaking cycle, we made public the best data available at the time of the proposed rule to allow hospitals to understand the anticipated impact of the proposed methodology and submit comments. In particular, the proposed Factor 3 data files were available concurrently with the publication of the IPPS proposed rule (Available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2027-ipps-proposed-rule-home-page*). This provided stakeholders with a robust public comment window to review the methodology and calculations of the proposed uncompensated care payment amounts. We consider commenters' other comments to be outside of the scope of the proposed rule and we do not address them here, though we appreciate commenters' input.

Comment: Some commenters expressed concerns regarding the accuracy and consistency of Worksheet S–10 data. A commenter urged CMS to continue refining its Worksheet S–10 policies to reduce volatility and improve accuracy. Another commenter urged CMS to use more recent cost report and utilization data to better reflect ''post-pandemic realities'' (*i.e.,* current uncompensated care cost conditions) following the COVID–19 PHE.

Response: We appreciate commenters' concerns regarding the accuracy and consistency of Worksheet S–10 data and their recommendations to continue refining our policies to reduce volatility and improve accuracy. Our use of the three-year average of the most recently

audited cost report data for FY 2027 and subsequent years is intended to smooth the variation in year-to-year uncompensated care payments and lessen the impacts of unforeseen events, such as the COVID–19 PHE. For the reasons stated earlier in this section of this final rule and in prior rulemakings (*see, e.g.* (87 FR 49038)), we continue to believe this methodology promotes stability in uncompensated care payments while continuing to rely on audited data that are the most appropriate data available for determining Factor 3.

Regarding the request to use more recent cost report and utilization data to better reflect uncompensated care cost conditions following the COVID–19 PHE, for reasons stated earlier in this section of this final rule, we believe that the three-year average methodology will mitigate fluctuations. We will continue to evaluate the data available for purposes of determining uncompensated care payments and to consider whether refinements to the methodology are warranted in future rulemaking. We also note that the audit process for Worksheet S–10 cost reports will continue to be an important part of promoting accuracy and consistency and identifying potential irregularities in the data.

Comment: Commenters expressed a range of views on the Worksheet S–10 audit process—supporting improvements to Worksheet S–10 audits while urging clearer guidance, standardized and targeted procedures, reduced burden for hospitals, and updates to the procedures to better capture full uncompensated care costs. A commenter acknowledged CMS's continued efforts to improve the consistency and reliability of uncompensated care reporting, while encouraging CMS to continue evaluating whether Worksheet S–10 accurately reflects hospitals' uncompensated care burden in an evolving coverage environment. The commenter recommended that CMS focus audits on key uncompensated care elements, including charity care determinations, bad debt, and subsequent adjustments.

A commenter urged CMS to revise the audit exhibits and procedures to focus on verifying charity care and bad debt write-offs, rather than reviewing entire account balances. Another commenter raised concerns regarding recent changes to the Worksheet S–10 audit templates, including expanded information requests such as patient insurance data, without sufficient explanation of how such information affects reimbursement determinations. The commenter requested standardized templates across MACs, advance notice of template changes, a comprehensive audit policy established through notice-and-comment rulemaking, and a workable appeal or review process to address Worksheet S–10 errors and inconsistent audit disallowances.

Response: We thank commenters for their feedback on the audits of the Worksheet S–10 data and their recommendations for future audits, as well as their acknowledgement of CMS's continued efforts to improve the consistency and reliability of uncompensated care reporting. As we have explained in previous rulemakings (*see, for example, 90 FR 36536*), audit protocols are provided to MACs in advance of the audit to ensure consistency and timeliness in the audit process.

We appreciate commenters' input and recommendations on how to improve the audit process and reiterate our commitment to continue working with MACs and providers on audit improvements, including making changes to increase the efficiency of the audit process and building on the lessons learned in previous audit years. We will take these recommendations into consideration for future rulemaking.

Regarding commenters' requests for standardized templates across MACs, advance notice of template changes, a comprehensive audit policy established through notice-and-comment rulemaking, and public disclosure of audit policies and protocols, as we previously explained, most recently in the FY 2024 IPPS/LTCH PPS final rule (*88 FR 58640*), we do not make our protocols public because CMS desk review and audit protocols are confidential and are for CMS and MAC use only. In addition, there is no requirement under either the Administrative Procedure Act or the Act that CMS adopt audit policies or protocols through notice-and-comment rulemaking. With respect to concerns about expanded information requests, including patient health insurance data, that information requested during the audit process is intended to assist CMS and the MACs in validating Worksheet S–10 data and identifying potential irregularities in the data. Finally, as noted in the FY 2024 IPPS/LTCH PPS final rule *(88 FR 58640),* to most efficiently and appropriately utilize our limited audit resources, we do not plan to introduce an audit appeal process at this time.

Comment: Commenters recommended that CMS provide additional clarification of the Worksheet S–10 instructions and related guidance and reconsider certain methodological approaches to improve consistency and accuracy. Specifically, a commenter requested that CMS clarify the Worksheet S–10 instructions for line 29 so that non-Medicare bad debt is not multiplied by the hospital's CCR. Another commenter suggested that CMS reduce reliance on financial assistance policies (FAPs) across uncompensated care categories, citing concerns regarding the complexity and variability associated with coverage denials, non-covered services, medical necessity determinations, out-of-network care, and compliance with state and federal requirements.

Response: We appreciate commenters' concerns regarding the need for clarification of the Worksheet S–10 instructions and guidance, including commenters' recommendations related to line 29 and FAPs. We reiterate our commitment to continuing to work with impacted parties to address their concerns regarding Worksheet S–10 instructions and reporting through provider education and further refinement of the instructions, as appropriate. We also encourage providers to share with their respective MAC any questions regarding clarifications of instructions, reporting, and submission deadlines.

We continue to believe that our past efforts to refine the Worksheet S–10 instructions and related guidance have improved provider understanding of Worksheet S–10 and have made the instructions clearer. We also recognize that there are continuing opportunities to further improve the accuracy and consistency of the information that is reported on Worksheet S–10, and to the extent commenters have raised questions and concerns regarding the reporting requirements, including concerns related to reliance on FAPs across uncompensated care categories, we do not mandate eligibility criteria that hospitals use under the hospital's FAPs, because we note that hospitals establish their own policies (*see* Form CMS–2552–10. Available on the CMS website at: *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/p152_40.zip*). We will also attempt to address commenters' concerns as may be appropriate through future rulemaking and/or sub-regulatory guidance and subsequent outreach to MACs and providers. However, as stated in previous rules (*see, e.g.,* (91 FR 19488)), we continue to believe that the Worksheet S–10 instructions are sufficiently clear and allow hospitals to accurately complete Worksheet S–10.

Regarding the commenter's request that CMS clarify the instructions for line 29 with respect to whether non-Medicare bad debt is multiplied by the CCR, we believe that the Worksheet S–10 instructions are clear and indicate that the CCR will not be applied to the deductible and coinsurance amounts for insured patients approved for charity care and non-reimbursed Medicare bad debt.

Comment: Two commenters recommended that CMS use the traditional payment reconciliation process to calculate final payments for uncompensated care costs pursuant to section 1886(r)(2) of the Act. These commenters did not object to CMS using prospective estimates, derived from the best data available, to calculate interim payments for uncompensated care costs. However, the commenters stated that interim payments should be subject to later reconciliation based on estimates derived from actual data from the federal fiscal year. The commenters also stated that CMS's current IPPS/LTCH PPS rulemaking process is flawed because CMS may use data and calculations in the final rules that were not included in the relevant proposed rules without providing advance notice to hospitals. The commenters claim that this limits hospitals' ability to provide informed comments. These same commenters stated that CMS's failures to provide meaningful explanations of its uncompensated care payment calculations violates the Administrative Procedure Act. These commenters recommended that CMS provide hospitals with the opportunity to review and comment on the more recent data used to calculate Factors 1, 2, and 3 in each final rulemaking cycle before the agency publishes the final rule.

Similarly, a commenter stated that a reconciliation process based on contemporaneous cost report data would be consistent with the payment reconciliation process for other Medicare payments and would avoid CMS updating the uncompensated care payment amounts based on inaccurate estimates.

Response: As we have explained in past rulemakings, we continue to believe that applying our best estimates of the three factors used in the calculation of uncompensated care payments to determine payments prospectively is most conducive to administrative efficiency, finality, and predictability in payments (*see, e.g., 83 FR 41144; 84 FR 42044; 85 FR 58432; 86 FR 44774; 87 FR 48780; 88 FR 58640; 89 FR 68986;* and *90 FR 36536*). We continue to believe that, in affording the Secretary the discretion of estimating the three factors used to determine uncompensated care payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system. As a result, we do not agree with commenters' suggestions that we should establish a process for reconciling our estimates of uncompensated care payments, which would be contrary to the notion of prospectivity in a payment system.

Further, we note that this rulemaking has been conducted consistent with the requirements of the Administrative Procedure Act and Title XVIII of the Act. Under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In this case, the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19479 through 19490) included a detailed discussion of our proposed methodology for calculating Factors 1 through 3 and noted that more recent data would be available for the final rule's development. We made public the best data available at the time of the proposed rule to allow hospitals to understand the anticipated impact of the proposed methodology and submit comments, and we have considered those comments in determining our final policies for FY 2027.

Comment: Several commenters requested that CMS reconsider our DSH uncompensated care policy to better reflect current hospital costs and protect access to care. In particular, a commenter recommended that CMS approach Congress regarding any statutory changes needed to realign DSH and UC payments with the current healthcare environment. Another urged CMS to ensure that DSH UC payment methodologies align with the current administration's priorities to support working families, make healthcare more affordable, and support hospitals serving Medicaid and safety-net populations.

Commenters also objected to the proposed 3.3 percent reduction in uncompensated care payments, particularly in light of CMS's projected increase in the uninsured rate and hospitals' rising uncompensated care costs. The commenters emphasized the potential impact on safety-net providers and access to care for vulnerable populations, including Medicaid beneficiaries, uninsured and underinsured patients, medically complex patients, and rural or low-income communities. Commenters urged CMS to ensure that DSH policy does not weaken access to care or destabilize providers serving these populations.

Response: CMS appreciates the feedback from commenters regarding the financial pressures faced by safety-net providers and the potential impact of UC payment adjustments on vulnerable patient populations. We understand the critical role these institutions play in maintaining access to care within rural and low-income communities. However, under Section 1886(r) of the Act, the calculation of hospitals' uncompensated care payments is governed by a three-factor statutory formula. and for the reasons stated earlier in this section of this final rule, we believe that our estimates of Factors 1 through 3 in the proposed rule adhere to those statutory requirements.

As we explained previously in this section, for FY 2027, we are also applying the scaling factor, new hospital, newly merged hospital, CCR trim methodology, UCC trim, and alternative trim methodology policies discussed in the previous section of the preamble of this final rule. For a hospital that is subject to either of the trims for potentially aberrant data (the UCC trim and alternative trim methodology explained in the previous section of the preamble of this final rule) and is ultimately determined to be DSH-eligible at cost report settlement, its uncompensated care payment will be calculated only after the hospital's reporting of insured charity care costs on its FY 2027 Worksheet S–10 has been reviewed. Accordingly, the MAC will calculate a Factor 3 for the hospital only after reviewing the uncompensated care information reported on Worksheet S–10 of the hospital's FY 2027 cost report. Then we will calculate Factor 3 for the hospital using the same methodology used to determine Factor 3 for new hospitals. Specifically, the numerator will reflect the uncompensated care costs reported on the hospital's FY 2027 cost report's Worksheet S–10 Part 1, line 30, while the denominator will reflect the sum of the uncompensated care costs reported on Worksheet S–10 Part 1, line 30 of the FY 2023 cost reports of all DSH-eligible hospitals. In addition, we will apply a scaling factor, as discussed previously, to the Factor 3 calculation for the hospital.

Under the CCR trim methodology, for purposes of the FY 2027 IPPS/LTCH PPS proposed and this final rule, the statewide average CCR was applied to 12 hospitals' FY 2021 reports, of which 6 hospitals had FY 2021 Worksheet S–10 data. The statewide average CCR was

applied to 10 hospitals' FY 2022 reports, of which 4 hospitals had FY 2022 Worksheet S–10 data. The statewide average CCR was applied to 12 hospitals' FY 2023 reports, of which 7 hospitals had FY 2023 Worksheet S–10 data.

Comment: A commenter supported our use of statistical trimming methodology, while another commenter suggested that CMS use caution when applying CCR, UCC, and alternative trim methodologies on hospital audited Worksheet S–10 data, noting that these trims may penalize hospitals with legitimately high uncompensated care burdens. The commenter requested that CMS ensure these trims do not override verified Worksheet S–10 cost report data.

Response: We appreciate the feedback regarding the use of statistical trimming methodologies. We recognize the critical importance of ensuring that these statistical trims do not disproportionately penalize or financially disadvantage hospitals that serve vulnerable communities and carry legitimately high uncompensated care burdens. The objective of CMS's auditing and trim methodologies is to identify extreme anomalies, reporting errors, or data outliers to ensure accurate and equitable distribution of uncompensated care payments. Trims are intended as an administrative safeguard rather than a mechanism to discount valid, verifiable data. We refer commenters to the FY 2027 IPPS/LTCH PPS proposed rule (*91 FR 19487* through 19489), where we describe the CCR, UCC, and alternative trim methodologies. For the reasons explained in the proposed rule (91 FR 19488) and earlier in this section of this final rule, we continue to believe that these trims are appropriate for hospitals with potentially aberrant data. We also note that the UCC and alternative trims are not applicable to hospitals with audited Worksheet S–10 data.

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19489), we stated that for purposes of the FY 2027 IPPS/LTCH PPS final rule, consistent with our Factor 3 methodology since the FY 2014 IPPS/LTCH PPS final rule (78 FR 50642), we intend to use data from the March 2026 HCRIS extract for this calculation, which would be the latest quarterly HCRIS extract that is publicly available at the time of the development of the FY 2027 IPPS/LTCH PPS final rule.

Comment: A commenter expressed concern regarding the reductions in uncompensated care payments and urged CMS to use more recent cost report and utilization data to better reflect post-COVID–19 PHE conditions.

Response: We appreciate the commenter's concern regarding reductions in uncompensated care payments and the recommendation that CMS use more recent cost report and utilization data to better reflect post-COVID–19 PHE conditions. We are finalizing the use of the March HCRIS extract to calculate Factor 3 for this FY 2027 IPPS/LTCH PPS final rule. For the reasons stated earlier in this final rule and in the proposed rule (91 FR 19485), we believe this is the best available data for the purposes of calculating Factor 3 for FY 2027. Consistent with prior IPPS/LTCH PPS rules (*see, e.g.* (91 FR 19488 and 19489), we also intend to continue utilizing the most recent data available for each rulemaking, which generally means the December HCRIS extract for each proposed rule for purposes of Factor 3 calculations. Furthe, as noted in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19489), we intend to continue using the respective March HCRIS for future final rules. CMS will continue to monitor the availability and quality of updated cost report and utilization data and will consider the use of more recent data in future rulemaking, as appropriate and consistent with applicable law.

Regarding requests from providers to amend and/or reopen previously audited Worksheet S–10 data for the most recent 3 cost reporting years that are used in the methodology for calculating Factor 3, we note that MACs follow normal timelines and procedures. For purposes of the Factor 3 calculation for the FY 2027 IPPS/LTCH PPS final rule, any amended reports and/or reopened reports would need to have completed the amended report and/or reopened report submission processes by the end of March 2026. In other words, if the amended report and/or reopened report is not available for the March HCRIS extract, then that amended and/or reopened report data would not be part of the FY 2027 IPPS/LTCH PPS final rule's Factor 3 calculation. In the proposed rule, we noted that the March HCRIS data extract would be available during the comment period for the proposed rule if providers wanted to verify that their amended and/or reopened data is reflected in the March HCRIS extract in advance of this final rule.

d. Per-Discharge Amount of Interim Uncompensated Care Payments for FY 2027

Since FY 2014, we have made interim uncompensated care payments during the fiscal year on a per-discharge basis. Typically, we use a 3-year average of the number of discharges for a hospital to produce an estimate of the amount of the hospital's uncompensated care payment per discharge. Specifically, the hospital's total uncompensated care payment amount for the applicable fiscal year is divided by the hospital's historical 3-year average of discharges computed using the most recent available data to determine the uncompensated care payment per discharge for that fiscal year.

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69328 and 69329), we finalized a policy to use a 3-year average of the most recent years of available historical discharge data to calculate a per-discharge payment amount that would be used to make interim uncompensated care payments to each projected DSH-eligible hospital during FY 2027 and subsequent fiscal years, codified at 42 CFR 412.106(i)(1). We are applying this policy for FY 2027. Interim uncompensated care payments made to a hospital during the fiscal year are reconciled following the end of the year to ensure that the final payment amount is consistent with the hospital's prospectively determined uncompensated care payment for the fiscal year.

As we explained in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69329 and 69330), we also finalized a voluntary process in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833 and 58834), through which a hospital may submit a request to its MAC for a lower per-discharge interim uncompensated care payment amount, including a reduction to zero, once before the beginning of the fiscal year and/or once during the fiscal year. In conjunction with this request, the hospital must provide supporting documentation demonstrating that there would likely be a significant recoupment at cost report settlement if the per-discharge amount is not lowered (for example, recoupment of 10 percent or more of the hospital's total uncompensated care payment, or at least $100,000). For example, a hospital might submit documentation showing a large projected increase in discharges during the fiscal year to support reduction of its per-discharge uncompensated care payment amount. As another example, a hospital might request that its per-discharge uncompensated care payment amount be reduced to zero midyear if the hospital's interim uncompensated care payments during the year have already surpassed the total uncompensated care payment calculated for the hospital.

Under the policy we finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833 and 58834), the hospital's MAC will evaluate these requests and the supporting documentation before the beginning of the fiscal year and/or with midyear requests when the historical average number of discharges is lower than the hospital's projected discharges for the current fiscal year. If, following review of the request and the supporting documentation, the MAC agrees that there likely would be significant recoupment of the hospital's interim Medicare uncompensated care payments at cost report settlement, the only change that will be made is to lower the per-discharge amount either to the amount requested by the hospital or another amount determined by the MAC to be appropriate to reduce the likelihood of a substantial recoupment at cost report settlement. If the MAC determines it would be appropriate to reduce the interim Medicare uncompensated care payment per-discharge amount, that updated amount will be used for purposes of the outlier payment calculation for the remainder of the fiscal year. We are continuing to apply this policy for FY 2027. We refer readers to the Addendum in the FY 2023 IPPS/LTCH final rule for a more detailed discussion of the steps for determining the operating and capital Federal payment rate and the outlier payment calculation (87 FR 49431 and 49432). No change will be made to the total uncompensated care payment amount determined for the hospital on the basis of its Factor 3. In other words, any change to the per-discharge uncompensated care payment amount will not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

e. Process for Notifying CMS of Merger Updates and To Report Upload Issues

As we have done for every proposed and final rule beginning in FY 2014, in conjunction with this final rule, we will publish on the CMS website a table listing Factor 3 for hospitals that we estimate will receive empirically justified Medicare DSH payments for FY 2027 (that is, those hospitals that will receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving an uncompensated care payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. However, we note that a Factor 3 will not be published for new hospitals and hospitals that are subject to the alternative trim for hospitals with potentially aberrant data that are not projected to be DSH-eligible.

We will also publish a supplemental data file containing a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. In the DSH uncompensated care supplemental data file, we list new hospitals and the 22 hospitals that will be subject to the alternative trim for hospitals with potentially aberrant data that are not projected to be DSH-eligible, with a N/A in the Factor 3 column.

Hospitals had 60 days from the date of public display of the FY 2027 IPPS/LTCH PPS proposed rule in the **Federal Register** to review the table and supplemental data file published on the CMS website in conjunction with the proposed rule and to notify CMS in writing of issues related to mergers and/or to report potential upload discrepancies due to MAC mishandling of Worksheet S–10 data during the report submission process.[160] In the proposed rule, we stated comments raising issues or concerns that are specific to the information included in the table and supplemental data file should be submitted by email to the CMS inbox at *Section3133DSH@cms.hhs.gov.* We stated that we would address comments related to mergers and/or reporting upload discrepancies submitted to the CMS DSH inbox as appropriate in the table and the supplemental data file that we publish on the CMS website in conjunction with the publication of the FY 2027 IPPS/LTCH PPS final rule. We also stated that all other comments submitted in response to our proposals for FY 2027 must be submitted in one of the three ways found in the **ADDRESSES** section of the proposed rule before the close of the comment period in order to be assured consideration. In addition, we noted that the CMS DSH inbox is not intended for Worksheet S–10 audit process related emails, which should be directed to the MACs.

We invited public comments on all the previously described proposals for Factor 3 for FY 2027.

[160] For example, a potential upload discrepancy related to MAC mishandling may exist if the report does not reflect audit results due to MAC mishandling, or the most recent report differs from a previously accepted, amended report due to MAC mishandling.

V. Other Decisions and Changes to the IPPS for Operating Costs

A. Changes to MS–DRGs Subject to Postacute Care Transfer Policy and MS–DRG Special Payments Policies (§ 412.4)

1. Background

Existing regulations at 42 CFR 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy set forth in § 412.4(f) provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full MS–DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally provides for payment that is twice the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases also are eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to (Fixed-Loss Outlier threshold for Nontransfer Cases adjusted for geographic variations in costs/Geometric Mean Length of Stay for the MS–DRG) * (Length of Stay for the Case plus 1 day).

We established the criteria set forth in § 412.4(d) for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004 MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care transfer policy. Specifically, if the MS–DRG's total number of discharges to postacute care equals or exceeds the

55th percentile for all MS–DRGs and the proportion of short-stay discharges to postacute care to total discharges in the MS–DRG exceeds the 55th percentile for all MS–DRGs, CMS will apply the postacute care transfer policy to that MS–DRG and to any other MS–DRG that shares the same base MS–DRG. The statute at subparagraph 1886(d)(5)(J) of the Act directs CMS to identify MS–DRGs based on a high volume of discharges to postacute care facilities and a disproportionate use of postacute care services. As discussed in the FY 2006 IPPS final rule (70 FR 47416), we determined that the 55th percentile is an appropriate level at which to establish these thresholds. In that same final rule (70 FR 47419), we stated that we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific MS–DRG.

For MS–DRGs subject to the postacute care policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) includes a special payment methodology that adjusts the per diem payment. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6))). For an MS–DRG to qualify for the special payment methodology, the geometric mean length of stay must be greater than 4 days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. MS–DRGs that are part of an MS–DRG severity level group will qualify under the MS–DRG special payment methodology policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

Prior to the enactment of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), under section 1886(d)(5)(J) of the Act, a discharge was deemed a ''qualified discharge'' if the individual was discharged to one of the following postacute care settings:

- A hospital or hospital unit that is not a subsection (d) hospital, as described in section 1886(d)(1)(B) of the Act .
- A skilled nursing facility.
- Related home health services provided by a home health agency provided within a timeframe established by the Secretary (beginning within 3 days after the date of discharge).

Section 53109 of the Bipartisan Budget Act of 2018 amended section 1886(d)(5)(J)(ii) of the Act to also include discharges to hospice care provided by a hospice program as a qualified discharge, effective for discharges occurring on or after October 1, 2018. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41394), we made conforming amendments to § 412.4(c) of the regulation to include discharges to hospice care occurring on or after October 1, 2018, as qualified discharges. We specified that hospital bills with a Patient Discharge Status code of 50 (Discharged/Transferred to Hospice—Routine or Continuous Home Care) or 51 (Discharged/Transferred to Hospice, General Inpatient Care or Inpatient Respite) are subject to the postacute care transfer policy in accordance with this statutory amendment.

2. Changes for FY 2027

As discussed in the proposed rule and section II.C of the preamble of this final rule, based on our analysis of FY 2025 MedPAR claims data, CMS proposed to make changes to a number of MS–DRGs, effective for FY 2027. Specifically, we proposed the following changes:

- Reassigning an ICD–10–PCS code describing the insertion of an endocardiac pacing electrode to MS–DRGs 228–229, deleting MS–DRGs 258, 259, 260, 261 and 262, and creating proposed new MS–DRGs 210 and 211 (Cardiac Pacemaker Revision or Device Replacement with MCC and without MCC, respectively).
- Reassigning the ICD–10–PCS codes describing extensive spinal fusions, fusions performed with a custom-made anatomically designed interbody fusion device and fusion of the sacroiliac joints using an internal fixation device with tulip connector from MS–DRGs 402, 426–428, 447–448, 450–451, and 456–458 to proposed new MS–DRGs 523, 524, and 525 (Extensive or Complex Spinal Fusion Procedures Except Cervical with MCC, with CC, and without CC/MCC, respectively).
- Redesignating an ICD–10–PCS code describing introduction of an antibiotic-eluting bone void filler from non-O.R. to non-O.R. affecting the MS–DRG assignment for MS–DRGs 463, 474, 477, 480, 492, 616, and 628.
- Deleting MS–DRGs 485–487, and creating proposed new MS–DRG 400 (Knee Procedures with Principal Diagnosis of Infection).
- Deleting MS–DRGs 466–468, and creating proposed new MS–DRG 449 (Revision of Hip or Knee Replacement).
- Creating proposed new MS–DRG 403 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC or Insertion of Antibiotic-eluting Bone Void Filler) and proposed new MS–DRG 404 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection without MCC).
- Deleting MS–DRGs 736, 737, 738, 739, 740 and 741 and creating proposed new MS–DRGs 731, 732, and 733 for uterine and adnexa procedures for female reproductive system malignancies.
- Deleting MS–DRG 264 (Other Circulatory System O.R. Procedures) and creating proposed new MS–DRGs 361 and 362 (Other Circulatory System O.R. Procedures with and without MCC, respectively).
- Adding ICD–10–PCS procedure codes describing the introduction of pancreatic islet cells to a new ''Islet Cell Transplant Procedures'' logic list in Pre-MDC MS–DRGs 008, 010, and 019.

When proposing changes to MS–DRGs that involve adding, deleting, and reassigning procedure or diagnosis codes between proposed new and revised MS–DRGs, we stated in the proposed rule that we continue to believe it is necessary to evaluate the affected MS–DRGs to determine whether they should be subject to the postacute care transfer policy. Considering the proposed changes to the MS–DRGs for FY 2027, according to the regulations under § 412.4(d), we evaluated the proposed new MS–DRGs using the general postacute care transfer policy criteria and data from the FY 2025 MedPAR file. We continue to believe it is appropriate to assess new MS–DRGs and reassess revised MS–DRGs when proposing reassignment of procedure codes or diagnosis codes that would result in material changes to an MS–DRG. We evaluated any current MS–DRG if we estimate that more than 5 percent of the current cases would shift from the current assigned MS–DRGs to proposed new MS–DRGs, or to a current MS–DRG from a proposed revised or deleted MS–DRG.

For existing MS–DRG 426 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device), MS–DRG 427 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC), and MS–DRG 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC)) and MS–DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively) we determined that more than 5 percent of the current cases would shift from the current assigned MS–DRGs to proposed new MS–DRGs 523, 524, and 525. For existing MS–DRGs 463, 464, and 465

(Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC with CC, and without CC/MCC, respectively) and MS–DRGS 474, 475, and 476 (Amputation for Musculoskeletal System and Connective Tissue Disorders with MCC, with CC, and without CC/MCC, respectively) we determined that more than 5 percent of the current cases would shift from the current assigned MS–DRGs to proposed new MS–DRGs 403 and 404. For existing MS–DRGs 616, 617, and 618 (Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC, with CC, and without CC/MCC, respectively) we determined that more than 5 percent of the current cases would shift from the current assigned MS–DRGs to MS–DRGs 622, 623, and 624 (Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Disorders with MCC, with CC, and without CC/MCC, respectively). We noted that for all other proposed changes, the relative volume of cases shifting to or from current MS–DRGs did not exceed the 5 percent threshold.

If an MS–DRG qualified for the postacute care transfer policy, we also evaluated that MS–DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6).

In the proposed rule, we noted that proposed new and revised MS–DRGs 210, 361, 362, 400, 403, 404, 426, 457, 463, 464, 474, 475, 523, 524, 616, and 617 would qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. As described in the regulations at § 42 CFR 412.4(d)(3)(ii)(D), MS–DRGs that share the same base MS–DRG will all qualify under the MS–DRG postacute care transfer payment policy if any one of the MS–DRGs that share that same base MS–DRG qualifies. We therefore proposed to add new or revised MS–DRGs 210, 211, 361, 362, 400, 403, 404, 456, 457, 458, 523, 524, and 525 to the list of MS–DRGs that are subject to the postacute care transfer policy.

We also noted that MS–DRGs 426, 427, 428, 463, 464, 465, 474, 475, 476, 616, 617, and 618 are currently subject to the postacute care transfer policy. As a result of our review, these revised MS–DRGs would continue to qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy.

As discussed in section II.C of this proposed rule, we are finalizing these proposed changes to the MS–DRGs, with modification to the proposed title for new MS–DRG 449 (Revision of Hip or Knee Replacement) to ''Revision of Hip or Knee Prosthesis''. This finalized policy is reflected in the table that follows. Using the March 2026 update of the FY 2025 MedPAR file, we have developed the following table which sets forth the most recent analysis of the postacute care transfer policy criteria completed for this final rule with respect to each of these finalized new or revised MS–DRGs. We note that these updated results confirm the previous analysis based on the December 2025 update of the FY 2025 MedPAR file, described in the proposed rule.

BILLING CODE 4169–69–P

LIST OF NEW OR REVISED MS-DRGS SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2027							
New or Revised MS-DRG	**MS-DRG Title**	**Total Cases**	**Postacute Care Transfer Cases (55th percentile: 1,091)**	**Short-Stay Postacute Care Transfer Cases**	**Percent of Short-Stay Postacute Care Transfers to all Cases (55th percentile: 9.697%)**	**FY 2026 Postacute Transfer Policy Status**	**Postacute Care Transfer Policy Status**
210	Cardiac Pacemaker Revision or Device Replacement with MCC	2,940	1,540	375	12.76%	New	Yes
211	Cardiac Pacemaker Revision or Device Replacement without MCC	3,945	1,211	124	3.14% *	New	Yes**
361	Other Circulatory System O.R. Procedures with MCC	5,700	3,562	1,074	18.84%	New	Yes
362	Other Circulatory System O.R. Procedures without MCC	2,714	1,658	335	12.34%	New	Yes
400	Knee Procedures with Principal Diagnosis of Infection	1,561	1,153	298	19.09%	New	Yes
403	Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC or Insertion of Antibiotic-eluting Bone Void Filler	3,898	3,322	1,283	32.91%	New	Yes
404	Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection without MCC	10,026	7,959	2,036	20.31%	New	Yes
426	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC	2,240	1,759	555	24.78%	Yes	Yes
427	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC	12,302	7,257	967	7.86% *	Yes	Yes**
428	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC	8,080	3,539	379	4.69% *	Yes	Yes**
449	Revision of Hip or Knee Prothesis+	985	691 *	181	18.38%	New	No
456	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or Infection with MCC	964	798 *	302	31.33%	No	Yes**
457	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or Infection with CC	2,356	1,566	375	15.92%	No	Yes
458	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or Infection without CC/MCC	1,144	473 *	69	6.03% *	No	Yes**
463	Wound Debridement or Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders	6,717	5,553	1,984	29.54%	Yes	Yes

	with MCC or Insertion of Antibiotic-eluting Bone Void Filler						
464	Wound Debridement or Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with CC	20,227	14,424	4,182	20.68%	Yes	Yes
465	Wound Debridement or Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders without CC/MCC	15,171	7,307	0	0.00% *	Yes	Yes**
474	Amputation for Musculoskeletal System and Connective Tissue Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler	2,412	1,997	777	32.21%	Yes	Yes
475	Amputation for Musculoskeletal System and Connective Tissue Disorders with CC	2,694	2,071	517	19.19%	Yes	Yes
476	Amputation for Musculoskeletal System and Connective Tissue Disorders without CC/MCC	338	196 *	29	8.58% *	Yes	Yes**
523	Extensive or Complex Spinal Fusion Procedures Except Cervical with MCC	1,729	1,525	723	41.82%	New	Yes
524	Extensive or Complex Spinal Fusion Procedures Except Cervical with CC	4,195	3,133	819	19.52%	New	Yes
525	Extensive or Complex Spinal Fusion Procedures Except Cervical without CC/MCC	727	415 *	75	10.32%	New	Yes**
616	Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler	3,257	2,419	892	27.39%	Yes	Yes
617	Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with CC	9,269	5,663	1,516	16.36%	Yes	Yes
618	Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders without CC/MCC	45	22 *	3	6.67% *	Yes	Yes**
731	Uterine and Adnexa Procedures for Malignancy with MCC	1,283	590 *	113	8.81% *	New	No
732	Uterine and Adnexa Procedures for Malignancy with CC	3,562	848 *	98	2.75% *	New	No
733	Uterine and Adnexa Procedures for Malignancy without CC/MCC	1,214	103 *	0	0.00% *	New	No

* Indicates a current postacute care transfer policy criterion that the MS-DRG did not meet.

** As described in the policy at 42 CFR 412.4(d)(3)(ii)(D), MS-DRGs that share the same base MS-DRG will all qualify under the postacute care transfer policy if any one of the MS-DRGs that share that same base MS-DRG qualifies.

+ As discussed in section II.C. of the preamble of this final rule, we are finalizing a modification to the proposed title for new MS-DRG 449 (Revision of Hip or Knee Replacement) to Revision of Hip or Knee Prosthesis.

BILLING CODE 4169–69–C

During our annual review of proposed new or revised MS–DRGs and analysis of the December 2025 update of the FY 2026 MedPAR file, we reviewed the list of proposed revised or new MS–DRGs that qualify to be included on the list of MS–DRGs subject to the postacute care transfer policy for FY 2027 to determine if any of these MS–DRGs would also be subject to the special payment methodology policy for FY 2027.

Based on our analysis of the proposed changes to the MS–DRGs included in the proposed rule, we determined that proposed new or revised MS–DRGs 362, 400, 404, 426, 457, 463, 617 met the criteria for the MS–DRG special payment methodology. As described in the regulations at § 412.4(f)(6)(iv), MS–DRGs that share the same base MS–DRG will all qualify under the MS–DRG special payment policy if any one of the MS–DRGs that share that same base MS–DRG qualifies. Therefore, we proposed that proposed new and revised MS–DRGs 361, 362, 400, 403, 404, 456, 457, 458, 463, 464, 465, 616, 617, 618 would be subject to the MS–DRG special payment methodology, effective for FY 2027. In the proposed rule, we also noted that MS–DRGs 426, 427, and 428 are currently subject to the special payment methodology. As a result of our review, these revised MS–DRGs would continue to qualify to be included on the list of MS–DRGs that are subject to the special payment methodology. As discussed in the proposed rule, we updated this analysis using the March 2026 update of the FY 2025 MedPAR. We note that these updated results confirm the previous analysis based on the December 2025 update of the FY 2025 MedPAR file, described in the proposed rule.

BILLING CODE 4169–69–P

LIST OF NEW OR REVISED MS-DRGs SUBJECT TO REVIEW OF SPECIAL PAYMENT POLICY STATUS FOR FY 2027

New or Revised MS-DRG	MS-DRG Title	Geometric Mean Length of Stay	Average Charges of 1-Day Discharges	50 Percent of Average Charges for all Cases within MS-DRG	FY 2026 Special Payment Policy Status	Proposed Special Payment Policy Status
210	Cardiac Pacemaker Revision or Device Replacement with MCC	5.38	$74,603	$81,582	New	No
211	Cardiac Pacemaker Revision or Device Replacement without MCC	2.61	$80,943	$48,763	New	No
361	Other Circulatory System O.R. Procedures with MCC	7.59	$64,868	$89,549	New	Yes*
362	Other Circulatory System O.R. Procedures without MCC	4.86	$54,417	$53,990	New	Yes
400	Knee Procedures with Principal Diagnosis of Infection	5.77	$62,583	$48,933	New	Yes
403	Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MMC or Insertion of Antibiotic-eluting Bone Void Filler	8.96	$89,936	$119,722	New	Yes*
404	Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection without MCC	4.6	$144,216	$78,443	New	Yes
426	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC	6.7	$335,099	$220,280	Yes	Yes
427	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC	3.7	$258,523	$157,693	Yes	Yes*
428	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC	2.51	$274,023	$133,765	Yes	Yes*
456	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or Infection with MCC	9.87	$170,007	$191,012	No	Yes*
457	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or Infection with CC	4.49	$220,785	$129,579	No	Yes
458	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or Infection without CC/MCC	2.11	$210,061	$94,372	No	Yes*
463	Wound Debridement or Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler	7.84	$130,171	$118,256	No	Yes
464	Wound Debridement or Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with CC	3.02	$122,312	$76,055	No	Yes*
465	Wound Debridement or Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders without CC/MCC	1.37	$119,112	$59,531	No	Yes*
474	Amputation for Musculoskeletal System and Connective Tissue Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler	9.65	$59,684	$93,995	No	No
475	Amputation for Musculoskeletal System and Connective Tissue Disorders with CC	5.97	$48,967	$52,180	No	No
476	Amputation for Musculoskeletal System and Connective Tissue Disorders without CC/MCC	2.6	$39,056	$29,195	No	No
523	Extensive or Complex Spinal Fusion Procedures Except Cervical with MCC	9.16	$178,774	$322,192	New	No
524	Extensive or Complex Spinal Fusion Procedures Except Cervical with CC	5.55	$216,478	$231,650	New	No
525	Extensive or Complex Spinal Fusion Procedures Except Cervical without CC or MCC	3.25	$320,890	$164,533	New	No
616	Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC or Insertion of Antibiotic-eluting Bone Void Filler	8.3	$46,378	$72,249	No	Yes*
617	Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with CC	5.3	$49,453	$41,600	No	Yes
618	Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders without CC/MCC	3.37	$8,517	$28,277	No	Yes*

* As described in the policy at 42 CFR 412.4(f)(6)(iv), MS–DRGs that share the same base MS–DRG will all qualify under the special payment transfer policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

BILLING CODE 4169–69–C

Comment: Multiple commenters raised concerns about CMS's proposal to add 13 new or revised MS–DRGs to the post-acute care transfer policy. Commenters stated that the policy creates a financial disincentive for short-term acute care hospitals to transfer patients to post-acute settings, such as LTCHs and IRFs, before the geometric mean length of stay is reached in order to avoid payment reductions. Commenters warned this would delay patient access to specialized services; undermining the principle of providing care in the most clinically appropriate setting. Some commenters emphasized that a disproportionately high percentage of Medicaid beneficiaries and uninsured individuals with greater clinical complexity incur front-loaded costs in the earliest days of admission that are not eliminated by early transfer, leaving these hospitals with inadequate reimbursement for care already delivered. Additionally, a commenter stated that the policy may infringe on Medicare beneficiaries' freedom to choose their post-acute care provider. Commenters recommended CMS to either reconsider the expansion entirely or, at minimum, adopt explicit safeguards such as targeted exceptions or payment protections for safety-net hospitals serving complex patients.

Response: We appreciate the commenters sharing their concerns regarding the addition of new or revised MS–DRGs to the post-acute care transfer policy and the potential impact on patient access to LTCHs or IRFs and other post-acute care services.

The post-acute care transfer policy was established to ensure that Medicare payments to transferring hospitals more accurately reflect the actual costs incurred during a patient's stay. When a patient is discharged to a post-acute care setting before the geometric mean length of stay for the assigned MS–DRG has been reached, the full MS–DRG payment may result in payment to the transferring hospital that is disproportionate to the resources expended during that shortened stay.

Regarding the addition of new or revised MS–DRGs to the policy, CMS's analysis of MedPAR data identified these MS–DRGs as having a significant proportion of cases resulting in transfers to post-acute care settings. The criteria for adding MS–DRGs to the post-acute care transfer policy are applied uniformly and are based on objective data, and we believe it is appropriate to evaluate new or significantly revised MS–DRGs when they are proposed to ensure annual consistency in payments. The policy does not prohibit or discourage clinically appropriate transfers; rather, it adjusts the payment to the transferring hospital to reflect the shorter length of stay. However, CMS intends to monitor any potential unintended adverse implications of the policy on appropriate transfer of patients to post-acute settings.

With respect to commenters' concerns about patient access to post-acute care settings, we note that the post-acute care

transfer policy is a payment adjustment applicable to the transferring IPPS hospital and does not affect a patient's right to receive care in the most clinically appropriate setting. Decisions regarding the timing and destination of patient transfers should be driven by clinical need, not by payment considerations. We encourage hospitals to continue making transfer decisions based on the best interests of the patient, consistent with their obligations under the Medicare Conditions of Participation, including transfer protocols described at 42 CFR 482.43(c). Beneficiaries retain the right to choose among Medicare-participating post-acute care providers, consistent with CMS's longstanding policy. The payment adjustment applies solely to the transferring hospital and has no bearing on the beneficiary's ability to select a preferred post-acute care setting.

Regarding concerns regarding patient populations with greater clinical complexity and higher front-loaded costs, we note that of the 13 new or revised MS–DRGs that were proposed to be added to the post-acute care transfer policy, 8 were also proposed to be added to the special payment policy. For special payment MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days. We believe this modification to the transfer adjusted payment mitigates negative financial implications for cases with higher-than-average up-front costs. Additionally, for cases with exceptionally high costs, the outlier payment policy could also provide additional payments to these hospitals.

After consideration of the comments received, CMS is finalizing the addition of the new or revised MS–DRGs to the post-acute care transfer policy and special payment policy as proposed. We believe this action is consistent with the policy's longstanding goal of aligning Medicare payments with the actual costs of care furnished during an acute care admission.

B. Changes in the Inpatient Hospital Update for FY 2027 (§ 412.64(d))

1. FY 2027 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2027, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2026. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.) Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS for FY 2027 is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to all of the following:

- A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act.
- A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act.
- An adjustment based on changes in economy-wide multifactor productivity (the productivity adjustment) in accordance with section 1886(b)(3)(B)(xi)(II) of the Act.

Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

As published in the FY 2006 IPPS final rule (70 FR 47403), in accordance with section 404 of Public Law 108–173, CMS determined a new frequency for rebasing the hospital market basket of every 4 years. In compliance with section 404 of Public Law 108–173, in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36859 through 36866), we replaced the 2018-based IPPS operating and capital market baskets with the rebased and revised 2023-based IPPS operating and capital market baskets beginning in FY 2026. Consistent with our established frequency of rebasing the IPPS market basket every 4 years, we plan on proposing to rebase and revise the IPPS market in the FY 2030 IPPS/LTCH PPS proposed rule.

We proposed to base the FY 2027 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2025 forecast of the 2023-based IPPS market basket rate-of-increase with historical data through third quarter 2025, which was estimated to be 3.2 percent. We also proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket update), we would use such data, if appropriate, to determine the FY 2027 market basket update in the final rule.

Comment: Several commenters expressed concern that the Employment Cost Index (ECI) may not be adequately capturing employment and labor cost growth in the market basket. They stated that they continue to stand ready to work with CMS to examine the market basket compensation indices and proxies to improve the accuracy of these measures and to ensure labor costs, inclusive of contract labor, are adequately reflected in the Medicare hospital payment.

Response: As we discussed in response to similar comments in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36865), we believe that the ECI for Wages and Salaries for All Civilian Workers in Hospitals and the ECI for Total Benefits for All Civilian Workers in Hospitals are accurately reflecting the price change associated with the labor used to provide hospital care in IPPS hospitals. The ECI appropriately does not reflect other factors that might affect the annual rate of price changes associated with labor costs, such as a shift in the occupations that may occur due to increases in case-mix or shifts in hospital purchasing decisions (for instance, to hire or to use contract labor). We believe that the prices of employed staff and contract labor are influenced by the same factors and as the Medicare cost report data show these measures have grown at similar rates over the last 10 years.

Comment: A commenter requested CMS provide additional publicly available data on the assumptions and inputs that go into developing a market basket update. A commenter stated it is imperative that CMS clarify how it is accounting for tariffs in payment policy, particularly the market basket update, for FY 2027.

Response: As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69450) and the FY 2026 IPPS/LTCH PPS final rule (90 FR 36987), information on the CMS market baskets can be found at the CMS website: *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.* This website provides information including but not limited to how a top-line market basket level is

derived from the detailed cost categories, how a four-quarter percent change moving average is calculated, and a link to a spreadsheet containing the calculation of the detailed market basket cost weights for the 2023-based IPPS market basket. In addition, the latest, publicly available CMS market baskets are available at the CMS website: *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-data.* We note that publicly available market baskets on the CMS website would reflect an updated forecast only after a proposed or final rule is published. Using these spreadsheets, stakeholders are able to replicate the top-line market basket index levels in the historical time period by multiplying the detailed index level for each cost category by the associated cost weight. These products (weight multiplied by index level) can then be summed up to derive the aggregate market basket index level.

In response to the commenter's request for specific assumptions and inputs, in this final rule, we are also providing the projected increase for FY 2027 for some of the aggregated cost categories that underlie the most recent forecast of the FY 2027 IPPS market basket increase (3.2 percent). This detail is consistent with the level of information that is published on the CMS website on a quarterly basis as described above. We note that forecasted FY 2027 prices for compensation costs, which account for about 51 percent of the market basket, are projected to increase 3.2 percent; and prices for All Other Products and Services, which account for about 46 percent of the market basket, are projected to increase 3.1 percent. While the projected market basket increase is calculated using the aggregation of the detailed price forecasts multiplied by their respective cost weights for each of the 22 individual cost categories, we want to provide an estimate of how the broader cost categories are contributing to the overall increase. As stated previously, the detailed price proxy forecasts that underlie the IPPS market basket percentage increase (and all CMS market baskets) are forecasted by IGI (a nationally recognized economic and financial forecasting firm). We also note that when developing its forecast for the various price indexes used in the IPPS market basket, IGI considers all macroeconomic factors that influence pricing trends, which would include factors that would affect supply prices such as tariffs. We strive for transparency regarding our methods and regularly respond to questions from the public regarding the market baskets via email at *cmsdnhs@cms.hhs.gov.*

Comment: A commenter requested CMS rebase the market baskets more frequently and at least every three years to ensure the market basket reflects the appropriate mix of services provided to Medicare beneficiaries.

Response: We appreciate the commenter's request. As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36868 through 36869), we discussed our frequency for rebasing and revising the IPPS market basket every four years. We note that we rebased and revised the market basket to reflect a 2023 base year in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36859 through 36873). Therefore, we believe that the 2023-based IPPS market basket is reflective of the cost structure and input price pressures facing hospitals. As noted in the FY 2026 IPPS/LTCH PPS final rule, we will continue to monitor the major cost weights (derived from the hospital Medicare cost reports) to determine whether a rebasing is warranted. A rebasing of the IPPS market basket would be subject to public comments through proposed and final rulemaking.

Comment: Several commenters expressed concern regarding the proposed net increase in operating payment rates for hospitals. They stated that the proposed 2.4 percent increase is too low and fails to account for the enduring impacts of high price inflation and cost increases. Commenters expressed specific concerns regarding compensation costs (highlighting increased contract labor utilization and workforce shortages), administrative costs (including what they described as unnecessary administrative costs for prior authorizations, claims appeals and denials from large commercial health insurers, including Medicare Advantage and Medicaid managed care plans), pharmaceuticals and supply costs. The commenters also referred to other economic headwinds creating uncertainty such as tariffs, which commenters stated would impact the prices of pharmaceuticals, medical equipment/supplies, and construction materials. They also expressed concern that recent actions, such as changes to federal student loan limits that exclude nurses and other clinicians from enhanced borrowing limits, will exacerbate workforce shortages, which contribute to higher costs for labor. They stated that their concerns are further compounded by the likelihood of additional funding reductions resulting from One Big Beautiful Bill Act (OBBBA) (affecting health insurance coverage and Medicaid funding).

Several commenters noted that the proposed update was below overall inflation, as measured by the Consumer Price Index (CPI). A commenter further stated that even though the CPI measures a different set of goods and services than the IPPS market basket, it is suggestive that later economic information on which the inflation updates are based shows prices growing more rapidly than reflected in the data used to forecast the FY 2027 IPPS updates.

In addition, commenters cited MedPAC's March 2026 report, which showed continuing negative Medicare fee-for-service operating margins of about −12 percent for 2022–2024. A commenter referenced AHA's analysis of their own Annual Survey data to indicate Medicare underpayments in 2024 (*https://www.aha.org/costsofcaring*). A commenter stated that according to the Kaiser Family Foundation, Medicare payments have not accommodated market increases for at least the last 10 years.

Several commenters urged CMS to focus on appropriately accounting for recent and future trends in inflationary pressures and cost increases in the hospital payment update, which they stated is essential to ensure that Medicare payments for acute care services more accurately reflect the cost of providing hospital care.

Several commenters stated CMS calculates the market basket based on forecasts rather than actual labor and supply cost increases, thus failing to incorporate the challenging circumstances brought on by unprecedented labor, supply, and drug cost increases. They recommended CMS look to alternative data sources (such as the Medicare cost reports) that they claim better reflect true labor and input cost increases in a timelier manner.

Commenters stated CMS must ensure and clarify that its final market basket update for FY 2027 appropriately includes the cost increases attributable to tariffs. A commenter requested CMS continue monitoring the impact of exogenous factors such as tariffs or geopolitical instability on supply chain costs so that, if necessary, CMS may invoke its full statutory authority to make appropriate adjustments to the market basket. Many commenters requested CMS use its special exceptions and adjustments authority to increase the market basket update from the proposed growth rate of 2.4 percent.

Commenters urged CMS to revisit both its market basket forecasts and the magnitude of the productivity

adjustment, and to consider their combined effect on provider reimbursements. A commenter encouraged CMS to update the market basket by at least 5 percent and to use its statutory adjustment authority to waive the productivity adjustment in FY 2027. Another commenter strongly urged CMS to use the later data on the market basket increase for FY 2027 as it has in past years.

Response: Section 1886(b)(3)(B)(iii) of the Act states the Secretary shall update IPPS payments based on a market basket percentage increase estimated by the Secretary before the beginning of the period or fiscal year, by which the cost of the mix of goods and services (including personnel costs but excluding nonoperating costs) comprising routine, ancillary, and special care unit inpatient hospital services, based on an index of appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services included in such inpatient hospital services, for the period or fiscal year will exceed the cost of such mix of goods and services for the preceding 12-month cost reporting period or fiscal year. For the FY 2026 IPPS/LTCH PPS final rule (90 FR 36859 through 36873), we rebased and revised the market basket to reflect a 2023 base year. We believe that the 2023-based IPPS market basket is consistent with the statute as it is a fixed-weight, Laspeyres-type price index that measures the change in price, over time, while maintaining a mix of goods and services purchased by hospitals consistent with a base period. Therefore, the market basket is designed to measure price inflation for IPPS hospitals and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services.

As stated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36901), CMS understands that the market basket updates may differ from other overall inflation indexes such as the topline CPI; however, we note that these topline indexes are not comparable since they measure different mixes of products, services, or wages than the legislatively defined CMS IPPS hospital market basket.

CMS welcomes feedback on alternative data sources for the market basket price proxies that appropriately measure price inflation and not costs. We note that suggestions can be emailed to *cmsdnhs@cms.hhs.gov.*

We appreciate the commenters' request for CMS to provide additional publicly available data on the assumptions and inputs that go into developing a market basket update. As noted, the detailed market basket cost weights (including the methodology) and price proxies used in the market baskets were set forth in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36859 through 36873). Additionally, shortly after the publication of the FY 2027 IPPS/LTCH PPS proposed rule, we made available on the CMS website (*https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-data*) the detailed historical growth rates for the market baskets as well as price forecasts for the aggregated cost weights (such as compensation, utilities). As stated previously, the detailed price proxies used in the market basket are forecasted by IGI (a nationally recognized economic and financial forecasting firm). We also note that general inquiries on the forecasting methodology can be emailed to *cmsdnhs@cms.hhs.gov,* as is also noted in the market basket spreadsheets on the CMS website.

We would highlight that the market basket percentage increase is a forecast of the price pressures that hospitals are expected to face in FY 2027. We also note that when developing its forecast for the various price indexes used in the IPPS market basket, IGI considers industry-specific and overall economic conditions. More specifically for the ECI for hospital workers, IGI considers overall labor market conditions (including the impact of wage pressures on skill mix) as well as trends in contract labor wages, which both have an impact on wage pressures for workers employed directly by the hospital.

As stated in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19496) we proposed a FY 2027 applicable percentage increase of 2.4 percent, reflecting the 2023-based IPPS market basket rate-of-increase of 3.2 percent and productivity adjustment of 0.8 percentage point, consistent with current law. We also proposed that if more recent data became available, we would use such data, if appropriate, to derive the final FY 2027 IPPS market basket update for the final rule. We appreciate the commenter's concern regarding inflationary pressure and the request to use more recent data to determine the FY 2027 IPPS market basket update. For this final rule (as proposed), we are using an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy. Based on more recent data available for this FY 2027 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2026 forecast of the 2023-based IPPS market basket rate-of-increase with historical data through the first quarter of 2026), we estimate that the FY 2027 market basket increase used to determine the applicable percentage increase for the IPPS is 3.2 percent. As discussed later in this section, based on more recent data available for this FY 2027 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2026 forecast of the productivity adjustment), the current estimate of the productivity adjustment for FY 2026 is 0.9 percentage point. Therefore, the applicable percentage increase applied to the standardized amount for hospitals that are considered to be a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act and submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act is 2.3 percent.

For these reasons, we believe that the 2023-based IPPS market basket appropriately reflects IPPS cost structures and we believe the price proxies used (such as those from BLS that reflect wage and benefit price growth) are an appropriate representation of price changes for the inputs used by hospitals in providing services.

We also note, as discussed previously, that section 1886(b)(3)(B)(i) of the Act establishes the statutory update for the national standardized amount for inpatient hospital operating costs through the ''applicable percentage increase'' (subject to the additional reductions prescribed in sections 1886(b)(3)(B)(viii) and 1886(b)(3)(B)(ix) of the Act). As discussed previously, and in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36902), given that we believe the 2023-based IPPS market basket reflects an index of appropriately weighted indicators of changes in wages and prices that are representative of the mix of goods and services included in such inpatient hospital services and the percentage change of the 2023-based IPPS market basket is based on IGI's more recent forecast of the expected input price pressures facing hospitals for FY 2027, we do not believe it is appropriate to use our exceptions and adjustments authority to create a separate payment that would have the effect of modifying the current law update.

Comment: Some commenters stated that CMS has consistently underestimated the market basket updates in recent years. Several commenters recommended that CMS consider adopting a prospective forecast

error correction policy for FY 2027 in the event that CMS again underestimates hospital inflation in a period of economic uncertainty and instability. In considering this request, the commenter requested that CMS consider that the productivity adjustment reduces the payment update below what the commenter claimed that OACT says is reasonable for hospitals to achieve.

Some commenters urged CMS to use its special exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to update the final payment rate to reflect the difference between prior years' actual and forecasted market basket increases. A commenter stated that the combined 4.3 percentage point understatement of the FY 2021 through FY 2023 market basket results in a permanent reduction in IPPS payments below the rate of inflation. The commenter stated that CMS should make an adjustment for forecast error consistent with the policy it has adopted under the SNF PPS, and use its special exceptions and adjustments authority to make a one-time retrospective adjustment.

Response: We responded to similar comments in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36903). In general, while projected IPPS hospital market basket updates can be underforecast (actual increases less forecasted increases were positive), over longer periods the forecasts have generally averaged close to the historical measures. CMS will continue to monitor the methods associated with the market basket forecasts to ensure there are not underlying systematic issues in the forecasting approach.

We note that the under forecast of the IPPS market basket increase in the recent time period (FY 2014 through FY 2025) was largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID–19 PHE. However, an analysis of the forecast error of the IPPS market basket over a longer period of time shows the forecast error has been both positive and negative. Only considering the forecast error for years when the final hospital market basket update was lower than the actual market basket update does not consider the full experience and impact of forecast error, in particular the numerous years that providers benefited from the forecast error. Relatedly, as we discussed in the FY 2024 IPPS/LTCH PPS final rule in response to similar comments (88 FR 59034), the SNF PPS forecast error adjustment was adopted very early in the payment system and, unlike what commenters are requesting here for the IPPS, forecast errors over many years have been consistently addressed within the SNF PPS.

For these reasons, we continue to believe it is not appropriate to include adjustments to the market basket update for future years based on the difference between the actual and forecasted market basket increase in prior years. After consideration of the comments received and consistent with our proposal, we are finalizing to use more recent data to determine the FY 2027 market basket update for the final rule. Specifically, based on more recent data available, we determined final applicable percentage increases to the standardized amount for FY 2027, as specified in the table that appears later in this section.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the productivity adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the U.S. economy. The productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is published by BLS as private nonfarm business total factor productivity ((TFP) previously referred to as multifactor productivity).[161] Please see *https://www.bls.gov/productivity/* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.*

For FY 2027, we proposed a productivity adjustment of 0.8 percent. Similar to the proposed market basket rate-of-increase, for the proposed rule, the estimate of the proposed FY 2027 productivity adjustment was based on IGI's fourth quarter 2025 forecast. As noted previously, we proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2027 productivity adjustment for the final rule.

Comment: Commenters expressed concerns about the application of the productivity adjustment, stating it is flawed because it is based on a measure for the private nonfarm business sector. Several commenters stated that the use of private nonfarm business total factor productivity effectively assumes the hospital field can mirror productivity gains achieved by private nonfarm businesses. Other commenters stated that private-sector productivity trends do not reflect the complex operational realities of hospital care (which they described as operating under fixed payment systems, extensive regulatory obligations, maintaining 24/7 operations, unpredictable patient volumes, and increasingly complex clinical demands), particularly during a time of sustained labor shortages and wage inflation and without regard to the unique impacts of COVID, and, more recently, the increase in targeting of cyberattacks to healthcare providers. Several commenters also claimed that it is well proven by the economic literature that the hospital and health care field cannot achieve the same productivity gains as the total economy. The commenters stated that an Office of the Actuary memo indicated that hospitals are unable to achieve the same productivity gains as the general economy over the long run. Specifically, some commenters requested CMS consider its own findings that hospitals historically have not achieved the same level of productivity as the general economy, referencing the June 2, 2022 memorandum where CMS's Office of the Actuary stated hospital TFP ranged from 0.2 percent to 0.5 percent compared to the average growth of private nonfarm business TFP of 0.8 percent. Commenters also referred to the BLS publication on a TFP measure for the combined Hospitals and Nursing and Residential Care Facilities industry, which indicated average TFP growth from 1990–2019 of −0.5 percent, even lower than either of OACT's estimates. Therefore, commenters stated that using the private nonfarm business sector TFP to adjust the market basket inappropriately exacerbates Medicare's chronic underpayments to hospitals.

Other commenters expressed concern regarding the increase in the productivity adjustment for FY 2027 relative to prior years. Commenters requested that CMS explain the magnitude of the proposed productivity adjustment, stating it is the largest CMS has used since FY 2019 and is the second largest in the 15 years for which

[161] *https://www.bls.gov/productivity/notices/2021/mfp-to-tfp-term-change.htm.*

CMS has published data. A commenter stated CMS should evaluate how the rolling average experienced such a significant increase when compared with the productivity adjustments of 0.5 percentage point or less in three of the last five years. Given the increase in the productivity adjustment, the commenter stated that it is likely that one or two years of significantly high outlier values contributed to the 10-year rolling average being 0.8 percentage points. Several commenters stated there was limited information available in the proposed rule regarding how the productivity adjustment was reached, including the underlying assumptions.

A commenter stated that the productivity adjustments have been in place for more than a decade now and it is hard to believe that hospital productivity has increased enough to warrant a reduction in cumulative payments of over 8.5 percent. They further stated that these same pressures also amplify the negative impact of the productivity adjustment on providers' ability to fund the very investments that can drive operational efficiencies. Given their concerns about the productivity adjustment, commenters requested CMS use its discretion under section 1886(d)(5)(I)(i) of the Act or to work with Congress to reduce or eliminate the productivity adjustment of 0.8 percentage point for FY 2027. Another commenter requested a FY 2027 productivity adjustment of 0.2 percentage point.

Several commenters expressed concern that the productivity adjustment appears to be applied only when it reduces Medicare payments. They stated that in the one year (FY 2021) where productivity in the non-farm business sector did not improve and measured TFP declined, CMS set the productivity adjustment to 0.0 rather than increasing payments. A commenter stated that while section 1886(b)(3)(B)(xi)(I) of the Act states that ''such percentage increase shall be reduced by the productivity adjustment'' it does not follow that the statute necessarily requires that the productivity adjustment be a subtraction from the otherwise applicable update. The commenter believes that CMS should make this issue subject to public notice and comment rulemaking.

A commenter also requested that CMS provide more transparency about how the productivity adjustment is calculated.

Response: We appreciate commenters' sharing their concerns and suggestions including working with Congress; however, section 1886(b)(3)(B)(xi) of the Act requires the application of the productivity adjustment. As required by statute, the FY 2027 productivity adjustment is derived based on the 10-year moving average growth in economy-wide private nonfarm business total factor productivity for the period ending FY 2027.

In the FY 2026 IPPS/LTCH PPS final rule (90 FR 36904), in response to similar comments regarding the methodology for calculating the productivity adjustment, we provided information on how the productivity adjustment is calculated using the TFP index levels (historical and projected). In addition, as stated in the FY 2026 IPPS/LTCH final rule, we have always made available on the CMS website the general method for calculating the productivity adjustment at (*https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/tfp_methodology.pdf*). In this same TFP methodology document, we also provide a link to the most recent BLS historical TFP data (*http://www.bls.gov/productivity*), which currently allows interested parties to obtain historical TFP annual index levels for 1987 through 2025 and we provide the IGI projection model which is currently used to derive annual TFP growth rates for 2026 and 2027. The annual index level derived from this method is then interpolated to quarterly levels, and the FY 2027 productivity adjustment is equal to the percent change in the 40-quarter moving average projected level for the period ending September 30, 2027 relative to the 40-quarter moving average projected level for the period ending September 30, 2026. We believe our methodology for the productivity adjustment is consistent with section 1886(b)(3)(B)(xi)(II) of the Act, which states that the productivity adjustment is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

At the time of this final rule, the FY 2027 productivity adjustment reflects BLS historical TFP data through 2025 (released on March 19, 2026) and IGI's forecasted TFP growth for 2026 and 2027. The average annual growth rate of historical TFP published by BLS for 2018 through 2025 is currently 1.0 percent and IGI is projecting average TFP growth of about 0.7 percent for 2026 and 2027 based on IGI's second-quarter 2026 forecast. Combining the historical and projected TFP data over the entire 10-year time period and interpolating into quarterly index levels results in a 10-year moving average growth rate of TFP of 0.9 percent for FY 2027. The productivity adjustment (based on the 10-year period ending with FY 2027) for the FY 2027 IPPS/LTCH PPS final rule is 0.1 percentage point higher than for the FY 2027 IPPS/LTCH PPS proposed rule mainly due to the incorporation of updated BLS historical data.

In response to commenters' concerns about the productivity adjustment only being applied if it reduces the payment update, we note that the statutory language in section 1886(b)(3)(B)(xi)(I) of the Act requires that the Secretary reduce (not increase) the market basket percentage increase by changes in economy-wide productivity.

We thank the commenters for their comments. After consideration of the comments received and consistent with our proposal, we are finalizing as proposed to use more recent data to determine the FY 2027 productivity adjustment for the final rule.

In summary, based on more recent data available for this FY 2027 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2026 forecast of the 2023-based IPPS market basket rate-of-increase with historical data through the first quarter of 2026), we estimate that the FY 2027 market basket update used to determine the applicable percentage increase for the IPPS is 3.2 percent. Based on more recent data available for this FY 2027 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2026 forecast of productivity adjustment), the current estimate of the productivity adjustment for FY 2027 is 0.9 percentage point. Based on these more recent data, for this final rule, we have determined four applicable percentage increases to the standardized amount for FY 2027, as specified in the following table:

TABLE V.B-01: FY 2027 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2027	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	3.2	3.2	3.2	3.2
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	-0.8	-0.8
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.4	0.0	-2.4
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.9	-0.9	-0.9	-0.9
Applicable Percentage Increase Applied to Standardized Amount	**2.3**	**-0.1**	**1.5**	**-0.9**

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42344), we revised our regulations at42 CFR 412.64(d) to reflect the current law for the update for FY 2020 and subsequent fiscal years. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we added paragraph (d)(1)(viii) to § 412.64 to set forth the applicable percentage increase to the operating standardized amount for FY 2020 and subsequent fiscal years as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, reduced by a productivity adjustment.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs is also subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act.

As discussed in section V.F. of the preamble of this final rule, section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75) extended the MDH program for FY 2027 discharges occurring before January 1, 2027. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2027. We refer readers to section V.F. of the preamble of this final rule for further discussion of the MDH program.

For FY 2027, we proposed the following updates to the hospital-specific rates applicable to SCHs and MDHs: A proposed update of 2.4 percent for a hospital that submits quality data and is a meaningful EHR user (as defined in section 1886(n) of the Act); a proposed update of 0.0 percent for a hospital that submits quality data and is not a meaningful EHR user; a proposed update of 1.6 percent for a hospital that fails to submit quality data and is a meaningful EHR user; and a proposed update of −0.8 percent for a hospital that fails to submit quality data and is not an meaningful EHR user. As previously discussed, we proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket update and the productivity adjustment), we would use such data, if appropriate, to determine the market basket update and the productivity adjustment in the final rule.

We did not receive any public comments on our proposed updates to hospital-specific rates applicable to SCHs and MDHs. The general comments we received on the proposed FY 2027 update (including the proposed market basket update and productivity adjustment) are discussed earlier in this section. For FY 2027, we are finalizing the proposal to determine the update to the hospital specific rates for SCHs and MDHs in this final rule using the more recent available data, as previously discussed.

For this final rule, based on more recent available data, we are finalizing the following updates to the hospital specific rates applicable to SCHs and MDHs: An update of 2.3 percent for a hospital that submits quality data and is a meaningful EHR user; an update of 1.5 percent for a hospital that fails to submit quality data and is a meaningful EHR user; an update of −0.1 percent for a hospital that submits quality data and is not a meaningful EHR user; and an update of −0.9 percent for a hospital that fails to submit quality data and is not a meaningful EHR user.

2. FY 2027 Puerto Rico Hospital Update

Section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket rate-of-increase, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. (We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.) The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674).

For FY 2027, consistent with section 1886(b)(3)(B) of the Act, as amended by section 602 of Public Law 114–113, we are setting the applicable percentage increase for Puerto Rico hospitals by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under

the IPPS for Puerto Rico hospitals will be equal to the rate of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for Puerto Rico hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to the productivity adjustment at section 1886(b)(3)(B)(xi) of the Act. As noted previously, section 1886(b)(3)(B)(xi) of the Act states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

In the FY2027 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2025 forecast of the 2023-based IPPS market basket update with historical data through third quarter 2025, in accordance with section 1886(b)(3)(B) of the Act, as discussed previously, for Puerto Rico hospitals we proposed a market basket update of 3.2 percent reduced by a productivity adjustment of 0.8 percentage point. Therefore, for FY 2027, depending on whether a Puerto Rico hospital is a meaningful EHR user, we stated that there are two possible applicable percentage increases that could be applied to the standardized amount. Based on these data, we determined the following proposed applicable percentage increases to the standardized amount for FY 2027 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we proposed a FY 2027 applicable percentage increase to the operating standardized amount of 2.4 percent (that is, the FY 2027 estimate of the proposed market basket rate-of-increase of 3.2 percent, less 0.8 percentage point for the proposed productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we proposed a FY 2027 applicable percentage increase to the operating standardized amount of 0.0 percent (that is, the FY 2027 estimate of the proposed market basket rate-of-increase of 3.2 percent, less 2.4 percentage points (the proposed market basket rate-of-increase of 3.2 percent × 0.75 for failure to be a meaningful EHR user), and less 0.8 percentage point for the proposed productivity adjustment).

As noted previously, we proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2027 market basket update and the productivity adjustment for the FY 2027 IPPS/LTCH PPS final rule.

We did not receive any public comments on our proposed updates to the standardized amount for FY 2027 for Puerto Rico hospitals. The general comments we received on the proposed FY 2027 update (including the proposed market basket update and productivity adjustment) are discussed in greater detail earlier in this section. For FY 2027, we are finalizing the proposal to determine the update to the standardized amount for FY 2027 for Puerto Rico hospitals in this final rule using the more recent available data, as previously discussed.

As previously discussed in section VI.B. of the preamble of this final rule, based on more recent data available for this final rule (that is, IGI's second quarter 2026 forecast of the 2023-based IPPS market basket rate-of-increase with historical data through the first quarter of 2026), we estimate that the FY 2027 market basket update used to determine the applicable percentage increase for the IPPS is 3.2 percent and a productivity adjustment of 0.9 percent. For FY 2027, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, in accordance with section 1886(b)(3)(B) of the Act, we determined the following applicable percentage increases to the standardized amount for FY 2027 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, an applicable percentage increase to the operating standardized amount of 2.3 percent (that is, the FY 2027 estimate of the market basket rate-of-increase of 3.2 percent reduced by 0.9 percentage point for the productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, an applicable percentage increase to the operating standardized amount of -0.1 percent (that is, the FY 2027 estimate of the market basket rate-of-increase of 3.2 percent, less an adjustment of 2.4 percentage point (the market basket rate-of-increase of 3.2 percent × 0.75 for failure to be a meaningful EHR user), and reduced by a productivity adjustment of 0.9 percentage point).

TABLE V.B-02: FY 2027 APPLICABLE PERCENTAGE INCREASES FOR PUERTO RICO HOSPITALS UNDER THE IPPS

FY 2027	Hospital is a Meaningful EHR User	Hospital is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	3.2	3.2
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.4
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.9	-0.9
Applicable Percentage Increase Applied to Standardized Amount	**2.3**	**-0.1**

C. Rural Referral Centers (RRCs) Annual Updates to Case-Mix Index (CMI) and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at 42 CFR 412.96 set forth the criteria that a hospital must meet to qualify under the IPPS as a rural referral center (RRC). RRCs receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of the Balanced Budget Act of 1997 (Pub. L. 105–33) states, in part, that any hospital classified as an RRC by the Secretary for

FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997, IPPS final rule with comment period (62 FR 45999 through 46000), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the designation of their geographic area as urban. Subsequently, in the August 1, 2000, IPPS final rule (65 FR 47087), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (42 CFR 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to 42 CFR 412.96(c)(1) through (5) and the September 30, 1988, **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if the hospital's—

- CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- Number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45217), in light of the COVID–19 PHE, we amended the regulations at 42 CFR 412.96(h)(1) to provide for the use of the best available data rather than the latest available data in calculating the national and regional CMI criteria. We also amended the regulations at 42 CFR 412.96(c)(1) to indicate that the individual hospital's CMI value for discharges during the same Federal fiscal year used to compute the national and regional CMI values is used for purposes of determining whether a hospital qualifies for RRC classification. We also amended the regulations 42 CFR 412.96(i)(1) and (2), which describe the methodology for calculating the number of discharges criteria, to provide for the use of the best available data rather than the latest available or most recent data when calculating the regional discharges for RRC classification.

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at 42 CFR 412.96(c)(1)(ii). The national median CMI value for FY 2027 is based on the CMI values of all urban hospitals nationwide, and the regional median CMI values for FY 2027 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in 42 CFR 413.75). These values are based on discharges occurring during FY 2025 (October 1, 2024, through September 30, 2025), and include bills posted to CMS' records through March 2026. We believe that this is the best available data for use in calculating the national and regional median CMI values and is consistent with our use of the FY 2025 MedPAR claims data for FY 2027 ratesetting.

In the FY 2027 IPPS/LTCH PPS proposed rule, we proposed that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2026, they must have a CMI value for FY 2025 that is at least—

- 1.7783 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in 42 CFR 413.75) calculated by CMS for the census region in which the hospital is located. (We refer readers to the table set forth in the FY 2027 IPPS/LTCH PPS proposed rule at 91 FR 19499). In the proposed rule, we stated that we intended to update the proposed CMI values in the FY 2027 IPPS/LTCH PPS final rule to reflect the updated FY 2025 MedPAR file, which contains data from additional bills received through March 2026.

Comment: Commenters supported our proposal to use FY 2025 data to calculate the national and regional median CMI values for FY 2027.

Response: We appreciate the commenters' support.

Therefore, based on the best available data (FY 2025 bills received through March 2026), in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2026, they must have a CMI value for FY 2025 that is at least:

- 1.778 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located. The final CMI values by region are set forth in the following table.

Region	Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.4865
2. Middle Atlantic (PA, NJ, NY)	1.5595
3. East North Central (IL, IN, MI, OH, WI)	1.6506
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.6851
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.6298
6. East South Central (AL, KY, MS, TN)	1.5649
7. West South Central (AR, LA, OK, TX)	1.772
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7903
9. Pacific (AK, CA, HI, OR, WA)	1.7284

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data is available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. In the FY 2027 IPPS/LTCH PPS proposed rule, we proposed to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2024 (that is, October 1, 2023, through September 30, 2024), which are the latest cost report data available at the time this final rule was developed. We believe that this is the best available data for use in calculating the median number of discharges by region and is consistent with our finalized data proposal to use cost report data from cost reporting periods beginning during FY 2024 for FY 2027 ratesetting. In the FY 2027 IPPS/LTCH PPS proposed rule, we proposed that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2026, must have, as the number of discharges for its cost reporting period that began during FY 2024, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- If less, the median number of discharges for urban hospitals in the census region in which the hospital is located. (We refer readers to the table set forth in the FY 2027 IPPS/LTCH PPS proposed rule at 91 FR 19499). In the proposed rule, we stated that we intended to update these numbers in the FY 2027 final rule based on the latest available cost report data.

Comment: Commenters supported our proposal to use FY 2024 data to calculate median number of discharges by region for FY 2027.

Response: We appreciate the commenters' support.

Therefore, based on the best available discharge data at this time, that is, for cost reporting periods that began during FY 2024, the final median number of discharges for urban hospitals by census region are set forth in the following table.

Region	Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,788
2. Middle Atlantic (PA, NJ, NY)	10,405
3. East North Central (IL, IN, MI, OH, WI)	8,283
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,643
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	11,313
6. East South Central (AL, KY, MS, TN)	8,646
7. West South Central (AR, LA, OK, TX)	6,598
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,398
9. Pacific (AK, CA, HI, OR, WA)	9,280

We note that because the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, under this final rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

D. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. The low-volume hospital payment adjustment is implemented in the regulations at 42 CFR 412.101. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is in addition to any payment calculated under section 1886 of the Act and is based on the per discharge amount paid to the qualifying hospital. In other words, the low-volume hospital payment adjustment is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment. The payment adjustment for low-volume hospitals is not budget neutral.

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19499 through 19503), section 2201 of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4) extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment under the IPPS, that is, the modified definition of low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals under section 1886(d)(12), through September 30, 2025. The Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (Pub. L. 119–37), enacted on November 12, 2025, provided an extension of those temporary changes to the qualifying criteria and payment adjustment methodology for certain low-volume hospitals through January 30, 2026. Most recently, the Consolidated Appropriations Act, 2026 (Pub. L. 119–75), provided an extension of those temporary changes to the qualifying criteria and payment adjustment methodology for certain low-volume hospitals through FY 2026 and the portion of fiscal year 2027 beginning on October 1, 2026, and ending on December 31, 2026. Absent further Congressional action, beginning January 1, 2027 the low-volume hospital qualifying criteria and payment adjustment revert to the statutory requirements that were in effect prior to FY 2011, and the preexisting low-volume hospital payment adjustment methodology and qualifying criteria, as implemented in FY 2005 and discussed later in this section, resume. We discuss the payment policies for FY 2027 in sections V.D.2 and V.D.3. of the preamble of this final rule.

TABLE V.D.-01: LOW-VOLUME HOSPITAL QUALIFYING CRITERIA AND PAYMENT ADJUSTMENT FOR FYs 2019 AND SUBSEQUENT FYs

Fiscal Years	Road Miles	Total Discharges	Payment Adjustment
FYs 2019 through 2026 and the portion of FY 2027 from 10/1/2026 through 12/31/2026	>15	<= 500	0.25
		> 500 < 3,800	0.25 - [0.25/3300] x (number of total discharges - 500) = (95/330) - (number of total discharges/13,200)
The portion of FY 2027 beginning on 1/1/2027 and FY 2028 and subsequent FYs	>25	< 200	0.25

2. Extension of Temporary Changes to Low-Volume Hospital Payment Definition and Payment Adjustment Methodology and Conforming Changes to Regulations

As discussed previously, section 2201 of the Full-Year Continuing Appropriations and Extensions Act, 2025, extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment through September 30, 2025. Section 6201 of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 further extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment under the IPPS for the portion of FY 2026 beginning on October 1, 2025, and ending on January 30, 2026. Most recently, section 6201 of the Consolidated Appropriations Act, 2026 extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment through FY 2026 and the portion of fiscal year 2027 beginning on October 1, 2026, and ending on December 31, 2026. We note the extension provided by the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 was addressed in Change Request 14341 (Transmittal 13564) and the extension provided by the Consolidated Appropriations Act, 2026 was addressed in Change Request 14415 (Transmittal 13735), issued April 14, 2026. For additional information, please refer to the transmittal R13564OTN and R13735OTN.

Under section 1886(d)(12)(C)(i) of the Act, as amended by the Consolidated Appropriations Act, 2026, for FYs 2019 through FY 2026 and the portion of FY 2027 beginning on October 1, 2026 and ending on December 31, 2026, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. In accordance with the existing regulations at § 412.101(a), we define the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(1). Under section 1886(d)(12)(D) of the Act, as amended, for discharges occurring in FYs 2019 through 2026 and the portion of FY 2027 beginning on October 1, 2026 and ending on December 31, 2026, the Secretary determines the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low volume hospitals with more than 3,800 discharges in the fiscal year. Consistent with the requirements of section 1886(d)(12)(C)(ii) of the Act, the term ''discharge'' for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399), we specified a continuous, linear sliding scale formula to determine the low volume payment adjustment, as reflected in the regulations at § 412.101(c)(3)(ii). Consistent with the statute, we provided that qualifying hospitals with 500 or fewer total discharges will receive a low-volume hospital payment adjustment of 25 percent. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment adjustment is calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. For qualifying hospitals with fewer than 3,800 total discharges but more than 500 total discharges, the low-volume hospital payment adjustment is calculated using the formula at § 412.101(c)(3)(ii) (which is shown in the Table V.D.–01). For this purpose, the term ''discharge'' refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges). The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low volume payment adjustment in the current year (§ 412.101(b)(2)(iii)). The low-volume hospital payment adjustment for FYs 2019 through 2025 is set forth in the current regulations at § 412.101(c)(3).

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19499), we proposed to make conforming changes to the regulation text in § 412.101 to reflect the extension of the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals in accordance with provisions of the Consolidated Appropriations Act, 2026. Specifically, we proposed to make conforming changes to paragraphs (b)(2)(iii) and (c)(3) introductory text of § 412.101 to reflect that the low-volume hospital payment adjustment policy in effect through FY 2026 and the portion of fiscal year 2027 beginning on October 1, 2026, and ending on December 31, 2026 is the same low-volume hospital payment adjustment policy in effect for FYs 2019 through 2025 (as described in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399) and in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36908 through 36912)). In addition, in accordance with the provisions of the Consolidated Appropriations Act, 2026, we proposed to make conforming changes to paragraphs (b)(2)(i) and (c)(1) of § 412.101 to reflect that beginning with the portion of fiscal year 2027 beginning on January 1, 2027, and ending on September 30, 2027, and for fiscal year 2028 and subsequent fiscal years, the low-volume hospital payment adjustment policy reverts back to the low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010, as described in section V.D.3. of the preamble of this final rule. We further proposed that if the temporary changes to the low-volume payment adjustment are extended through legislation beyond December 31, 2026, we would make the conforming changes to the regulations at § 412.101(b)(2)(i) and (iii) and (c)(1) and (3) to reflect any further extension.

We received no comments on our proposed conforming changes to the regulations to codify this extension and we are finalizing the proposed changes to the regulations text in § 412.101 without modification.

3. Payment Adjustment for the Portion of FY 2027 Beginning on January 1, 2027 and Subsequent Fiscal Years

In accordance with section 1886(d)(12) of the Act, as amended by the Consolidated Appropriations Act, 2026, beginning with FY 2027 discharges occurring on or after January 1, 2027 the low-volume hospital definition and payment adjustment methodology revert to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act and subsequent legislation. Specifically, section 1886(d)(12)(B) of the Act requires, for discharges occurring in FYs 2005 through 2010 and for discharges occurring during the portion of FY 2027 beginning on or after January 1, 2027, and subsequent fiscal years, that the Secretary determine an applicable percentage increase for these low-volume hospitals based on the ''empirical relationship'' between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges. The statute thus mandates that the Secretary develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals.

Therefore, absent further Congressional action, effective for the portion of FY 2027 beginning on January 1, 2027, and ending on September 30, 2027, and for FY 2028 and subsequent fiscal years, under current policy at § 412.101(b), to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year. For the portion of FY 2027 beginning on January 1, 2027 and for subsequent fiscal years, the statute specifies that a low-volume hospital must have less than 800 discharges during the fiscal year. However, as required by section 1886(d)(12)(B)(i) of the Act, the Secretary has developed an empirically justifiable payment adjustment based on the relationship, for IPPS hospitals with less than 800 discharges, between the additional incremental costs (if any) that are associated with a particular number of discharges. Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25 percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief for low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. (Under the policy we established in that same final rule, hospitals with between 200 and 799 discharges do not receive a low-volume hospital adjustment.)

As discussed previously, for FYs 2005 through 2010 and FY 2019 and subsequent years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges. The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(i)). We use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. We note that, for FYs 2011 through 2018, we used the most recently available MedPAR data to determine the hospital's Medicare discharges because only Medicare discharges were used to determine if a hospital met the discharge criterion for those years.

In addition to the discharge criterion, a hospital must also meet the mileage criterion to qualify for the low-volume payment adjustment. As specified by section 1886(d)(12)(C)(i) of the Act, a low-volume hospital must be more than 25 road miles (or 15 road miles for FYs 2011 through the portion of FY 2027 ending on December 31, 2026) from another subsection (d) hospital. Accordingly, for the portion of FY 2027 beginning on January 1, 2027, and for subsequent fiscal years, in addition to the discharge criterion, the eligibility for the low-volume payment adjustment is also dependent upon the hospital meeting the mileage criterion at § 412.101(b)(2)(i), which specifies that a hospital must be located more than 25 road miles from the nearest subsection (d) hospital, consistent with section 1886(d)(12)(C)(i) of the Act. We define, at § 412.101(a), the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(1) (75 FR 50238 through 50275 and 50414). As previously noted, we proposed to make conforming changes to paragraphs (b)(2)(i) and (c)(1) of § 412.101 to reflect that for the portion of FY 2027 beginning on January 1, 2027, and for subsequent fiscal years, the low-volume hospital payment adjustment policy is the same as that in effect for FYs 2005 through 2010.

Comment: Similar to previous extensions, many commenters supported the legislative extension of the temporary changes to the definition and payment adjustment for low-volume hospitals through December 31, 2026, and expressed support for additional legislative extensions. Many commenters continued to request that CMS work with Congress to extend or make permanent the temporary modifications to the low-volume hospital payment policy. Several commenters expressed financial instability concerns, particularly those in rural areas or that serve primarily Medicare patients, in the absence of a further extension of the temporary modifications to the low-volume hospital payment policy. A commenter stated that the proposed changes to the mileage and discharge criteria do not account for the business decisions that hospitals have made in reliance on the low-volume adjustment since current criteria took effect in FY 2019. A commenter urged CMS to use its legal authority to make low-volume hospital payments to all current low-volume hospitals in the absence of an extension of the temporary modifications. A few commenters requested CMS provide a transition payment to hospitals impacted by the expiration of the temporary modifications to the low-volume hospital payment policy.

Several commenters again sought clarification on how CMS would handle any legislation that would further extend the modified low-volume hospital payment policy beyond the end of the year. Other commenters urged CMS to expeditiously process claims and provide instructions to MACs for any subsequent extensions, especially in instances when extensions are made retroactively to avoid significant financial strain to affected hospitals and potential lower Medicare reimbursement from MA plans (as they stated many MA plans do not make retrospective payments for extensions that occur retrospectively until after CMS issues instructions to the MACs).

Response: We appreciate the commenters sharing their support for legislative action and the commenters' concerns about the expiration of the temporary changes to the low-volume hospital policy and the corresponding financial impact. As previously discussed, section 1886(d)(12) of the Act sets forth the applicable low-volume hospital policy beginning January 1, 2027, and the statute mandates that the Secretary develop an empirically justifiable adjustment based on the

relationship between costs and discharges for low volume hospitals. As described previously, a 25 percent low-volume adjustment for qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement. We understand commenters' concerns with the financial impact of the expiration of the temporary modifications to the low-volume hospital policy, however, we note that since the current criteria under the expanded low-volume hospital adjustment took effect in FY 2019, those modifications have been temporary.

As we have said in the past, we make every effort to implement any extension of the low-volume hospital payment policy as expeditiously as possible. As with past extensions, CMS will evaluate enacted legislation to determine the most appropriate approach to implement changes to the law, including issuing instructions to the MACs and to communicate with affected hospitals. However, we believe it would be premature to opine on exactly how any subsequent extension would be implemented. As with past extensions, we would continue to work to implement any subsequent extensions as quickly and seamlessly as possible based on the specific legislative requirements of the particular extension.

Comment: As in past years, several commenters stated that it is not the intent of Congress for the low-volume hospital payment policy to revert to the historical statutory requirements. Some of these commenters believe that CMS is ignoring the congressional intent of this policy and denying a group of IPPS providers low-volume hospital payments with the reversion to the policy that was originally established for FY 2005. A few commenters also stated that CMS did not explain why limiting the low-volume hospital payment adjustment to hospitals with fewer than 200 discharges is ''most consistent'' with statute. These commenters requested expanding eligibility for the discharge criteria to match the statutory requirement to include IPPS hospitals with 200–799 discharges. A commenter requested that CMS evaluate whether hospitals with greater than 200 discharges continue to experience the financial vulnerabilities that the low-volume adjustment was designed to address.

Response: We continue to disagree that it is contrary to the congressional intent for the low-volume hospital policy to revert to the policy established under the original historical statutory requirements. As previously discussed, the extension of the temporary changes to the qualifying criteria and payment adjustment methodology for certain low-volume hospitals provided by section 6201 of the Consolidated Appropriations Act, 2026 is through December 31, 2026, only. Consistent with the discussion in the FY 2005 IPPS final rule (69 FR 49100), despite the statutory definition of a low-volume hospital as a subsection (d) hospital that has less than 800 discharges, the statutory provision mandating this adjustment also requires the Secretary to determine the empirical relationship between the standardized cost-per-case, the total number of discharges, and the amount of incremental costs (if any) associated with the number of discharges (emphasis added). The statute requires that the applicable percentage increase shall be based upon such relationship in a manner that reflects such incremental costs. We continue to believe that the statutory language thus gives the Secretary the flexibility to set the percentage increase at zero for a given number of discharges if the empirical evidence shows that hospitals experience no higher incremental costs when they reach that number of discharges. In other words, the statute does not require the Secretary to provide an adjustment in the absence of empirical evidence that an adjustment is warranted by higher incremental costs.

As discussed in response to public comments in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53408 through 53409), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50612 through 50613), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38184 through 38189), and the FY 2026 IPPS/LTCH PPS final rule (90 FR 36910 through 36911), to implement the original low-volume hospital payment adjustment provision, and as mandated by statute, we developed an empirically justified adjustment based on the relationship between costs and total discharges of hospitals with less than 800 total (Medicare and non-Medicare) discharges. Specifically, we performed several regression analyses to evaluate the relationship between hospitals' costs per case and discharges, and found that an adjustment for hospitals with less than 200 total discharges is most consistent with the statutory requirement to provide for additional payments to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with lower numbers of discharges (69 FR 49101 through 49102). Based on these analyses, we established a low-volume hospital policy under which qualifying hospitals with less than 200 total discharges receive a payment adjustment of an additional 25 percent. (Section 1886(d)(12)(B)(iii) of the Act limits the applicable percentage increase adjustment to no more than 25 percent.) At this time, we are not aware of any analysis or empirical evidence that would support expanding the originally established low-volume hospital adjustment policy and we did not make any proposals regarding the low-volume hospital payment adjustment for FY 2027. For these reasons, we are not making any changes to the low-volume hospital payment adjustment policy in this final rule.

Comment: A few commenters expressed support for the methodology for calculating the low-volume payment adjustment using a single, non-sliding scale adjustment of 25 percent for qualifying hospital discharges beginning January 1, 2027, when the temporary changes expire under current law.

Response: We appreciate commenters' support for the single, non-sliding scale payment adjustment for qualifying hospitals beginning January 1, 2027.

After consideration of the public comments we received regarding the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals for FY 2027, we are finalizing our proposals without modification.

4. Process for Requesting and Obtaining the Low-Volume Hospital Payment Adjustment for FY 2027

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414) and subsequent rulemaking, most recently in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19501 through 19503), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. Under this previously established process, a hospital makes a written request for the low-volume payment adjustment under § 412.101 to its MAC. This request must contain sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. The MAC will determine if the hospital qualifies as a low-volume hospital by reviewing the data the hospital submits with its request for low-volume hospital status in addition to other available data. Under this approach, a hospital will know in advance whether or not it will receive a payment adjustment under the low-volume hospital policy. The MAC and CMS may review available data such as the number of discharges, in addition to the data the hospital submits with its request for

low-volume hospital status, to determine whether or not the hospital meets the qualifying criteria. (For additional information on our existing process for requesting the low-volume hospital payment adjustment, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401).)

As explained earlier, for FY 2019 and subsequent fiscal years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as was the case for FYs 2005 through 2010. Under § 412.101(b)(2)(i) and (iii), a hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 and 41400), we use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. (For FYs 2011 through 2018, the most recently available MedPAR data were used to determine the hospital's Medicare discharges because non-Medicare discharges were not used to determine if a hospital met the discharge criterion for those years.) Therefore, a hospital must refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) to decide whether or not to apply for low-volume hospital status for a particular fiscal year.

In addition to the discharge criterion, eligibility for the low-volume hospital payment adjustment is also dependent upon the hospital meeting the applicable mileage criterion specified in section 1886(d)(12)(C)(i) of the Act, which is codified at § 412.101(b)(2), for the fiscal year. To meet the mileage criterion to qualify for the low-volume hospital payment adjustment for the portion of FY 2027 beginning October 1, 2026 through December 31, 2026, a hospital must be located more than 15 road miles from the nearest subsection (d) hospital, as reflected in revised § 412.101(b)(2). Additionally, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for the portion of FY 2027 beginning January 1, 2027 through September 30, 2027, a hospital must be located more than 25 road miles from the nearest subsection (d) hospital. (We define in § 412.101(a) the term ''road miles'' to mean ''miles'' as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).) For establishing that the hospital meets the mileage criterion, the use of a web-based mapping tool as part of the documentation is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospital(s), location on a map, and distance from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the applicable mileage criterion.

In accordance with our previously established process, a hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the applicable low-volume hospital payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). For a hospital whose request for low-volume hospital status is received after September 1, if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the MAC's low-volume status determination.

Consistent with this previously established process, for FY 2027, we proposed that a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria (as described earlier). Specifically, for the portion of FY 2027 beginning October 1, 2026 through December 31, 2026, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2026, in order for the low-volume, add-on payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2026. If a hospital's written request for low-volume hospital status for the portion of FY 2027 beginning October 1, 2026 through December 31, 2026 is received after September 1, 2026, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2027 discharges beginning October 1, 2026 through December 31, 2026, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

Additionally, we proposed that a hospital must also submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital continues to meet the applicable mileage and discharge criteria for the portion of FY 2027 beginning on January 1, 2027 through September 30, 2027 (as described earlier). Specifically, for the portion of FY 2027 beginning on January 1, 2027, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than December 1, 2026, in order for the 25-percent, low-volume, add-on payment adjustment to be applied to payments for its discharges beginning on or after January 1, 2027. If a hospital's written request for low-volume hospital status for the portion of FY 2027 beginning on January 1, 2027 is received after December 1, 2026, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2027 discharges on or after January 1, 2027, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

A hospital may choose to make a single written request for low-volume hospital status to its MAC for both the portion of FY 2027 beginning on October 1, 2026 and ending December 31, 2026 and the portion of FY 2027 beginning on January 1, 2027 through September 30, 2027 by the September 1, 2026 deadline discussed previously. Alternatively, a hospital may choose to submit separate written requests, one for the portion of FY 2027 beginning on October 1, 2026 and ending on December 31, 2026 (by the September 1, 2026 deadline discussed previously), and another for the portion of FY 2027 beginning on January 1, 2027 through September 30, 2027 (by the December 1, 2026 deadline discussed previously).

Under this process, a hospital that qualified for the low-volume hospital payment adjustment for FY 2026 may continue to receive a low-volume hospital payment adjustment for FY 2027 without reapplying if it meets both the discharge criterion and the mileage criterion applicable for FY 2027 (that is, the discharge criterion and mileage criterion for the period beginning October 1, 2026 through December 31, 2026, as well as the discharge criterion and mileage criterion for the period

beginning on January 1, 2027 through September 30, 2027, respectively). As discussed previously, for the portion of FY 2027 beginning on January 1, 2027, the discharge and the mileage criteria are reverting to the statutory requirements that were in effect prior to FY 2011, and to the preexisting low-volume hospital qualifying criteria, as implemented in FY 2005 and specified in the existing regulations at § 412.101(b)(2)(i). As in previous years, we proposed that such a hospital must send written verification that is received by its MAC no later than September 1, 2026 or December 1, 2026, respectively, stating that it meets the mileage criterion for the applicable portion(s) of FY 2027, as described previously. For example, for the portion of FY 2027 beginning October 1, 2026 through December 31, 2026, the hospital must state it is located more than 15 road miles from the nearest ''subsection (d)'' hospital. Similarly, for the portion of FY 2027 beginning on January 1, 2027, the hospital must state it is located more than 25 road miles from the nearest ''subsection (d)'' hospital. For FY 2027, we are further proposed that this written verification must also state, based upon the most recently submitted cost report, that the hospital meets the discharge criterion for the applicable portion(s) of FY 2027, as described previously. For example, for the portion of FY 2027 beginning October 1, 2026 through December 31, 2026, the hospital must have less than 3,800 discharges total, including both Medicare and non-Medicare discharges. Similarly, for the portion of FY 2027 beginning on January 1, 2027, the hospital must have less than 200 discharges total, including both Medicare and non-Medicare discharges. If a hospital's request for low-volume hospital status for FY 2027 is received after September 1, 2026, (or after December 1, 2026 for the portion of FY 2027 beginning on January 1, 2027) and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume add-on payment adjustment to determine the payment for the hospital's discharges for the applicable portion of FY 2027, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

We received no comments on our proposed process for requesting and obtaining the low-volume hospital payment adjustment for FY 2027 and therefore are finalizing this proposal without modification.

E. Changes in the Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)

1. Background for the MDH Program

Section 1886(d)(5)(G) of the Act provides special non-budget neutral payment protections, under the IPPS, to a Medicare-dependent, small rural hospital (MDH). MDHs are paid for their hospital inpatient services based on the higher of the Federal rate or a blended rate based in part on the Federal rate and in part on the MDH's hospital specific rate. (For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).) Under current law, the MDH program provisions at section 1886(d)(5)(G) of the Act will expire for discharges on or after January 1, 2027. Beginning with discharges occurring on or after January 1, 2027, absent further Congressional action, all hospitals that previously qualified for MDH status will be paid based on the Federal rate.

2. Implementation of Legislative Extension of MDH Program

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program has been extended by subsequent legislation, most recently through December 31, 2026 (that is, for discharges occurring before January 1, 2027), as discussed further in this section. (Additional information on the extensions of the MDH program through FY 2025 can be found in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36912).) As discussed in the FY 2026 IPPS/LTCH PPS final rule, the MDH program provision at section 1886(d)(5)(G) of the Act was set to expire at the end of FY 2025 (90 FR 36913). Subsequently, the MDH program was extended by additional legislation as follows:

- Section 6202 of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (Pub. L. 119–37), enacted on November 12, 2025, provided for an extension of the MDH program through January 30, 2026.
- Section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75), enacted on February 3, 2026, provided for an extension of the MDH program through December 31, 2026 (that is, for discharges occurring before January 1, 2027).

Specifically, section 6202 of Public Law 119–75 amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act by striking ''January 31, 2026'' and inserting ''January 1, 2027.'' Section 6202 of Public Law 119–75 also made conforming amendments to sections 1886(b)(3)(D)(i) and 1886(b)(3)(D)(iv) of the Act. Therefore, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19503) we proposed to make conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect the extension of the MDH program through December 31, 2026.

Generally, as a result of these extensions, a provider that was classified as an MDH as of September 30, 2025 may continue to be classified as a MDH as of October 1, 2025, with no need to reapply for MDH classification. (For more information on the MDH extensions through December 31, 2026, see Change Request 14341 (Transmittal 13564), issued December 23, 2025 and Change Request 14415 (Transmittal 13703), issued March 27, 2026, which are available online at *https://www.cms.gov/medicare/regulations-guidance/transmittals/2025-transmittals/r13564otn* and *https://www.cms.gov/medicare/regulations-guidance/transmittals/2026-transmittals/r13703otn.*

3. Expiration of the MDH Program

Because section 6202 of the Consolidated Appropriations Act, 2026 extended the MDH program through December 31, 2026 only, beginning January 1, 2027, the MDH program will no longer be in effect. Since the MDH program is not authorized by statute beyond December 31, 2026, absent Congressional action, beginning January 1, 2027, all hospitals that previously qualified for MDH status under section 1886(d)(5)(G) of the Act will no longer have MDH status and will be paid based on the Federal rate.

When the MDH program was set to expire at the end of FY 2012, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405), we revised our sole community hospital (SCH) policies to allow MDHs to apply for SCH status in advance of the expiration of the MDH program and be paid as such under certain conditions. We codified these changes in the regulations at § 412.92(b)(2)(i) and (v). For additional information, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53674). We note that a MDH that classifies as a SCH in anticipation of the MDH program expiration would have to reapply for MDH classification in accordance with the regulations at 42 CFR 412.108(b) and

meet the classification criteria at 42 CFR 412.108(a) in the event that the MDH program is further extended, and the provider wishes to return to its classification as a MDH.

As noted, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19503), we proposed to make conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect the extension of the MDH program through December 31, 2026. We also proposed that if the MDH program were to be extended by law beyond December 31, 2026, similar to how it was extended by prior legislation as described previously, we would, depending on timing of such legislation in relation to the final rule, modify our proposed conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect any such further extension of the MDH program. We also noted that these modifications to our proposed conforming changes would only be made if the MDH program were to be extended by statute beyond December 31, 2026.

Comment: Many commenters expressed support for extending the MDH program or making the MDH program permanent and noted that they would continue supporting congressional action to protect the MDH program and develop long term solutions to the financial challenges facing rural hospitals. They noted the uncertainty that these hospitals face and the resulting inability to make long-term capital and infrastructure investments or expansion of patient services.

A few commenters urged CMS to continue to communicate to Congress the importance of extending the MDH program. Several State hospital associations and hospital chains expressed their concern that their hospitals would experience significant payment decreases as a result of the expiration of the MDH program. Commenters underscored the critical nature of the MDH program in supporting hospital solvency and preserving access to care in rural communities. A commenter requested that CMS consider additional transition protections for vulnerable providers. Another commenter urged CMS to include regulatory or policy clarification that supports continuity of MDH payment methodologies during any transition period.

Other commenters supported an additional base rate for calculating MDH payments.

Response: We understand the commenters' concerns about the expiration of the MDH program and the financial impact to affected providers if the MDH program is not extended beyond December 31, 2026. CMS does not have the authority under current law to extend the MDH program beyond the statutory expiration date. Similarly, section 1886(b)(3)(D) of the Act specifies the applicable base years or ''target amounts'' for hospitals classified as MDHs. These comments are similar to comments we received previously, prior to the most recent statutory extensions of the MDH program for FY 2026 and the portion of FY 2027 beginning October 1, 2026 through December 31, 2026. We refer commenters to our discussion in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36912). In response to the comment requesting a regulatory or policy clarification that supports continuity of MDH payment methodologies during any transition period, as discussed previously, under current law, the MDH program is not authorized by statute beyond December 31, 2026. Absent further Congressional action, CMS may consider this for future rulemaking.

Comment: Commenters requested that CMS clearly communicate how it will implement program extensions and prepare systems to facilitate expedited retroactive payments in the event that the MDH program lapses. Commenters urged CMS to implement any potential retroactive restoration and/or extensions of the MDH program more expeditiously to avoid significant financial strain to affected hospitals and potential lower Medicare reimbursement from MA plans. They requested that CMS engage stakeholders early to establish lines of communication, minimize confusion, and mitigate any potential delays in reimbursement and signal readiness to support impacted hospitals with technical guidance and financial planning resources. Another commenter requested that CMS issue guidance outlining how claims would be processed for discharges occurring after December 31, 2026 if the program expires.

A commenter requested that CMS evaluate the projected impact of expiration on rural hospital margins and access to care and analyze the relationship between payment instability and service line reductions in rural communities. Another commenter requested that CMS publish hospital-specific modeling or impact data to allow affected providers to properly understand and prepare for potential financial risk.

Response: We appreciate the commenters' sharing their concerns relating to a retroactive restoration of the MDH program. As with past extensions, CMS will evaluate enacted legislation to determine the most appropriate approach to implement changes to the law, including issuing instructions to the MACs to reinstate MDH status to eligible hospitals and to communicate with affected hospitals. As in the past, we will make every effort to implement any extension of the MDH program as expeditiously as possible. In response to the comment requesting that CMS issue guidance outlining how claims would be processed for discharges occurring after the MDH program expires, as noted previously, beginning with discharges occurring on or after January 1, 2027, absent further Congressional action, all hospitals that previously qualified for MDH status under section 1886(d)(5)(G) of the Act will no longer have MDH status and claims will be processed and will be paid based on the Federal rate.

Following the issuance of the IPPS/LTCH PPS final rule each year, if the MDH program is set to expire, as part of the associated annual CR, CMS includes instructions to the Medicare contractors on how to modify the provider type for MDH providers in the Provider Specific File (PSF). The provider type is used by the claims processing system to apply the special payment provisions for eligible MDHs. For example, for the FY 2026 IPPS/LTCH PPS final rule, CMS issued Change Request 14203 (Transmittal 13398) on September 22, 2025, which is available online at *https://www.cms.gov/files/document/r13398otn.pdf.*

In response to the comments requesting that CMS evaluate the projected impact of expiration on rural hospital margins and access and hospital-specific modeling or impact data, we refer the commenter to the provider data used in creating Table I—Impact Analysis of Changes to the IPPS for Operating Costs for FY 2027, in Appendix A of this final rule and posted on the web which can be used to estimate individual hospital's payments for FY 2027. The data can be found on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acuteinpatient-pps.* In addition, we note in Table I in Appendix A of this final rule, the line for MDHs under ''Special Hospital Types'' reflects the expected impact for hospitals classified as MDH prior to the expiration on January 1, 2027, under current law.

In summary, under current law, beginning January 1, 2027, all hospitals

that previously qualified for MDH status will no longer have MDH status. After consideration of the public comments we received, we are adopting as final the proposed conforming changes to the regulations text at §§ 412.90 and 412.108 to reflect the extension of the MDH program through December 31, 2026 in accordance with section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75). We are finalizing the proposed changes in paragraphs (a)(1) and (c)(2)(iii) of § 412.108 and paragraph (j) of § 412.90 without modification.

F. Payment for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83

1. Background

Section 1886(h) of the Social Security Act (the Act), as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983, through September 30, 1984). The base year PRA is updated annually for inflation.

In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at non-provider sites, when applicable), and the hospital's Medicare share of total inpatient days. Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital (and, for discharges occurring on or after October 1, 1997, at non-provider sites, when applicable) to the number of inpatient hospital beds.

The calculation of both direct GME payments and the IME payment adjustment is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress established a limit on the number of allopathic and osteopathic residents that a hospital could include in its FTE resident count for direct GME and IME payment purposes in the Balanced Budget Act of 1997 (Pub. L. 105–33).

Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME cannot exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

2. Requirements To Prohibit Unlawful Discrimination in Approved Medical Residency Programs

Hospitals may receive direct GME and IME payments for residents in ''approved medical residency training programs.'' Section 1886(h)(5)(A) of the Act defines an ''approved medical residency training program'' as ''a residency or other postgraduate medical training program participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary.'' ''Approved medical residency program'' and equivalent terms are defined in the regulations at §§ 412.105(f)(1)(i), 413.75(b), and 415.152. In general, under these regulations, an ''approved'' program is a program accredited by one of several national accrediting bodies or that leads toward board certification by the American Board of Medical Specialties (ABMS).

Therefore, to ensure that accreditation for approved medical residency programs is in compliance with applicable laws related to race-based admission policies and to improve the accreditation process, in the CY 2026 OPPS/ASC final rule (90 FR 54024 through 54027), we finalized changes to the regulations at §§ 412.105(f)(1)(i), 413.75(b), and 415.152, to state that accrediting organizations may not use accreditation criteria that promote or encourage discrimination on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. We also clarified that prohibited practices under this policy include all other conduct in violation of federal antidiscrimination laws, including any ''unlawful practices'' under the Attorney General's *Guidance for Recipients of Federal Funding Regarding Unlawful Discrimination* (July 29, 2025).

The policy finalized in the CY 2026 OPPS/ASC final rule applied specifically to graduate medical education accrediting bodies. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19504), we proposed a similar policy that would apply to approved medical residency programs themselves. Specifically, we proposed to require that, in addition to meeting other applicable requirements, an approved medical residency training program must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. We indicated that we believe such a policy is necessary to ensure that, even in the absence of discriminatory accreditation standards, individual programs do not implement policies that constitute unlawful discrimination under Federal law. The effective date of this proposed policy would be October 1, 2026.

To streamline the regulations text and ensure consistent application of the requirements to approved medical residency programs and GME accrediting organizations, we also proposed to consolidate the majority of our existing and proposed non-discrimination requirements under proposed new 42 CFR 413.84. We proposed to cross-reference this new

section as necessary in the regulations at §§ 412.105(f)(1)(i), 413.75(b), and 415.152. In section V.G.3. of the proposed rule (91 FR 19520), we proposed conforming policies with respect to approved nursing and allied health (NAH) education programs and accrediting bodies under 42 CFR 413.85.

In this section of the final rule, we are combining our summary of and responses to the comments we received on the proposed requirements to prohibit unlawful discrimination by approved medical residency programs, approved NAH education programs, and NAH accrediting bodies. (As noted previously, we finalized requirements applicable to accreditors of graduate medical education programs in the CY 2026 OPPS final rule.) We refer readers to section V.G.3. of this final rule for discussion of comments that address concerns specific to payments for nursing and allied health education.

Comment: We received several comments in support of our proposals to consolidate the existing GME-related antidiscrimination requirements under new 42 CFR 413.84 and to extend the requirements to individual graduate medical education programs, as well as to nursing and allied health education programs and accreditors. The commenters discussed instances in which they or others believed they experienced discriminatory treatment because of their religious or moral objections to certain training requirements and stated that, as a result of such reportedly hostile training environments, clinicians who object to performing abortions may be disincentivized from pursuing OB/GYN training, thus exacerbating workforce shortages in maternity care. A commenter stated that diversity, equity and inclusion criteria in admissions and employment are often a guise for unlawful discrimination and stated that the proposed requirements are necessary in light of the Accreditation Council for Graduate Medical Education's (ACGME) historical inclusion of DEI-related initiatives in its Common Program Requirements.

A commenter that supported the proposal further urged CMS to require that abortion training be offered under an opt-in only model, as opposed to the opt-out model currently required by the ACGME, stating that the opt-out model creates a coercive environment both for residents with conscientious objections to training in induced abortions and for faith-based programs that are required to incorporate such training into their curricula. The commenter also expressed concern that Medicare GME funding may be used to pay for abortions, in violation of the Hyde Amendment, which generally prohibits the use of Federal funding for abortion except under limited circumstances.

Another commenter encouraged CMS to expand the scope of the proposed regulations to include procedures besides abortion that are frequently implicated in discussions over conscience protections and religious freedom. Specifically, the commenter recommended adding an additional paragraph to the regulations under proposed § 413.84(c) recognizing approved programs that would be accredited except for the accrediting agency's reliance upon an accreditation standard the requires an entity to ''[p]rescribe or provide procedures for contraception, sterilization, assisted suicide, euthanasia, or sex-rejecting interventions (what advocates call 'gender affirmative care'), or require, provide, or refer for training in the performance of such procedures, or make arrangements for such training, regardless of whether the standard provides exceptions or exemptions.'' The commenter stated that this modification would further help enforce compliance with Federal conscience statutes, which extend to procedures in addition to abortion.

Response: We thank the commenters for their support of our proposals. While we note that the most recent revisions to the ACGME's Common Program Requirements no longer include the diversity, equity and inclusion requirements cited by a commenter, we continue to believe our proposed policies are necessary to ensure that, even in the absence of discriminatory accreditation standards, individual programs do not implement policies that constitute unlawful discrimination under Federal law. Therefore, we are finalizing, without modification, our proposal that approved medical residency training programs, as well as approved nursing and allied health education programs and accrediting bodies, must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. In addition, we are finalizing our proposal to consolidate various GME- and NAH-related antidiscrimination requirements under new 42 CFR 413.84.

In response to comments recommending further expansion of the proposed policies, we may take these comments into consideration for future rulemaking. We emphasize that regardless of the inclusion of explicit language in the GME regulations, no entity or individual may be forced to act contrary to objections protected by Federal conscience and nondiscrimination statutes. We also note with regard to the Hyde Amendment that both direct GME and IME payments are made only with respect to services otherwise payable under Medicare, and that abortion services are not payable under Medicare except under the limited circumstances specified in the Hyde Amendment (as codified most recently at §§ 506–507 of Division B, Title V, of the Consolidated Appropriations Act, 2026, Pub. L. 119–75).

Comment: Many commenters supported the overall goal of prohibiting unlawful discrimination but expressed concern about our proposal to codify these requirements as part of the definition of ''approved'' programs for purposes of Medicare GME and NAH payments. If CMS implements the proposed requirements, commenters stated that we should do so in a manner that is transparent and administratively feasible, and requested clarification on the following points:

- How hospitals would be evaluated for compliance with the proposed antidiscrimination requirements, including what constitutes an ''intentional proxy'' for protected characteristics under the proposed regulations text;
- How the proposed requirements would align with existing accreditation standards and Federal civil rights laws;
- The role that Medicare contractors, accrediting bodies, regulated institutions and other parties would assume in enforcing the proposed requirements; and
- What due process protections would be afforded to hospitals, including notice and response opportunities, appeal rights, and the postponement of any adverse payment consequence until a final determination of noncompliance has been reached by the appropriate body.

Commenters warned that the absence of objective and administrable standards, duplication of established accreditation and civil rights requirements, lack of clearly delineated responsibilities, and unresolved questions about due process would increase compliance risks and create payment uncertainty for hospitals, potentially hampering development of the physician, nursing and allied health workforce pipelines. In addition, some

commenters urged CMS to delay implementation of the proposed requirements to give hospitals time to demonstrate compliance with the proposed regulations.

A couple of commenters, while expressing support for compliance with Federal antidiscrimination laws, objected to the proposed prohibition on the use of identity characteristics or intentional proxies for those characteristics as selection criteria for residency programs. The commenters emphasized the importance of a diverse physician workforce in achieving positive health outcomes, especially among vulnerable groups, and stated that ignoring identity-based characteristics in the selection process could disadvantage qualified applicants from marginalized backgrounds.

Response: While we appreciate commenters' concerns regarding the operationalization and enforcement of the antidiscrimination policies that we are finalizing in this final rule, we do not believe that prohibiting unlawful discrimination on the part of approved GME and NAH education programs would impose a significant administrative burden or create compliance risk or payment uncertainty for hospitals. Under the policy that we are codifying at 42 CFR 413.84, effective October 1, 2026, approved GME and NAH programs, must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. For a non-exhaustive list of unlawful policies and practices that are prohibited under these regulations, we refer readers to the Attorney General's *Guidance for Recipients of Federal Funding Regarding Unlawful Discrimination* (June 29, 2025). We note that section B.1 of this guidance includes discussion of the prohibited use of proxies for protected characteristics, including examples of potentially unlawful proxies.

We also disagree with commenters who advocated for the use of identity-based characteristics, or proxies for such characteristics, as selection criteria in residency training programs. As we stated in the CY 2026 OPPS/ASC final rule (90 FR 54027, November 25, 2025), we believe that race-conscious elements of diversity, equity and inclusion policies are generally impermissible under Federal law, as strongly suggested by the Supreme Court's ruling in *Students for Fair Admissions* v. *President Fellows of Harvard College* (2023). In addition, we remain unpersuaded by commenters' arguments that such policies are necessary for achieving positive health outcomes and reiterate our position that patients and society at large have a compelling need for medical education to be focused primarily on excellence and delivering the best possible care to patients. Accordingly, emphasize that GME and NAH education programs should review their selection criteria to ensure that such criteria do not unlawfully discriminate on the basis of race or other protected characteristics or intentional proxies for those characteristics.

Comment: Several commenters urged us to withdraw the proposal to prohibit unlawful discrimination in approved GME and NAH education programs. Instead, commenters stated that CMS should rely on existing Federal civil rights laws to address concerns related to unlawful discrimination and defer to the medical community and accrediting organizations to develop evidence-based standards that safeguard patient safety and promote an effective learning environment. A commenter argued that CMS has failed to explain why the proposed requirements are necessary or how they would advance the objectives of the Medicare GME program. Another commenter emphasized the importance of physician self-governance and expressed concern that additional restrictions could set a precedent for further government interference in residency training.

Response: We respectfully disagree with the commenters' objections. As we stated in the proposed rule, we believe that the policy we are finalizing is necessary to ensure that, even in the absence of discriminatory accreditation standards, individual residency programs do not implement policies that constitute unlawful discrimination under Federal law. In addition, we continue to believe that similar concerns about unlawful discrimination apply in the context of nursing and allied health education.

After consideration of public comments, we are finalizing, without modification, our proposal that in addition to meeting other applicable requirements, an approved medical residency training program must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits.

We are also finalizing, without modification, our proposal that, in addition to meeting other applicable requirements, individual NAH education programs and NAH accrediting bodies must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. We are also finalizing our proposal to consolidate various GME- and NAH-related antidiscrimination requirements under 42 CFR 413.84 and to cross-reference this new section as necessary in the regulations at §§ 412.105(f)(1)(i), 413.75(b), and 415.152. The effective date of these policies is October 1, 2026.

3. Modifications to the Criteria for New Residency Programs

a. Background

Section 1886(h)(4)(H)(i) of the Act requires CMS to establish rules for applying the direct GME cap in the case of medical residency training programs established on or after January 1, 1995. Under section 1886(d)(5)(B)(viii) of the Act, this provision also applies for purposes of the IME adjustment. These statutory requirements are implemented in the direct GME (DGME) regulations at §§ 413.79(e)(1) through (3) and the IME regulations at § 412.105(f)(1)(vii), which provide for an FTE cap increase for certain hospitals that begin training residents in a new medical residency training program(s) on or after January 1, 1995, and specify the methodology for determining the permanent cap adjustment.

Under these rules, cap adjustments are not provided for expansions of existing programs. Rather, a new urban teaching hospital receives a single five-year cap-building window to start new residency programs and grow those new residency programs, after which point its IME and DGME caps are permanently set. However, a rural teaching hospital may receive a separate cap adjustment each time it starts a new program. CMS originally implemented these policies in the August 29, 1997 FY 1998 IPPS Final Rule (62 FR 46005) and in the May 12, 1998 ''Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1998 Rates'' final rule (63 FR 26333); the calculation of both the

DGME cap and IME cap for new programs is discussed in the August 31, 2012 FY 2013 IPPS Final Rule (77 FR 53416).

Section 413.79(l) defines a new medical residency training program as ''a medical residency that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995.'' In the August 27, 2009 ''Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals'' final rule (74 FR 43908 through 43917), CMS clarified the definition of a ''new'' residency program and adopted supporting criteria regarding whether a residency program can be considered new for the purpose of determining if a hospital can receive additional direct GME and/or IME cap slots for that program. CMS adopted these criteria in part to prevent situations where a program at an existing teaching hospital might be transferred to a new teaching hospital, resulting in cap slots created for the same program at two different hospitals.

Under this policy, in addition to receiving initial accreditation, to be considered a ''new'' program for which new cap adjustments can be established, a residency program must satisfy three primary criteria (74 FR 43912):

- The program director is new; *and*
- The teaching staff are new; *and*
- The residents are new.

Over the years, we have received questions regarding the application of these criteria, such as whether CMS would still consider a program to be new for cap adjustment purposes if the three criteria are partially, but not fully, satisfied. We have answered such questions by stating that, generally, a residency program's newness would not be compromised if the ''overwhelming majority'' of the residents and staff are not coming from previously existing programs in the same specialty.

b. The FY 2025 Proposed Rule

In the FY 2025 IPPS/LTCH PPS proposed rule (May 2, 2024; 89 FR 36221 through 36224), we noted that the question of what constitutes a ''new'' program eligible to receive additional Medicare-funded GME slots has taken on increasing significance in light of the ability of urban hospitals to reclassify as rural under 42 CFR 412.103 for IME payment purposes and thus to receive additional IME cap slots for any new program started, leading to significant increases in aggregate Medicare IME spending. We stated that to ensure that new cap slots are created appropriately, we ultimately would like to establish additional criteria through rulemaking for determining program newness. However, we indicated that we were not yet certain about some of the criteria that should be proposed. Accordingly, we issued a proposal regarding the threshold for determining whether the ''overwhelming majority'' of residents in a program are new and solicited public input on other topics via a Request for Information (RFI) (89 FR 36222).

Regarding the newness of residents, we proposed that, for a residency program to be considered new, at least 90 percent of the individual resident trainees (not FTEs) must not have previous training in the same specialty as the new program. If more than 10 percent of the trainees (not FTEs) transferred from another program at a different hospital/sponsor in the same specialty, even during their first year of training, we proposed that this would render the program as a whole (but not the entire hospital or its other new programs, if applicable) ineligible for new cap slots.

In addition, we stated that there may be certain challenges that are unique to small or rural-based programs in developing new residencies, and that meeting the proposed threshold of 90 percent of resident trainees with no previous training experience in the specialty may be more difficult for those programs. Accordingly, we solicited comment on what should be considered a ''small'' program and what percentage threshold or other approach regarding new resident trainees should be applied to these programs. We specifically sought comment on defining a small residency program as a program accredited for 16 or fewer resident positions.

For further detail regarding our proposal on the newness of residents, we direct readers to the discussion in the FY 2025 proposed rule at 89 FR 36222.

As stated previously, in the FY 2025 proposed rule we also issued a Request for Information on other aspects of the policy for determining program newness. We noted that it would be reasonable for a new residency program to seek to hire some experienced staff members, and we therefore solicited feedback on what an appropriate threshold should be for the percentage of faculty with no previous experience teaching in a program in the same specialty. We also solicited comment on whether it would be appropriate to define a certain period of time (for example, 10 years or 5 years) during which a faculty member or program director must not have been employed by another program in the same specialty to be considered ''new.'' Finally, we sought input on two additional scenarios that might have implications for determining the newness of a residency program: the sharing of certain clinical and didactic experiences among residents from different programs, which we referred to as ''commingling''; and situations in which one hospital operates two (or more) programs in the same specialty.

For further details regarding the topics on which we solicited public comment, we direct readers to the discussion in the FY 2025 proposed rule at 89 FR 36222 through 36224.

c. The FY 2025 Final Rule

In the FY 2025 IPPS/LTCH PPS final rule (August 28, 2024; 89 FR 69377 through 69380), we published a summary of the comments we received in response to our proposal that, for a residency program to be considered new, at least 90 percent of the individual resident trainees (not FTEs) must not have previous training in the same specialty as the new program. We explained that, given the lack of consensus on this issue, we would not finalize our proposal in that rule. Instead, we initiated another comment solicitation particularly focused on the criterion regarding newness of residents. As part of that request, we asked commenters to consider the broad statutory authority provided to the Secretary in this area, our prior rulemaking on this issue, and the public comments on our proposal as summarized in the final rule. In the interest of facilitating consensus, we encouraged commenters to provide feedback on which alternatives to their preferred approach they would consider most acceptable among those suggested by other commenters.

We also noted that, in response to our Requests for Information, most commenters opposed any restrictions on the hiring of experienced faculty and program directors, as well as on the commingling of residents or sponsorship of multiple programs in the same specialty by a single hospital.

d. Summary of Responses to the Second Comment Solicitation

We received 14 timely pieces of correspondence to our second comment solicitation on an appropriate standard for determining the newness of residents in a new program, including potential exceptions for small and/or rural programs. In addition, commenters submitted additional feedback on other topics on which we had previously issued Requests for Information, including the hiring of experienced faculty and staff, commingling of

residents, and sponsorship of multiple programs in the same specialty by a single hospital. Later in this section, we present a summary of the responses we received and discuss our proposed policy for determining whether a residency program should be considered new for purposes of receiving additional Medicare-funded GME slots.

Several commenters continued to urge CMS to define a ''new'' residency program as one that has received initial accreditation from the ACGME and to disregard other factors in determining program newness. However, most commenters (including some who expressed a preference for the initial accreditation criterion) indicated that considering the previous training experience of residents could be an appropriate way for CMS to determine whether a residency program is genuinely new for cap-building purposes. Several commenters also indicated that the 90 percent threshold that we had originally proposed in the FY 2025 IPPS/LTCH PPS proposed rule could be an acceptable standard, while urging CMS to provide exceptions for programs that fall short of the threshold due to various extenuating circumstances. (We discuss feedback pertaining specifically to exceptions for small and/or rural programs separately later in this section.)

For example, several commenters mentioned that hospitals sometimes need to replace residents who depart from a program for various reasons, including residents accepted via the supplemental match process who subsequently transfer to another residency in their preferred specialty. The commenters recommended that CMS allow programs to replace departing residents with other residents at the same training level, and that these replacements should not count against a program's compliance with the 90 percent threshold. More generally, several commenters stated that the 90 percent requirement should apply only to residents at the Program Year 1 level, while residents recruited at the Program Year 2 level or above should not disqualify a program from consideration as ''new.'' In addition, several commenters recommended that CMS allow a program to demonstrate that it would have met the 90 percent threshold were it not for the results of the National Resident Matching Program (NRMP, or the ''Match'') or other GME matching programs. Commenters noted that the results of the Match are binding on hospitals, and that not selecting candidates with prior training experience could violate the Match code of conduct and result in programs being banned from participation in the Match.

A few commenters indicated that, for purposes of determining whether a program complies with the minimum new resident threshold, CMS should consider all the individual residents that enter the program during its five-year cap-building period. Additionally, some commenters recommended that CMS conduct interim reviews during the cap-building period to determine whether a new program is on track to meet the requirements and to give providers a chance to make necessary changes before a final newness determination is made. Several commenters also indicated that residents with previous training experience could be excluded from the final cap calculation without disqualifying the program itself from consideration as new. A commenter suggested that, instead of establishing an overall new resident threshold, CMS should only limit the number of residents admitted from the *same* existing program.

In general, commenters reiterated their strong opposition to any restrictions on the hiring of experienced faculty and program directors, stating that such a policy would be harmful to the development of new residency programs. However, some commenters suggested a compromise policy whereby CMS would consider the previous experience of faculty and program director in conjunction with the previous experience of residents. Under this policy, CMS would continue to assess newness primarily based upon the proportion of residents with previous experience training in a program in the same specialty, but would conduct an ''enhanced review'' under certain circumstances, as follows:

- 100 percent new residents: the program qualifies as new, without further review;
- At least 90 percent but less than 100 percent new residents: the program must demonstrate that residents have not previously trained in an existing residency program in the same specialty with any faculty or with the program director from the new residency program;
- Less than 90 percent new residents: the program does not qualify as new (subject to exceptions for certain categories of residents, as discussed previously).

The commenters stated that this policy would effectively prevent the transfer of existing programs without unduly restricting the ability of programs to hire experienced staff.

Other commenters recommended that CMS adopt a ''safe harbor'' policy, whereby a separately accredited program would be considered ''new'' regardless of any potential overlap (in terms of residents, faculty or program director) with an existing program, if the existing program remains in operation for at least one year. Commenters argued that the concurrent operation of both programs would make it clear that the new program does not constitute a relocation of the existing program or an inappropriate duplication of the existing program's cap slots. Similarly, a commenter recommended that, instead of considering the previous experience of residents or staff, CMS should only consider whether these individuals are ''solely committed'' to the new program going forward.

Commenters agreed that CMS should create exceptions to the new requirements for small and/or rural programs. Most commenters also agreed that a ''small'' program should be defined as one that is accredited for 16 or fewer resident positions, although a few commenters indicated that only small programs located in rural or urban underserved areas should qualify for an exception. (We note that a commenter recommended a higher ceiling of 22 resident positions.) The commenters recommended various more lenient newness criteria for programs that would qualify for an exception, with a few commenters recommending that such programs be exempted entirely from the newness requirements. In general, commenters urged CMS to ensure that the new program criteria do not unfairly disadvantage small programs or impede the development of residency programs in rural and/or urban underserved areas, with a few commenters also voicing particular concern about the effect of potential policies on Rural Track Programs.

Finally, commenters generally reiterated their opposition to any restrictions on ''commingling'' of residents or on hospitals sponsoring multiple residency programs in the same specialty. Commenters asserted the educational soundness of shared clinical and didactic experiences and indicated that such arrangements are increasingly required by the ACGME. In addition, commenters provided examples of circumstances under which a hospital might sponsor multiple programs in the same specialty, such as in the wake of a merger of hospitals, or in the case of a hospital that serves a large geographic area.

e. Proposal

We thanked the commenters for their thoughtful feedback in response to the comment solicitation published in the FY 2025 IPPS final rule. While commenters continued to recommend various ways of defining a ''new'' residency program for purposes of establishing FTE caps, we believed there was sufficient consensus on the major issues for us to propose certain modifications to our existing policy in the FY 2027 IPPS LTCH proposed rule.

(1) Initial Accreditation

First, we acknowledged that several commenters continued to urge CMS to define a new residency program as one that has received initial accreditation from the ACGME and to disregard other factors in determining program newness. While we conceded that this approach would be simple administratively, we reiterated the concerns that we originally discussed in the August 27, 2009 ''Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals'' final rule (74 FR 43754). In that final rule, we explained that the mission and priorities of CMS differ from those of the accrediting bodies, and that, in determining whether a residency program is genuinely new, it is appropriate for CMS to consider factors in addition to the accrediting body's characterization of that program (see discussion at 74 FR 43909 through 43913). We emphasized that a primary concern of CMS, not shared by the accrediting bodies, remains the inappropriate duplication of FTE cap slots associated with the relocation of an existing program from one hospital to another. Thus, although the existing regulations at § 413.79(l) refer to initial accreditation as one of the criteria for determining whether a program is genuinely new for cap-building purposes, we continued to believe that we cannot rely solely on the characterization of an accrediting body in making this determination.

(2) Removal of Restrictions on Experienced Faculty and Staff

Nevertheless, we were persuaded by commenters' arguments that some of the supporting factors promulgated in the August 27, 2009 ''Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals'' final rule may be overly restrictive. We were persuaded by commenters who argued that CMS should not restrict the ability of new residency programs to hire experienced faculty and program directors. After considering the feedback we received in response to our original Requests for Information and our subsequent comment solicitation, we believed that considering the previous training experience of residents (as discussed in more detail later in this section) should provide a sufficient guardrail to ensure that existing programs are not being transferred between hospitals.

Thus, we proposed that, effective for programs started on or after October 1, 2026, we would no longer consider the previous employment of the faculty or program director in determining whether a residency program should be considered genuinely new for cap-building purposes. That is, a hospital would no longer have to demonstrate that the faculty and program director in a new program have not previously been employed in an existing program in the same specialty. We noted that programs started on an earlier date that are still within the five-year cap-building period as of October 1, 2026, would continue to be subject to the newness criteria established in the August 27, 2009 ''Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals'' final rule.

(3) Requirement for New Residents

While we proposed to remove the requirement related to previous employment of the faculty or program director, we do believe it is still appropriate for CMS to consider the previous training experience of residents in determining whether a residency program should be considered genuinely new. As discussed previously in the summary of responses to our second comment solicitation, most commenters indicated that a 90 percent threshold could be an appropriate standard for determining whether the ''overwhelming majority'' of residents in a program are in fact new. Additionally, as discussed in the FY 2025 IPPS proposed rule (89 FR 36222), a 90 percent threshold would be generally consistent with the concept of an ''overwhelming majority.'' We have precedent for such a threshold in the regulations for section 5506 of the Affordable Care Act, which state that a hospital is considered to have taken over an ''entire'' program from a closed hospital if it can demonstrate that it took in 90 percent or more of the FTE residents in that program. Therefore, we proposed that, effective for programs starting on or after October 1, 2026, for a residency program to be considered new, in addition to receiving initial accreditation from the appropriate accrediting body, at least 90 percent of the individual resident trainees (not FTEs) must not have previous training in the same specialty as the new program. Apart from the exceptions, discussed later in this section, this proposal regarding the newness of residents is substantially the same as the policy we proposed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36222).

For example, if a hospital establishes a new residency program in internal medicine, then, under our proposal, at least 90 percent of the residents in that program must not have previous training experience in another internal medicine program. If a resident was formally enrolled in another internal medicine program (whether preliminary or categorical), even if that resident switched programs during their first year of training, we would consider that resident to have previous training in the same specialty. By contrast, if an individual previously trained in a specialty *other* than internal medicine, and that resident switched into the new internal medicine program and began training in that program as a first-year resident, then the resident would *not* be considered to have previous training in the same specialty and would be counted as a new resident for purposes of determining compliance with the 90 percent threshold.

Consistent with the definition of ''resident'' at 42 CFR 413.75(b), in the example noted previously, we are distinguishing between a resident that was actually accepted, enrolled, and participated in an internal medicine residency program from a resident who was *not* enrolled in an internal medicine program but who may have done a rotation in internal medicine as part of the requirements for a different specialty. Additionally, we note that an individual who enters a subspecialty training program, after having previously completed a residency in the antecedent specialty, would be counted as a new resident—for example, a resident who enters a critical care medicine fellowship after having previously completed a residency program in internal medicine would be counted as a new resident under our proposal.

Under the proposed policy, we would determine whether a program has satisfied the 90 percent threshold by tallying all of the individual residents who enter a program during the five-year cap building period (that is, for new urban teaching hospitals, during the first five program years of the first new program's existence; and for rural hospitals, during the first five program years of each new program). For example, if 50 trainees (not FTEs) enter

the program over the course of the five-year cap building period, then at least 45 of the trainees (that is, 90 percent of 50) must enter the program as brand-new first-year residents in that particular specialty. If more than 10 percent of the individual trainees (not FTEs) previously trained in another program in the same specialty, we proposed that this would render the program not new and therefore ineligible for an FTE cap adjustment.

We would apply standard rounding in instances where the quotient does not equal a whole number, rounding down to the nearest whole number when the remainder is less than 0.5, and rounding up to the nearest whole number when the remainder is greater than or equal to 0.5. For example, if 48 trainees (not FTEs) enter a program over the course of the five-year cap building period, then at least 43 of the trainees (90 percent of 48 = 43.2, which rounds down to 43) must not have previous experience training in a different program in the same specialty.

We proposed that, after the end of the five-year cap building period, the Medicare administrative contractor (MAC) would review the previous training experience of each individual trainee and determine the newness of the residency program prior to calculating the IME and DGME cap adjustments for the hospital. Consistent with our historical policy, the MAC would not be required to provide an initial assessment of ''newness'' prior to the end of the five-year cap building period.

(4) Exceptions for Certain Categories of Residents

As noted previously, we proposed to create a limited exception to the counting rules for certain residents admitted via the National Resident Matching Program (the Match) or other third-party resident matching programs whose results are binding on hospitals. (Examples of other matching programs that would fall under this provision include the Supplemental Offer and Acceptance Program (SOAP), the Urology Residency Match Program, and the SF Match for Ophthalmology and Plastic Surgery residency programs.) Based on feedback received from commenters, we understand that the Match and similar programs are generally used to match prospective first-year residents to residency programs in their chosen specialties, and that hospitals do not have the discretion to refuse admission to a resident matched via this process. We also understand that candidates applying through the various matching programs may occasionally have previous experience training in another program in the same specialty—for example, an individual who may have withdrawn from a residency program and is seeking to restart his or her training.

While hospitals may rank their preferred candidates, they cannot predict the ultimate complement of first-year residents allocated via the Match or other matching programs. As a result, a hospital that included multiple candidates with previous training experience on its ranked list could be required to accept a mix of residents that would cause it to fall short of our proposed 90 percent requirement. We agree with commenters that in such situations hospitals should not be penalized for the results of the Match or other binding resident matching programs.

Accordingly, for purposes of determining compliance with the 90 percent requirement, we proposed to exclude from the count of trainees any individuals with previous experience training in another program in the same specialty who enter the new program as first-year residents through the National Resident Matching Program or another binding third-party resident matching program. That is, *such first year individuals would be excluded both from the numerator and from the denominator of the calculation used to determine the proportion of new vs. experienced residents.* However, assuming that the program otherwise satisfies the proposed 90 percent threshold, the hospital would report such individuals on the new resident lines of the hospital cost report (that is, lines 15 and 15.01 of Worksheet E–4 and line 16 of Worksheet E, Part A) and the individuals would be included in the calculation of the hospital's permanent cap adjustment at the conclusion of the five-year cap-building period.

We also proposed to exclude from the count of trainees any residents admitted into the new program from another program in the same specialty who meet the definition of a ''displaced resident'' under 42 CFR 413.79(h)(1)(iii). That is, *such individuals would be excluded both from the numerator and from the denominator of the calculation used to determine the proportion of new vs. experienced residents.* To prevent the inappropriate duplication of cap slots associated with a closed program or closed hospital, we proposed that displaced residents must not be reported on the new resident lines or included in the hospital's permanent cap adjustment. Instead, such individuals would be reported on the displaced resident lines (lines 16 and 16.01 of Worksheet E–4 and line 17 of Worksheet E, Part A) if the hospital qualifies for a temporary cap adjustment under 42 CFR 413.79(h). Otherwise, the individuals must be reported on the regular FTE lines (line 6 of Worksheet E–4 and line 10 of Worksheet E, Part A), subject to the hospital's existing DGME and IME FTE caps.

Furthermore, since rotation schedules, and not cost report entries, are used to identify individual residents training in the new program for the purpose of calculating the permanent cap at the end of the five-year cap building period under 42 CFR 413.79(e)(1)(i)(A), the displaced residents listed on the rotation schedule would be excluded from the new program cap calculation. We note that under certain circumstances, if a hospital trains residents displaced by a hospital closure, it may receive priority for receipt of cap slots if it applies for a permanent cap adjustment under the provisions of section 5506.

For example, suppose that 50 individual trainees (not FTEs) enter a program during the five-year cap-building period, and that 4 of those individuals enter the program as first-year residents via the Match and have previous experience training in another program in the same specialty. Additionally, the program admits 2 residents displaced from a closed program in the same specialty. If all 50 residents were included in the count, then at least 6 out of 50 or 12 percent of the residents in the program would be considered not new, rendering the program not new under our proposed 90 percent threshold. Under the proposed exceptions, we would exclude from this calculation the 4 first-year residents with previous training experience admitted via the Match, as well as the 2 residents displaced from the closed program. Thus, the hospital would have to demonstrate that at least 90 percent of the remaining 44 residents (that is, 39.6 ≈ 40 residents) do not have previous experience training in another program in the same specialty. During the initial years of the new program, the hospital would report the 4 first-year residents on the new program lines, while it would report the 2 displaced residents on the displaced resident lines or the regular FTE lines, as applicable. At the conclusion of the cap-building period, the calculation of the hospital's permanent cap adjustment would include the 4 first-year residents admitted via the Match and exclude the 2 residents displaced from the closed program.

Comment: Comments were overwhelmingly supportive and appreciative of our proposals to no longer consider the previous employment of the faculty or program director in determining whether a residency program should be considered genuinely new for cap-building purposes. Many commenters also were supportive of our proposal to require that at least 90 percent of the individual resident trainees (not FTEs) must not have previous training in the same specialty, in addition to receiving initial accreditation from the appropriate accrediting body.

Response: We appreciate the commenters' support for our proposals.

Comment: A commenter requested that CMS consider reducing the threshold for residents without previous training in the program's specialty from 90 percent to 80 percent. The commenter believed that the lower threshold would provide greater flexibility to accommodate residents with prior training. The commenter alternatively suggested that CMS could refine the proposal to ''temporally weight'' the calculation of residents that do not have prior training in the specialty or subspecialty (*i.e.,* counting resident years rather than residents), so that new programs are not unduly constrained when replacing residents that do not complete the program.

Another commenter asked that CMS reduce the 90 percent threshold to 51 percent, allowing for up to 49 percent of individual residents during the cap building period to have received previous training in the same specialty. This commenter suggested that to safeguard against the inappropriate transfer of existing programs, CMS could impose a requirement that individual residents who had received previous training in the same specialty as the new program must have received such training at a program that continues to train residents throughout the completion of each resident's training. If the other programs continue to train residents, the new program cannot also be the progeny of one of those programs.

Other commenters requested that CMS add exceptions for resident hardship situations where a resident needs to relocate due to reasons beyond his or her control, for residents who join a program specifically to replace residents who left unexpectedly, or in general, where ''it is clear'' that the program was not transferred.

Response: As discussed previously in the summary of responses to our second comment solicitation, most commenters indicated that a 90 percent threshold could be an appropriate standard for determining whether the ''overwhelming majority'' of residents in a program are in fact new. Additionally, as discussed in the FY 2025 IPPS proposed rule (89 FR 36222), a 90 percent threshold would be generally consistent with the concept of an ''overwhelming majority,'' and we have precedent for such a threshold in the regulations for section 5506 of the Affordable Care Act, which state that a hospital is considered to have taken over an ''entire'' program from a closed hospital if it can demonstrate that it took in 90 percent or more of the FTE residents in that program. Therefore, we are not accepting these commenters' suggestions to reduce to 90 percent threshold to 80 percent or 51 percent. We also believe that alternative measures such as weighting the residents that do not have prior training experience in the same specialty would add unnecessary complexity to the determination of program newness.

Regarding the comment that suggested CMS impose a requirement that individual residents who received previous training in the same specialty as the new program must have received such training at a program that continues to train residents throughout the completion of each resident's training, we addressed this scenario in the August 27, 2009 ''Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals'' final rule (74 FR 43914). We stated that because it was (and still is) our intent to ensure that no duplicative FTE resident slots are created by virtue of an inappropriate ''new program'' adjustment, a hospital considering starting a new program should ask several questions, one of which is, ''is this program part of any existing hospital's FTE cap determination (74 FR 43914)?'' The point of asking such a question is to assess whether the slots continue to be incorporated into the national aggregate FTE caps.

We stated that we do not believe it would be appropriate to consider a program that is substantially the same as a previous program at another hospital that remains open to be a new program. We reiterated our primary concern that there should be no duplicative FTE resident cap slots, thereby we would ensure to the extent possible that no FTE cap increases are granted when there is another ''active'' FTE cap of which the transferred program was a part. Accordingly, we do not agree with the commenter that an appropriate safeguard against the transfer of existing programs would be that individual residents who had received previous training in the same specialty as the new program must have received such training at a program that continues to train residents throughout the completion of each resident's training.

We also do not believe that it is necessary to create an explicit exception to the 90 percent rule for resident hardship, meaning for residents who have prior experience in the same specialty, but who join a program specifically to replace residents who depart unexpectedly from the program, or for other reasons. If a resident needs to transfer to a different program in the same specialty due to circumstances outside of his or her control, or if a resident needs to be replaced, the 10 percent exception is sufficient to provide the opportunity for such residents to still transfer into a program that is within its cap building, while not immediately jeopardizing the newness of the program.

Comment: A commenter asked that in light of a national projected shortage of physicians, CMS should consider establishing an exception to the 90 percent new resident threshold if a community need for additional physicians practicing in the program's specialty within the community can be established, and any other program in the same specialty operating within the community continues to train residents during the five year cap building period of the new program.

Response: Granting a larger exception to the 90 percent rule would not meaningfully address an impending physician shortage, as such an exception would only serve to permit residents already training in their specialty of choice to move from one existing program to another, rather than adding actual new medical school graduates into newly created residency programs. Therefore, we are not adopting the commenter's request.

Comment: Several commenters who supported the proposals also asked CMS to apply the revised criteria to programs still in their five-year cap-building period as of October 1, 2026, rather than the proposed effective date of new programs that start on or after October 1, 2026. Commenters stated that it is necessary to apply the effective date for new programs still within their 5-year cap building period to ease the physician shortage pipeline and to provide a consistent effective date for hospitals that are simultaneously within the cap-building period for new programs and are also planning to start new programs after October 1, 2026.

A commenter argued that CMS's existing standard of ''overwhelming majority'' was not adopted in notice-

and-comment rulemaking as required under section 1871 of the Social Security Act and cannot be applied; therefore, CMS should provide instructions to its MACs confirming that a program established before October 1, 2026 will still be treated as new as of the date it receives accreditation or begins training if the program was not moved in its entirety from one hospital to another.

Response: We have considered the commenters' requests to revise the effective date of the proposal, and we agree that to more quickly reduce regulatory burden, we should revise our proposed effective date for the definition of a new program to be effective for new programs still within their 5-year cap building period as of October 1, 2026. That is, in this final rule, the effective date for the definition of what constitutes a new program for cap building purposes (*i.e.,* meeting the 90 percent threshold) is for programs still within their 5-year cap building period as of October 1, 2026. However, we note that one important reason for the proposal to redefine the criteria for what constitutes a new program for cap building purposes is to provide a prospective, clear, standard for hospitals to utilize when planning and developing new residency programs. Accordingly, hospitals still within their 5-year cap building periods as of October 1, 2026 are on notice to abide by the new definition (*i.e.,* that at least 90 percent of the individual residents that participate in the program during the 5-year cap building period must not have previous experience training in another program in the same specialty), and provide the complete training history to their MACs for each resident that entered the program over the 5-year period, even if the hospitals' 5-year cap building period ends shortly after October 1, 2026.

We disagree with the commenter that argued that because CMS's existing standard of ''overwhelming majority'' was not adopted in notice-and-comment rulemaking, CMS should provide instructions to its MACs confirming that a program established before October 1, 2026 will still be treated as new as of the date it receives accreditation or begins training if the program was not moved in its entirety from one hospital to another. This commenter is overlooking what was established in notice and comment rulemaking in the August 27, 2009 ''Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals'' final rule, which was that, in addition to receiving initial accreditation, to be considered a ''new'' program for which new cap adjustments can be established, a residency program must satisfy three primary criteria (74 FR 43912):

- The program director is new; *and*
- The teaching staff are new; *and*
- The residents are new.

These criteria do not include the commenter's request that a program is to be treated as new if the program was not moved in its entirety from one hospital to another. Therefore, we cannot provide such instructions to the MACs for programs established prior to October 1, 2026.

Comment: A commenter stated that the proposal to wait until after the 5-year cap building closes and then to tally all individual residents who enter a program during the five-year cap building period is an excessive administrative burden. In addition, the commenter stated that by the time the hospital with the new program files its cost report in which the newness and cap calculation would be determined, there are already five or six previous cost reporting periods where the hospital had claimed FTE counts for residents in the new programs and for which the final settlements have been issued. If there is an adverse finding on the ''newness'' of a program, the earliest of these cost reporting periods may no longer be subject to reopening. The commenter recommended that the determination of newness should be made at the time of the review of the first cost reporting period where the hospital is claiming FTE residents in the new program, and that the assessment of the newness should generally not need to be continually made in the second through the fifth years of a new program's existence. However, the issue should be addressed if there is any evidence of there being a transfer of an existing program from one hospital to another. Another commenter urged CMS to provide clear implementation guidance on the documentation hospitals will be expected to maintain to demonstrate compliance.

Response: Under the proposed policy, we would determine whether a program has satisfied the 90 percent threshold by tallying all individual residents who enter a program during the five-year cap building period (that is, for new urban teaching hospitals, during the first five program years of the first new program's existence; and for rural hospitals, during the first five program years of each new program). For example, if 50 trainees (not FTEs) enter the program over the course of the five-year cap building period, then at least 45 of the trainees (that is, 90 percent of 50) must enter the program as brand-new first-year residents in that particular specialty.

We proposed that after the end of the five-year cap building period, the MAC would review the previous training experience of each individual trainee and determine the newness of the residency program prior to calculating the IME and DGME cap adjustments for the hospital. We stated that, consistent with our historical policy, the MAC would not be required to provide an initial assessment of ''newness'' prior to the end of the five-year cap building period.

We understand that particularly with larger programs, reviewing the training history of all residents that enter a program over the course of 5 years can be a significant amount of work for the MAC. Simultaneously, the hospital is responsible for maintaining and providing the training history of each of those residents and to provide that documentation to the MAC in an orderly and auditable format at the end of the 5-year period. We do note, however, that much of this information should be the same or similar to documentation needed to establish and record the resident's Initial Residency Period (IRP) under 42 CFR 413.79(a) in the Intern and Resident Information System (IRIS). In both situations, it is necessary for the hospitals involved and the MAC to know when and in what specialty did the resident *first* begin training, and to verify where and in what specialty the resident subsequently trained to know whether a hospital can claim the FTE training time of each resident.

The proposal and finalizing of clearer rules regarding what constitutes a new program should assist hospitals in planning and developing new programs that will be eligible for additional cap slots at the end of the 5-year cap building period. We are hopeful that hospitals can avoid unfortunate determinations that their programs do not comply with CMS's definition of a new program, and that reopenings and recoupments of overpayments from earlier cost reports within the 5-year cap building period would be minimal or avoided altogether.

In addition, we do not agree with the commenter that the determination of whether a program is new can be done after the hospital's first cost reporting period in training the new residents and should generally not need to be reviewed again during the second through fifth years of the program, unless there is evidence that a program was transferred. Unless the MAC reviews the history of each resident accepted into the program in years 2 through 5, the MAC may not learn about residents that enter the program via a

program transfer. That is, if only year 1 of the new program is reviewed, there would be no additional guardrails preventing the hospital from accepting a significant number of residents with previous training in the same specialty in program years 2 through 5.

Therefore, we believe it is most appropriate for the MAC to wait until after the end of the five-year cap building period to review the previous training experience of each individual trainee and determine the newness of the residency program prior to calculating the IME and DGME cap adjustments for the hospital. The MAC would not be required to provide an initial assessment of ''newness'' prior to the end of the five-year cap building period. A determination of newness and attending IME and DGME cap increases cannot be provided to a hospital that does not provide sufficient, auditable documentation (*e.g.,* curricula vitae or other detailed documentation showing full training history) regarding each resident's training history it wishes to include in its FTE cap calculation.

Comment: A comment expressed significant concern over our proposal that for purposes of determining compliance with the 90 percent requirement, we would exclude from the count of trainees any individuals with previous experience training in another program in the same specialty who enter the new program through the NRMP (the Match) or another binding third-party resident matching program. The commenter stated that with most residency positions being filled through the NRMP, it seems this aspect of the proposal renders the 90 percent threshold meaningless.

Response: We appreciate the concern raised by the commenter, as we would agree that an exception that excludes all residents that enter through the NRMP would render the 90 percent threshold meaningless. However, we did not propose that all residents that enter through the NRMP would be excluded from the determination of the 90 percent threshold. Rather, we proposed that, for purposes of determining compliance with the 90 percent requirement, we would exclude from the count of trainees any individuals with previous experience training in another program in the same specialty who enter the new program as first-year residents through the NRMP or another binding third-party resident matching program (91 FR 19508).

The key is that to be excluded from the 90 percent threshold calculation, the trainee with previous experience *in that same specialty* would have to enter the new program as a *first-year resident, thereby starting his/her training over again from the beginning of the PGY–1 year.* We understand that, generally, if an individual already has previous training in a specialty, he/she would try to avoid repeating training in the same specialty for a variety of reasons (such as not wanting to unnecessarily extend training time, facing a reduced DGME weighting factor due to expiration of the Initial Residency Period toward the end of his/her training, etc.). Accordingly, we believe that the proposed exception to the 90 percent threshold for individuals with previous experience in the same specialty that enter the new program as first year residents via the NRMP or similar binding matching program will be invoked relatively infrequently.

Comment: Several commenters opposed the proposed exclusion of displaced residents accepted into new small or rural programs from cap-building, asserting that not infrequently, rural hospitals, unlike urban counterparts, rely on displaced residents to fill positions that were not filled through the NRMP or SOAP. Another commenter objected to excluding displaced residents from cap-building, arguing it could disincentivize new programs from accepting them. The commenter also expressed concern about CMS's specification of the clause ''in the same specialty,'' noting that if the displaced resident would be transferring from a different specialty, concerns about duplicating cap would still be present. This commenter suggested CMS instead require the displaced resident's original hospital to relinquish the associated FTE from its permanent cap.

Response: In the FY 2027 IPPS/LTCH proposed rule (91 FR 19508), we proposed to exclude any residents admitted into the new program from another program in the same specialty who meet the definition of a ''displaced resident'' (under 42 CFR 413.79(h)(1)(iii) both from the numerator and from the denominator of the calculation used to determine the proportion of new vs. experienced residents). We made this proposal in order to prevent the inappropriate duplication of cap slots associated with a closed program or closed hospital, and stated that such displaced individuals would not count toward the new program's cap calculation, but instead must be reported on the displaced resident lines (lines 16 and 16.01 of Worksheet E–4 and line 17 of Worksheet E, Part A) if the hospital qualifies for a temporary cap adjustment under 42 CFR 413.79(h). Otherwise, the individuals must be reported on the regular FTE lines (line 6 of Worksheet E–4 and line 10 of Worksheet E, Part A), subject to the hospital's existing DGME and IME FTE caps.

Furthermore, since rotation schedules, and not cost report entries, are used to identify individual residents training in the new program for the purpose of calculating the permanent cap at the end of the five-year cap building period under 42 CFR 413.79(e)(1)(i)(A), the displaced residents listed on the rotation schedule would be excluded from the new program cap calculation. We also noted that under certain circumstances, if a hospital trains residents displaced by a hospital closure, it may receive priority for receipt of cap slots if it applies for a permanent cap adjustment under the provisions of section 5506 of the Affordable Care Act.

We continue to believe that individuals that meet the definition of ''displaced resident'' (under 42 CFR 413.79(h)(1)(iii)) should not count toward the new program cap calculation as a necessary guardrail to prevent the inappropriate duplication of cap slots associated with a closed program or closed hospital. To the extent that this guardrail may serve as a disincentive for some new programs to accept displaced residents, we note that hospitals closing or closing their programs may opt to lend FTE cap slots to receiving hospitals under 42 CFR 413.79(h).

Regarding the comment questioning why CMS specified ''in the same specialty,'' the commenter is correct in pointing out that if the displaced resident would be transferring from a different specialty, concerns about duplicating cap would still be present, and it would be irrelevant if the displaced resident is coming from the same specialty as the new program or coming from a different specialty. Therefore, in this final rule, we are removing the words ''in the same specialty,'' and instead stating that we would exclude any residents admitted into the new program from another program who meet the definition of a ''displaced resident'' (under 42 CFR 413.79(h)(1)(iii)) both from the numerator and from the denominator of the calculation used to determine the proportion of new vs. experienced residents. However, we cannot, as a commenter suggests, require the displaced resident's original hospital to relinquish the associated FTE from its permanent cap. In the instance of hospital closure (*i.e.,* the hospital terminates its Medicare provider agreement), CMS has the authority to permanently remove a hospital's IME and DGME FTE caps, per section 5506

of the ACA as implemented at 42 CFR 413.79(o); section 5506 does not apply in the instance of program closure where the provider agreement remains active.[162]

(5) Exception for Small Programs

In addition, we proposed to create an exception to the 90 percent requirement for small residency programs. We proposed to define a ''small'' program as one that is accredited for 16 or fewer resident (or fellow) positions, regardless of whether the program is located in an urban or a rural area. Based on the feedback we received from commenters, we believe that small programs are at the greatest risk of failing to meet the 90 percent threshold for reasons beyond their control. Accordingly, we proposed to exempt small residency programs from the requirement that at least 90 percent of the residents who enter the program during the five-year cap-building period must not have previous experience training in another program in the same specialty. We did not propose any minimum proportion of new residents that a small program must achieve to be considered new for cap-building purposes. However, programs accredited for 16 or fewer positions must still obtain initial accreditation from the appropriate accrediting body.

We note that we did not propose to adopt various other exceptions or policies recommended by commenters, as summarized in the preceding section of this preamble. We believe that the criterion we have proposed would accomplish our stated goal of preventing the inappropriate duplication of FTE cap slots, while the exception for small programs provides a reasonable safeguard for those programs at greatest risk of failing to meet the proposed requirement for reasons beyond their control. Additionally, we believe that the proposed policies have the advantage of being unambiguous and administratively simple. We wish to avoid scenarios in which CMS or the MACs would need to review individual hospitals' circumstances on a case-by-case basis and introduce greater uncertainty into the process for hospitals.

Additionally, we note that we did not propose any distinct policies with respect to the commingling of residents. Rather, we proposed that program newness should be determined consistently based upon initial accreditation and the 90 percent new resident threshold. That is, we proposed that if a particular program has received initial accreditation, and at least 90 percent of the individual trainees (not FTEs) entering the program during the five-year cap building period are new (with previously noted exceptions), then the program would be considered new for cap-building purposes, regardless of whether residents in that program have shared educational experiences with residents of an existing program in the same specialty.

Similarly, we proposed one hospital operating two or more programs in the same specialty would be permissible for cap-building purposes, if the second or subsequent program separately received initial accreditation and at least 90 percent of the individual trainees (not FTEs) entering the program during the five-year cap building period are new (with previously noted exceptions). Note that this would be a change from existing policy, under which it is permissible for one hospital to operate two or more programs in the same specialty provided that the programs have separate program directors, staff, and separately matched residents without meeting any additional requirements (see discussion of existing policy in the August 27, 2009 ''Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals'' final rule at 74 FR 43913).

Comment: A commenter requested that the CMS Administrator ''simply abandon this proposal in its entirety,'' as the proposal is insufficient to blunt the significant increases in Medicare IME spending that result from the ability of urban hospitals to reclassify as rural under 42 CFR 412.103 for IME payment purposes, and in order to receive additional IME cap slots for any new program started. This commenter stated that the proposed definition of and exception for small programs will allow for the inappropriate transfer of existing programs or the duplication of FTE cap slots for ''small'' programs by exempting them from meeting any ''newness'' requirement beyond the receipt of an initial accreditation from the ACGME, particularly in the case of fellowship programs at urban hospitals, which typically are not more than 16 residents.

Another commenter warned that the small-program exception may allow urban hospitals to be reclassified as rural to ''skirt'' cap limitations but acknowledged that without clearer statutory guidance in the statute, CMS faces challenges addressing this issue. The commenter recommended that in determining the 16-resident limit for a small program, CMS should distinguish between CMS-funded hospital slots from accredited resident positions. The commenter recommended clarifying that the 16-resident small-program exception should be based on the size of the accredited residency program itself, not on the number of residents reported by any individual participating hospital. The commenter recommended that CMS add language saying: ''Cost reported and CMS-funded slots are not the same as resident positions in an accredited program. Therefore the 16-resident exception for small programs is in reference to the program and its accreditation, not any single participating hospital and the number of residents claimed in its cost report.''

Response: We proposed to define a ''small'' program as one that is accredited for 16 or fewer resident (or fellow) positions, regardless of whether the program is located in an urban or a rural area. We also proposed that programs accredited for 16 or fewer positions must still obtain initial accreditation from the appropriate accrediting body. The commenter is correct that if a program is accredited for 16 or fewer positions, and receives initial accreditation, this program would not need to meet the 90 percent threshold.

We share the commenters' concerns regarding urban hospitals' possible use of rural reclassifications to obtain increased cap limits. However, the proposal regarding the exception to the 90 percent threshold for small programs does not exclude urban hospitals reclassified as rural under 42 CFR 412.103 because, as a commenter alludes, of the statutory requirement at section 1886(d)(8)(E)(i) of the Act to treat § 412.103 hospitals 'as being located in the rural area' of the state'' (88 FR 58976). Thus, urban hospitals that reclassify as rural under 42 CFR 412.103 and start new programs are

[162] In the instance where the originating teaching hospital closes, and a hospital that is within its 5 year cap building period takes in a resident or some residents displaced by a teaching hospital's closure, the host hospital might be able to receive FTE cap slots permanently associated with the displaced residents, if it meets certain criteria and applies under the section 5506 of the ACA application process initiated by CMS subsequent to the closure of the originating teaching hospital. In the November 24, 2010 OPPS final rule (75 FR 72229), we stated that if a nonteaching hospital assumes an entire program(s) from the closed teaching hospital, this hospital would not have the opportunity to receive a further cap increase as a new teaching hospital under 42 CFR 413.79(e). Nonteaching hospitals that take in a portion of a program(s) from the closed teaching hospital (*i.e.,* just one or a few displaced residents) could still qualify to start new programs and receive a cap increase under 42 CFR 413.79(e). Thus, even though we are finalizing our proposal to exclude from the FTE cap calculation any displaced residents the host hospital trains under 42 CFR 413.79(h), the host hospital that is also within its 5 year cap building period might be able to receive FTE cap slots permanently under section 5506 of the ACA for training those displaced FTEs in the instance where it is not assuming an entire program(s) from the closed teaching hospital.

included in the exemption for small (rural) programs.

We also agree that the 16-resident exemption is based on the accredited size of the program, not based on FTEs, as we proposed that a ''small'' program is one that is *accredited* for 16 or fewer positions. We agree that the 16-resident exception for small programs is in reference to the program and its accreditation, not any single participating hospital and the number of FTE residents claimed in its cost report.

Comment: A commenter requested that small programs still in their cap building period as of October 1, 2026, be permitted to opt in to application of the Small Program Exception back to May 2, 2024, the date of publication of the FY 2025 IPPS proposed rule (89 FR 35934), when CMS first acknowledged that small or rural residencies face unique challenges in satisfying historically implemented criteria for determining program newness. In the alternative, the commenter requested that CMS interpret the ''start'' date of a program as the date on which it begins training residents, rather than the date of initial accreditation. Such an interpretation would allow new small programs which were initially accredited prior to October 1, 2026, but have not commenced training residents by that date, to fall within the Small Program Exception.

Response: As noted in response to other comments, we are revising the effective date in this final rule to state that for programs still within their 5-year cap building period as of October 1, 2026, or for programs started on or after October 1, 2026, at least 90 percent of the individual residents that participate in the program during the 5-year cap building period must not have previous experience training in another program in the same specialty. The 90 percent requirement does not apply to a program accredited for 16 or fewer resident positions. This final effective date extends earlier than the commenter's requested effective date of May 2, 2024, as there may be programs accredited for 16 or less residents that are still within their 5-year cap building period as of October 1, 2026, that started even prior to May 2, 2024. In this final rule, while receipt of initial accreditation for the program is still required, the date of that initial accreditation is not relevant, as the effective date applies to when residents start training in the new program. Thus, even if a program received initial accreditation prior to October 1, 2026, but residents first start training in the program on or after October 1, 2026, this program would be subject to the effective date, definitions, and exclusions we are adopting in this final rule.

Comment: A commenter requested that CMS define a small program as a program that is accredited for five or fewer residents per program year, where a 3-year residency program is approved for up to sixteen residents, a four-year program is approved for up to twenty residents, and a five-year program is approved for up to twenty-five residents; each of which would all fall within the Small Program Exception. The commenter believed this modification would not favor certain, shorter programs and inadvertently incentivize formations of three-year programs over programs that require more years of training.

Response: In the May 2, 2024 IPPS/LTCH PPS proposed rule (89 FR 36222), we stated that we are soliciting comments on whether a small residency program should be defined as a program accredited for 16 or fewer resident positions, because 16 positions would encompass the minimum number of resident positions required for accredited programs in certain specialties, such as primary care and general surgery, that have historically experienced physician shortages, and therefore have been prioritized by Congress and CMS for receipt of slots under sections 5503 and 5506 of the Affordable Care Act. While primary care programs are typically accredited for 3 years and general surgery is accredited for 5 years, yet both can be accredited for 16 positions. Therefore, we do not believe it is necessary to adopt the commenter's suggestion where 3, 4, and 5-year programs would have their own ''small program'' exception amount, as 16 seems to sufficiently apply to 3, 4, and 5-year programs.

Comment: A commenter suggested the following revisions to the regulatory text to more closely align with the proposed policy and avoid ambiguities (added/edited text in italics):

§ 413.79(l) For purposes of this section, a new medical residency training program means a program that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995, and, *in the case of a medical residency training program that receives such initial accreditation or begins training residents on or after October 1, 2026,* that meets the following additional conditions:

(1) Subject to the provisions of paragraphs (l)(2) and (l)(3) of this section, *effective for programs started on or after October 1, 2026, ...*

Response: We agree that the commenter's edits add clarity to the regulations text, and we accept them, with modification to the effective date that we are finalizing in this rule, as follows:

413.79(l) For purposes of this section, a new medical residency training program means a program that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995, and in the case of a medical residency training program that receives initial accreditation by the appropriate accrediting body and is still within its 5-year cap building period as of October 1, 2026, or starts training residents on or after October 1, 2026, that meets the following conditions:

(1) Subject to the provisions of paragraphs (l)(2) and (l)(3) of this section, at least 90 percent of the individual residents that participate in the program during the 5-year cap building period . . .

In summary, we are finalizing our proposal that, in addition to receiving initial accreditation by the appropriate accrediting body, for a residency program to be considered new, at least 90 percent of the individual resident trainees (not FTEs) must not have previous experience training in another program in the same specialty. We would no longer consider the previous employment of the faculty or program director in determining whether a residency program is genuinely new for cap-building purposes. We would determine compliance with the 90 percent threshold by tallying all of the individual residents who enter a program during the five-year cap building period (that is, for new urban teaching hospitals, during the first five program years of the first new program's existence; and for rural hospitals, during the first five program years of each new program). This tally would exclude individuals with previous experience training in another program in the same specialty who enter the new program as first-year residents through the National Resident Matching Program or another binding third-party resident matching program, as well as individuals who meet the definition of a ''displaced resident'' under 42 CFR 413.79(h)(1)(iii). The requirement that at least 90 percent of the individual residents must be new would not apply to small programs, defined as programs accredited for 16 or fewer resident positions, regardless of geographic designation. However, programs accredited for 16 or fewer positions must still receive initial accreditation from the ACGME. We are adopting commenters' requests

regarding modifying the proposed effective date and in this final rule, we are stating that these policies will be effective for programs still within their 5-year cap building period as of October 1, 2026, or for programs started on or after October 1, 2026.

To ensure that the regulations text appropriately reflects our final policy, we are revising the text of 42 CFR 413.79(l) to state that a new medical residency training program means a program that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995, and in the case of a medical residency training program that receives initial accreditation by the appropriate accrediting body and is still within its 5-year cap building period as of October 1, 2026, or starts training residents on or after October 1, 2026, that meets the following conditions:

- Subject to the following provisions, at least 90 percent of the individual residents (not FTEs) that enter the program during the five-year cap building period (that is, for new urban teaching hospitals, during the first five program years of the first new program's existence under § 413.79(e)(1); and for rural hospitals, during the first five program years of each new program under § 413.79(e)(3)) must not have previous experience training in another program in the same specialty.
- For purposes of determining whether a program satisfies the preceding requirement of this section, the count of individual residents excludes an individual—

++ With previous experience training in another program in the same specialty who enters the program as a first-year resident through the National Resident Matching Program or another binding third-party resident matching program; or

++ Who meets the definition of a ''displaced resident'' under paragraph (h)(1)(iii).

- The 90 percent requirement does not apply to a program accredited for 16 or fewer resident positions.

4. Calculation of Direct GME and IME Payments Following a Merger of Hospitals

When a hospital merger involves one or more teaching hospitals, the surviving provider experiences an influx of FTE residents from the terminating providers' residency programs. The surviving hospital also absorbs those providers' FTE caps (63 FR 26329) and receives a merged per resident amount for purposes of direct GME payment (71 FR 48073). In addition, the Medicare Part A and Medicare Advantage (MA) patient loads of the surviving hospital represent the combined Medicare utilization of all hospitals (teaching and non-teaching) participating in the merger.

The surviving provider also experiences changes in the payment rates that determine the amount of its indirect medical education adjustment. In addition to the influx of FTE residents from the terminating providers' residency programs, the surviving provider absorbs those hospitals' existing IME FTE caps and available beds, resulting in a change to its intern- and resident-to-bed (IRB) ratio. The total amount of IME payment is also affected by the combination of the merged hospitals' Part A and simulated MA DRG revenues.

While we did not propose any new policies at this time, we are taking the opportunity to clarify in rulemaking the methodology for calculating DGME and IME payments for the surviving provider following a merger of hospitals. We discuss the procedure for calculating each payment type separately later in this section.

a. Calculating DGME Payments Following a Merger of Hospitals

If the surviving hospital begins a new cost reporting period effective with the date of the merger, then direct GME payment for that initial merged period and subsequent periods is determined based on the hospital's new, combined DGME payment rates (with special consideration for the rolling average during the first two cost reporting periods, as discussed further later in this section). However, if the merger takes place in the middle of the surviving hospital's cost reporting period, then the hospital's DGME payment for that period must reflect the different payment rates that apply before and after the merger.

In the August 18, 2006 FY 2007 IPPS final rule and interim final rule with comment period (71 FR 48075–48076), we stated that direct GME payment for the surviving hospital would be calculated on the basis of two distinct sets of PRAs (that is, two distinct primary care PRAs and two distinct nonprimary care PRAs, or two distinct single PRAs, as applicable), one for the pre-merger period and one for the post-merger period. Thus, to calculate the DGME payment for the surviving hospital for the cost reporting period in which the merger occurred, the MAC performs a series of off-the-cost-report calculations, treating the pre-merger and post-merger periods of the surviving hospital's cost reporting period as if they were two short cost reporting periods.

The MAC would calculate the direct GME payment for the surviving hospital for the portion of the cost reporting period prior to the merger using only the surviving hospital's FTE counts, PRA(s) and Medicare utilization rate. Separately, the MAC would calculate the surviving hospital's post-merger direct GME payment using the merged weighted average PRA(s) updated using special CPI–U factors; a combined rolling average FTE count reflecting the merged hospitals' FTE counts; and a combined Medicare utilization rate reflecting the portion of the cost reporting period following the merger. The MAC would add the pre-merger and post-merger payments to determine the surviving hospital's total reimbursement for that cost reporting period. We also stated in the 2006 rule that similar pre-merger and post-merger calculations are performed for the intern- and resident-to-bed ratio for purposes of IME payment, as discussed later in this preamble.

In effect, the pre- and post-merger timeframes are treated as though they were individual short cost reporting periods, with virtual payment rates established for each period based upon the best available data for all providers. Later in this section, we provide a detailed step-by-step explanation, with an illustrative example, of how to calculate pre- and post-merger direct GME payments according to the policy outlined previously.

To facilitate the calculation of the DGME payment amounts, the MAC determines the following variables separately for the pre- and post-merger timeframes, consistent with the FTE counting rules for non-12-month cost reporting periods as clarified in the August 4, 2025 FY 2026 IPPS final rule (90 FR 36915). In general, the pre-merger payment rates are based on data from the surviving provider only, while post-merger rates utilize data from all participating hospitals:

- *FTE resident count—Calculate separately for the pre-merger and post-merger periods:* To determine the partial year unweighted DGME FTE counts, the sum of allowable rotations for all residents during each period is divided by 365 or 366, using data from the master rotation schedule or a similar source (see 90 FR 36915–16 for further details). The weighted counts are obtained by applying the appropriate weighting factor to the rotations associated with each resident, and separate weighted counts are determined for primary care and non-primary care residents. For the pre-

merger period, the count includes rotations allowable to the surviving provider only; for the post-merger period, the count includes the sum of all rotations allowable to the merged entity.[163]

• *FTE resident limit (cap)—Calculate separately for the pre-merger and post-merger periods:* The partial year DGME FTE resident limit is calculated by prorating the hospitals' original FTE caps, including any applicable adjustments, for the number of days in each respective period. The pre-merger limit is derived from the FTE caps of the surviving provider only, whereas the post-merger limit includes the combined caps of all hospitals participating in the merger. The prorated FTE caps are applied to the partial year FTE resident counts according to the usual procedure as described in the August 4, 2025 FY 2026 IPPS Final Rule (90 FR 36917). If any of the merged hospitals have residents participating in a rural track program or residents counted under section 422 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173, codified at section 1886(h)(7) of the Act) (MMA), then those counts and caps are also determined and applied separately for the pre- and post-merger periods.

• *Rolling average FTE count—Calculate separately for the pre-merger and post-merger periods:* The current, prior- and penultimate-year weighted FTE counts, which serve as the inputs to the three-year rolling average, must also be determined separately for the pre- and post-merger timeframes. The current year FTE counts are calculated as explained previously, while the prior- and penultimate-year counts are obtained from lines 12 and 13 of Worksheet E–4 of the respective hospitals' cost reports, and prorated according to the procedure described in the August 4, 2025 FY 2026 IPPS final rule (90 FR 36917).[164] The numerator of the rolling average for the pre-merger period consists of the prorated FTE counts of the surviving provider only, while the post-merger numerator equals the sum of the prorated FTE counts of the surviving and terminating providers, simulating what the effect of the merger would have been during the prior and penultimate cost reporting periods.

Note that a ''virtual'' rolling average must also be calculated for the merged provider's first two cost reporting periods beginning on or after the effective date of the merger: that is, the surviving and terminating providers' FTE counts must be combined as though they were merged during the prior and/or penultimate years (with proration applied as necessary to account for differences in the length of the respective hospitals' cost years). This procedure applies whether the merger occurred in the middle of the surviving provider's cost reporting period. Standard computation of the rolling average would resume in the third full post-merger cost reporting period.

In addition to the FTE resident count, FTE resident limit, and rolling average FTE count, the MAC also determines separate per resident amounts and Medicare patient loads (for both Part A and managed care enrollees) for the pre- and post-merger timeframes:

• *Per resident amount—Calculate separately for the pre-merger and post-merger periods:* Direct GME payment for the pre-merger period is calculated using the surviving provider's original primary care and non-primary care PRAs, or single PRA, as applicable, updated to the midpoint of the pre-merger period. The post-merger payment is calculated using the merged primary care and non-primary care PRAs, or merged single PRA, as applicable, determined according to the procedure finalized in the August 18, 2006 FY 2007 IPPS Final rule/Interim Final Rule with Comment Period (71 FR 48075–76); the merged PRA(s) is updated for inflation to the midpoint of the post-merger period.

If the surviving and/or terminating providers count additional residents under the provisions of section 422 of the MMA, then direct GME payments for those residents would be calculated separately for the pre- and post-merger periods, as applicable, with the special per resident amounts updated according to the same procedures outlined previously.

• *Medicare patient load—Calculate separately for the pre-merger and post-merger periods:* Separate Medicare Part A and MA patient loads are determined for the pre- and post-merger periods using data from the hospitals' Provider Statistical and Reimbursement (PS&R) reports (see specific fields in the example table later in this section). For the pre-merger period, the numerator and denominator of the Medicare patient load comprise the Medicare and total inpatient days, respectively, attributable to the surviving provider during that period; for the post-merger period, the numerator and denominator comprise the sum of all inpatient days attributable to the merged hospitals (including any non-teaching hospitals absorbed by the surviving provider).

If either the pre- or post-merger period straddles multiple calendar years, then separate MA patient loads must also be determined for the portions of that period occurring prior to and on or after January 1, so that the MA DGME payments may be adjusted by the percentage reduction applicable to each calendar year (as required by the regulations at § 413.76(d)).

Since the cost report does not support the use of multiple DGME payment rates for portions of a single cost year, these calculations must be performed off the cost report, and the results are summed to determine total DGME payment for the cost reporting period. Placeholder values based on the combined payment rates of the merged hospitals are reported as necessary on the applicable lines of Worksheet E–4.[165]

The following example illustrates the application of the policies described previously.

Example:

Consider a merger between teaching Hospitals A and B, effective November 1, 2023, where Hospital A is the surviving provider. Prior to the merger, Hospitals A and B had fiscal year ends of June 30 and December 31, respectively. As the surviving provider, Hospital A elects to maintain its existing fiscal year, and files a cost report for the period July 1, 2023, to June 30, 2024. Since different payment rates apply to the timeframes 07/01/23–10/31/23 and 11/01/23–06/30/24, two separate direct GME payments must be calculated for Hospital A's cost reporting period ending June 30, 2024. These calculations are performed off the cost report, and the sum of the total payments is reported on line 31 of Worksheet E–4 of the hospital cost report (Form CMS–2552–10). Hospital B would file a terminating cost report for the period January 1, 2023–October 31, 2023, with direct GME payment determined in accordance with the rules applicable to short cost reporting periods, as clarified in the August 4, 2025 FY 2026 IPPS Final Rule (90 FR 36915).

The following table summarizes the data that will be used to calculate Hospital A's pre- and post-merger

[163] If any of the merged hospitals is training displaced residents or residents in the initial years of a new program, those weighted counts would be determined according to the same procedure, and the FTEs would be added to the respective rolling averages calculated for the pre- and post-merger periods.

[164] Note that the proration factor is applied *after* the prior- and penultimate-year FTE counts have been determined based on data from the respective cost reports, consistent with the instructions to lines 12 and 13 of Worksheet E–4.

[165] For example, the FTE caps and adjustments of the surviving and terminating providers would be added and reported on the applicable FTE cap lines as though the providers had been merged for the entire cost reporting period.

DGME payments, based on the surviving and terminating providers' historical cost reports, as well as other sources such as rotation schedules and PS&R reports:

Data Point	Hospital A	Hospital B	Source
DGME FTE resident count (weighted): 1/1/23 – 6/30/23	[not shown]	[9.75]	Rotation schedule or similar documentation
DGME FTE resident count (weighted): 7/1/23 – 10/31/23	14.28	[6.80]	Rotation schedule or similar documentation
DGME FTE resident count (weighted): 11/1/23 – 6/30/24	27.72	13.20	Rotation schedule or similar documentation
Prior year weighted DGME FTE resident count	40.00	21.50	Cost report data
Penultimate year weighted DGME FTE resident count	39.00	19.25	Cost report data
DGME FTE resident limit (including applicable adjustments)	40.00	25.00	Cost report data
Per resident amount (single PRA)	$134,000	$127,500	Cost report data[166]
Part A inpatient days: 7/1/23 – 10/31/23	8,303	[6,888]	PS&R report type 110
Part A inpatient days: 11/1/23 – 6/30/24	16,335	13,552	PS&R report type 110
MA inpatient days: 7/1/23 – 10/31/23	2,768	[3,936]	PS&R report type 118
MA inpatient days: 11/1/23 – 12/31/23	1,373	1,952	PS&R report type 118
MA inpatient days: 1/1/24 – 6/30/24	4,073	5,492	PS&R report type 118
Total inpatient days: 7/1/23 – 10/31/23	18,450	[19,680]	Hospital census data
Total inpatient days: 11/1/23 – 6/30/24	36,300	38,420	Hospital census data
MA DGME percent reduction: CY 2023		2.74%	FY 2025 IPPS final rule (89 FR 69384)
MA DGME percent reduction: CY 2024		2.33%	FY 2026 IPPS final rule (90 FR 36919)

• Since the hospitals are merged effective November 1, 2023, Hospital B does not have a separate FTE resident count, or separate inpatient days, during the period 11/01/23–06/30/24; post-merger data for Hospital B are broken out for illustrative purposes only. In addition, Hospital B's pre-merger FTE counts and inpatient days for its 2023 cost year are printed in brackets since they do not factor into the merged provider's DGME payment rates for fiscal year end (FYE) 06/30/24. However, note that Hospital B's pre-merger FTE counts will be used to calculate the rolling average for the merged provider's subsequent cost reports, as explained later in this section. Hospital B would file its terminating cost report and receive DGME payment for the period 01/01/23–10/31/23 in accordance with the rules applicable to short cost reporting periods.

As noted later in this section, we assume in this example that Hospitals A and B each have a single PRA; accordingly, the FTE counts in this table represent combined totals for residents in both primary and non-primary care programs.

• The prior- and penultimate-year FTE counts are required to calculate the three-year rolling averages for the pre- and post-merger periods. Hospital A's prior- and penultimate-year cost reporting periods end on June 30, 2023, and June 30, 2022, respectively; Hospital B's cost reporting periods end on December 31, 2022, and December 31, 2021.

• The hospitals' DGME FTE resident limits include any applicable adjustments, such as those for new programs or slots received under various statutory provisions. For this example, we assume that neither hospital received additional residency slots under section 422.

• Consistent with the policy finalized in the August 18, 2006 FY 2007 IPPS Final Rule/Interim Final Rule with Comment Period (71 FR 48075), the individual hospitals' original (pre-merger) PRAs are sourced from the most recently settled cost reports. In this example we assume that the most recently settled cost reports of Hospitals A and B are those ending on June 30, 2021, and December 31, 2020, respectively. For the sake of convenience, we assume each hospital has a single PRA applicable to residents in all specialties.

• Managed care and total inpatient days during the post-merger period 11/01/23–06/30/24 are further broken out into portions occurring before and after January 1, since different percentage reductions to MA DGME payments apply to calendar years 2023 and 2024.

Pre-Merger Direct GME Payment (July 1, 2023, to October 31, 2023)

To calculate the surviving provider's direct GME payment for the pre-merger period 07/01/23–10/31/23, the following variables are determined based on Hospital A's individual records for the relevant timeframe:

• *FTE resident count:* As indicated in the table outlined previously, Hospital A's weighted DGME FTE resident count during the period 07/01/23–10/31/23 is 14.28 FTEs, based on data from Hospital A's rotation schedules or similar documentation and determined according to the methodology clarified in the August 4, 2025 FY 2026 IPPS Final Rule (90 FR 36915).

• *FTE resident limit:* The FTE resident limit for the pre-merger period is obtained by prorating Hospital A's full-year DGME FTE cap. Since there are 123 days during the period 07/01/23–10/31/23 and the full cost reporting period includes February 29, the prorated FTE cap equals: $40 \times (123 \div 366) = 13.44$, which is less than the actual weighted DGME count of 14.28. Accordingly, Hospital A's effective DGME resident count for the pre-merger period is 13.44 FTEs.

• *Rolling average FTE count:* To determine the three-year rolling average, Hospital A's prior- and penultimate-year FTE counts are divided by the number of days in the respective cost reporting periods and multiplied by 123 [167]:

++ *Prior year:* $40 \times (123 \div 365) = 13.48$ FTEs.

++ *Penultimate year:* $39 \times (123 \div 365) = 13.14$ FTEs.

The rolling average therefore equals: $(13.44$ [168] $+ 13.48 + 13.14) \div 3 = 13.35$ FTEs.

• *Per resident amount:* Hospital A's updated single PRA for its most recently

[166] From the providers' most recently settled cost reports, as explained below under Notes.

[167] This assumes that Hospital A's prior- and penultimate-year CRPs are both standard 12-month periods.

[168] From FTE resident limit.

settled cost reporting period ending June 30, 2021, was $134,000. This PRA must be updated from the calendrical midpoint of Hospital A's June 30, 2021 fiscal year to the midpoint of the period 07/01/23–10/31/23, that is, from December 30, 2020, to August 31, 2023, using an appropriate inflation factor to estimate the change in the CPI–U during this period. Accordingly, Hospital A's FY 2021 PRA is updated by an inflation factor of 1.1777: $134,000 × 1.1777 = $157,812. (The calculation of the inflation factor itself is omitted for the sake of brevity; contact a MAC for additional guidance.)

- *Medicare patient load:* Based on the data from the table noted previously, Hospital A's Medicare Part A patient load for the period 07/01/23–10/31/23 is 8,303 ÷ 18,450 = 0.45; the Medicare Advantage patient load for the same period is 2,768 ÷ 18,450 = 0.15.

With these data points established, we can calculate total Part A and MA DGME payment for Hospital A during the pre-merger period 07/01/23–10/31/23. (*Note:* MA DGME payment is reduced by the percentage determined by CMS for calendar year 2023 and published in the **Federal Register**):

- *Part A:* $157,812 × 13.35 × 0.45 = $948,055.59.
- *MA:* $157,812 × 13.35 × 0.15 × (1 − 0.0274) = $307,359.62.

Thus, Hospital A's total DGME payment for the pre-merger period is: $948,055.59 + $307,359.62 = $1,255,415.21.

Post-Merger Direct GME Payment (November 1, 2023, to June 30, 2024)

For the post-merger period, the same payment variables are calculated using data from the records of both the surviving and terminating providers:

- *FTE resident count:* The combined weighted DGME resident count of Hospitals A and B (that is, the newly merged entity) for the period 11/01/23–06/30/24 is 27.72 + 13.20 = 40.92 FTEs.
- *FTE resident limit:* The merged provider's combined DGME FTE cap is 40 + 25 = 65 FTEs, which must be prorated for the partial cost reporting period. Since there are 243 days during the period 11/01/23–06/30/24 and the full cost reporting period includes February 29, the prorated FTE cap equals: 65 × (243 ÷ 366) = 43.16, which is greater than the actual weighted DGME count of 40.92. Accordingly, the provider's effective DGME resident count for the post-merger period is 40.92 FTEs.
- *Rolling average FTE count:* To determine a representative three-year rolling average for the post-merger timeframe, we must treat Hospitals A and B as though they had been merged during their preceding two cost reporting periods. Accordingly, the prior-year FTE count used in the rolling average calculation (before proration) is equal to the combined prior-year FTE counts of the two hospitals: 40 + 21.5 = 61.50 FTEs; and the penultimate-year FTE count is equal to: 39 + 19.25 = 58.25 FTEs. These totals are then divided by the number of days in the respective cost reporting periods and multiplied by 243: [169]
  - *Prior year:* 61.50 × (243 ÷ 365) = 40.94 FTEs.
  - *Penultimate year:* 58.25 × (243 ÷ 365) = 38.78 FTEs.

The rolling average therefore equals: (40.92 + 40.94 + 38.78) ÷ 3 = 40.21 FTEs.

- *Per resident amount:* The merged per resident amount for the post-merger period is determined according to the procedure finalized in the August 18, 2006 FY 2007 IPPS Final rule/Interim Final Rule with Comment Period:
  - Hospital A's FY 2021 PRA of $134,000 is updated by an inflation factor of 1.1416 to $152,974.
  - Hospital B's FY 2020 PRA of $127,500 is updated by an inflation factor of 1.1530 to $147,007.

To determine the weighted average merged PRA, each hospital's individual PRA is weighted by the number of DGME FTE residents on its most recently settled cost report. Assume that on their FY 2021 and FY 2020 cost reports, Hospitals A and B reported 40 FTEs and 20 FTEs, respectively. The merged PRA is then equal to: ((40 × $152,974) + (20 × $147,007)) ÷ 60 = $150,985.

Finally, the merged PRA as established previously is updated from the calendrical midpoint of Hospital A's June 30, 2023 fiscal year (that is, from December 30, 2022) to the midpoint of the period 11/01/23–06/30/24, (that is, to March 1, 2024). Using the same methodology as previously, the merged PRA of $150,985 is updated by an inflation factor of 1.0448 to $157,749.

- *Medicare patient load:* The Medicare patient load for the period 11/01/23–06/30/24 is determined based on the combined inpatient days attributable to the merged hospitals. Since the period straddles multiple calendar years, separate MA patient loads must be determined for the periods before and after January 1:
  - *Part A:* 29,887 ÷ 74,720 = 0.399
  - *MA (before Jan. 1):* 3,325 ÷ 74,720 = 0.044
  - *MA (from Jan. 1):* 9,565 ÷ 74,720 = 0.128

(In these calculations, the denominator is equal to the total number of inpatient days at the merged hospital for the entire period 11/01/23–06/30/24 (that is, the sum of the inpatient days at Hospitals A and B, as indicated in the table noted previously); the numerators are obtained by summing the relevant categories of inpatient days for the respective periods.)

With these data points established, we can calculate total Part A and MA DGME payment for the merged provider during the post-merger period 11/01/23–06/30/24. (*Note:* MA DGME payments are reduced by the percentages determined by CMS for calendar years 2023 and 2024 and published in the **Federal Register**):

- *Part A:* $157,749 × 40.21 × 0.399 = $2,530,891.83.
- *MA (before Jan. 1):* $157,749 × 40.21 × 0.044 × (1 − 0.0274) = $271,448.61.
- *MA (from Jan. 1):* $157,749 × 40.21 × 0.128 × (1 − 0.0233) = $792,997.55

Thus, the provider's total DGME payment for the post-merger period is: $2,530,891.83 + $271,448.61 + $792,997.55 = $3,595,337.99.

Subsequent Cost Reporting Periods (FYEs June 30, 2025, and June 30, 2026)

Direct GME payments for subsequent cost reporting periods are based on the provider's merged DGME payment rates and calculated according to the usual procedures. However, during the first two cost reporting periods following the merger (that is, FYE 06/30/25 and FYE 06/30/26), the rolling average must be calculated as though the hospitals had been merged for the entirety of their prior- and penultimate-year cost reporting periods. This ensures that the rolling average is representative of the training that occurs at the post-merger entity. (Note that this procedure applies whether the merger occurs in the middle of the surviving provider's cost reporting period, as in this example, or coincides with the start of a new cost reporting period.)

Accordingly, in this example, the prior- and penultimate-year FTE counts for the merged provider's cost reporting period ending June 30, 2025, would be determined as follows:

- *Prior year:* The prior cost reporting periods of Hospitals A and B are those ending on June 30, 2024, and October 31, 2023, respectively, and the prior-year FTE count is equal to the hospitals' combined weighted FTE counts,

[169] This assumes that the hospitals' prior- and penultimate-year CRPs are all standard 12-month periods. If not, the appropriate proration factors would need to be applied *prior to* summing the hospitals' respective FTE counts (since the proration factor would be different for each hospital).

determined based on data from the respective cost reports, consistent with the instructions to lines 12 and 13 of Worksheet E–4. (Note that Hospital B's FYE 10/31/23 is its terminating cost reporting period that began January 1, 2023.) Based on data from the applicable cost reports, and as shown in the table, Hospital A's individual FTE count (subject to the cap) during FYE 06/30/24 is 40 FTEs,[170] while Hospital B's individual FTE count (subject to the cap) during FYE 10/31/23 is 16.55 FTEs.[171]

Since Hospital B's prior cost reporting period was only 10 months long, its prior-year FTE count must be inflated to a 12-month equivalent, consistent with the policy clarified in the August 4, 2025 FY 2026 IPPS Final Rule (90 FR 36917): 16.55 ÷ 304 × 365 = 19.87 FTEs. Accordingly, the combined prior-year FTE count of the merged entity is: 40 + 19.87 = 59.87 FTEs.

• *Penultimate year:* The penultimate cost reporting periods of Hospitals A and B end on June 30, 2023, and December 31, 2022, respectively. Based on data from the applicable cost reports, and as shown in the table, the sum of the providers' individual FTE counts during those respective periods is equal to: 40 + 21.5 = 61.50 FTEs.

For the following cost reporting period ending June 30, 2026, the prior year-FTE count would be the merged provider's weighted DGME count, subject to the cap, as reported on the preceding cost report (FYE 06/30/2025; not shown); and the penultimate-year FTE count would be the hospitals' combined count as determined previously for the periods 07/01/23–06/30/24 and 01/01/23–10/31/23, that is, 59.87 FTEs. Beginning with the provider's FYE 06/30/2027 cost report, the rolling average would be calculated in accordance with normal procedure.

[170] I.e., the lesser of its DGME FTE cap of 40 or the actual weighted FTE count during this period, plus any podiatric or dental FTEs (not applicable to this example). Since the actual weighted FTE count is 14.28 + 27.72 = 42, the effective DGME count for the prior year is 40 FTEs. (Note that this prior year-FTE count would be equal to the placeholder value reported on line 11 of Worksheet E–4 of Hospital A's FYE 06/30/2024 cost report.)

[171] On Hospital B's FYE 10/31/23 cost report, the weighted FTE count of 16.55 on Worksheet E–4, line 8, represents 10 months of aggregate rotations allowable for purposes of DGME payment (9.75 during 01/01/23–06/30/23 and 6.80 during 07/01/23–10/31/23, as show in the table). Hospital B's DGME FTE cap of 25 FTEs, as reported on line 5, would also be prorated to reflect the short cost reporting period: 25 ÷ 365 × 304 = 20.82. Thus, Hospital B's prior year DGME FTE count is the lesser of 16.55 FTEs or its prorated DGME FTE cap of 20.82. (Note that this would be equal to the value reported on line 11 of Worksheet E–4 of Hospital B's FYE 10/31/23 cost report.)

b. Calculating IME Payments Following a Merger of Hospitals

As stated previously, when a hospital merger involves one or more teaching hospitals, the surviving provider experiences an influx of FTE residents from the terminating providers' residency programs and absorbs those hospitals' existing IME FTE caps and available beds, resulting in a change to its IRB ratio. The merged provider also experiences an increase in both Part A and simulated managed care DRG revenue.

The IME payment associated with a particular discharge reflects the payment rates applicable on the date the discharge occurs: if the discharge occurs prior to the effective date of the merger, the provider's individual IME payment rates are used; if the discharge occurs on or after the effective date of the merger, the IME adjustment is computed based on the combined payment rates of the merged providers. For cost reporting purposes, the surviving provider's total IME payment is based on the payment rate(s) applicable during each cost reporting period or portion thereof. Specifically, if the surviving hospital begins a new cost reporting period effective with the date of the merger, then total IME payment for that initial merged period and subsequent periods is determined based on the hospital's new, combined IME payment rates (with special consideration for the IRB ratio cap and rolling average during the first two cost reporting periods, as discussed further later in this section). However, if the merger takes place in the middle of the surviving hospital's cost reporting period, then the hospital's total IME payment for that period must reflect the different payment rates that apply before and after the merger.

Principles similar to what is discussed previously for direct GME apply to the calculation of the surviving provider's total IME payment amounts: that is, the MAC divides the cost reporting period into pre- and post-merger portions and calculates separate IME payments for each portion (according to the procedure described later in this section). In effect, the pre- and post-merger timeframes are treated as though they were individual short cost reporting periods, with virtual payment rates established for each period on the basis of the best available data for all providers and consistent with the FTE counting policies for non-12-month cost reporting periods as clarified in the August 4, 2025 FY 2026 IPPS Final Rule (90 FR 36915).

To facilitate the calculation of the IME payment amounts, the MAC determines separate IRB ratios for the pre- and post-merger portions of the cost reporting period, which involves determining separate FTE resident counts, FTE caps, rolling average FTE counts, and available bed counts, as well as the separate application of the IRB ratio cap. The resulting teaching adjustment factors are multiplied by DRG revenue to obtain total Part A and managed care IME payments for the respective timeframes. Specific procedures for determining these variables are discussed later in this section; as clarified previously for DGME, the pre-merger IME payment rates are based on data from the surviving provider only, while post-merger rates utilize data from all participating hospitals.

IRB Ratio—Numerator

The numerator of the current year IRB ratio (prior to the application of the IRB ratio cap) consists of the allowable IME FTE resident count, subject to the IME FTE cap and the three-year rolling average. These variables are determined for the pre- and post-merger periods as follows:

• *FTE resident count—Calculate separately for the pre-merger and post-merger periods:* To determine the partial year IME FTE counts, the sum of allowable rotations for all residents during the pre- and post-merger periods is divided by the actual number of days in each respective period, using data from the master rotation schedule or a similar source (see 90 FR 36915–16 for further details). For the *pre-merger* period, the count includes rotations allowable to the surviving provider only; for the *post-merger* period, the count includes the sum of all rotations allowable to the merged entity.[172]

• *FTE resident limit (cap)—Calculate separately for the pre-merger and post-merger periods:* Consistent with the FTE counting policies clarified in the August 4, 2025 FY 2026 IPPS Final Rule (90 FR 36917), it is not necessary to prorate the IME cap for non-12-month cost reporting periods; the partial year IME FTE resident limits are thus equal to the hospitals' original FTE caps, including any adjustments, without the application of a proration factor. The *pre-merger* limit is equal to the FTE cap of the surviving provider only, whereas the *post-merger* limit consists of the combined caps of all hospitals participating in the merger. The FTE

[172] If any of the merged hospitals is training displaced residents or residents in the initial years of a new program, those FTE counts would be determined according to the same procedure, and the FTEs would be added to the respective rolling averages calculated for the pre- and post-merger periods.

caps are applied to the partial year FTE resident counts according to the usual procedure as described in the August 4, 2025 FY 2026 IPPS Final Rule (90 FR 36917). If any of the merged hospitals has residents participating in a rural track program or residents counted under section 422, then those counts and caps are also determined and applied separately for the pre- and post-merger periods.

• *Rolling average FTE count—Calculate separately for the pre-merger and post-merger periods:* The current, prior- and penultimate-year IME counts, which serve as the inputs to the three-year rolling average, must also be determined separately for the pre- and post-merger timeframes. The current year FTE counts are calculated as explained previously, while the prior- and penultimate-year counts are obtained from lines 13 and 14 of Worksheet E, Part A, of the respective hospitals' cost reports (without the application of proration factors; see 90 FR 36917). The numerator of the rolling average for the *pre-merger* period consists of the FTE counts of the surviving provider only, while the *post-merger* numerator equals the combined FTE counts of the surviving and terminating providers, simulating what the effect of the merger would have been during the prior and penultimate cost reporting periods.

Note that a ''virtual'' rolling average must also be calculated for the merged provider's first two cost reporting periods beginning on or after the effective date of the merger: that is, the surviving and terminating providers' FTE counts must be combined as though they were merged during the prior and/or penultimate years. This procedure applies even if the merger occurred in the middle of the surviving provider's cost reporting period. Standard computation of the rolling average would resume in the third full post-merger cost reporting period.

Also note that the procedures for determining the partial year IME resident counts, caps, and rolling averages closely resemble the corresponding procedures described previously for direct GME, except that the IME variables are not adjusted relative to a standard 12-month cost reporting period, consistent with the policy clarified in the August 4, 2025 FY 2026 IPPS Final Rule (90 FR 36917).

IRB Ratio—Denominator (Available Beds)

The denominator of the current year IRB ratio (prior to the application of the IRB ratio cap) consists of the number of available beds, determined for the pre- and post-merger periods as follows:

• *Available bed count—Calculate separately for the pre-merger and post-merger periods:* Consistent with the methodology at 42 CFR 412.105(b), the available bed count is equal to the number of available bed days divided by the number of days in the virtual cost reporting period. For the *pre-merger* period, only the surviving provider's available bed days are counted. Thus, the pre-merger bed count is computed by counting the number of available bed days during the pre-merger period for the surviving provider and dividing by the number of days in the pre-merger period. For the *post-merger* period, the count includes the available bed days of the surviving and terminating providers, including any non-teaching hospitals participating in the merger.[173] Thus, the post-merger bed count is computed by counting the number of available bed days during the post-merger period for all participating hospitals, and dividing by the number of days in the post-merger period.

IRB Ratio Cap

Similar to the rolling average, the IRB ratio cap must be determined and applied separately for the pre- and post-merger timeframes, with the post-merger cap simulating what the effect of the merger would have been during the hospitals' preceding cost reporting periods:

• *Prior year numerator—Calculate separately for the pre-merger and post-merger periods:* The numerator of the IRB ratio cap is derived from the allowable IME FTE counts, subject to the IME FTE cap (but before application of the rolling average), reported on Worksheet E, Part A, line 12 of the respective hospitals' prior year cost reports: the numerator of the pre-merger cap consists of the FTE count of the surviving provider only (that is, the FTE count reported on line 12 of Worksheet E, Part A, of the surviving provider's prior year cost report), while the numerator of the post-merger cap equals the sum of the FTE counts of the surviving and terminating providers (that is, of the sum of the FTE counts reported on line 12 of Worksheet E, Part A, of each participating hospital's prior year cost report). If a hospital reports displaced residents or residents in the initial years of a new program, or if its FTE count has increased in the current year due to an affiliation agreement, then those residents are added to the prior year numerator, consistent with the instructions to line 20 of Worksheet E, Part A.

• *Prior year denominator—Calculate separately for the pre-merger and post-merger periods:* Similarly, the denominator of the IRB ratio cap is derived from the available bed counts reported on Worksheet E, Part A, line 4 of the respective hospitals' prior year cost reports: the denominator of the pre-merger cap includes the available beds of the surviving provider only, while the denominator of the post-merger cap, consists of the sum of the available beds of the surviving and terminating providers. The available bed counts are obtained from line 4 of Worksheet E, Part A, of the hospitals' prior year cost reports; if any non-teaching hospital participates in the merger, that hospital's bed count would be determined by dividing the prior year Worksheet S–3, Part I, column 3, line 14, plus line 32, by the number of days in the prior year cost reporting period.

For reasons analogous to those discussed elsewhere in this preamble and in the August 4, 2025 FY 2026 IPPS Final Rule (90 FR 36915), the components of the IRB ratio cap are derived without the application of a proration factor. Consistent with the usual policy under § 412.105(a)(1), the respective IRB ratios and IRB ratio caps, as determined previously, are compared, and the lesser values are used to calculate the teaching adjustment factors for the pre- and post-merger timeframes.

Similar to the rolling average, a ''virtual'' IRB ratio cap, consisting of the combined FTE and available bed counts of the surviving and terminating providers, must also be determined for the first cost reporting period beginning on or after the effective date of the merger, to simulate what the effect of the merger would have been during the prior year. This procedure applies whether the merger occurred in the middle of the surviving provider's cost reporting period. Standard computation of the IRB ratio cap would resume in the second full post-merger cost reporting period.

DRG Revenue and Total IME Payment

To calculate total IME payments, the pre- and post-merger teaching adjustment factors, as determined previously, are multiplied by the hospitals' Part A and simulated managed care DRG revenue for the respective timeframes:

[173] Available bed days of terminating non-teaching providers are included in the post-merger count because the IRB ratio represents teaching intensity across the entire merged entity. This is analogous to the inclusion of the inpatient days of non-teaching providers in the Medicare patient load for purposes of determining post-merger DGME payments.

• *DRG revenue (Part A and simulated managed care)—Calculate separately for the pre-merger and post-merger periods:* The teaching adjustment factor for the *pre-merger* period is multiplied by the pre-merger DRG revenue of the surviving provider only, while the teaching adjustment factor for the *post-merger* period is multiplied by the combined DRG revenue of the surviving and terminating providers. Both Part A and simulated managed care DRG revenue are accumulated on the Provider Statistical and Reimbursement (PS&R) Report based on claims submitted by the hospital.

Note that if the surviving and/or terminating providers count additional residents under the provisions of section 422, the total IME payments for those residents would be calculated separately for the pre- and post-merger periods, as applicable, using the formula multiplier of 0.66.

Since the cost report does not support the use of multiple IME payment rates for portions of a single cost year, the calculations described in this section must be performed off the cost report, and the results are summed together to determine total IME payment for the cost reporting period. Placeholder values based on the combined payment rates of the merged hospitals are reported as necessary on the applicable lines of Worksheet E, Part A.[174]

The following example illustrates the application of the policies described previously.

Example:

(*Note:* This example generally replicates the scenario outlined previously in the discussion of direct GME payment, adjusted as necessary to reflect the variables involved in the IME payment calculation.)

Consider a merger between teaching Hospitals A and B, effective November 1, 2023, where Hospital A is the surviving provider. Prior to the merger, Hospitals A and B had fiscal year ends of June 30 and December 31, respectively. As the surviving provider, Hospital A elects to maintain its existing fiscal year, and files a cost report for the period July 1, 2023, to June 30, 2024. Since different payment rates apply to the timeframes 07/01/23–10/31/23 and 11/01/23–06/30/24, two separate IME payment totals must be calculated for Hospital A's cost reporting period ending June 30, 2024. These calculations are performed off the cost report, and the total Part A and managed care payments are reported on lines 29 and 29.01, respectively, of Worksheet E, Part A of the hospital cost report (Form CMS–2552–10). Hospital B would file a terminating cost report for the period January 1, 2023–October 31, 2023, with IME payment determined in accordance with the rules applicable to short cost reporting periods, as clarified in the August 4, 2025 FY 2026 IPPS Final Rule.

The following table summarizes the data that will be used to calculate Hospital A's pre- and post-merger IME payments, based on the surviving and terminating providers' historical cost reports, as well as other sources such as rotation schedules and PS&R reports:

Data Point	Hospital A	Hospital B	Source
IME FTE resident count: 1/1/23 – 6/30/23	[not shown]	[20.00]	Rotation schedule or similar documentation
IME FTE resident count: 7/1/23 – 10/31/23	42.00	[20.00]	Rotation schedule or similar documentation
IME FTE resident count: 11/1/23 – 6/30/24	42.00	20.00	Rotation schedule or similar documentation
Prior year IME FTE resident count	40.00	21.50	Cost report data
Penultimate year IME FTE resident count	39.00	19.25	Cost report data
IME FTE resident limit (including applicable adjustments)	40.00	25.00	Cost report data
Available bed count: 1/1/23 – 6/30/23	[not shown]	[250]	Hospital census data
Available bed count: 7/1/23 – 10/31/23	300	[250]	Hospital census data
Available bed count: 11/1/23 – 6/30/24	300	250	Hospital census data
Prior year available bed count	300	250	Cost report data
Part A DRG revenue: 7/1/23 – 10/31/23	$15,625,000	[not shown]	PS&R report type 110
Part A DRG revenue: 11/1/23 – 6/30/24	$30,625,000	$25,375,000	PS&R report type 110
Managed care DRG revenue (simulated): 7/1/23 – 10/31/23	$5,187,500	[not shown]	PS&R report type 118
Managed care DRG revenue (simulated): 11/1/23 – 6/30/24	$10,125,000	$13,750,000	PS&R report type 118

Notes:

• Since the hospitals are merged effective November 1, 2023, Hospital B technically does not have a separate FTE resident count, separate available bed count, or separate DRG revenue during the period 11/01/23–06/30/24; post-merger data for Hospital B are broken out for illustrative purposes only. In addition, Hospital B's pre-merger FTE counts and available bed counts for its 2023 cost year are printed in brackets since they do not factor into the merged provider's IME payment rates for FYE 06/30/24. However, note that Hospital B's pre-merger FTE and bed counts will be used to calculate the rolling average and the IRB ratio cap for the merged provider's subsequent cost reports, as explained further below. Hospital B would file its terminating cost report and receive IME payment for the period 01/01/23–10/31/23 in accordance with the rules applicable to short cost reporting periods.

• The prior- and penultimate-year FTE counts are required to calculate the three-year rolling averages for the pre- and post-merger periods. Hospital A's prior- and penultimate-year cost reporting periods end on June 30, 2023, and June 30, 2022, respectively; Hospital B's cost reporting periods end on December 31, 2022, and December 31, 2021.

• The hospitals' IME FTE resident limits include any applicable adjustments, such as those for new programs or slots received under various statutory provisions. For this example, we assume that neither hospital has received additional residency slots under section 422.

• As explained previously, the available bed count is equal to the number of available bed days divided by the number of days in the cost reporting period (or virtual period, as here). For this example, we assume that each hospital's available bed count remains constant over time.

Pre-Merger IME Payment (July 1, 2023, to October 31, 2023)

To calculate the surviving provider's IME payment for the pre-merger period 07/01/23–10/31/23, the following variables are determined based on Hospital A's individual records for the relevant timeframe:

• *FTE resident count:* As indicated in the table noted previously, Hospital A's IME FTE resident count during the period 07/01/23–10/31/23 is 42.00 FTEs, based on data from Hospital A's rotation schedules or similar documentation and determined according to the methodology clarified in the August 4, 2025 FY 2026 IPPS Final Rule.

• *FTE resident limit:* Hospital A's IME FTE resident limit is 40.00, which is less than the actual IME count of 42 FTEs during this timeframe.

[174] For example, the FTE caps and adjustments of the surviving and terminating providers would be added and reported on the applicable FTE cap lines as though the providers had been merged for the entire cost reporting period.

Accordingly, Hospital A's effective IME resident count for the pre-merger period is 40.00 FTEs. (Note that neither the IME FTE count nor the IME FTE cap is prorated for the short virtual cost reporting period.)

- *Rolling average FTE count:* As shown in the table, Hospital A's prior- and penultimate-year IME FTE counts are 40 and 39 FTEs, respectively. (Again, note that these values are not prorated for the shortened cost reporting period.) The rolling average therefore equals: (40 + 40 + 39) ÷ 3 = 39.67 FTEs.
- *IRB ratio:* The unadjusted IRB ratio for the pre-merger period is equal to the rolling average FTE count divided by the count of available beds: 39.67 ÷ 300 = 0.132.
- *IRB ratio cap:* The IRB ratio cap is equal to the prior year IME FTE count (subject to the cap but before application of the rolling average) divided by the count of available beds: 40 ÷ 300 = 0.133, which is greater than the actual IRB ratio of 0.132. Accordingly, Hospital A's effective IRB ratio for the pre-merger period is 0.132.
- *DRG revenue:* Hospital A's total Part A DRG revenue during the pre-merger period is $15,625,000, and its simulated managed care DRG revenue (based on shadow claims submitted during the same period) is $5,187,500.

Based on the data noted previously, the IME teaching adjustment factor for Hospital A during the pre-merger period 07/01/23–10/31/23 equals: $1.35 \times ((1 + 0.132)^{0.405} - 1) = 0.07$. Accordingly, Hospital A's total IME payment amounts during this period are:

- *Part A IME:* 0.07 × $15,625,000 = $1,093,750.
- *Managed care (MA) IME:* 0.07 × $5,187,500 = $363,125.

Thus, Hospital A's total IME payment for the pre-merger period is: $1,093,750 + $363,125 = $1,456,875.

Post-Merger IME Payment (November 1, 2023, to June 30, 2024)

For the post-merger period, the same payment variables are calculated using data from the records of both the surviving and terminating providers:

- *FTE resident count:* The combined IME FTE resident count of Hospitals A and B (that is, the newly merged entity) for the period 11/01/23–06/30/24 is 42 + 20 = 62.00 FTEs.
- *FTE resident limit:* The merged provider's IME combined IME cap is 40 + 25 = 65 FTEs, which is greater than the actual IME count of 62. Accordingly, the provider's effective IME resident count for the post-merger period is 62.00 FTEs.
- *Rolling average FTE count:* To determine a representative three-year rolling average for the post-merger timeframe, we must treat Hospitals A and B as though they had been merged during their preceding two cost reporting periods. Accordingly, the prior-year FTE count used in the rolling average calculation is equal to the combined prior-year FTE counts of the two hospitals: 40 + 21.5 = 61.50 FTEs; and the penultimate-year FTE count is equal to: 39 + 19.25 = 58.25 FTEs. The rolling average therefore equals: (62 + 61.5 + 58.25) ÷ 3 = 60.58 FTEs.
- *IRB ratio:* The unadjusted IRB ratio for the post-merger period is equal to the rolling average FTE count divided by the total count of available beds at both hospitals: 60.58 ÷ (300 + 250) = 0.11.
- *IRB ratio cap:* The IRB ratio cap is equal to the combined prior year IME FTE count (subject to the combined cap but before application of the rolling average) divided by the total count of available beds: (40 + 21.5) ÷ (300 + 250) = 0.112, which is greater than the actual IRB ratio of 0.11. Accordingly, the merged provider's effective IRB ratio for the post-merger period is 0.11.
- *DRG revenue:* The merged provider's total Part A DRG revenue during the post-merger period is $30,625,000 + $25,375,000 = $56,000,000, and its simulated managed care DRG revenue (based on shadow claims submitted during the same period) is $10,125,000 + $13,750,000 = $23,875,000.

Based on the data noted previously, the IME teaching adjustment factor for the merged provider during the post-merger period 11/01/23–06/30/24 equals: $1.35 \times ((1 + 0.11)0.405–1) = 0.058$. Accordingly, the provider's total IME payment amounts during this period are:

- *Part A IME:* 0.058 × $56,000,000 = $3,248,000.
- *Managed Care (MA) IME:* 0.058 × $23,875,000 = $1,384,750.

Thus, the provider's total IME payment for the post-merger period is: $3,248,000 + $1,384,750 = $4,632,750.

Subsequent Cost Reporting Periods (FYEs June 30, 2025, and June 30, 2026)

Total IME payments for subsequent cost reporting periods are based on the provider's merged IME payment rates and calculated according to the usual procedures. However, during the first cost reporting period following the merger (that is, FYE 06/30/25), the IRB ratio cap must be calculated as though the hospitals had been merged for the entirety of their prior cost reporting periods. In addition, as for direct GME, during the first two cost reporting periods following the merger (that is, FYE 06/30/25 and FYE 06/30/26), the rolling average must be calculated as though the hospitals had been merged for the entirety of their prior- and penultimate-year cost reporting periods. This ensures that both the IRB ratio cap and the rolling average are representative of the training that occurs at the post-merger entity. (Note that this procedure applies whether the merger occurs in the middle of the surviving provider's cost reporting period, as in this example, or coincides with the start of a new cost reporting period.)

Accordingly, in this example, the IRB ratio cap for the merged provider's cost reporting period ending June 30, 2025, would be determined as follows:

- *Prior-year numerator:* The prior cost reporting periods of Hospitals A and B are those ending on June 30, 2024, and October 31, 2023, respectively, and the prior-year FTE count is equal to the hospitals' combined IME FTE counts, determined based on data from the respective cost reports, consistent with the instructions to line 20 of Worksheet E, Part A. (Note that Hospital B's FYE 10/31/23 is its short terminating cost reporting period that began January 1, 2023.) Based on the data from the applicable cost reports, and as shown in the table, Hospital A's individual FTE count (subject to the cap but before application of the rolling average) during FYE 06/30/24 is 40 FTEs, while Hospital's B's individual FTE count (subject to the cap but before application of the rolling average) during FYE 10/31/23 is 20 FTEs.[175] Accordingly, the combined prior year numerator is equal to 40 + 20 = 60.00 FTEs.
- *Prior-year denominator:* As shown in the table, the hospitals' total available bed count during their prior cost reporting periods is equal to 300 + 250 = 550 beds.

Thus, the IRB ratio cap for the merged provider during this period is: 60 ÷ 550 = 0.11. Beginning with the provider's FYE 06/30/2026 cost report, the IRB ratio cap would be calculated in accordance with normal procedure.

For a demonstration of how to calculate the rolling average for the cost reporting periods ending on June 30, 2025, and June 30, 2026, refer to the direct GME example earlier in this preamble. Beginning with the provider's

[175] I.e., the lesser of each hospital's IME FTE cap or actual IME FTE count, plus any podiatric and dental FTEs (not applicable to this example), during the respective periods. In this example, Hospital A's prior year numerator would be equal to the placeholder value reported on line 12 of Worksheet E, Part A, of its FYE 06/30/2024 cost report; while Hospital B's prior year numerator would be equal to the value reported on line 12 of Worksheet E, Part A, of its FYE 10/31/2023 cost report.

FYE 06/30/2027 cost report, the rolling average would be calculated in accordance with normal procedure.

Comment: Commenters supported and appreciated the transparency regarding CMS's clarification of the payment methodology following hospital mergers.

Response: We appreciate the commenters' support and are finalizing our clarified policy.

5. Notice of Closure of Teaching Hospitals and Opportunity To Apply for Available Slots

a. Background

Section 5506 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, ''Affordable Care Act''), authorizes the Secretary to redistribute residency slots after a hospital that trained residents in an approved medical residency program closes. Section 5506 of the Affordable Care Act instructs the Secretary to establish a process by regulation that redistributes slots from teaching hospitals that close to hospitals that meet certain criteria, with priority given to certain hospitals including those located in the same Core Based Statistical Area (CBSA), in a contiguous CBSA or in the same state as the closed hospital.

Specifically, section 5506 of the Affordable Care Act amended the Act by adding subsection (vi) to section 1886(h)(4)(H) of the Act and modifying language at section 1886(d)(5)(B)(v) of the Act. These changes instruct the Secretary to establish a process to increase the FTE resident caps at other hospitals based upon the FTE resident caps at teaching hospitals that closed on or after March 23, 2008. In the CY 2011 Outpatient Prospective Payment System (OPPS) final rule with comment period (75 FR 72264), we established regulations at 42 CFR 413.79(o) and an application process for qualifying hospitals to apply to CMS to receive direct GME and IME FTE resident cap slots from the hospital that closed. We made certain additional modifications to § 413.79 in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434), and we made changes to the section 5506 application process in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50122 through 50134). The procedures we established apply to teaching hospitals that closed between March 23, 2008, and August 3, 2010, and to teaching hospitals that close after August 3, 2010 (75 FR 72215).

b. Notice of Closure of Insight Hospital and Medical Center Trumbull Located in Warren, OH, and the Application Process—Round 30

CMS learned of the closure of Insight Hospital and Medical Center Trumbull, located in Warren, OH (CCN 360055). Accordingly, we are providing notice of the closure of this teaching hospital and initiating another round of the application and selection process to redistribute the closed hospital's FTE resident caps. This round will be the 30th round (''Round 30'') of the application and selection process. Table V.F.01 contains the identifying information for the closed teaching hospital and its IME and direct GME FTE resident caps, which are part of the Round 30 application process under section 5506 of the Affordable Care Act.

TABLE V.F.01: INSIGHT HOSPITAL AND MEDICAL CENTER TRUMBULL FTE RESIDENT CAPS

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap	Direct GME FTE Resident Cap
360055	Insight Hospital and Medical Center Trumbull	Warren, OH	49660	October 10, 2025	75.11[1]	76.93 [2]

1 Insight Hospital and Medical Center Trumbull's 1996 IME FTE resident cap is 75.11.
2 Insight Hospital and Medical Center Trumbull's 1996 DGME FTE resident cap is 76.93.

c. Notice of Closure of M Health Fairview St. Joseph's Hospital Located in Saint Paul, MN, and the Application Process—Round 31

CMS learned of the closure of M Health Fairview St. Joseph's Hospital, located in Saint Paul, MN (CCN 240063). Accordingly, we are providing notice of the closure of this teaching hospital and initiating another round of the application and selection process to redistribute the closed hospital's FTE resident slots. This round will be the 31st round (''Round 31'') of the application and selection process. Table V.F.02 contains the identifying information for the closed teaching hospital and its IME and direct GME FTE resident caps, which are part of the Round 31 application process under section 5506 of the Affordable Care Act.

TABLE V.F.02: M HEALTH FAIRVIEW ST. JOSEPH'S HOSPITAL FTE RESIDENT CAPS

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap (including +/- MMA Sec. 422[1] adjustments)	Direct GME FTE Resident Cap (including +/- MMA Sec. 422 adjustments)
240063	M Health Fairview St. Joseph's Hospital	Saint Paul, MN	33460	July 1, 2022	15.18 – 1.82 sec. 422 reduction = 13.36[2]	15.27 – 1.89 sec. 422 reduction = 13.38 [3]

1 Section 422 of the MMA, Public Law 108–173, redistributed unused IME and direct GME residency slots effective July 1, 2005.
2 M Health Fairview St. Joseph's Hospital's 1996 IME FTE resident cap is 15.18. Under section 422 of the MMA, the hospital received a reduction of 1.82 to its IME FTE cap = 15.18 – 1.82 = 13.36.
3 M Health Fairview St. Joseph's Hospital's 1996 DGME FTE resident cap is 15.27. Under section 422 of the MMA, the hospital received a reduction of 1.89 to its DGME FTE cap = 15.27 – 1.89 = 13.38.

d. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 of the Affordable Care Act is 90 days following notice to the public of a hospital closure (77 FR 53436). Therefore, hospitals that wish to apply for and receive slots from the previously noted hospitals' FTE resident caps must submit Round 30 and 31 applications using the electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™) no later than October 29, 2026. The Section 5506 application can be accessed at: *https://mearis.cms.gov/public/home.*

CMS will only accept Round 30 and 31 applications submitted via MEARIS™. Applications submitted through any other method will not be considered. Within MEARIS™, we have built in several resources to support applicants:

- Please refer to the ''Resources'' section for guidance regarding the application submission process at: *https://mearis.cms.gov/public/resources.*
- Technical support is available under ''Useful Links'' at the bottom of the MEARIS™ web page.
- Application related questions can be submitted to CMS using the form available under ''Contact'' at: *https://mearis.cms.gov/public/resources.*

Application submission through MEARIS™ will not only help CMS track applications and streamline the review process, but it will also create efficiencies for applicants when compared to a paper submission process.

We have not established a deadline for when CMS will issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we review all applications received through MEARIS™ by the application deadline and notify applicants of our determinations as soon as possible.

We refer readers to the CMS Direct Graduate Medical Education (DGME) website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/direct-graduate-medical-education-dgme.* Hospitals should access this website for a list of additional section 5506 guidelines for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

G. Reasonable Cost Payment for Nursing and Allied Health Education Programs (§ 413.85 and § 413.87)

1. General

Under section 1861(v) of the Act, Medicare has historically paid providers for Medicare's share of the costs that providers incur in connection with approved educational activities. The costs of these activities are excluded from the definition of ''inpatient hospital operating costs'' and are not included in the calculation of payment rates for hospitals or hospital units paid under the IPPS, IRF PPS, or IPF PPS, and are excluded from the rate-of-increase ceiling for certain facilities not paid on a PPS. These costs are separately identified and ''passed through'' (that is, paid separately on a reasonable cost basis).

Under the existing regulations at 42 CFR 413.85, approved nursing and allied health (NAH) education programs must meet State licensure requirements or be accredited by a recognized national professional organization. Additionally, an approved NAH education program must be operated by a provider. The most recent substantive rulemakings on these regulations were in the January 12, 2001, final rule (66 FR 3358 through 3374), and in the August 1, 2003, final rule (68 FR 45423 and 45434).

2. Medicare Advantage Nursing and Allied Health Education Payments

Section 541 of the Balanced Budget Refinement Act (BBRA) of 1999 (codified at section 1886(l) of the Act) provides for additional payments to hospitals for costs of nursing and allied health (NAH) education associated with services to Medicare+Choice (now called Medicare Advantage) (MA) [176] enrollees. Hospitals that operate approved NAH education programs and receive Medicare reasonable cost reimbursement for these programs (NAH Part A payments) may receive additional payments to account for MA enrollees. Section 541 of the BBRA limits total spending under the provision for MA enrollees to no more than $60 million in any calendar year (CY). (In this document, we refer to the total amount of $60 million or less as the payment ''pool.'' We also note that section 4143 of Public Law 117–328 waived the $60 million limit for calendar years 2010 through 2019: see August 28, 2023, Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2024 Rates at 88 FR 59058.)

Section 541 of the BBRA also provides that direct graduate medical education (GME) payments for MA utilization (MA direct GME payments) be reduced to the extent CMS makes additional payments for NAH education programs for MA utilization (NAH MA payments). The provisions of section 541 are effective for portions of cost reporting periods occurring in a calendar year on or after January 1, 2000.

Section 512 of the Benefits Improvement and Protection Act (BIPA) of 2000 changed the formula for determining the additional amounts to be paid to hospitals for MA NAH costs. Under section 541 of the BBRA, the additional payment amount was determined based on the proportion of each individual hospital's NAH education payment to total NAH education payments made to all hospitals. However, this formula did not account for a hospital's specific MA utilization. Section 512 of the BIPA revised this payment formula to specifically account for each hospital's MA utilization. This provision was effective for portions of cost reporting periods occurring in a calendar year beginning with CY 2001.

The regulations at 42 CFR 413.87 implement these statutory provisions. We first implemented the BBRA NAH MA provision in the August 1, 2000 IPPS interim final rule with comment period (IFC) (65 FR 47036 through 47039), and we subsequently implemented the BIPA provision in the August 1, 2001 IPPS final rule (66 FR 39909 and 39910). In those rules, we outlined the qualifying conditions for a hospital to receive the NAH MA payment, how we would calculate the NAH MA payment pool, and how a qualifying hospital would calculate its ''share'' of payment from that pool. Determining a hospital's NAH MA payment essentially involves applying a ratio of the hospital-specific NAH Part A payments, total inpatient days, and MA inpatient days to national totals of those same variables from cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year. The formula is as follows:

(((Hospital NAH Part A payment/
Hospital Part A Inpatient Days) *
(Hospital MA Inpatient Days))
divided by
((National NAH Part A payment/
National Part A Inpatient Days) *

[176] The M+C program in Part C of Medicare was renamed the Medicare Advantage (MA) Program under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which was enacted in December 2003.

(National MA Inpatient Days))) * Current Year Payment Pool.

In determining the total national amounts for NAH Part A payment, Part A inpatient days, and MA inpatient days, we note that section 1886(l) of the Act, as added by section 541 of the BBRA, gives the Secretary the discretion to ''estimate'' the national components of the formula noted previously. For example, section 1886(l)(2)(A) of the Act states that the Secretary shall estimate the ratio of payments for all hospitals for portions of cost reporting periods occurring in the year under section 1886(h)(3)(D) of the Act to total direct GME payments estimated for the same portions of periods under section 1886(h)(3) of the Act.

Accordingly, we stated in the August 1, 2000, IFC (65 FR 47038) that each year, we would determine and publish in a final rule the total amount of NAH education payments made across all hospitals during the fiscal year 2 years prior to the current calendar year. We would use the best available cost reporting data for the applicable hospitals from the Hospital Cost Report Information System (HCRIS) for cost reporting periods in the fiscal year that is 2 years prior to the current calendar year.

To calculate the pool, in accordance with section 1886(l) of the Act, we stated that we would estimate a total amount for each calendar year, not to exceed $60 million (65 FR 47038). To calculate the proportional reduction to MA direct GME payments, we stated that the percentage is estimated by calculating the ratio of the NAH MA payment pool for the current calendar year to the projected total MA direct GME payments made across all hospitals for the current calendar year. We stated that the projections of MA direct GME and Part A direct GME payments are based on the best available cost report data from the HCRIS (for example, for CY 2000, the projections are based on the best available cost report data from FY 1998 HCRIS), and these payment amounts are increased using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for MA direct GME and the Consumer Price Index (CPI–U) increases for Part A direct GME). We also stated that we would publish the applicable percentage reduction each year in the IPPS proposed and final rules (65 FR 47038).

Thus, in the August 1, 2000, IFC, we described our policy regarding the timing and source of the national data components for the NAH MA payment and the percent reduction to the MA direct GME payments, and we stated that we would publish the rates for each calendar year in the IPPS proposed and final rules. While the rates for CY 2000 were published in the August 1, 2000, IFC (see 65 FR 47038 and 47039), the rates for subsequent CYs were only issued through Change Requests (CRs) (CR 2692, CR 11642, CR 12407). After issuance of the CY 2019 rates in CR 12407 on August 19, 2021, we reviewed our update procedures, and were reminded that the August 1, 2000 IFC states that we would publish the NAH MA rates and MA direct GME percent reduction every year in the IPPS rules.

Accordingly, for CY 2020 and CY 2021we proposed and finalized the NAH MA rates in the FY 2023 IPPS/LTCH PPS proposed and final rules (see 87 FR 49073, August 10, 2022). We stated that for CYs 2022 and after, we would similarly propose and finalize the respective NAH MA rates and MA direct GME percent reductions in subsequent IPPS/LTCH PPS rulemakings (see 87 FR 49073, August 10, 2022).

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19520 April 14, 2026), we proposed the rates for CY 2025. Consistent with the use of HCRIS data for past calendar years, we proposed to use data from cost reports ending in FY 2023 HCRIS (the fiscal year that is 2 years prior to CY 2025) to compile these national amounts: NAH Part A payments, Part A Inpatient Days, and MA Inpatient Days.

For the proposed rule calculations, we accessed the FY 2023 HCRIS data from the third quarterly HCRIS update of 2025. However, to calculate the ''pool'' and the MA direct GME percent reduction, we projected Part A direct GME payments and MA direct GME payments for the current calendar year, which in the proposed rule is CY 2025, based on the ''best available cost report data from the HCRIS'' (65 FR 47038) for CY 2025. Next, consistent with the method we described previously in the August 1, 2000, IFC, we increased these payment amounts from midpoint to midpoint of the appropriate calendar year using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for MA direct GME, and the Consumer Price Index-Urban (CPI–U) increases for Part A direct GME). For the proposed rule, the direct GME projections for CY 2025 were based on the third quarterly update of CY 2023 HCRIS data, adjusted for the CPI–U and for increasing MA enrollment up to CY 2025.

The proposed national rates and percentages for CY 2025 and their data sources, are set forth in this table. We stated in the proposed rule that we intend to update these numbers in the FY 2027 final rule based on the latest available cost report data.

Proposed CY 2025 NAH MA Rates	Proposed CY 2025	SOURCE
NAH Part A Payments	$288,934,483	Cost reports ending in FY 2023 HCRIS
Part A Inpatient Days	74,710,041	Cost reports ending in FY 2023 HCRIS
MA Inpatient Days	17,735,281	Cost reports ending in FY 2023 HCRIS
Part A Direct GME	$3,066,894,317	CY 2023 HCRIS + CPI-U + MA enrollment
MA Direct GME	$2,575,061,976	CY 2023 HCRIS + CPI-U + MA enrollment
Pool (not to exceed $60 million)	$60,000,000	((MA DGME /Part A DGME) * (NAH Part A Payments))
Percent Reduction to MA DGME Payments	2.33%	Pool/MA direct GME

Comment: We received several comments in support of CMS using the most recent available data for NAH education payment calculations, saying current data helps ensure accurate reimbursement and continued investment in the healthcare workforce pipeline. We also received a comment that was out of scope, urging CMS not to adopt NAH MA payment, reimbursement, or cost-reporting policies that would reduce reimbursable NAH costs, create unnecessary compliance risk, or destabilize provider-based workforce training programs.

Response: We appreciate the commenters' support for the publication of our most recent available data for NAH MA payments. As the NAH MA payment is statutory, we did not and

cannot make any proposals to not adopt NAH MA payment policies.

After consideration of the public comments, we are finalizing our methodology and updating the numbers in the above chart for this FY 2027 final rule based on the latest available cost report data. For this final rule, we accessed the FY 2023 HCRIS data from the first quarterly HCRIS update of 2026, which is the ''best available cost report data from the HCRIS'' (consistent with 65 FR 47038). To calculate the NAH MA pool and the MA direct GME percent reduction, we project Part A direct GME payments and MA direct GME payments for the current calendar year (CY 2025), based on this best available data. Next, in accordance with the method we described previously in the August 1, 2000, IFC, we increase these payment amounts from midpoint to midpoint of the appropriate calendar year using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for MA direct GME, and the CPI–U increases for Part A direct GME). For this final rule, the direct GME projections for CY 2025 are based on the first quarterly update of 2026 for CY 2023 HCRIS, adjusted for the CPI–U and for increasing MA enrollment up to CY 2025.

The final national rates and percentages for CY 2025 and their data sources, are set forth in this table.

Final CY 2025 NAH MA Rates	Final CY 2025	SOURCE
NAH Part A Payments	$280,527,548	Cost reports ending in FY 2023 HCRIS
Part A Inpatient Days	74,837,287	Cost reports ending in FY 2023 HCRIS
MA Inpatient Days	17,756,856	Cost reports ending in FY 2023 HCRIS
Part A Direct GME	$3,080,838,356	CY 2023 HCRIS + CPI-U + MA enrollment
MA Direct GME	$2,563,924,098	CY 2023 HCRIS + CPI-U + MA enrollment
Pool (not to exceed $60 million)	$60,000,000	((MA DGME /Part A DGME) * (NAH Part A Payments))
Percent Reduction to MA DGME Payments	2.34%	Pool/MA direct GME

3. Requirements To Prohibit Unlawful Discrimination in Approved Nursing and Allied Health Education Programs and Accreditation Standards

Hospitals may receive nursing and allied health education pass-through payments for costs incurred in connection with approved programs. The statute does not explicitly define ''approved programs'' for purposes of NAH education payments. Instead, section 1886(l)(1) of the Act refers to ''approved educational activities for nurse and allied health professional training''. Under the existing regulations at § 413.85(e), CMS considers an activity to be an ''approved nursing and allied health education program'' if the program is a planned program of study that is licensed by State law, or if licensing is not required, is accredited by the recognized national professional organization for the particular activity. The regulations note that such national accrediting bodies include, but are not limited to, the Commission on Accreditation of Allied Health Education Programs, the National League of Nursing Accrediting Commission, the Association for Clinical Pastoral Education Inc., and the American Dietetic Association.

In the CY 2026 OPPS/ASC final rule (90 FR 54024 through 54027), for purposes of Medicare GME payment, we finalized changes to the definition of ''approved medical residency program'' and equivalent terms, to state that accrediting organizations may not use accreditation criteria that promote or encourage discrimination on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. Our intent in finalizing this policy was to ensure that accreditation for approved medical residency programs would comply with applicable laws related to race-based admission policies and to improve the accreditation process. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19504), we indicated that we believe additional requirements are necessary to ensure that, even in the absence of discriminatory accreditation standards, individual programs do not implement policies that constitute unlawful discrimination under Federal law. Therefore, we proposed a similar policy that would apply to approved medical residency programs themselves.

As we explained elsewhere in the proposed rule (91 FR 19520), we believe that similar concerns related to unlawful and discriminatory accreditation standards and program requirements also apply to approved nursing and allied health education programs. Therefore, we proposed to require that, in addition to meeting other applicable requirements, individual NAH education programs and NAH accrediting bodies must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. These policies would be effective October 1, 2026, and would be codified under proposed new 42 CFR 413.84, which we proposed to cross-reference as necessary in the regulations at § 413.85.

Separately, we proposed to remove from § 413.85(e) the language specifying individual accrediting organizations of nursing and allied health education programs. In the January 12, 2001 Payment for Nursing and Allied Health Education final rule (66 FR 3365 through 3366), we eliminated the list of nursing and allied health specialty programs and respective accrediting bodies at § 413.85(e) and instead established the general requirement that an approved NAH program must be a planned program of study that is licensed by State law, or if licensing is not required, is accredited by the recognized national professional organization for the particular activity. Nevertheless, we continued to provide examples of recognized accrediting bodies in the regulations text, specifically, the Commission on Accreditation of Allied Health Education Programs, the National League of Nursing Accrediting Commission, the Association for

Clinical Pastoral Education Inc., and the American Dietetic Association. While it is our understanding that these organizations continue to accredit programs in their respective specialties, we indicated that we no longer believe it is useful to reference a limited number of specific accreditors in the regulations, given the evolving nature of the field and the large number of additional accrediting bodies active across various disciplines.

In section V.F.2. of this final rule, we combine our summary of and responses to the comments we received on the proposed requirements to prohibit unlawful discrimination by approved medical residency programs, approved NAH education programs, and NAH accrediting bodies, and explain our final policies. Below, we respond to several comments we received addressing issues specific to the proposals concerning nursing and allied health education programs and accreditors.

Comment: A few commenters expressed concern about the accreditation-related language at proposed 42 CFR 413.84(c), and particularly proposed § 413.84(c)(2), which would specify that approved nursing and allied health education programs include programs that would be accredited except for the accrediting agency's reliance upon an accreditation standard that requires an entity to perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training, regardless of whether the standard provides exceptions or exemptions. The commenters requested clarification that NAH programs would not lose eligibility for pass-through payment due to good-faith reliance on existing accreditation requirements, State law, or established clinical training standards. Commenters also stated that CMS should delay implementation of any accreditation-related change until it has issued subregulatory guidance and allowed programs sufficient time to assess their accreditation and affiliation agreements.

Response: The proposed regulations text at § 413.84(c)(2) is a conforming change to align the definition of approved nursing and allied health education programs with the definition of an approved medical residency program. We note that the exception for programs that would be accredited except for the accrediting agency's reliance upon an accreditation standard that requires an entity to perform or otherwise provide for induced abortions is a longstanding element of the definition of an ''approved medical residency program'' under existing § 413.75(b). The exception was finalized in the August 30, 1996 Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1997 Rates final rule (61 FR 46213) to implement the requirements of section 245 of the Public Health Service Act (commonly referred to as the Coats-Snowe amendment), which prohibits certain abortion-related discrimination by the Federal Government and State and local governments. In addition to a ''post-graduate physician training program,'' section 245(a)(3) of the PHS Act refers to ''any other program of training in the health professions.'' The proposed conforming amendment to the regulations is therefore necessary to comply with the requirements of the statute. We further note that the statutory exception is intended to protect training programs that would be accredited except for the accrediting agency's reliance on certain accreditation standards. Accordingly, we do not believe that this requirement would jeopardize the accreditation status or funding eligibility of existing nursing and allied health education programs.

Comment: A few commenters expressed concern regarding our proposal to remove from § 413.85(e) the language specifying individual accrediting organizations of nursing and allied health education programs, stating that the removal of the examples could create uncertainty for hospitals and auditors and that CMS should provide a clear standard for determining whether an accrediting body is the recognized national professional organization for the activity. The commenters recommended that we should finalize this proposal only if we also provide clear guidance confirming that programs accredited by nationally recognized professional accrediting organizations are recognized as approved NAH education programs under the regulation.

Response: We disagree that the removal of the specific examples of nationally recognized accreditors from § 413.85(e) will create uncertainty regarding identification of approved NAH education programs. While many programs are accredited by organizations other than those currently listed in the regulations text, we are not aware of, nor have the commenters cited, instances in which a program has been disapproved because of uncertainty over whether an accreditor is nationally recognized. We therefore consider the proposal to be a technical correction to the regulations rather than a substantive change in policy.

After consideration of the public comments, we are finalizing, without modification, our proposal to codify the anti-discrimination requirements under new 42 CFR 413.84 and to cross-reference that section as necessary in the regulations at § 413.85. We are also finalizing, without modification, our proposal to amend § 413.85(e) to remove the language specifying individual accrediting organizations of nursing and allied health education programs. These changes will be effective October 1, 2026.

4. Changes to the Regulations for Determining the Net Cost of Nursing and Allied Health Education Programs and Clarifications Regarding the Correct Allocation of Overhead Costs

a. Overview of Existing Regulations and Cost Report Instructions

In the January 12, 2001, final rule (66 FR 3358) ''Medicare Program; Payment for Nursing and Allied Health Education,'' we codified the payment regulations regarding NAH education program costs at 42 CFR 413.85. With regard to determining the net costs that are allowed for ''pass-through'' payment, § 413.85(d)(2)(i) states that the net cost of approved educational activities is determined by deducting the revenues that a provider receives from tuition and student fees from the provider's total allowable educational costs that are directly related to approved educational activities. Section 413.85(d)(2)(ii) further states that a provider's total allowable educational costs are those costs incurred by the provider for trainee stipends, compensation of teachers, and other costs of the activities as determined under the Medicare cost-finding principles in § 413.24. These costs do not include patient care costs, costs incurred by a related organization, or costs that constitute a redistribution of costs from an educational institution to a provider or costs that have been or are currently being provided through community support. Worksheet A of the Medicare cost report captures the direct costs associated with a hospital's various cost centers, including its NAH education programs. The direct costs associated with operating a hospital's approved NAH education programs are reported on Worksheet A, line 20 (nursing programs) and line 23 (paramedical/allied health education programs). The instructions to these lines state—

Lines 20 and 23—If you have an approved nursing or allied health education program that meets the criteria of 42 CFR 413.85(e), classroom and clinical portions of the costs

may be allowable as pass-through costs as defined in 42 CFR 413.85(d)(2). (CMS Pub. 15–2, section 4013.)

In addition to direct costs, hospitals also incur indirect or overhead costs associated with their operations. Overhead costs are assigned to the general service cost centers on lines 1 through 23 of Worksheet A, which are a hospital's non-patient care/non-revenue producing cost centers, and which include the administrative & general (A&G) cost center on line 5. The general cost report instructions for Worksheet A state—

Lines 1 through 23—These lines are for the general service cost centers. These costs are expenses incurred in operating the facility as a whole *that are not directly associated with furnishing patient care* such as, but not limited to mortgage, rent, plant operations, administrative salaries, utilities, telephone charges, computer hardware and software costs, etc. General service cost centers provide services to both general service areas and to other cost centers in the provider. (CMS Pub. 15–2, section 4013; emphasis added.)

Because the costs of operating a hospital's NAH education programs are not directly associated with furnishing patient care, these cost centers are also included among the general service cost centers on Worksheet A. As noted in the cost report instructions cited previously, general service cost centers may furnish services to other general service areas. Thus, for example, a hospital's A&G cost center may furnish services to its NAH education cost centers.

The regulations and cost report instructions require that, prior to allocating overhead costs to the revenue producing cost centers, a provider must make appropriate reclassifications and adjustments to its direct costs. Worksheet A–6 is used to reclassify costs between cost centers on the cost report, while Worksheet A–8 is used to adjust both revenue and non-revenue producing cost centers for (1) expenses to reflect actual expenses incurred; (2) those items that constitute recovery of expenses through sales, charges, fees, etc.; (3) expenses in accordance with the Medicare principles of reimbursement; and (4) those items that are provided for separately in the cost apportionment process. (CMS Pub. 15–2, section 4016.)

Adjustments, including the recovery of expenses through various forms of revenue, occur prior to cost finding, which is the process by which indirect costs (that is, the costs of the general service cost centers) are allocated to other cost centers (both other general service cost centers and revenue producing cost centers). Worksheets B, Part I, and B–1 have been designed to accommodate the stepdown method of cost finding described at 42 CFR 413.24(d)(1). Certain other cost adjustments, referred to as post-stepdown adjustments, occur after the allocation of indirect and overhead costs and are reported separately on Worksheet B–2.

On November 17, 2017, CMS issued Transmittal 12, which contained clarifications to the hospital cost report instructions at CMS Pub. 15–2, chapter 40. Transmittal 12 added the following clarification to line 19 of Worksheet A–8:

Line 19—For each NAHE program on Worksheet A, line 20, and its subscripts, and Worksheet A, line 23, and its subscripts, enter the revenue adjustments (for tuition, fees, books, etc.) to be applied against total allowable costs that are directly related to the approved NAHE activities. Subscript this line to separately report the revenue offset for each NAHE program reported on line 20 and line 23 [and their subscripts]. (CMS Pub. 15–2, section 4016.)

Transmittal 12 also added to Worksheet B–2 specific instructions for post-stepdown adjustments for certain costs associated with NAHE nonprovider-operated programs under 42 CFR 413.85(g)(2), with the following note:

Note: Do not use this worksheet to reduce the total allowable costs that are directly related to the NAHE programs by the revenue received from tuition and student fees. Use Worksheet A–8 to offset NAHE program costs by tuition and student fees (42 CFR 413.85(d)(2)(i)). Do not use a post step-down adjustment. (CMS Pub. 15–2, section 4022.)

In issuing these cost report clarifications in Transmittal 12, CMS was clarifying the rules regarding the appropriate order of operations for assigning costs and allocating overhead to the NAH education pass-through cost centers. Specifically, Transmittal 12 made it clear that adjustments to the direct costs of NAH education programs due to revenue received from tuition, student fees, and other sources should occur on Worksheet A–8, prior to the allocation of overhead costs, and not as post-stepdown adjustments on Worksheet B–2.

b. Recent Litigation and Rulemaking Activity

On February 9, 2024, the U.S. District Court for the District of Columbia (D.D.C.) issued a decision involving five plaintiff hospitals. See *Mercy Health—St. Vincent Medical Center LLC d/b/a Mercy St. Vincent Medical Center* v. *Becerra,* 717 F. Supp. 3d 33 (D.D.C. 2024). The providers disputed the order of operations for determining ''net costs'' of approved educational activities under 42 CFR 413.85(d)(2)(i). The providers disagreed with the clarified instructions in Transmittal 12, and argued that the offsets for revenue from tuition and student fees should be made after indirect costs are allocated, using Worksheet B–2, which comes after the allocation of indirect costs on Worksheet B, Part I. According to the providers, the regulations require that indirect costs be included as part of a provider's total allowable educational costs before tuition and student fees are offset, and the clarification of the cost reporting instructions in 2017 was a change in policy that conflicts with the regulations. The court agreed with the providers, holding that the plain text of 42 CFR 413.85(d)(2)(i) requires this order of operations.

In the FY 2026 IPPS proposed rule (90 FR 18280 through 18282), we proposed to revise 42 CFR 413.85(d)(2)(i) to define the net cost of approved educational activities in a manner consistent with the cost reporting clarifications in Transmittal 12. Specifically, we proposed that revenues from tuition, student fees, and other sources should be subtracted from the allowable direct costs of a provider's NAH education programs prior to the allocation of overhead costs. We also clarified that, to mitigate the reduction in overhead costs that might result from this procedure, a provider could seek permission from its MAC to utilize a statistical basis other than accumulated cost for the purpose of allocating indirect costs to its NAH cost centers.

More specifically, we explained that a provider may elect to subscript (*i.e.,* componentize) its A&G cost center (line 5 of Worksheet A) for overhead costs directly related to its NAH education programs and employ a statistical basis other than accumulated cost that would accurately reflect the services rendered to those departments. In addition, we stated that the proposed order of operations to offset revenue from direct costs on Worksheet A–8 would be consistent with the policy that A&G costs allocated to the NAH cost centers must be *directly related* to the operation of specific approved programs, as finalized in the January 12, 2001 final rule (66 FR 3367).

We received many comments in opposition to our proposal to determine the net cost of approved NAH education programs by deducting tuition and other revenue from direct costs prior to the allocation of indirect costs. Commenters objected that the proposed policy would be inconsistent with general cost-finding principles and would result in the NAH cost centers receiving less than their share of institutional overhead.

Due to the number and nature of the comments we received, we decided not to finalize changes to our existing policy in the FY 2026 IPPS final rule (90 FR 36921). Instead, we stated that we expected to revisit the treatment of NAH education costs in future rulemaking.

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19522), we explained that, after considering the feedback we received on our earlier proposal, we continue to believe that correct accounting procedures require the deduction of tuition and other revenue from the direct costs of a provider's approved educational activities on Worksheet A–8, prior to the allocation of overhead, consistent with the clarifications contained in Transmittal 12. However, we acknowledged that it would be helpful to provide additional technical context to explain how the proposed order of operations is consistent with general Medicare cost-finding principles. We also modified our original proposal to ensure that the deduction of revenue on Worksheet A–8 would not inappropriately reduce the allocation of overhead to the NAH cost centers when hospitals allocate A&G costs using accumulated cost as the default statistical basis.

In addition, we acknowledged that some portions of our discussion in the FY 2026 proposed rule may have caused confusion about our existing policies regarding allowable indirect costs of approved NAH education programs. In particular, some commenters believed that we had defined allowable indirect costs in such a way as to essentially preclude the recognition of overhead for purposes of NAH pass-through payment. Therefore, in the FY 2027 proposed rule, we also proposed to clarify the nature of allowable indirect costs of approved educational activities and to refine the cost reporting procedures to ensure that hospitals appropriately allocate overhead costs to the NAH cost centers.

c. Determination of Net Cost of Approved Nursing and Allied Health Education Activities (§§ 413.85(d)(2)(i) and (ii))

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19522), we proposed to change the regulations text at 42 CFR 413.85(d)(2)(i) and (ii) to state that the net cost of approved educational activities is determined by taking the allowable direct costs incurred by the provider for trainee stipends and compensation of faculty employed by the provider, and subtracting from those direct costs the revenues the provider receives from students or on behalf of students enrolled in the program, such as, but not limited to, tuition, student fees, or textbooks purchased for resale. After subtracting revenues from allowable direct costs, indirect costs would be allocated to the NAH cost centers (limited to those costs that the provider itself incurs as a consequence of the operation of its approved educational activities), consistent with Medicare cost-finding principles at 42 CFR 413.24.

We proposed that these changes would be effective for cost reporting periods beginning on or after October 1, 2026. We did not propose changes to the existing portion of the regulations at § 413.85(d)(2)(ii) stating that net NAH costs do not include patient care costs, costs incurred by a related organization, or costs that constitute a redistribution of costs from an educational institution to a provider or costs that have been or are currently being provided through community support. (We discuss and respond to comments on our proposed clarification of allowable indirect costs of educational activities and the associated cost reporting procedures, in the following subsection of this preamble.)

As we stated in the FY 2026 proposed rule (90 FR 18281), we understand that it is not uncommon for a provider's allowable NAH education programs to generate revenues from tuition, student fees, and other sources that exceed the allowable direct costs the provider incurs for those programs. Because of that, the revenue offset on Worksheet A–8 might result in a zero or negative balance prior to the allocation of overhead costs; on Worksheet B–1, the accumulated cost statistic, which serves as the recommended statistical basis for allocating A&G costs, would consequently also be reduced to zero. Even if the provider were to componentize their A&G cost center (consistent with our proposal for allocating general service costs), certain components might continue to be allocated on the basis of accumulated cost, limiting the amount of A&G allocated to the provider's NAH cost centers, regardless of the extent to which those cost centers benefit from the hospital's administrative functions.

To ensure that the deduction of revenue on Worksheet A–8 does not understate the A&G costs allocated to the NAH cost centers, in the FY 2027 proposed rule we proposed the following modifications to the procedures for offsetting revenue and computing the accumulated cost statistic. First, we proposed that providers offset the total revenue generated by each NAH program, which may result in a credit balance (negative amount) on the corresponding line(s) of Worksheet A. Next, we proposed that providers utilize the reconciliation column on Worksheet B–1 to adjust the accumulated cost statistic by the total amount of NAH revenue offset on Worksheet A–8, effectively reversing that offset for purposes of overhead allocation only.

We provided the following example to illustrate the application of this procedure when total revenues from tuition and other sources exceed the direct costs that the provider incurs for a particular NAH program. (Note that the same procedure would be followed if total revenues do not exceed direct costs.)

- Suppose that Hospital A incurs $1,000,000 in direct costs for an allied health education program; Hospital A reports $1,000,000 on line 23, column 5, of Worksheet A, which represents the direct costs of the program prior to any adjustments.
- Hospital A receives $1,200,000 in tuition and fees from students enrolled in the program; Hospital A reports a revenue adjustment of $1,200,000 on line 19, column 2 of Worksheet A–8, representing a recovery of expenses associated with that program.
- The revenue adjustment of $1,200,000 carries over to line 23, column 6 of Worksheet A. This results in a negative expense of ($200,000) ($1,000,000 minus $1,200,000 equals ($200,000)) on line 23, column 7. Assume for purposes of this example that there are no further adjustments (positive or negative) to Hospital A's direct NAH costs.
- On Worksheet B–1, the hospital then utilizes the reconciliation column (line 23, column 5A) to increase the accumulated cost statistic by the amount of revenue offset previously, $1,200,000. (*Note:* in the cost report software, the provider must ensure to indicate ''override with value'' and check to add this value to the existing accumulated cost from Worksheet B, Part I, line 23, column 4A.)
- The accumulated cost statistic for purposes of allocating A&G on Worksheet B, Part I, will be equal to the adjusted expense on Worksheet A, column 7, line 23 (negative $200,000), plus the amount of revenue from tuition and fees deducted on Worksheet A–8 ($1,200,000), plus any amounts already allocated to the NAH cost center on Worksheet B, Part I, line 23, columns 1 through 4.
- From this point, the stepdown process on Worksheet B, Part I, continues according to normal

procedures. While the accumulated cost statistic will thus allocate an appropriate share of institutional overhead to the NAH cost center, the amount of NAH costs available for allocation on Worksheet B, Part I, line 23, column 23 will continue to reflect the revenue offset, ensuring that the unallowable costs are not allocated from NAH to the patient care cost centers.

We emphasized in the proposed rule that the deduction of tuition and other revenue on Worksheet A–8, prior to the allocation of indirect costs on Worksheet B, Part I, would be consistent with general Medicare cost-finding principles as described in the Provider Reimbursement Manual (PRM) (CMS Pub. 15–1), chapter 23, and the cost report instructions in CMS Pub. 15–2, chapter 40, and as codified in the regulations at 42 CFR 413.24. The general service cost centers, including the NAH cost centers, represent a hospital's allowable non-patient care expenses, which are allocated to all the cost centers they serve via the stepdown method on Worksheet B, Part I. Once these expenses have been allocated to the patient care cost centers, Medicare's share of allowable costs is determined based on the hospital's Medicare utilization. It is therefore necessary to remove those costs that are not generally allowable to Medicare *prior to* the stepdown process.

Such generally unallowable costs include indirect expenses that are recovered through related non-patient care revenue, as reported on lines 6 through 25 on Worksheet G–3 (including tuition on line 19). For example, interest expense and cafeteria expense are allowable general service non-patient care expenses; however, interest expense is reduced by investment income, and cafeteria expense is reduced by income from the sale of food and drink, before those expenses are allocated to the patient care cost centers via the stepdown method. Similarly, the tuition and other revenue received for a hospital's NAH education programs constitute non-patient care revenues that must be used to offset (reduce) the related NAH program expense on Worksheet A–8, consistent with the handling of other non-patient care revenue as described above.

In the FY 2027 proposed rule (91 FR 19523), we also addressed concerns raised during the FY 2026 rulemaking that the proposed order of operations for deducting tuition and other revenue would be inconsistent with our treatment of organ acquisition costs, which are also reimbursed on a pass-through basis. We explained that, in contrast to the NAH cost centers, the organ acquisition cost centers are ancillary/revenue-producing centers related to patient care. Revenue for organs sold to other organ procurement organizations or transplant hospitals may only be used to reduce Medicare's share of costs for organs claimed as Medicare usable organs. Those costs are not determined until the full apportionment process on Worksheet D–4, after the allocation of indirect costs on Worksheet B, Part I. By contrast, NAH costs are general service (non-revenue-producing) costs that are not directly related to patient care and are reimbursed to the extent the costs incurred have not been recovered through tuition and other fees. Only the net cost that the hospital bears is allocated to other departments. Thus, adjustments for tuition and other NAH revenue must occur on Worksheet A–8, which modifies total costs, not Medicare's share of costs. (Note, also, that if there are generally non-allowable costs included in an organ acquisition cost center, those costs similarly would be removed on Worksheet A–8, prior to determining Medicare's share of costs.)

Comment: Several commenters supported our proposal to codify the deduction of tuition and other revenue from the net costs of approved educational activities as a pre-stepdown adjustment and to utilize the reconciliation column on Worksheet B–1 to return previously deducted costs to the accumulated cost statistic for purposes of allocating indirect costs. The commenters stated that, as a result of this methodology, the NAH cost centers would continue to receive an appropriate share of a hospital's A&G costs during the stepdown process.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern that the proposal to deduct tuition and revenue prior to stepdown would be inconsistent with general cost-finding principles and result in under-allocation of legitimate overhead costs to the NAH cost centers, with a couple of commenters arguing that we had not articulated a sufficient basis for proposing to calculate net costs in a manner contrary to the interpretation of the court in *Mercy St. Vincent.* While a few commenters acknowledged that our proposal to adjust the accumulated cost statistic via reconciliation column appears to mitigate the downstream impact of the pre-stepdown revenue offset, they stated that the procedure would impose significant administrative burden on hospitals, especially those with multiple NAH education programs.

The commenters requested that we make the procedure optional, provide detailed cost reporting instructions, allow for a two-year transition period, and extend audit protections to hospitals that make a good-faith effort to comply with the requirements. Another commenter stated that we must codify in regulations the procedure for utilizing the reconciliation column to give the policy the force and effect of law. In addition, some commenters who otherwise supported the proposal requested that we permit hospitals to use the reconciliation methodology for cost reporting periods beginning prior to October 1, 2026, or modify the cost report instructions to align with the current version of the regulations until the effective date of the final rule.

Response: We disagree with the commenters' objections and recommendations for modifying the proposal. We do not believe that the proposal is inconsistent with general cost-finding principles or that we failed to articulate a satisfactory explanation for deducting tuition and other revenue as a pre-stepdown adjustment to allowable NAH education costs. As we explained in the proposed rule (91 FR 19523), once a hospital's overhead costs have been allocated to the patient care cost centers, Medicare's share of allowable costs is determined based on the hospital's Medicare utilization. It is therefore necessary to remove any of those costs that are not generally allowable to Medicare *prior* to the stepdown process. Such generally unallowable costs include indirect expenses that are recovered through related non-patient care revenue, as reported on lines 6 through 25 on Worksheet G–3 (including tuition on line 19). Thus, if we left in place the existing regulations as interpreted by the court in *Mercy St. Vincent,* we would be allocating unallowable costs to the patient care cost centers and introducing downstream inaccuracies into the cost reporting process.

Our proposal was intended to facilitate the removal of unallowable costs at the appropriate stage of the cost reporting process while ensuring that the NAH cost centers continue to receive their fair share of the hospital's A&G costs. We believe that our proposed use of the reconciliation column on Worksheet B–1 accomplishes these goals without imposing a significant administrative or compliance burden on hospitals. As illustrated in our example of the proposed procedure (91 FR 19523), utilizing the reconciliation column to adjust the accumulated cost statistic results in only one additional step that hospitals

must complete prior to the allocation of indirect costs on Worksheet B, Part I. Since hospitals must already report costs of multiple NAH programs on separate subscripts of the applicable cost reporting worksheets, we also do not believe that the procedure would result in significant additional complexity for hospitals with multiple programs. Accordingly, we do not believe there is a need for audit protections or a two-year transitional period as some commenters proposed.

We also disagree with the commenter's statement that we must explicitly codify the procedure for adjusting the accumulated cost statistic using the reconciliation column. Since providers may request to use an alternative basis for allocating A&G costs, we do not believe the regulations should codify a procedure specific to the use of the accumulated cost statistic. Rather, we intend to issue revisions to the cost report instructions to reflect the procedure for utilizing the reconciliation column as described in this final rule. In addition, we disagree with commenters that it would be appropriate to apply these policies retroactively to cost reporting periods beginning prior to October 1, 2026. Each update to the cost report instructions requires time to draft and publish, at which point many cost reports with fiscal year end dates prior to October 1, 2026, will have already been submitted to the MACs. Therefore, a prospective effective date is more administratively feasible and equitable.

After consideration of public comments, we are finalizing, with modification, our proposed amendments to the regulations at 42 CFR 413.85(d)(2)(i) and (ii) to codify the requirement that tuition and other revenue must be subtracted from the direct costs of approved educational activities prior to the allocation of indirect costs, as determined under the Medicare cost-finding principles in § 413.24. As we explain in response to a subsequent comment, we are adopting a minor change to the regulations text at § 413.85(d)(2)(i)(C) to state that indirect costs are limited to those costs that are ''directly attributable'' to the approved educational activities. We are also finalizing, without modification, the policy that, for purposes of allocating indirect costs to the NAH cost centers, providers must utilize the reconciliation column on Worksheet B–1 to adjust the accumulated cost statistic so that it includes tuition and other revenue previously deducted on Worksheet A–8 (as illustrated in the example above). We intend to issue revisions to cost report instructions reflecting these procedures.

These policies will be effective for cost reporting periods beginning on or after October 1, 2026.

d. Identification of Allowable Indirect (Overhead) Costs of Approved Educational Activities

The FY 2026 proposed rule included a discussion of the types of costs allowable for purposes of pass-through payment under 42 CFR 413.85 (90 FR 18281 through 18282). That discussion referred to our longstanding NAH education payment policies finalized in the January 12, 2001 final rule (66 FR 3367), in which we clarified the meaning of the term ''tuition'' and specified that ''total costs'' include direct and indirect costs incurred by a provider that are directly attributable to the operation of an approved educational activity. We explained in the 2001 final rule that such costs do not include usual patient care costs that would be incurred in the absence of the educational activity, such as the salary costs for nursing supervisors who oversee the floor nurses and student nurses; moreover, these costs do not include costs incurred by a related organization.

In the FY 2026 proposed rule, we observed that a significant portion of the indirect costs that certain hospitals allocate to their NAH cost centers include costs incurred by a related organization (such as a home office), in violation of the regulation at § 413.85(d)(2)(ii),[177] as well as A&G costs that may be incurred by the hospital but are not directly attributable to the operation of the hospital's NAH education programs. We stated that those A&G costs not directly incurred as a result of operating a hospital's NAH education programs are paid as normal operating costs under the IPPS (or other applicable hospital payment system) rather than on a pass-through basis. As examples of such costs, we listed costs that benefit the hospital as a whole and that would generally be incurred in the absence of a provider's NAH programs, such as Infection Control, Admissions, Patient Registration, Telecommunications, etc. We stated that it is therefore the provider's responsibility to request permission from its MAC to use an allocation method for overhead costs that accurately and appropriately reflects overhead costs incurred by the provider as a direct result of operating its NAH education programs.

We intended the discussion in the FY 2026 proposed rule to serve as a restatement and clarification of various elements of our existing NAH payment policies. Nevertheless, we received several comments objecting to our characterization of the allowable costs of educational activities. Commenters alleged that we had defined allowable indirect costs in such a way as to effectively preclude the allocation of overhead to the NAH cost centers, by requiring that indirect costs be ''directly attributable'' to the operation of a provider's NAH education programs. A commenter also objected to our examples of unallowable indirect costs and specifically to our characterization of the salary costs of a nursing supervisor as ''usual patient care costs that would be incurred in the absence of the educational activity'' and that are thus not allowable for purposes of NAH pass-through payment. Therefore, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19524), we proposed to further clarify our existing policies concerning the nature of allowable costs of NAH education programs, as well as specific procedures for correctly allocating those costs on the hospital cost report.

First, we proposed to clarify the meaning of the statement in the January 12, 2001 final rule that ''total costs'' include only ''direct and indirect costs incurred by a provider that are directly attributable to the operation of an approved educational activity.'' We observed that these costs are explicitly contrasted with ''usual patient care costs that would be incurred in the absence of the educational activity, such as the salary costs for nursing supervisors who oversee the floor nurses and student nurses'' (66 FR 3367). With respect to the assignment of direct costs on Worksheet A, we clarified that the purpose of this requirement is to distinguish between the costs of NAH educational activities engaged in by the hospital's NAH staff, which would not occur in the absence of a hospital's approved NAH programs and which are thus ''directly attributable'' to the operation of such programs, and the costs of usual patient care services, which may be furnished by some of the same staff members and which the hospital would incur even in the absence of its NAH programs.

[177] In addition to the regulation under 413.85(d)(2)(ii), we note that under § 413.85(f)(1)(i), the provider itself must directly incur the training costs in order for a program to be deemed provider-operated and thus eligible for pass-through payments. Accordingly, we caution related parties about incurring NAH training costs (including indirect costs), as that could jeopardize the provider's status as the operator of the program. We discuss the requirements for provider-operated programs in more detail as part of our response to commenters later in the preamble of this final rule.

For example, a nursing supervisor who oversees floor nurses and student nurses may spend part of his or her time engaged in usual patient care activities, such as monitoring patient vital signs or directing the clinical activities of the floor nurses, and part of the time instructing students in the hospital's nursing program. We explained that a portion of the salary costs of the nursing supervisor would be considered direct costs of the nursing program, and the salary costs would thus be apportioned between the hospital's patient care and nursing education cost centers, based on the percentage of time the supervisor spent on each activity. We stated that this procedure is analogous to the apportionment of the salary costs of teaching physicians who spend part of their time supervising residents and part of their time providing clinical services to the hospital's patients.

With respect to the allocation of indirect costs on Worksheet B, Part I, we clarified that the requirement that such costs must be ''directly attributable to the operation of an approved educational activity'' does not categorically preclude the allocation of institutional overhead to the NAH cost centers. Rather, this requirement emphasizes the general principle that indirect costs allocated to a particular cost center must *proportionately* reflect the extent to which that department benefits from the hospital's various overhead functions. For example, if only certain staff in a hospital department work on administrative functions related to the NAH program, then only the salary costs of those particular staff, and not the costs of the entire department/cost center, should be allocated to the NAH cost centers, as only the salary costs of those particular staff are ''directly attributable to the operation of an approved educational activity.''

We proposed to clarify that, if a hospital's NAH education program benefits from a particular overhead function whose costs are incurred directly by the provider (rather than a related party), then the corresponding NAH cost center must only receive a proportional share of the indirect costs associated with that function, since the function may also provide a benefit to the hospital's other departments, and since the provider would have incurred costs for that function in the absence of its approved NAH programs. That is, the fact that hospital departments are complex and service multiple areas of the hospital necessitates a distinction between those costs that do and do not provide a benefit to a hospital's NAH programs, and the accurate apportionment of only those costs that provide a benefit to the NAH cost centers. Furthermore, we reiterated the policy finalized in the January 12, 2001, final rule that allowable costs do *not* include costs incurred by a related organization, such as a corporate home office.

We further clarified that if a program does *not* derive a benefit from a particular overhead function, then it should *not* receive any of the indirect costs that the provider incurs for that function. In the FY 2026 proposed rule, we listed examples of several types of overhead, such as Infection Control, Admissions, Patient Registration, Telecommunications, etc., that we believe would usually not provide a benefit to hospitals' NAH education programs, and whose costs should therefore not be allocated to the NAH cost centers. However, as we stated in the FY 2027 proposed rule, we recognize that hospitals' operations vary and that different NAH programs may require different forms of administrative support, potentially including one or more of the functions enumerated in the FY 2026 proposed rule. As stated above, whether a particular overhead cost should be allocated to the NAH cost centers depends upon whether that function provides a benefit to the hospital's NAH programs.

In the FY 2027 proposed rule, we stated that the general service cost centers, including the A&G cost center, comprise a variety of distinct overhead functions, some of which may benefit the hospital's NAH education programs, while others may not. To properly distinguish between the costs associated with these distinct functions, and to ensure that the pass-through cost centers receive only those indirect costs allowable under our longstanding policies, we proposed to require providers with approved NAH education programs to componentize (that is, to fragment or subscript) their general service cost centers according to the procedures described below.

We proposed that if a hospital operates ''approved educational activities,'' as defined under § 413.85(c) and subject to the provider-operated requirements under § 413.85(f), then the hospital must identify any general service cost center that comprises costs of multiple overhead functions, where some of those functions provide a benefit to the hospital's NAH programs and others do not. For each such general service cost center, the hospital must create one or more subscripts that contain only those costs that provide a benefit to its NAH programs. (We noted that such costs may also provide a benefit to other departments of the hospital.) As a result of this process, the general service cost center would contain the following components (in addition to any other subscripts created by the hospital for other purposes): (1) Indirect costs that provide a benefit to the hospital's NAH programs, and (2) Indirect costs that do not provide a benefit to NAH.

Only those costs contained in component (1) would flow to Worksheet D, Parts III and IV, to be reimbursed on a pass-through basis. On lines 20 and 23 (and subscripts thereof) of Worksheet B–1, the hospital would delete (zero out) the allocation statistic in the column corresponding to component (2), so that those costs are allocated to the departments that they serve but not to the NAH cost centers.

We also observed that a similar procedure would apply to certain nonprovider-operated programs whose clinical costs are paid on a pass-through basis under 42 CFR 413.85(g)(1) and (2). In contrast to provider-operated programs paid under § 413.85(f), providers that qualify for reasonable cost payment of clinical costs associated with nonprovider operated programs under § 413.85(g) may receive reasonable cost payment for the clinical training costs only, including the clinical training costs incurred by a related organization (§ 413.85(g)(2)(v); 66 FR 3367); however, the January 12, 2001 final rule explicitly states that ''overhead costs incurred by a related organization generally would not be considered allowable'' under this provision (66 FR 3369).

Accordingly, under our proposal, a provider that claims pass-through costs under §§ 413.85(g)(1) and (2) would be required to further distinguish between overhead costs incurred directly by the provider and those incurred by a related party. This would be accomplished by creating an additional subscript of the general service cost center containing only those related party costs.[178] We further observed that any excess clinical training costs as defined at § 413.85(g)(2)(iii) would continue to be removed as a post-stepdown adjustment

[178] General service costs incurred by a related party are reported on Worksheet A–8–1 of the hospital cost report. Under our proposal, if the hospital reports related party overhead costs associated with a NAH program on Worksheet A–8–1, then it would be required to create an additional subscript for each corresponding general service cost center containing only those related party costs. Overhead costs incurred by a related organization and allocated to the NAH cost centers would be removed as a post-stepdown adjustment on Worksheet B–2. Such costs are not paid on a pass-through basis but instead are allowable as normal operating costs of the hospital included in the prospective payment rates.

on Worksheet B–2, consistent with the instructions in CMS Pub. 15–2, section 4022.

We stated that these procedures would ensure that only indirect costs incurred by the provider that are ''directly attributable'' to the provider's operation of approved educational activities are allocated to the pass-through NAH cost centers. We observed that the subscripting of general service cost centers is consistent with longstanding Medicare cost reporting procedures as described in CMS Pub. 15–1, section 2307(B). In addition, we clarified that the hospital must ensure that the statistical basis used to allocate each general service cost center and its subscripts (if applicable) must reasonably relate to the general service costs and must appropriately reflect the proportion of those costs attributable to the downstream cost centers, including NAH. For further discussion of the use of appropriate allocation statistics, we referred readers to section X.D.3. of the proposed rule (''Clarification and Codification of Cost Allocation Principles''; 91 FR 19744).

We provided the following example to illustrate the application of our proposed procedures in the case of a hospital with a subset of A&G costs allowable for purposes of NAH pass-through payment. For the purposes of this example, assume the hospital's NAH programs are deemed provider-operated consistent with the requirements at § 413.85(f).

Example: A hospital reports $100,000,000 in A&G costs, of which $75,000,000 is attributable to specific overhead functions (such as executive salaries, accounting services, and facility administrative services) that provide a benefit to the hospital's approved NAH education programs, as well as to the rest of the hospital. The remaining $25,000,000 is attributable to functions (such as legal services and inpatient admissions) that do not provide a benefit to the hospital's NAH programs. The hospital would subscript its A&G cost center on Worksheet A as follows:

- One subscript (for example, line 5.01), would contain the $75,000,000 in A&G costs that provide a benefit to the hospital's NAH programs.
- Another subscript (for example, line 5.02), would contain the residual $25,000,000 in A&G costs not attributable to the hospital's NAH programs.
- Cost center 5.01 would be allocated among all cost centers on an appropriate statistical basis (for example, accumulated cost, adjusted so as to reverse the offset of tuition and/or other revenue, as described in the preceding section of this proposal); any costs allocated to the NAH cost centers would flow to Worksheet D, Parts III and IV, and be reimbursed on a pass-through basis.
- The hospital would delete (zero out) the allocation statistic on Worksheet B–1, lines 20 and 23, column 5.02; this would prevent the $25,000,000 of A&G costs unrelated to the hospital's NAH programs from being allocated to the NAH cost centers.

We proposed that these policies would be effective for cost reporting periods beginning on or after October 1, 2026.

Comment: While some commenters appreciated our clarification that indirect costs are not categorically precluded from allocation to the NAH cost centers, several commenters nevertheless objected to our characterization of the types of indirect costs allowable for purposes of pass-through payment and specifically our proposal to amend the regulations at § 413.85(d)(2)(i) to codify the policy that indirect costs are limited to those costs that the provider itself incurs as a consequence of operating the approved educational activities. Commenters voiced concern that our proposed clarification and codification might invite aggressive scrutiny from MAC auditors concerning the types of indirect costs allowable for pass-through payment, even though NAH programs rely on the same shared infrastructure as the rest of the hospital, including functions such as admissions, information technology, and telecommunications.

Accordingly, several commenters requested clarification that reasonable, consistently allocated indirect costs remain allowable when they support the operation of an approved provider-based NAH program. In response to our example in which we referred to legal services as a hypothetical type of indirect cost unrelated to a hospital's NAH programs, several commenters specifically requested clarification regarding the allowability of legal services for NAH pass-through payment.

Some commenters objected to our proposed clarification on the grounds that it would be inconsistent with the nature of indirect costs, which, the commenters assert, by definition cannot be attributed to a specific activity. A commenter stated that by restricting indirect costs to those incurred ''as a consequence of'' a hospital's NAH programs, we would effectively prevent any indirect costs from flowing to the NAH cost centers, in violation of the reasonable cost statute at section 1861(v)(1)(a) of the Act, which requires Medicare to take into account both direct and indirect costs of providers. The commenter argued that the proposed regulatory text at § 413.85(d)(2)(i) therefore contradicts our clarification that the longstanding policy established in 2001 does not categorically preclude allocation of indirect costs to NAH. According to the commenter, if CMS intends to clarify the policy as discussed in the proposed rule, we should replace the ''as a consequence'' language with language that reflects the 2001 policy that indirect costs must be ''directly attributable to the operation of an approved educational activity.''

For similar reasons, commenters opposed our related proposal that providers with approved NAH education programs must componentize (subscript) their general service cost centers to distinguish between functions that provide a benefit to their NAH programs and those that do not. Commenters argued that the proposal is predicated on a narrow view of the word ''benefit'' that ignores the interconnectedness of a hospital's operations, including its educational and patient care activities. Again, commenters emphasized that NAH programs benefit from many hospital functions even when those functions are not exclusively or primarily educational, and that a hospital's shared institutional overhead cannot readily be disaggregated in the manner we proposed.

Commenters also objected that, contrary to our statement in the proposed rule, mandatory componentization of the general service cost centers would represent a departure from established cost reporting principles, including the use of the step-down method and of accumulated cost as a reasonable proxy for resource consumption, and that this procedure could reduce legitimate NAH overhead costs. A few commenters argued that CMS was singling out the NAH cost centers for disparate treatment as a means of reducing Medicare expenditures, with a commenter arguing that our proposal would violate the ''averaging principle,'' under which ''it is presumed that where a particular cost might be allocated disproportionately to or from the [Medicare] program, there will be other costs disproportionately allocated in the other direction which will compensate for the first cost.'' According to the commenter, CMS would be abandoning the averaging principle at the sole expense of NAH, without implementing a similar

componentization requirement for other cost centers.

In addition, commenters warned that overly granular componentization of general service costs would introduce subjectivity and uncertainty into the cost reporting process and create compliance difficulties for hospitals, with different MACs potentially applying inconsistent standards in auditing hospitals' overhead allocations. Furthermore, the need to develop multiple subscripts and allocation statistics, with associated tracking and documentation requirements, would result in significant administrative burden, with commenters stating that the proposal would require extensive changes to existing cost reporting processes and that many hospitals lack the systems and resources necessary to track overhead costs in such detail. Commenters feared that the additional compliance burdens and payment uncertainties would have detrimental effects on hospitals' ability to operate training programs, develop the NAH workforce, and deliver patient care.

For these reasons, commenters urged us to abandon the componentization proposal in its current form. If CMS believes changes to the cost reporting process are necessary, commenters requested that we issue clear standards, including examples of appropriate allocation bases, and provide for a transition period to allow hospitals to implement any new requirements. In addition, commenters stated that any changes should be mindful of hospitals' operational constraints and urged us to adopt a ''flexible reasonableness'' standard that would allow hospitals to rely on traditional cost-finding methodologies where appropriate.

Response: We disagree with commenters who argued that our proposed clarification regarding the types of indirect costs allowable for purposes of NAH pass-through payment conflicts with the nature of indirect costs and with standard cost reporting principles. As we explained in the proposed rule (91 FR 19524), the longstanding requirement, established in the January 12, 2001 final rule (66 FR 3367), that indirect costs must be ''directly attributable to the operation of an approved educational activity'' emphasizes the general principle that indirect costs allocated to a particular cost center must *proportionately* reflect the extent to which that cost center benefits from the hospital's various overhead functions. In other words, as discussed in another section of the proposed rule (91 FR 19744), the statistical basis used to allocate a general service cost center must reflect the cause-and-effect relationship between the cost and the activities or services receiving the allocation.

However, we agree with a commenter who recommended text of the regulations should align more closely with the language used in the 2001 final rule. Accordingly, we are finalizing, with modification, our proposal to define allowable indirect costs at § 413.85(d)(2)(i)(C) as limited to those costs that the provider itself incurs and that are directly attributable to the approved educational activities.

We also maintain the position that it is possible to distinguish between overhead functions that provide a benefit to a particular cost center and those that do not, and that this distinction follows logically from the general principle that costs must be allocated on a proportional basis. Whether or not a ''benefit'' exists depends on whether there is a cause-and-effect relationship between the overhead cost and the cost center that would receive the allocation. As noted above, this relationship would be reflected in the statistical basis used to allocate the cost, which, for purposes of allocation to a cost center that receives no measurable benefit, would be equal to zero.

Furthermore, we maintain that because the A&G cost center comprises multiple discrete overhead functions, it is reasonably possible to identify and evaluate each of those functions separately to determine whether such a cause-and-effect relationship exists with respect to the hospital's other cost centers, including NAH. Which specific overhead functions provide a measurable benefit to NAH would depend on the nature of the individual hospital's operations in a cost reporting period. In response to commenters who specifically requested clarification on whether the cost of legal services is an allowable NAH cost, we are clarifying that a portion of such costs may be allowable if, in a particular cost reporting period, the hospital's NAH programs derived a benefit from the services of its legal department.

For these reasons, we disagree that accurate allocation of overhead costs at the level of detail that we proposed would introduce subjectivity into the cost reporting process or invite inconsistent treatment by the MACs. The use of subscripts on the Medicare cost report is a well-established practice, and hospitals are already required to adjust their allocation statistics to ensure that they accurately reflect the costs associated with their specific departments. In response to commenters who argued that our proposal violates the averaging principle and singles out NAH for disparate treatment, we observe that the averaging principle is not codified in the Medicare regulations or described in the PRM and thus does not override hospitals' obligation to report accurate costs for all cost centers, including NAH. Moreover, for cost centers, such as NAH, that are paid on a reasonable cost basis, inaccurate cost reporting practices directly impact Medicare payments to a greater extent than under a prospective payment system. We are therefore finalizing our clarification that the NAH cost centers may only receive a proportional share of the costs associated with those overhead functions that provide a benefit to the hospital's NAH education programs. However, based on commenters' concerns regarding administrative burden, we are not finalizing our proposal that, if a hospital operates approved NAH education programs, it must componentize its general service cost centers to distinguish between those overhead functions that provide a benefit to its NAH programs and those that do not.

Nevertheless, we emphasize that even in the absence of a specific componentization requirement, hospitals must continue to avail themselves of appropriate cost reporting mechanisms to ensure that only allowable indirect costs, as clarified above, are allocated to the NAH cost centers. In addition, we note that all hospitals, whether they operate NAH programs or not, must adhere to the general cost allocation requirements that we are codifying under 42 CFR 413.24(d)(8), as discussed separately in section X.D.3. of this final rule.

Comment: Several commenters objected to our clarification concerning the apportionment of direct costs between a hospital's patient care and NAH cost centers and to our example of apportioning the salary costs of a nursing supervisor based on the percentage of time spent on each activity. Commenters urged caution about drawing sharp distinctions between clinical education and a hospital's patient-care activities, stating that while time studies may be appropriate in some cases, CMS should not impose unrealistic documentation requirements on hospital staff. The commenters requested that CMS provide practical documentation standards for mixed clinical and educational roles. Other commenters stated that the example does not reflect standard Medicare cost reporting procedures: namely, that if a nursing supervisor spends portions of his or her

time on various activities, the associated salary costs are reclassified as direct costs of the respective cost centers via Worksheet A–6 of the cost report, while the remaining costs of the Nursing Administration cost center are allocated proportionally.

Response: The commenters are correct that under standard Medicare cost reporting procedures the salary costs of a hospital's nursing staff, captured in the Nursing Administration cost center, attributable to the hospital's educational activities would be reclassified as direct costs of the NAH cost centers on Worksheet A–6 of the hospital cost report, while the remaining costs of the Nursing Administration cost center would be allocated proportionally to the patient care cost centers via the stepdown process on Worksheet B, Part I. Additionally, as several commenters acknowledged, the reclassification of salary costs as direct costs of a hospital's NAH cost centers must be supported by adequate documentation, which may take the form of a detailed time report or, in lieu of such a report, a periodic time study. For requirements applicable to periodic time studies, refer to CMS Pub. 15–1, section 2313.2.E. We note that time studies are a long-standing tool for both physicians and non-physicians to use as adequate documentation for allocating direct salary and wage costs.

We are therefore finalizing our clarification that salary costs must be apportioned (reclassified) to the NAH cost centers based on the percentage of time that clinical staff devote to each activity. As explained above, this apportionment must be adequately supported by appropriate documentation, which may take the form of a detailed time report or a periodic time study. The time report or time study must properly distinguish between educational activities, such as mentoring and evaluating students or completing teaching activity reports, and patient care activities. Any activities associated with diagnosing, treating, or preparing treatment plans for specific patients, even if conducted in the presence of students, are not considered educational activities, and the salary costs attributable to such patient care activities must not be reclassified to the NAH cost centers.

Comment: Many commenters objected to our policies concerning the treatment of related party costs, and especially home office costs, for purposes of NAH pass-through payment. Commenters stated that the prohibition on related party costs overlooks the realities of modern hospital operations and the legitimate role of such costs in supporting NAH training: by centralizing common administrative functions in a home office, hospitals can improve efficiency, reduce costs, and devote more resources to their educational mission. Several commenters stated that CMS should not ''penalize'' hospitals simply because certain educational functions are housed in a related home office. More specifically, some commenters pointed to the cost report instructions at CMS Pub. 15–2, section 4017, which generally recognizes related party costs as allowable costs to the hospital provided they do not exceed the amount that a prudent buyer would pay elsewhere. The commenters stated that there is no justification for treating related party costs differently for purposes of allocation to NAH *versus* other cost centers. Accordingly, commenters generally urged CMS not to finalize a policy whereby related party overhead costs would be categorically excluded from allocation to the NAH cost centers. Instead, CMS should recognize costs that are reasonable, necessary, not duplicative, and directly connected to approved educational activities.

Several commenters challenged the notion that home office costs are precluded from allocation to the NAH cost centers under the policies adopted in the January 12, 2001 final rule. The commenters argued that the 2001 final rule specifically prohibited the redistribution of costs from a related educational institution, but that it did not define a ''related party'' to include a home office. According to a commenter, since the publication of the 2001 final rule, many hospitals have moved shared administrative functions to the home office level for the sake of efficiency, but these costs nonetheless remain ''directly attributable'' to the hospitals' NAH education programs. Another commenter stated that by disallowing home office costs we would be treating the ''administrative portion'' of the hospital inconsistently depending on whether it is freestanding or co-located with the rest of the hospital.

A few commenters expressed concern that NAH education programs could be deemed nonprovider-operated simply because the programs depend on centralized administrative resources such as payroll processing, accounting systems, human resources support, etc. The commenters stated that reliance on shared infrastructure does not alter the fact that the hospital directly controls and operates its NAH programs, as required under § 413.85(f). Accordingly, the commenters requested that we clarify that a provider's or program's use of centralized administrative infrastructure does not, by itself, invalidate a program's provider-operated status or otherwise preclude allowable pass-through reimbursement if the hospital continues to satisfy the substantive operational control requirements under the regulations.

In addition, a couple of commenters objected to what they characterized as CMS's arbitrary or punitive audit protocols that have resulted in the disallowance of certain NAH education programs, including pharmacy residency programs, and requested that CMS respond to this issue and update its NAH program guidance in light of developments within the healthcare industry.

Response: Our understanding is that the commenters are addressing two distinct, but related, provisions of the regulations concerning payment for NAH education programs under 42 CFR 413.85. Under existing § 413.85(d)(2)(ii), a provider's total allowable education costs do not include patient care costs, *costs incurred by a related organization,* or costs that constitute a redistribution of costs from an educational institution to a provider or costs that have been or are currently being provided through community support. Separately, the regulations at § 413.85(f) specify the requirements that a provider must meet in order to be considered the operator of an approved NAH education program, including that the provider must directly incur the training costs, have direct control of the curriculum, control the administration of the program, employ the teaching staff, and provide and control both classroom instruction and clinical training. We note that these provisions were originally codified in the January 12, 2001 final rule (66 FR 3374) and that we did *not* propose any changes to our policies concerning related party costs or the definition of provider-operated programs in the FY 2027 IPPS/LTCH PPS proposed rule.

We further note that, although much of the discussion in the January 12, 2001 final rule focused on redistribution of costs from an educational institution, section 413.85(d)(2)(ii) explicitly prohibits costs incurred by a ''related organization,'' which includes a health system home office, as discussed in CMS Pub. 15–2, section 3900 (see below). Accordingly, except for the clinical training costs of certain nonprovider-operated programs under §§ 413.85(g)(1) and (2), both direct and indirect costs incurred by a related party remain categorically precluded from NAH pass-through payment under § 413.85.

As discussed earlier, we are not finalizing our proposal that, if a hospital operates approved NAH education programs, then it must componentize its general service cost centers to distinguish between those overhead functions that provide a benefit to its NAH programs and those that do not. Similarly, we are not finalizing a separate requirement for providers to componentize their general service cost centers to identify costs incurred by a related party. However, we reiterate that the existing regulations at § 413.85(d)(2)(ii) state that a provider's total allowable education costs do not include patient care costs, *costs incurred by a related organization,* or costs that constitute a redistribution of costs from an educational institution to a provider or costs that have been or are currently being provided through community support.

Accordingly, hospitals must continue to avail themselves of appropriate cost reporting mechanisms to ensure that only allowable direct and indirect costs are included in the NAH cost centers. We also note that, consistent with the policy established in the January 12, 2001 final rule, even for certain nonprovider-operated programs under §§ 413.85(g)(1) and (2), allowable costs generally do not include indirect costs incurred by a related organization (66 FR 3367).

We are also taking the opportunity to respond to commenters who objected to the disallowance of pass-through payment for certain NAH education programs after those programs were reviewed and found not to be provider-operated, as defined under § 413.85(f). We recognize that as the healthcare industry has evolved, many hospitals currently are components of larger healthcare systems. In many cases, central offices or other related entities may be providing consolidated non-clinical and administrative functions. This evolution has complicated the ability of hospitals to demonstrate eligibility for meeting the ''provider-operated'' and ''direct control'' requirements for Medicare pass-through funding for NAH programs.

Thus, the audit challenges that some hospitals are experiencing may not result from inappropriate auditing but are a consequence of the central office or corporate headquarters facility performing certain functions rather than the hospital itself. More specifically, a corporate headquarters (historically referred to as a ''home office'') is a related organization to the hospital; it is *not* the hospital itself. As stated in CMS Pub. 15–2, section 3900:

> The home office of a chain is not in itself certified by Medicare. Therefore, its costs may not be directly reimbursed by Medicare. The relationship of the home office to Medicare is that of a related organization to participating providers.

Likewise, the January 12, 2001 final rule (66 FR 3367) states:

> [O]ur policy has been that the provider, rather than the related organization, must directly incur the costs on its books and records before the costs will be recognized for Medicare payment purposes.

In other words, to be considered the operator of an approved NAH education program and for the costs to be allowable for NAH pass-through payment, the hospital itself must incur the costs of the program in the first instance from its own funds (*e.g.,* cash, accounts payable entries). Therefore, if a home office is incurring costs (such as salary costs) associated with the NAH education program, holding the W–2s of the teaching staff and residents, operating payroll, or providing other administrative functions, these factors would be evidence that the hospital itself is not ''directly'' incurring the costs or controlling the teaching staff or students.

While it is true that the regulations at § 413.85(f)(1)(iii) state that ''A provider may contract with another entity to perform some administrative functions,'' the regulations also state that ''the provider must maintain control over *all* aspects of the contracted functions'' (emphasis added). We continue to stress that in all cases the burden of proof is on the hospital to demonstrate that its program satisfies all criteria listed at § 413.85(f)(1) for provider-operated status. The costs associated with a program that does not qualify for Medicare reasonable cost pass-through payment would instead be considered normal operating costs paid under the IPPS (see 49 FR 234, January 3, 1984, and 66 FR 3362, January 12, 2001).

H. Payment Adjustment for Certain Immunotherapy Cases (§§ 412.85 and 412.312)

Effective for FY 2021, we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which were reported using ICD–10–PCS procedure codes XW033C3 or XW043C3 (85 FR 58599 through 58600). Effective for FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106).

Effective for FY 2021, we modified our relative weight methodology for MS–DRG 018 to develop a relative weight that is reflective of the typical costs of providing CAR T-cell therapies relative to other IPPS services. Specifically, under our finalized policy we do not include claims determined to be clinical trial claims that group to MS–DRG 018 when calculating the average cost for MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, with the additional refinements that: (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for MS–DRG 018 to the extent such claims can be identified in the historical data; and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for MS–DRG 018 to the extent such claims can be identified in the historical data (85 FR 58600). The term ''expanded access'' (sometimes called ''compassionate use'') is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when, among other criteria, there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition (21 CFR 312.305).[179]

Effective FY 2021, we also finalized an adjustment to the payment amount for applicable clinical trial and expanded access immunotherapy cases that group to MS–DRG 018 using the same methodology that we used to adjust the case count for purposes of the relative weight calculations (85 FR 58842 through 58844). (As previously noted, effective beginning FY 2022, we

[179] *https://www.fda.gov/news-events/expanded-access/expanded-access-keywords-definitions-and-resources.*

revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106).) Specifically, under our finalized policy we apply a payment adjustment to claims that group to MS–DRG 018 and include ICD–10–CM diagnosis code Z00.6, with the modification that when the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the payment adjustment will not be applied in calculating the payment for the case. We also finalized that when there is expanded access use of immunotherapy, the payment adjustment will be applied in calculating the payment for the case. Effective FY 2026, we also finalized the application of the payment adjustment for clinical trial and expanded access use of immunotherapy cases to other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost. This payment adjustment is codified at 42 CFR 412.85 (for operating IPPS payments) and 412.312 (for capital IPPS payments), for claims appropriately containing Z00.6, as described previously, and reflects that the adjustment is also applied for cases involving expanded access use immunotherapy, and that the payment adjustment only applies to applicable clinical trial cases; that is, the adjustment is not applicable to cases where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product. The regulations at 42 CFR 412.85(c) also specify that the adjustment factor will reflect the average cost for cases assigned to MS–DRG 018 that involve expanded access use of immunotherapy, are part of an applicable clinical trial, or for discharges occurring on or after October 1, 2025, other cases where the immunotherapy product is not purchased in the usual manner, such as provided at no cost, to the average cost for all other cases assigned to MS–DRG 018 (90 FR 36922).

For FY 2027, we proposed to continue to apply an adjustment to the payment amount for expanded access use of immunotherapy and applicable clinical trial cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, that group to MS–DRG 018, calculated using the same methodology, as modified in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59062), that we proposed to use to adjust the case count for purposes of the relative weight calculations, including our proposed modifications to that methodology for FY 2027, as described in section II.D. of the preamble of this final rule.

As discussed in the FY 2024 IPPS/LTCH PPS final rule, the MedPAR claims data now includes a field that identifies whether or not the claim includes expanded access use of immunotherapy. For the FY 2023 MedPAR data and for subsequent years, this field identifies whether or not the claim includes condition code 90. The MedPAR files now also include information for claims with the payer-only condition code ''ZC'', which is used by the IPPS Pricer to identify a case where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product so that the payment adjustment is not applied in calculating the payment for the case (for example, see Change Request 11879, available at *https://www.cms.gov/files/document/r10571cp.pdf*). We refer the readers to section II.D. of this final rule for further discussion of our proposed and finalized methodology for identifying clinical trial claims and expanded access use claims in MS–DRG 018 and our methodology used to adjust the case count for purposes of the relative weight calculations, as modified in the FY 2024 IPPS/LTCH PPS final rule, and as further modified for FY 2026 to identify other claims for which the immunotherapy product was not purchased in the usual manner, such as obtained at no cost.

Using the same methodology that we proposed to use to adjust the case count for purposes of the relative weight calculations, we proposed to calculate the adjustment to the payment amount for expanded access use of immunotherapy, applicable clinical trial cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost as follows:

- Calculate the average cost for cases assigned to MS–DRG 018 that: (a) contain ICD–10–CM diagnosis code Z00.6 and do not contain condition code ''ZC''; (b) contain condition code ''90''; or (c) contain standardized drug charges below the median standardized drug charge of clinical trial cases in MS–DRG 018.
- Calculate the average cost for all other cases assigned to MS–DRG 018.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply this adjustor when calculating payments for expanded access use of immunotherapy, applicable clinical trial cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, that group to MS–DRG 018 by multiplying the relative weight for MS–DRG 018 by the adjustor.

We refer the readers to section II.D. of the preamble of this final rule for further discussion of our methodology.

Consistent with our calculation of the proposed adjustor for the relative weight calculations, for the proposed rule we proposed to calculate this adjustor based on the December 2025 update of the FY 2025 MedPAR file for purposes of establishing the FY 2027 payment amount. Specifically, in accordance with 42 CFR 412.85 (for operating IPPS payments) and 412.312 (for capital IPPS payments), we proposed to multiply the FY 2027 relative weight for MS–DRG 018 by a proposed adjustor of 0.17 as part of the calculation of the payment for claims determined to be applicable clinical trial claims, expanded access use immunotherapy claims, or other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, that group to MS–DRG 018, which includes CAR T-cell and non-CAR T-cell therapies and other immunotherapies. We also proposed to update the value of the adjustor based on more recent data for the final rule.

We did not receive any comments specifically relating to the proposed payment adjustment for applicable clinical trial cases, expanded access use immunotherapy cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, and are therefore finalizing our proposal without modification. We are also finalizing our proposal to update the value of this adjustor based on more recent data for this final rule. Therefore, using the March 2026 update of the FY 2025 MedPAR data, we are finalizing an adjustor of 0.16 for FY 2027, which will be multiplied by the final FY 2027 relative weight for MS–DRG 018 as part of the calculation of the payment for claims determined to be applicable clinical trial cases, expanded use access immunotherapy claims, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, that group to MS–DRG 018.

I. Hospital Readmissions Reduction Program

1. Regulatory Background

Section 1886(q) of the Act sets forth the requirements of the Hospital Readmissions Reduction Program effective for discharges from applicable hospitals beginning on or after October 1, 2012. Under the Hospital Readmissions Reduction Program, payments to applicable hospitals must be reduced to account for certain excess readmissions after an initial treatment for specified diagnoses (referred to in section 1886(q)(5)(A) of the Act as ''applicable conditions,'' certain high-volume or high-expenditure conditions specified by the Secretary). We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240) for a general overview of the Hospital Readmissions Reduction Program. We also refer readers to 42 CFR 412.152 through 412.154 for codified Hospital Readmissions Reduction Program requirements.

2. Hospital Readmissions Reduction Program Measures

a. Summary of Adopted Measures for the Hospital Readmissions Reduction Program

Table V.I.—01. shows the Hospital Readmissions Reduction Program measure set for the FY 2027 program year and subsequent years, that is, the ''applicable conditions'' used to calculate excess readmission ratios.[180] Additional resources on the measure technical specifications and methodology for the Hospital Readmissions Reduction Program are available on the CMS QualityNet website (available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*).

TABLE V.I.-01.: SUMMARY OF FINALIZED HOSPITAL 30-DAY, ALL-CAUSE, RISK-STANDARDIZED UNPLANNED READMISSION MEASURES IN THE HOSPITAL READMISSIONS REDUCTION PROGRAM

Applicable Condition or Procedure	FY 2027	FY 2028	FY 2029	FY 2030
Acute Myocardial Infarction	X	X	X	X
Chronic Obstructive Pulmonary Disease	X	X	X	X
Heart Failure	X	X	X	X
Pneumonia	X	X	X	X
Coronary Artery Bypass Graft Surgery	X	X	X	X
Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty	X	X	X	X
Sepsis*		†	†	X

*In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19528 to 19539), we proposed to adopt the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization Measure Beginning with the FY 2029 program year. In Section I.2 of this final rule, we are finalizing this proposal with modification to provide early look reports in FY 2028 and FY 2029; the measure will be used for payment adjustments beginning with the FY 2030 program year. See Section I.2. for more details on how this policy is being finalized.
†Providers will receive confidential early look reports. See Section I.2. for further description of early look reports.

b. Adoption of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization Measure

(1) Background

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19528), we stated that Sepsis, or septicemia, is a life-threatening condition that results from the body's dysregulated response to infection and is a leading cause of mortality, hospitalization, and readmission in the United States.[181] It is the most frequent principal diagnosis among non-maternal, non-neonatal inpatients, with over 2.2 million hospitalizations reported in 2018.[182] Of the 1.7 million adults diagnosed with sepsis annually, approximately 20 percent die.[183] [184] [185]

[180] § 412.152

[181] An Assessment of Sepsis in the United States and its Burden on Hospital Care. Rockville, MD: Agency for Healthcare Research and Quality; 2024. AHRQ Pub No. 24–0087.

[182] McDermott K.W., Roemer M. (2021). Most Frequent Principal Diagnoses for Inpatient Stays in U.S. Hospitals, 2018. Healthcare Cost and Utilization Project (HCUP) Statistical Brief #277. Available at: *https://pubmed.ncbi.nlm.nih.gov/34428003/*.

[183] Centers for Disease Control and Prevention. About Sepsis. August 2025. Available at: *https://www.cdc.gov/sepsis/about/index.html*.

[184] U.S. Department of Health and Human Services. Agency for Healthcare Research and Quality. Report to Congress: An Assessment of Sepsis in the United States and its Burden on Hospital Care. 2024. Available at: *https://www.ahrq.gov/sites/default/files/publications2/files/sepsis-report-to-congress_0.pdf*.

[185] Page B, Klompas M, Chan C, et al. Surveillance for healthcare-associated infections: hospital-onset adult sepsis events versus current reportable conditions. Clin Infect Dis 2021; 73:1013–9.

Consistent with section 1886(q)(5)(A) of the Act, which, as noted above, defines an ''applicable condition'' in the Hospital Readmissions Reduction Program, sepsis readmissions are both high volume and high expenditure. Thirty-day average readmission rates for patients with sepsis are estimated to be about 21 percent.[186] Sepsis is also associated with poor health outcomes, such as the development of chronic conditions and functional impairment,[187] as well as higher costs compared to other conditions included in CMS value-based and quality reporting programs.[188] Between 2016 and 2021, the aggregate hospital costs for patients with sepsis aged 65 and older increased from $16.7 billion to $26.3 billion, and the average total cost of sepsis stays for this population increased from $21,700 to $25,000 over this period.[189] Approximately 50 percent of the total hospital costs for sepsis stays in 2020 and 2021 were associated with stays expected to be billed to Medicare.[190] A recent study concluded that the quality reporting and payment-for-performance programs should address these concerns after finding that sepsis readmissions occurred at a rate similar to that of other conditions included in the Hospital Readmissions Reduction Program (for example, heart failure, chronic obstructive pulmonary disease, acute myocardial infarction).[191]

Sepsis readmissions are often preventable, highlighting the need for targeted interventions to reduce sepsis-related mortality and improve post-discharge outcomes including readmissions.[192] Readmission following a sepsis hospitalization may be a result of inadequate treatment of the initial infection, complications of hospital care, or secondary to the many challenges in implementation of care transitions and immediate post-discharge care among a complex patient population.[193] [194] Research has demonstrated that targeted quality improvement initiatives can reduce sepsis readmission rates. One study at a large, academically-affiliated hospital showed that the use of multimodal interventions, such as clinical decision support tools, sepsis response teams, standardized order sets, and data-driven quality tracking, has been associated with a lower rate of infection-related readmissions as well as lower overall readmission rates.[195] Another study of patients with severe sepsis showed that post-discharge strategies, including timely home health visits and outpatient physician follow-up within the first week, reduced all-cause 30-day readmissions.[196] A randomized clinical trial at a multisite facility showed that a multicomponent post-sepsis transition service led by a nurse navigator was associated with a 20 percent reduced risk of 30-day readmission or mortality compared to usual care.[197] These findings highlight the effectiveness of both in-hospital and post-discharge quality improvement efforts in improving outcomes for sepsis patients.

(2) Overview of Measure

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19528 through 19538), we proposed to adopt the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure (Sepsis Readmission measure) for the Hospital Readmissions Reduction Program beginning with an applicable period of July 1, 2025, to June 30, 2027, for the FY 2029 program year. The purpose of the Sepsis Readmission measure is to improve patient outcomes by providing patients, physicians, hospitals, and policymakers with important information about hospital-level unplanned readmission rates following hospitalization for sepsis. The Sepsis Readmission measure encourages hospitals to improve patient safety and the quality of care provided across the care continuum by tracking hospital-level rates of sepsis readmission. The measure also promotes adherence to evidence-based practices, including standardized clinical protocols, implementation of targeted post-discharge interventions, and appropriate discharge planning. This measure also gives consumers meaningful insights into the quality of care received by Medicare patients.[198]

The measure aligns with our Meaningful Measures 2.0 priority area of ''Seamless Care Coordination,'' which aims to ensure patients receive timely and coordinated care, reduce the risk of errors, and improve overall patient outcomes.[199] The Sepsis Readmission measure has been specified to include both Medicare Fee-for-Service and Medicare Advantage beneficiaries. Including Medicare Advantage beneficiaries in CMS hospital outcome measures helps ensure that hospital quality is measured consistently across all Medicare beneficiaries.[200] This is also consistent with the program's finalization of a policy in the FY 2026 IPPS/LTCH PPS final rule to integrate Medicare Advantage beneficiaries into the cohorts of the Hospital Readmissions Reduction Program measure set beginning with the FY 2027 program year (90 FR 36923 through 36929).

[186] Shankar-Hari, et al. Rate and Risk Factors for Rehospitalization in Sepsis Survivors: Systematic Review and Meta-analysis. 2020. Intensive Care Med; 46(4):619–636. doi: 10.1007/s00134–019–05908–3

[187] Van der Slikke, E.C., Beumeler, L. F., Holmqvist, M., Linder, A., Mankowski, R.T., & Bouma, H. R. (2023). Understanding post-sepsis syndrome: how can clinicians help?. *Infection and Drug Resistance,* 6493–6511. *https://doi.org/10.2147/IDR.S390947.*

[188] Weiss A, Jiang J. Overview of clinical conditions with frequent and costly hospital readmissions by payer, 2018 #278. *hcup-us.ahrq.gov*. Published 2021. *https://hcup-us.ahrq.gov/reports/statbriefs/sb278-Conditions-Frequent-Readmissions-By-Payer-2018.jsp.*

[189] Owens, P. L., et al. (2024). Overview of Outcomes for Inpatient Stays Involving Sepsis, 2016–2021 (HCUP Statistical Brief No. 306). Agency for Healthcare Research and Quality. Available at: *https://hcup-us.ahrq.gov/reports/statbriefs/sb306-overview-sepsis-2016-2021.pdf.*

[190] Owens, P. L., et al. (2024). Overview of Outcomes for Inpatient Stays Involving Sepsis, 2016–2021 (HCUP Statistical Brief No. 306). Agency for Healthcare Research and Quality. Available at: *https://hcup-us.ahrq.gov/reports/statbriefs/sb306-overview-sepsis-2016-2021.pdf.*

[191] Cam C, Bridging the Gap: Developing a Standardized Metric for Sepsis Readmission Using CMS Methodology. Hospital Quality Institute. 2025. *https://hqinstitute.org/file/analysis-paper-developing-a-standardized-metric-for-sepsis-readmission-using-cms-methodologies/.*

[192] Taylor, Stephanie et al., 43: Effect of a Navigator-Led Transition and Recovery Program on Mortality and Readmission After Sepsis. Critical Care Medicine 49(1):p 22. (2021). doi: 10.1097/01.ccm.0000726200.09497.d2

[193] Ackermann K, Lynch I, Aryal N, Westbrook J, Li L. Hospital readmission after surviving sepsis: A systematic review of readmission reasons and meta-analysis of readmission rates. Journal of Critical Care. 2025/02/01/2025;85:154925. doi: 10.1016/j.jcrc.2024.154925

[194] Gadre S.K., Shah M, Mireles-Cabodevila E, Patel B, Duggal A. Epidemiology and Predictors of 30-Day Readmission in Patients With Sepsis. CHEST. 2019;155(3):483–490. doi:10.1016/j.chest.2018.12.008

[195] Alnababteh M.H., Huang S.S., Ryan A, McGowan K.M., Yohannes S. A Multimodal Sepsis Quality-Improvement Initiative Including 24/7 Screening and a Dedicated Sepsis Response Team-Reduced Readmissions and Mortality. Crit Care Explor. 2020 Nov 24;2(12):e0251. doi: 10.1097/CCE.0000000000000251

[196] Deb P, Murtaugh C.M., Bowles K.H., et al. Does Early Follow-Up Improve the Outcomes of Sepsis Survivors Discharged to Home Health Care? Medical Care. 2019;57(8):633–640. doi:10.1097/mlr.0000000000001152

[197] Taylor S.P., Murphy S, Rios A, et al. Effect of a Multicomponent Sepsis Transition and Recovery Program on Mortality and Readmissions After Sepsis: The Improving Morbidity During Post-Acute Care Transitions for Sepsis Randomized Clinical Trial*. Critical Care Medicine. 2022.

[198] *https://p4qm.org/measures/5275.*

[199] Centers for Medicare & Medicaid Services. (November 2025). Cascade of Meaningful Measures. Available at: *https://www.cms.gov/medicare/quality/cms-national-quality-strategy/meaningful-measures-20-moving-measure-reduction-modernization.*

[200] *https://p4qm.org/measures/5275.*

The Sepsis Readmission measure we proposed addresses a significant performance gap in healthcare quality. Sepsis represents a critical public health challenge, with substantial variation in hospital readmission rates following an index sepsis hospitalization. This variation reflects differences in the quality of initial treatment, discharge planning, and post-discharge care transitions across healthcare facilities. Based on our calculations using data from 2022–2023, the mean 30-day all-cause risk-standardized readmission rate (RSRR) for sepsis using the proposed measure methodology (see section I.b.4 for the proposed Sepsis Readmission measure methodology) for all hospitals with at least 25 eligible discharges for the measure is about 18.09 percent. Among hospitals with at least 25 eligible discharges for the Sepsis Readmission measure, hospitals with a Disproportionate Share Hospital (DSH) patient percentage of at least 65 percent and teaching hospitals with 100 or more residents have the highest mean RSRRs (18.63 percent and 18.62 percent, respectively). Additionally, safety-net hospitals with at least 25 eligible discharges have a slightly higher mean RSRR than non-safety-net hospitals with at least 25 eligible discharges (18.37 percent and 18.02 percent, respectively).

TABLE V.I.-02.: MEAN SEPSIS RSRRS BY HOSPITAL CHARACTERISTIC

	Number of Hospitals with 25 or more sepsis discharges [a]	Mean Sepsis Risk Standardized Readmission Rate (%) [b]
All Hospitals	2,597	18.09
By Geographic Location		
Urban hospitals	2,037	18.14
1-99 beds	376	17.84
100-199 beds	627	18.16
200-299 beds	393	18.32
300-399 beds	270	18.21
400-499 beds	118	18.02
500 or more beds	253	18.23
Rural hospitals	556	17.90
1-49 beds	209	17.74
50-99 beds	180	17.93
100-149 beds	94	18.13
150-199 beds	42	17.99
200 or more beds	31	18.05
By Teaching Status [c]		
No teaching	1,357	17.97
Fewer than 100 residents	941	18.09
100 or more residents	295	18.62
By Ownership Type		
Government	337	18.05
Proprietary	501	18.52
Voluntary	1,755	17.97
By Safety-net Status [d]		
Safety-net hospitals	525	18.37
Non-safety-net hospitals	2,068	18.02
By Disproportionate Share Hospital (DSH) Patient Percentage [e]		
0-24	923	18.07
25-49	1,405	18.01
50-64	154	18.51
65 and over	111	18.63
By Medicare Cost Report (MCR) Percentage [f]		

0-24	1,334	18.09
25-49	1,223	18.09
50-64	35	18.03
65 and over	1	16.76
By Region		
New England	118	18.51
Middle Atlantic	300	18.32
East North Central	422	18.15
West North Central	197	17.75
South Atlantic	465	18.29
East South Central	216	18.02
West South Central	335	18.05
Mountain	188	17.44
Pacific	355	18.02

Source: Measure results based on preliminary Sepsis Readmission measure results that were available using data from January 1, 2022, through December 31, 2023. Preliminary Sepsis Readmission measure results include hospitals that are not eligible to participate in the Hospital Readmissions Reduction Program (such as CAHs) in the estimation of RSRRs. Although data from all subsection (d), Maryland hospitals, and hospitals that are not eligible to participate in the Hospital Readmissions Reduction Program hospitals were used in calculations of each hospital's RSRR, this table does not include results for Maryland hospitals, hospitals that are not eligible to participate in the Hospital Readmissions Reduction Program, and hospitals that are not open as of the October 2025 public reporting open hospital list because these hospitals are not included in the Hospital Readmissions Reduction Program. Data from the FY 2026 IPPS/LTCH PPS proposed rule impact file were used to identify hospital characteristics. The number of hospitals with each characteristic may not sum to the total number of hospitals due to some hospitals having missing characteristic data in the impact file. This table only includes results for hospitals with at least 25 eligible discharges for the sepsis measure, as measure performance cannot be reliably estimated for hospitals with fewer than 25 eligible discharges.

[a] This table only includes results for hospitals with at least 25 eligible discharges for the sepsis measure as measure performance cannot be reliably estimated for hospitals with fewer than 25 eligible discharges.
[b] The RSRR is the ratio of the predicted readmission rate based on the hospital's performance with its patient case mix to the expected readmission rate based on readmission rates at an average hospital with a patient case mix similar to that hospital's, multiplied by the national observed readmission rate.
[c] A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operation PPS greater than zero.

[d] A hospital is considered a safety-net hospital if it is in the top DSH quintile.

[e] DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.
[f] MCR (Medicare Cost Report) percentage is the percentage of total inpatient stays from Medicare patients.

As discussed in the Background section, research demonstrates that thirty-day hospital readmissions following sepsis hospitalization often stem from ineffective initial treatment, poor discharge planning, and insufficient post-discharge follow-up. Studies have shown that facilities implementing a higher number of evidence-based transitional care processes experience lower readmission rates, indicating substantial opportunity for quality improvement across the healthcare system.

Given that infection (either new or recurrent) is the leading cause of sepsis-related readmission, and that evidence-based interventions such as care coordination, medication reconciliation, patient education, and timely post-discharge follow-up have been proven effective in reducing readmissions, this measure would provide hospitals with actionable feedback to enhance quality across the entire care continuum and reduce preventable readmissions for a population not captured in CMS' other condition- and procedure-specific readmission measures.

(3) Measure Specifications

(a) Numerator

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19531), we stated that the numerator of the measure is defined as Medicare Fee-for-Service or Medicare Advantage beneficiaries aged 65 years and older, who were discharged from the hospital with a principal diagnosis of sepsis (including post-procedural sepsis), who were then readmitted to an acute care hospital for any cause within 30 days. Patients must have been enrolled in Medicare Fee-for-Service or Medicare Advantage during the index admission and for the 12 months prior to the date of admission, discharged alive from a non-federal short-term acute care hospital, and not transferred to another acute care facility. Only an unplanned inpatient admission to a short-term acute care hospital can qualify as a readmission. Planned readmissions, which are generally not a signal of quality of care, are not included in the numerator. For details of the measure methodology, we refer readers to the measure methodology report, available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology.*

(b) Denominator

The measure denominator includes all Medicare Fee-for-Service or Medicare Advantage beneficiaries aged 65 years and older, hospitalized at non-federal short-term acute care hospitals who are discharged alive following a principal hospital discharge diagnosis of sepsis (including post-procedural sepsis), and with a continuous 12-month Medicare enrollment period prior to the index hospitalization.

This measure excludes index admissions for patients who meet additional exclusion criteria, including: (1) admissions during which patients leave the hospital against medical advice (AMA) (excluded because providers may not have the opportunity to deliver full care and prepare the patient for discharge); (2) admissions for patients without at least 30 days post-discharge enrollment in Medicare Fee-for-Service or Medicare Advantage (excluded because the 30-day

readmission outcome cannot be assessed in this group); (3) admissions resulting in patients discharged to hospice (readmission may not be a meaningful outcome for these hospice patients and the discharging hospital is not the most appropriate party to hold accountable for the readmission from hospice for this measure); (4) sepsis admissions captured in the pneumonia readmission measure (to avoid overlap with the pneumonia readmission measure); and (5) sepsis admissions within 30 days of an eligible sepsis index admission (excluded because they are considered readmissions, not index admissions). For more information about the measure specifications, we refer readers to the methodology report, available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*.

(c) Risk Adjustment

To account for differences in case mix across hospitals, the Sepsis Readmission measure includes risk adjustments for patient factors such as age, comorbid diseases, and indicators of patient frailty. The measure also adjusts for the aggressiveness of the infectious organism (bacteria, virus, or fungus) causing sepsis, a transplant recipient indicator, and clinical markers of severe sepsis. These factors are included in risk adjustment calculations for the measure because they are clinically relevant and are related to the measure outcome. For each patient, risk adjustment variables are obtained from inpatient, outpatient, and physician Medicare administrative claims data (Medicare Fee-for-Service Part A and Part B claims, hospital-submitted Medicare Advantage claims, and Medicare Advantage Organization-submitted encounter data) extending up to 12 months prior to the index hospitalization, and secondary diagnoses documented as present on admission during the index hospitalization. The risk adjustment does not include complications that arise during the course of the index hospitalization because they reflect the quality of care delivered and fall within the causal pathway rather than patient risk.[201] For more information on risk adjustment we refer readers to the methodology report, available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology.*

[201] *https://p4qm.org/measures/5275.*

(4) Calculating Sepsis Risk-Standardized Readmission Rate

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19532), we stated that the Sepsis Readmission measure calculates hospital-level 30-day all-cause risk-standardized readmission rates (RSRR) for sepsis. The sepsis RSRR will be calculated as the ratio of the number of predicted readmissions based on the hospital's performance with its observed case mix to the number of expected readmissions based on the average national level of performance with that hospital's case mix, multiplied by the national observed readmission rate. This is the same measure calculation methodology as the current measures in the Hospital Readmissions Reduction Program. For more detail on how the Sepsis Readmission measure would be used to calculate the 30-day Risk-Standardized Readmission Rate, we refer readers to the methodology report, available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology.*

(5) Calculating the Excess Readmission Ratio

As we proposed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19532), the Sepsis Readmission measure would use the same methodology and statistical modeling approach as the current measures in the Hospital Readmissions Reduction Program. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673 through 51676), we finalized the excess readmission ratio pursuant to section 1886(q)(4)(C) of the Act. The ratio is calculated using hierarchical logistic regression. The method adjusts for variation across hospitals in how sick their patients are when admitted to the hospital (and therefore, variation in hospital patients' readmission risk) as well as the variation in the number of patients that a hospital treats to reveal differences in quality. The method produces an adjusted actual (or ''predicted'') number in the numerator and an ''expected'' number in the denominator. The expected calculation is similar to that for logistic regression—it is the sum of all patients' expected probabilities of readmission, given their risk factors and the risk of readmission at an average hospital with a similar patient case mix. For each hospital, the numerator of the ratio used in the consensus-based entity methodology (actual adjusted readmissions) is calculated by estimating the probability of readmission for each patient at that hospital and summing up over all the hospital's patients to get the actual adjusted number of readmissions for that hospital. The ratio compares the total adjusted actual readmissions at the hospital to the number that would be expected if the hospital's patients were treated at an average hospital with similar patients. Hospitals with more adjusted actual readmissions than expected readmissions will have a risk-standardized ratio (excess readmission ratio) greater than one.

For additional detail on the methodology of excess readmission ratio calculations, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53380 through 53381). We also refer readers to section V.I.2.b.(9) of this final rule for a description of how the Sepsis Readmission measure would be incorporated into the Hospital Readmissions Reduction Program payment adjustment beginning with the FY 2029 program year.

(6) Reliability Testing

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19532), we stated that reliability testing was conducted to assess the consistency and stability of the Sepsis Readmission measure in distinguishing hospital performance. The testing methodology evaluated whether observed differences in hospital readmission rates reflect true differences in quality of care rather than random variation.

The reliability analysis employed standard statistical approaches to examine measure performance across hospitals with varying patient volumes. Specifically, we assessed split-half reliability, also called split-sample reliability, to test the internal consistency or stability of the measure. Reliability was estimated both at the measure score and accountable-entity levels.

Reliability testing was assessed using 2 years of data from January 1, 2022, through December 31, 2023. Table V.I.-03 shows split-half reliability results at the measure score level for hospitals with a minimum case of ≥ 2 cases and ≥ 25 cases (the proposed threshold for public reporting), respectively. The results indicate that the measure is sufficiently reliable for distinguishing between high- and low-performing hospitals, consistent with the minimum standard for reliability set forth by the Partnership for Quality Measurement (≥ 0.60).[202]

[202] For more details on reliability guidance, we refer readers to the Reliability Guidance for the Endorsement and Maintenance of Clinical Quality Measures Document available at: *https://p4qm.org/em/resources.*

TABLE V.I.-03.: MEASURE SCORE SPLIT-HALF RELIABILITY (JANUARY 1, 2022 – DECEMBER 31, 2023)

Minimum Case Volume	Number of Hospitals (%)	Number of Patients (%)	Split-half Reliability Score
>=2	4,287 (100)	1,326,427 (100)	0.6
>=25	3,053 (71.2)	1,315,690 (99.2)	0.6

Table V.I.–04 shows the accountable entity-level reliability results for hospitals with a minimum case of ≥ 25 cases (the proposed threshold for public reporting). Hospitals were categorized into volume deciles to assess reliability across different facility sizes and patient populations. Using this method, 69 percent of accountable entities met the split-half reliability estimate threshold of ≥ 0.60. This indicates that the measure is sufficiently reliable for distinguishing between high- and low-performing hospitals.

TABLE V.I.-04.: ACCOUNTABLE ENTITY LEVEL RELIABILITY ESTIMATE (JANUARY 1, 2022 – DECEMBER 31, 2023)

	Overall	Min	Decile 1	Decile 2	Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10	Max
Mean Reliability	0.682	0.205	0.254	0.384	0.521	0.642	0.727	0.782	0.826	0.862	0.894	0.932	0.986
Mean Performance Score	18.085	18.107	17.944	17.984	17.939	18.037	18.064	18.155	18.074	18.177	18.264	18.21	20.756
N of Entities	**3,053**	21	312	296	309	305	306	302	308	305	306	304	1
N of Persons / Encounters / Episodes	**1,315,690**	525	10,421	18,064	33,027	53,529	79,658	105,855	142,821	186,672	253,832	431,811	6,769

The Sepsis Readmission measure demonstrates acceptable reliability based on the split-half reliability method, both at the measure score level, and at the entity level. The measure's strong reliability, combined with evidence of substantial performance variation, indicates that it will provide hospitals with actionable, consistent feedback to drive improvements in sepsis care transitions and reduce preventable readmissions.

We also conducted additional analyses to examine coding variability as a source of bias in entity level performance scores; and post-discharge mortality within 30 days of discharge to account for competing risk of mortality in readmission risk. The analyses found no correlation between the hospital level use of sepsis code A41.9 (the most widely used code) and readmission or mortality risk. There was also no correlation between post-discharge mortality and readmission risk at the entity (hospital) level. Post-discharge mortality was stable with increasing duration of time since discharge and up to 30 days. Please refer to the measure methodology report on QualityNet for more detailed information on these analyses, available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology.*

(7) Pre-Rulemaking Process and Measure Endorsement

(a) Recommendation From the Pre-Rulemaking Measure Review (PRMR) Process

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19533), we referred readers to the Partnership for Quality Measurement website for details on the PRMR process, including the voting procedures used to reach consensus on measure recommendations.[203] [204] The PRMR Hospital Committee met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available ''2025 Measures Under Consideration List,'' including the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure (MUC2025–055).[205]

The voting results of the PRMR Hospital Recommendation Group for the proposed Sepsis Readmission measure within the Hospital Readmissions Reduction Program were as follows: 13 (65 percent) of the Recommendation Group members recommended adopting the measure into the Hospital Readmissions Reduction Program; seven (35 percent) of the Recommendation Group members voted not to recommend the measure for adoption.[206] With 65 percent of the votes for recommend, consensus was not reached, but the majority of the Recommendation Group expressed some support for use of the measure in the Hospital Readmissions Reduction Program. Recommendation Group members who voted not to recommend adoption of the measure for the Program provided the following rationales: (1) concerns about adopting the Sepsis Readmission measure directly into the Hospital Readmissions Reduction Program; (2) methodological concerns; and (3) the need for greater consistency in sepsis definitions across measures and payers.

The Recommendation Group expressed concerns about adopting the Sepsis Readmission measure directly into the Hospital Readmissions Reduction Program, given the payment implications and the perception that hospitals may need time to adapt. Several members recommended a staged approach—initial implementation in the Hospital Inpatient Quality Reporting Program for multiple years, followed by later consideration for Hospital Readmissions Reduction Program—so hospitals have adequate time to understand the measure before the measure is tied to payment.

We appreciate these implementation concerns and agree that careful rollout planning is important for any measure proposed for pay-for-performance programs. We agree that hospitals will benefit from understanding their performance on the Sepsis Readmission measure and potential impacts to their payment under the Hospital Readmissions Reduction Program prior to using the measure for payment adjustments. We considered whether to first adopt this measure in the Hospital Inpatient Quality Reporting Program, in

[203] Battelle, Partnership for Quality website. Available at: *https://p4qm.org/.*

[204] In 2025, we updated the PRMR voting process such that committee members will vote to either ''recommend'' or ''do not recommend'' that a measure be added to the intended CMS program(s), thus, removing the ''recommend with conditions'' voting option. The threshold to reach consensus on a given measure continues to be a minimum of 75 percent agreement among members. Committee members can provide considerations for CMS to review prior to implementation.

[205] Centers for Medicare & Medicaid Services. (2025). 2025 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview.* Accessed February 26, 2026.

[206] Battelle. (February 2026). National Consensus Development and Strategic Planning for Health Care Quality Measurement 2025–2026 Pre-Rulemaking Measure Review (PRMR) Recommendation Group Final Meeting Summary: Hospital Committee. *https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf* Accessed February 26, 2026.

order to give hospitals time to become familiar with the measure before adopting it in a penalty program. However, given the significant morbidity and mortality linked to sepsis and the high case volume and cost of hospital readmissions, we proposed to adopt the measure directly into the Hospital Readmissions Reduction Program, but using a phased approach, in an effort to balance implementation concerns against our intention to address this CMS priority in a timely manner. Specifically, we proposed to implement the Sepsis Readmission measure with ''early look'' reports for FY 2028—discussed further in section V.I.2.b.(9)—that would include sepsis readmission rates as well as estimated Hospital Readmissions Reduction Program payment adjustments with the addition of the Sepsis Readmission measure before beginning to use this measure in the FY 2029 payment adjustment. In addition, we stated in the proposed rule that we would continue to evaluate measure performance characteristics (including hospital-level reliability, stability year-over-year, and subgroup impacts such as rural/low-volume hospitals) as part of routine measure maintenance.[207]

Committee members also raised methodological concerns, including the perceived imprecision of claims-based readmission measures and uncertainty about risk adjustment adequacy, particularly for rural hospitals and hospitals facing documentation constraints (for example, non-employed clinicians, limited resources). We acknowledge the committee's view of the limitations and variability in the accuracy of claims-based measures; however, claims-based readmission measures are widely used in CMS programs because they are nationally scalable, consistently available, and minimize provider reporting burden while enabling standardized comparisons across hospitals. For this measure specifically, we conducted analyses to examine variation in the use of sepsis codes across hospitals, stratified by volume of sepsis cases treated, and observed no correlation with 30-day readmission or mortality, indicating that documentation practices are not driving hospital measure performance. We wish to emphasize that the risk adjustment variables were identified through a deliberative and empirical process that resulted in a robust risk adjustment model that includes clinically relevant variables such as severity of sepsis, source of infection, how aggressive the infectious organism is, immunocompromised state of the patient, and organ failure/dysfunction. The risk model demonstrated strong calibration and discrimination in testing including for patients with differing severity of sepsis. For more details on our analysis of measure reliability and the risk adjustment methodology, we refer readers to subsection (6) in this section and to the measure methodology report, available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology.*

Finally, the committee emphasized the need for greater consistency in sepsis definitions across measures and payors, with many urging alignment with Sepsis-3 as the most current international consensus definition.[208] CMS noted that differing definitions can reflect deliberate tradeoffs between sensitivity and specificity; [209] a scan of the literature shows that the most common problems with sepsis diagnoses relate to under-coding by providers due to inconsistent coding practices.[210] The developer noted that the current approach yields excellent model performance and identifies a clinically meaningful at-risk population for readmission. We appreciate the committee's request for clarity and standardization, particularly given reported coding and claims-denial dynamics that may influence whether sepsis is included on a claim. We note that we conducted analyses to examine coding practices as a factor that impacts performance scores and found no evidence to support this relationship. Further, as a part of routine measure maintenance, we conduct ongoing monitoring and evaluation analyses to watch for any unintended consequences.

(b) Measure Endorsement

We refer readers to the Partnership for Quality Measurement website for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. The measure was submitted for review in the Fall 2025 cycle. The Cost and Efficiency Recommendation Group reviewed the Hospital-Level, Risk-Standardized 30-day All-Cause Readmission Following Hospitalization for Sepsis (CBE# 5275) on February 6, 2026. The voting results of the Recommendation Group were: 16 members (84 percent) voted to endorse the measure, and 3 members (16 percent) voted not to endorse the measure. With a vote of 84 percent, the measure was endorsed, without conditions.[211]

(8) Payment Reductions

The payment adjustment factor under the Hospital Readmissions Reduction Program is calculated as the greater of 1 minus the ratio of aggregate payments for excess readmissions for the applicable condition to aggregate payments for all discharges or the applicable floor adjustment factor, as defined by Section 1886(q)(3)(A) of the Act. The definition for ''aggregate payments for excess readmissions'' is codified at § 412.152 and the methodology to calculate the payment adjustment factor is codified at § 412.154(c).

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19534), we stated that as a result of the proposal to add sepsis as an applicable condition under the Hospital Readmissions Reduction Program, excess readmissions for sepsis would be included in the calculation of aggregate payments for excess readmissions beginning with the FY 2029 program year. Consistent with the definition codified at § 412.152, aggregate payments for excess readmissions would include the aggregate base operating DRG payments for excess readmissions associated with sepsis, as applicable. Accordingly, the

[207] We conduct an annual reevaluation of measures implemented in its quality reporting and value-based purchasing programs to ensure that they remain valid and reflective of current clinical practice and coding standards. As part of this process, we may update measure cohorts, risk adjustment models, or outcomes, as appropriate. These updates are informed by review of the most recent scientific literature, stakeholder input, empirical analyses, and assessments of coding trends that may indicate shifts in clinical practice or billing patterns.

[208] Singer M, Deutschman CS, Seymour CW, et al. The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). *JAMA.* 2016;315(8):801–810. doi:10.1001/jama.2016.0287

[209] While there is no one consensus definition of sepsis, Sepsis-2 (based mainly on Systemic Inflammatory Response Syndrome criteria or SIRS) is highly sensitive, often identifying patients before severe deterioration. Sepsis-3 (based primarily on Sequential Organ Failure Assessment or SOFA) is highly specific, meaning it risks missing patients. Based on detailed expert clinical and TEP input, we elected to align the measure with Sepsis-2 definition in order to ensure cases were not missed, but also ensured no overlap with existing condition- and procedure-specific 30-day readmission measures.

[210] Liu B, Hadzi-Tosev M, Liu Y, Lucier KJ, Garg A, Li S, Heddle NM, Rochwerg B, Ning S. Accuracy of International Classification of Diseases, 10th Revision Codes for Identifying Sepsis: A Systematic Review and Meta-Analysis. Crit Care Explor. 2022 Nov 9;4(11):e0788. doi: 10.1097/CCE.0000000000000788. PMID: 36382338; PMCID: PMC9649267.

[211] *https://p4qm.org/sites/default/files/Cost%20and%20Efficiency/material/ContractNo-75FCMC23C0010-Cost-EM-Technical-Report-Fall-2025-508.pdf.*

inclusion of sepsis as an applicable condition would be reflected in the calculation of the payment adjustment factor consistent with the established methodology of the program.

To assess the expected impact on hospital payment adjustments resulting from the proposal to adopt the Sepsis Readmission measure, we estimated hospitals' payment adjustment factors including the Sepsis Readmission measure. Table V.I.–05. shows the estimated total Medicare savings with and without the Sepsis Readmission measure included in the program measure set. Based on our analysis, the estimated average payment reduction per penalized hospital when including the Sepsis Readmission measure increased by approximately $63,500.

TABLE V.I.-05.: ESTIMATED TOTAL MEDICARE SAVINGS OF PROPOSED ADOPTION OF SEPSIS READMISSION MEASURE TO HOSPITAL READMISSIONS REDUCTION PROGRAM MEASURE SET

	Current measure set (without sepsis)	Proposed measure set with sepsis	Difference between proposed and current measure sets	Percentage difference between proposed and current measure sets
Estimated total Medicare savings	$361,347,626	$530,998,964	$169,651,338	47%
Number of penalized hospitals	2,358	2,450	92	4%

Our analysis, as reflected in Table V.I.–05, also assessed the impact of the proposed Sepsis Readmission measure adoption on the number of hospitals that could be penalized under the Hospital Readmissions Reduction Program (that is, they have 25 or more eligible discharges for at least one measure), the number and percentage of penalized hospitals, and penalties as a share of payments overall and by hospital characteristics. The results for the current measure set are equal to those in Table V.I.–02., which show the estimated results for the FY 2027 Hospital Readmissions Reduction Program by hospital characteristic. The second and sixth columns in Table V.I.–06. indicate the total number of hospitals that could be penalized under the Hospital Readmissions Reduction Program. Poorly performing hospitals included in the program may receive a penalty if they are non-Maryland subsection (d) hospitals with 25 or more eligible discharges for at least one measure during the applicable period. The third and seventh columns in the table indicate the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is, penalized hospitals). The fourth and eighth columns in the table indicate the estimated percentage of penalized hospitals among those that could be penalized by hospital characteristic. The fifth and ninth columns in the table estimate the financial impact on hospitals by hospital characteristic, referred to as the penalty as a share of payments. The penalty as a share of payments is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals. For example, under the current measure set without sepsis, the penalty as a share of payments for urban hospitals is 0.48 percent, and with the proposed updates, the penalty as a share of payments for urban hospitals is 0.68 percent. This means that total penalties for all urban hospitals are 0.48 percent of total payments for urban hospitals under the current measure set and 0.68 percent with the proposed measure set to add sepsis. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals with the characteristic when comparing the financial impact of the program on different groups of hospitals.

TABLE V.I.-06.: COMPARISON OF PROPOSED SEPSIS READMISSION MEASURE IN HOSPITAL READMISSIONS REDUCTION PROGRAM BY HOSPITAL CHARACTERISTIC

	Current measure set (without Sepsis Readmission measure)				Proposed measure set (with Sepsis Readmission measure)			
Hospital Characteristic	Number of Hospitals Eligible for a Penalty [a]	Number of Penalized Hospitals [b]	Percentage of Hospitals Penalized (%) [c]	Penalty as a Share of Payments (%) [d]	Number of Hospitals Eligible for a Penalty [a]	Number of Penalized Hospitals [b]	Percentage of Hospitals Penalized (%) [c]	Penalty as a Share of Payments (%) [d]
All Hospitals	2,832	2,358	83.26	0.48	2,836	2,450	86.39	0.68
By Geographic Location								
Urban hospitals	2,180	1,876	86.06	0.48	2,183	1,937	88.73	0.68
1-99 beds	511	358	70.06	0.48	514	382	74.32	0.64
100-199 beds	635	562	88.50	0.56	635	580	91.34	0.79
200-299 beds	393	365	92.88	0.57	393	372	94.66	0.84
300-399 beds	270	251	92.96	0.49	270	256	94.81	0.69
400-499 beds	118	111	94.07	0.45	118	112	94.92	0.63
500 or more beds	253	229	90.51	0.39	253	235	92.89	0.57
Rural hospitals	646	480	74.30	0.47	647	509	78.67	0.69
1-49 beds	295	183	62.03	0.37	296	200	67.57	0.47
50-99 beds	184	148	80.43	0.49	184	156	84.78	0.69
100-149 beds	94	82	87.23	0.52	94	84	89.36	0.84
150-199 beds	42	38	90.48	0.50	42	39	92.86	0.72
200 or more beds	31	29	93.55	0.46	31	30	96.77	0.69
By Teaching Status [e]								
Non-teaching	1,578	1,241	78.64	0.51	1,582	1,303	82.36	0.72
Fewer than 100 residents	953	838	87.93	0.50	953	859	90.14	0.70
100 or more residents	295	277	93.90	0.42	295	284	96.27	0.63
By Ownership Type								
Government	397	324	81.61	0.32	397	339	85.39	0.47
Proprietary	611	492	80.52	0.66	612	516	84.31	0.99
Voluntary	1,818	1,540	84.71	0.47	1,821	1,591	87.37	0.66
By Safety-net Status [f]								
Safety-net hospitals	566	470	83.04	0.44	567	498	87.83	0.65
Non-safety-net hospitals	2,260	1,886	83.45	0.49	2,263	1,948	86.08	0.69
By Disproportionate Share Hospital (DSH) Patient Percentage [g]								
0-24	1,069	868	81.20	0.54	1,072	899	83.86	0.77
25-49	1,470	1,255	85.37	0.44	1,470	1,294	88.03	0.62
50-64	166	132	79.52	0.51	166	144	86.75	0.76
65 and over	121	101	83.47	0.58	122	109	89.34	0.89
By Medicare Cost Report (MCR) Percentage [h]								
0-24	1,404	1,192	84.90	0.39	1,407	1,238	87.99	0.58
25-49	1,355	1,124	82.95	0.56	1,356	1,166	85.99	0.79
50-64	60	38	63.33	0.71	60	40	66.67	0.90
65 and over	7	2	28.57	2.73	7	2	28.57	2.73
By Region								
New England	120	115	95.83	0.63	120	116	96.67	0.89
Middle Atlantic	313	293	93.61	0.62	313	295	94.25	0.87
East North Central	443	379	85.55	0.49	443	390	88.04	0.70
West North Central	223	176	78.92	0.38	223	185	82.96	0.47
South Atlantic	485	424	87.42	0.49	486	443	91.15	0.74
East South Central	252	208	82.54	0.43	252	219	86.90	0.61
West South Central	422	322	76.30	0.37	424	341	80.42	0.55
Mountain	206	140	67.96	0.32	207	149	71.98	0.45
Pacific	367	301	82.02	0.43	367	311	84.74	0.63

Source: Current and proposed measure set results based on preliminary Medicare Advantage and Medicare-Fee-for-Service readmission measure results that were available using data from January 1, 2022, through December 31, 2023. Preliminary Medicare Advantage and Medicare-Fee-for-Service and Sepsis Readmission measure results included hospitals that were not eligible to participate in the Hospital Readmissions Reduction Program (such as CAHs) in the estimation of excess readmission ratios (ERRs). Although data from all subsection (d), Maryland hospitals, and hospitals that were not eligible to participate in the Hospital Readmissions Reduction Program hospitals were used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals, hospitals that are not eligible to participate in the Hospital Readmissions Reduction Program, and hospitals that were not open as of the October 2025 public reporting open hospital list because these hospitals were not included in the Hospital Readmissions Reduction Program. Dual proportions and Fee-for-Service base operating DRG ratios were calculated from July 1, 2021, through June 30, 2023. MedPAR data from October 1, 2022, through September 30, 2023 (FY 2023) were used to calculate the payment adjustment as a proportion of total base operating DRG payments. Data from the FY 2026 IPPS/LTCH PPS proposed rule impact file was used to identify hospital characteristics. The number of hospitals with each characteristic may not sum to the total number of hospitals due to some hospitals having missing characteristic data in the impact file. This table only includes results for hospitals that could be penalized under the program on the basis of having at least 25 eligible discharges for at least one measure. The average share of penalties as a percentage of all base operating DRG payments was calculated as the sum of all Medicare savings for the group of hospitals divided by total base operating DRG payments for all hospitals in that group.

[a] This column is the number of applicable hospitals within the characteristic that could be penalized (that is, they have 25 or more eligible discharges for at least one measure).

[b] This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an estimated payment adjustment factor less than 1) within the characteristic.

[c] This column is the percentage of applicable hospitals that are penalized among hospitals that could be penalized, by characteristic.

[d] This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments in this way allows for comparisons across hospital characteristics that accounts for differences in the amount of base operating DRG payments for different groups of hospitals. MedPAR data from October 1, 2022, through September 30, 2023 (FY 2023), are used to estimate the total base operating DRG payments.

[e] A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operation PPS greater than zero.

[f] A hospital is considered a safety-net hospital if it is in the top DSH quintile.

[g] DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[h] MCR (Medicare Cost Report) percentage is the percentage of total inpatient stays from Medicare patients.

(9) Data Submission, Early Look, and Public Reporting

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19538), we stated that the Sepsis Readmission measure uses Medicare administrative data (Medicare Fee-for-Service Part A and Part B claims, hospital-submitted Medicare Advantage claims, and Medicare Advantage Organization-submitted encounter data) for Medicare Fee-for-Service and Medicare Advantage beneficiaries hospitalized for sepsis. Because this measure utilizes CMS administrative data, a hospital would not be required to submit additional data for calculating the measure. In the FY 2026 IPPS/LTCH PPS final rule, we finalized our policy to use 2 years of claims data to calculate readmission measures (90 FR 36931 through 36932) in conjunction with the policy to integrate Medicare Advantage beneficiaries into the cohorts of the Hospital Readmissions Reduction Program measure set (90 FR 36923 through 36929) beginning with the FY 2027 program year.

We considered whether to first adopt this measure in the Hospital Inpatient Quality Reporting Program, in order to give hospitals time to become familiar with the measure before adopting it in

a penalty program. However, as discussed in section V.I.2.b.(1) of the FY 2027 IPPS/LTCH PPS proposed rule, given the significant morbidity and mortality linked to sepsis and the high case volume and cost of hospital readmissions, and our intention to address this CMS priority in a timely manner, we proposed to adopt the measure in the Hospital Readmissions Reduction Program without delay, but also to provide hospitals with an ''early look'' of their Sepsis Readmission measure results and estimated Hospital Readmissions Reduction Program payment adjustments with the addition of the Sepsis Readmission measure for the FY 2028 program year, for which the applicable period is from July 1, 2024, to June 30, 2026. As proposed, data used in this early look would not be publicly reported or used for payment adjustment; the early look would provide hospitals with confidential reports of their measure and program results prior to public reporting of the Sepsis Readmission measure beginning with the FY 2029 program year.

We proposed that the Sepsis Readmission measure would be used for payment adjustment beginning with the FY 2029 program year, for which the applicable period is from July 1, 2025, to June 30, 2027. We recognize that the first year of data used to calculate the Sepsis Readmission measure would include patient data from a period of time predating the proposal of the measure. We note that the approach of including that data in public reporting and payment determination is consistent with prior claims-based measure adoptions in the Hospital Readmissions Reduction Program. We reiterate that this measure will not require any additional data from hospitals and that the proposed implementation timeline would support our goal of addressing the health care quality gap in sepsis care in a timely manner. Consistent with the standard of care for patients with sepsis, we expect that hospitals are already providing the types of discharge planning and care coordination services that would be expected to minimize readmissions. Additionally, more than half of the proposed first reporting period would take place after the intended publication date of the FY 2027 IPPS/LTCH PPS proposed rule. This will allow hospitals to make any necessary improvements to their discharge planning and care coordination processes. We refer readers to the FY 2015 IPPS/LTCH PPS final rule for an example of such an instance (79 FR 50033 through 50039). We will continue to publicly report readmission rates by publicly posting the readmission measure results annually for the applicable conditions for each hospital on the Compare tool or successor website(s), currently available at *https://www.medicare.gov/care-compare/*, and on the Provider Data Catalog, available at *https://data.cms.gov/provider-data/,* as codified at § 412.154(f).

We invited public comment on our proposal to adopt the Sepsis Readmission measure as part of the Hospital Readmissions Reduction Program measure set beginning with an early look for the FY 2028 program year (applicable period of July 1, 2024, to June 30, 2026), and use for the FY 2029 program year (applicable period of July 1, 2025, to June 30, 2027) and subsequent years.

Comment: Several commenters supported the adoption of the Sepsis Readmission measure into the Hospital Readmissions Reduction Program for use in the FY 2029 program year and subsequent years, stating that it will improve quality, care coordination, and safety of post-sepsis transitions of care and reduce recurrent infection and complications following sepsis treatment. A commenter supported the inclusion of Medicare Advantage (MA) patients, stating that the inclusion will improve the accuracy of performance comparisons by more fully reflecting patient populations.

Response: We thank commenters for their support. We agree that the Sepsis Readmission measure will support quality of care for patients with sepsis discharging from hospitals.

Comment: A few commenters supported the proposal but had suggestions for future rulemaking. A commenter stated that CMS should align the measure with existing sepsis quality measures to create a coherent set of initiatives. Another commenter requested that CMS incorporate diagnostic-informed clinical decision-making, risk stratification, and care planning as part of future measure refinements.

Response: We thank commenters for their support and will consider these suggestions in future rulemaking.

Comment: Many commenters expressed concern that the proposal to include the Sepsis Readmission measure in the Hospital Readmissions Reduction Program did not allow sufficient time for hospitals to review the methodology, receive feedback, validate performance, and understand how patient complexity is addressed. Commenters were appreciative of the ''early look'' reports, but a few commenters requested that CMS provide at least two full years of an early look, to include providing hospitals with confidential, hospital-specific feedback, before incorporating the measure into Hospital Readmissions Reduction Program for payment purposes. A few commenters noted that hospitals are already halfway through the performance period for which they would be held financially accountable. A commenter recommended delaying implementation of the measure for performance-based accountability until the FY 2031 program year.

Response: We appreciate the commenters' concerns and are finalizing the proposal with modification. Specifically, we will adopt the Sepsis Readmission measure as part of the Hospital Readmissions Reduction Program measure set beginning with early looks for the FY 2028 (applicable period of July 1, 2024 to June 30, 2026) and FY 2029 (applicable period of July 1, 2025 to June 30, 2027) program years. The measure will then be used in the Hospital Readmissions Reduction Program for payment adjustment beginning with the FY 2030 program year (applicable period of July 1, 2026 to June 30, 2028) and subsequent years.

During the ''early look'' periods, data will not be publicly reported or used for payment adjustment; the early look will provide hospitals with confidential reports of their measure and program results prior to public reporting of the Sepsis Readmission measure beginning with the FY 2030 program year. We believe one additional year of confidential reporting prior to impacting hospital payments appropriately balances the need to address an important area of quality measurement with commenters' requests for additional time to understand measure specifications, review performance results, and assess and enact potential improvement opportunities for their hospital operations. The additional year also addresses the concern that we are finalizing this measure during the period that will inform the first early look. During this period, hospitals will have the opportunity to evaluate their performance, familiarize themselves with measure methodology, and better understand how risk adjustment, patient complexity, and attribution are reflected in their results before the measure affects payment.

Comment: Many commenters stated that the measure should be implemented into the Hospital Inpatient Quality Reporting Program for further testing and public reporting before it is used to determine payment penalties.

Response: As we stated in the proposed rule, given the significant

morbidity and mortality linked to sepsis and the high case volume and cost of hospital readmissions, we will adopt the measure directly into the Hospital Readmissions Reduction Program using a phased approach in an effort to balance implementation concerns against our intention to address this CMS priority in a timely manner. To further address commenters' concerns, we are finalizing an additional early look period for the FY 2029 program year before the Sepsis Readmission measure is used for payment adjustments beginning with the FY 2030 program year.

Comment: Another commenter noted that the Partnership for Quality Measurement's Hospital Recommendation Group did not reach consensus and recommended additional monitoring in a non-penalty context before broader program use.

Response: We appreciate the commenter's concern regarding the lack of consensus from the Pre-Rulemaking Measure Review (PRMR) Hospital Recommendation Group. The Cost and Efficiency Recommendation Group reviewed the Hospital-Level, Risk-Standardized 30-day All-Cause Readmission Following Hospitalization for Sepsis (CBE# 5275) on February 6, 2026. Sixteen members (84 percent) voted to endorse the measure, and 3 members (16 percent) voted not to endorse the measure. The measure was therefore endorsed, without conditions. While the PRMR Hospital Recommendation Group did not reach consensus on adoption, a majority supported the measure, and we maintain that this measure addresses a high-priority area.

Comment: Many commenters raised methodological concerns regarding the incorporation of Medicare Advantage (MA) data and the risk-adjustment methodology. Several commenters expressed concern about the inclusion of MA beneficiaries in the measure and stated that CMS did not provide sufficient information on how this change will impact the reliability and validity of the measure. A few commenters suggested that CMS maintain distinct MA and FFS results to preserve established benchmarks and allow evaluation of differences in MA performance. A commenter expressed concern that the Sepsis Readmission measure will rely on MA encounter data rather than paid claims to calculate hospital results and that doing so will affect the integrity of any readmissions data. The commenter recommended that CMS clarify which data elements it intends to use.

Response: As we stated in the proposed rule, the Sepsis Readmission measure has been specified to include both Medicare Fee-for-Service and MA beneficiaries. Including MA beneficiaries in CMS hospital outcome measures helps ensure that hospital quality is measured consistently across all Medicare beneficiaries.[212] We believe combining FFS and MA beneficiaries is appropriate, because hospitals generally provide care to both populations through the same clinical systems and care processes. We note that MA beneficiaries comprise a growing share of Medicare enrollees and that hospitals are responsible for providing high quality care to all their patients, regardless of payer. Hospitals must work closely with insurers, including MA plans, to ensure high quality care for all their patients. By adding the MA cohort to the Hospital Readmissions Reduction Program measures, we would provide a more robust and holistic view of the quality of care provided to all Medicare beneficiaries. In addition, the measure testing included the combined FFS and MA population and demonstrated acceptable reliability and validity. We believe inclusion of MA beneficiaries improves the representativeness of the measure and better reflects the patient populations served by hospitals. Measure development and testing demonstrated that inclusion of MA beneficiaries increases the number of eligible cases available for assessment and supports measure reliability than compared to the FFS-only cohort, particularly for hospitals with lower sepsis volumes. We combined Medicare Advantage Organization (MAO)-submitted encounter data and hospital-submitted MA admission claims because each source captures admissions not fully reflected in the other. MAO-submitted encounter data include admissions absent from hospital-submitted claims, and a smaller share of admissions appear only in hospital-submitted claims. Combining both sources provides a more complete capture of MA admissions than either source alone. The risk-adjustment methodology was developed and validated using these data sources. Internal measure development and testing results showed that, on average, observed readmission rates were similar between FFS- and MA-only patients for most conditions and procedures.[213] To account for any case-mix difference between FFS and MA patients, the risk model includes an indicator for MA versus FFS enrollment. Additionally, calibration plots showed that the model performs well for MA and FFS respectively. We do not believe that the use of MA encounter data compromises the integrity of the measure. Rather, inclusion of these data allows for a more complete assessment of hospital performance across the Medicare population.

With respect to suggestions that we maintain separate MA and FFS results, we note that the purpose of the measure is to assess hospital performance across the Medicare population as a whole. Keeping FFS and MA patients together for purposes of this measure's calculation will keep the hospitals' total volume higher for more reliable measure scores. We will provide data regarding payers for hospitals to review through annual confidential feedback reports and continue to monitor measure performance, including the impact of MA data inclusion, as part of our ongoing measure maintenance activities. In the future, we may consider providing separate MA and FFS measure rates that hospitals could use for internal quality improvement efforts, while maintaining the combined MA and FFS cohort as the official publicly reported statistic.

Finally, we also note that, in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36536, 36927–29), we addressed similar concerns regarding MA data completeness and reliability, explaining that we have evaluated MA data for quality measurement since 2017, recent policies have improved the timeliness, completeness, and accuracy of MA data. Specific examples of the use of MA data across multiple CMS initiatives include hospital-submitted MA claims used for DSH and Graduate Medical Education payment calculations, and MAO-submitted encounter data are used to calculate MA beneficiary risk scores with 100 percent of the risk score using risk-adjustment eligible diagnoses from MA encounter data and FFS claims.

Comment: A few commenters expressed additional recommendations regarding the measure specifications and risk-adjustment. These recommendations included removing clinical markers of severe sepsis, adopting a new sepsis definition for consistency in reporting and care guidelines, and broadening the transplant recipient indicator. They also recommended accounting for other types of immunosuppressed patients and patients who may have planned readmissions. A commenter also suggested that CMS explore machine learning or empiric risk adjustment from the data obtained, including elements

[212] *https://p4qm.org/measures/5275.*

[213] CMS internal analysis.

like access to care that capture whether the patient resides in a rural area and their distance from a hospital. A commenter also requested that CMS clarify how the measure will be adjusted for the aggressiveness of the infectious organism (bacteria, virus, or fungus) causing sepsis. Another commenter recommended further study into reasons that sepsis survivors are so likely to experience readmission within 30 days and identify a more precise target to measure.

Response: We thank the commenters for their recommendations. We agree that appropriate risk adjustment is particularly important for the Sepsis Readmission measure because patients hospitalized with sepsis often have complex clinical profiles and varying baseline risk. As described in the proposed rule, the Sepsis Readmission measure risk-adjusts for patient factors such as age, comorbid diseases, indicators of frailty, clinical markers of severe sepsis, transplant-recipient status, organ failure or dysfunction, source of infection, immunocompromised state, and the aggressiveness of the infectious organism causing sepsis. We selected these factors through a deliberative and empirical process because they are clinically relevant and related to the readmission outcome. As we also noted in the proposed rule, the risk-adjustment model demonstrated strong calibration and discrimination in testing, including among patients with differing severity of sepsis.

We do not agree that clinical markers of severe sepsis should be removed from the risk-adjustment model at this time. These markers help distinguish patients with greater baseline acuity at the time of admission and therefore help ensure that hospitals are compared on outcomes for clinically similar patients. We also recognize commenters' concerns about consistency in sepsis definitions. In the proposed rule, we acknowledged that there is not one universally accepted sepsis definition and we stated that the measure aligns with a Sepsis-2-based approach to avoid missing patients, while also avoiding overlap with existing condition- and procedure-specific 30-day readmission measures. We will continue to monitor evolving clinical standards, coding practices, and measure performance through routine measure maintenance and may consider future refinements if evidence supports doing so.

We appreciate the recommendation to broaden the transplant-recipient indicator to include other immunosuppressed patients. The proposed risk model already includes variables related to immunocompromised state, in addition to a transplant-recipient indicator. We believe this approach appropriately captures clinically important baseline risk using standardized administrative data available for both Medicare Fee-for-Service and MA beneficiaries. We will continue to evaluate whether additional claims-based indicators of immunosuppression would improve model performance without reducing transparency, stability, or comparability across hospitals.

We also clarify that planned readmissions are not counted in the numerator of the measure. As described in the measure specifications, only unplanned inpatient admissions to short-term acute care hospitals qualify as readmissions; planned readmissions, which generally are not signals of poor quality, are excluded from the numerator. This approach is consistent with the Hospital Readmissions Reduction Program's existing methodology for readmission measures.

With respect to machine learning and additional empiric risk-adjustment approaches, we agree that risk models should be informed by empirical data. The current model is empirically derived and uses the same hierarchical logistic regression framework used for other Hospital Readmissions Reduction Program measures, which supports national comparability, interpretability, and consistency. We are open to continued evaluation of alternative modeling approaches, including more advanced empirical methods, but any such approach would need to be transparent, reproducible, clinically interpretable, stable over time, and appropriate for use in a national payment program.

Regarding rural residence, distance from a hospital, and other access-to-care variables, we agree that these factors may affect post-discharge care and readmission risk. However, including such variables in patient-level risk adjustment requires careful consideration because adjustment for access barriers may mask disparities in outcomes or obscure opportunities for improvement in discharge planning, care coordination, and follow-up. As we stated in the proposed rule, we will continue evaluating hospital-level reliability, year-over-year stability, and subgroup impacts, including impacts for rural and low-volume hospitals, as part of routine measure maintenance.

We also clarify how the measure accounts for the aggressiveness of the infectious organism. The measure uses claims-based risk-adjustment variables derived from inpatient, outpatient, and physician Medicare administrative claims data from the 12 months before the index hospitalization and from secondary diagnoses documented as present on admission during the index hospitalization. Organism-related variables, including whether the infection is bacterial, viral, or fungal, are included in the risk-adjustment calculations when available in the claims data. These variables affect the patient's predicted risk of readmission within the hierarchical model; they do not function as exclusions from the measure. Complications that arise during the index hospitalization are not included in risk adjustment because they may reflect the quality of care delivered and fall within the causal pathway rather than baseline patient risk.

Finally, we agree that continued study of post-sepsis readmissions is important. The proposed rule noted that readmissions after sepsis may stem from inadequate treatment of the initial infection, complications of hospital care, challenges in care transitions, and post-discharge care needs. We also cited evidence that care coordination, medication reconciliation, patient education, timely follow-up, home health visits, and multicomponent post-sepsis transition services can reduce readmissions. We believe an all-cause 30-day risk-standardized readmission measure remains appropriate because post-sepsis readmissions are multifactorial and often reflect the quality of both inpatient care and discharge-to-community transitions. We will continue to assess whether future measure refinements, companion measures, or additional analyses could identify more targeted opportunities to improve outcomes for sepsis survivors.

Comment: Many commenters raised methodological concerns about whether the measure is sufficiently valid, citing concerns regarding sample size and reliability. A few commenters expressed concern with the minimum measure reliability and referenced their own minimum measure reliability analysis at 0.205 across more than 3,000 facilities with at least 25 admissions. A commenter noted that this indicated that the measure is not yet stable for payment use, recommending that CMS increase the minimum sample size to produce a higher intraclass correlation coefficient of 0.6 or higher. A commenter suggested that, instead of a national benchmark, CMS consider a standard such as a low threshold percentage or shift to an improvement framework in which hospitals are compared to their own performance—either showing improvement, or in cases

of high performance, maintaining excellence.

Response: With regard to the concerns regarding the measure's reliability and the minimum reliability estimates, we note that reliability testing demonstrated that the measure meets accepted reliability standards. Specifically, among accountable entities with at least 25 eligible discharges, approximately 69 percent achieved a split-half reliability estimate of at least 0.60, a threshold commonly used to distinguish higher- and lower-performing providers. We believe this level of reliability is sufficient for public reporting and payment applications, particularly when considered in conjunction with the increased case volume resulting from inclusion of MA beneficiaries. While we acknowledge that reliability varies across hospitals based on volume and case mix, we think the testing results support adoption of the measure. We note that this measure was endorsed by the Cost and Efficiency Recommendation Group of the Partnership for Quality Measurement, the consensus-based entity for measure review and endorsement, which process includes a rigorous review of reliability testing results. We will continue to monitor reliability and performance stability over time, including among rural and lower-volume hospitals.

Comment: A few commenters expressed concern with the proposed reduction in the Hospital Readmissions Reduction Program performance period from three years to two years as CMS has not provided sufficient evidence that the concerns associated with two-year periods specifically that a two-year period was known to produce volatile results, have been resolved and hospitals will have difficulty determining their impact.

Response: We maintain that with the increased cohort size, a two-year performance period appropriately balances measure reliability with timeliness. A shorter performance period enables hospitals to receive feedback that is reflective of more current clinical performance and improvement efforts while maintaining acceptable reliability. Measure testing demonstrated that reliability remains satisfactory under the proposed approach, particularly with the inclusion of MA beneficiaries. As we discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36931), more timely performance information better supports the goals of the Hospital Readmissions Reduction Program by allowing hospitals to evaluate and respond to performance trends sooner than would be possible under a longer measurement period.

Comment: Several commenters expressed concern with the inclusion of the Sepsis Readmission measure in the Hospital Readmissions Reduction Program because the sepsis diagnosis is broad and includes patients with diverse clinical presentations, making it difficult to apply a uniform definition across all cases. A few commenters expressed concern that the Sepsis Readmission measure proposed for the Hospital Readmissions Reduction Program relies on claims-based sepsis identification methods. These commenters stated that there is a lack of consensus regarding sepsis diagnostic definitions and coding methodologies.

Response: Although sepsis encompasses a clinically heterogeneous population and there continues to be ongoing discussion regarding optimal approaches to sepsis identification, the measure cohort is sufficiently defined and supported by the available evidence. The measure was developed through a rigorous testing and validation process using nationally available Medicare administrative data and established coding methodologies. In the proposed rule we acknowledged that there is not one universally accepted sepsis definition and we stated that the measure aligns with a Sepsis-2-based approach to avoid missing patients, while also avoiding overlap with existing condition- and procedure-specific 30-day readmission measures. The measure appropriately identifies a population of patients hospitalized with sepsis who are at substantial risk for readmission and for whom hospitals can meaningfully influence outcomes through inpatient care, discharge planning, care coordination, and post-discharge transition processes.

We acknowledge that multiple clinical and surveillance frameworks currently exist for identifying sepsis and that differences among those frameworks may result in variation in patient populations. However, we note that claims-based measurement approaches are widely used across CMS quality programs because they are nationally available, consistently reported, broadly applicable across hospitals, and feasible for large-scale implementation. The measure underwent extensive development and testing using Medicare administrative data, and the claims-based approach provides a practical and reliable method for identifying eligible cases and assessing hospital performance.

We further note that we evaluated the relationship between hospital-level sepsis coding practices and measured outcomes and found no meaningful association between coding rates and readmission risk. These analyses support the conclusion that differences in hospital performance are not primarily driven by variation in coding practices, and therefore the measure provides a valid assessment of readmission outcomes among patients hospitalized with sepsis.

Comment: A few commenters urged CMS to delay any sepsis-related readmission measures until there is national alignment regarding sepsis definitions and clearly defined drivers for improvement and to consider aligning future sepsis quality programs to minimize burden for hospitals.

Response: We maintain that the absence of complete uniformity across all sepsis measurement frameworks should not preclude the use of a measure that has undergone rigorous development, testing, and validation and that addresses an important area of patient safety and healthcare quality. Delaying implementation until all sepsis definitions and measurement approaches are fully harmonized could significantly postpone opportunities to improve outcomes for a patient population that experiences substantial morbidity, mortality, and healthcare utilization.

Comment: A commenter recommended that CMS provide additional details regarding the diagnosis codes, exclusion criteria, attribution rules, and clinical rationale for the measure cohort.

Response: The measure underwent extensive testing and validation. Additional analyses found no meaningful association between hospital-level sepsis coding rates and measured readmission or mortality risk, suggesting that coding variation is not driving performance differences. We examined coding variability as a potential source of bias and found low correlation between hospital-level use of sepsis code A41.9 and readmission risk (r ranging from less than 0.001 to 0.07) or mortality risk (r ranging from 0.04 to 0.15) within hospitals with at least 25 eligible cases. We also found low correlation between post-discharge mortality and hospital-level readmission risk ($r = -0.11$). Therefore, the claims-based methodology provides an appropriate and objective basis for identifying eligible cases and assessing hospital performance. We will continue to monitor coding trends, documentation variation, and subgroup impacts through routine measure maintenance.

We note that detailed measure specifications, including cohort

definitions, diagnosis code lists, inclusion and exclusion criteria, attribution methodology, and risk-adjustment approaches, are publicly available through the measure development and rulemaking process. The measure excludes planned readmissions, and in the event of a transfer, the outcome is attributed to the hospital that ultimately discharges the patient to a non-acute care setting. These specifications were developed to ensure that the measure cohort is clinically coherent and that outcomes are appropriately attributed to the accountable hospital. For more information about the measure specifications, we refer readers to the methodology report, available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology.*

Comment: A commenter expressed concern with the change from HCCs to individual ICD–10 codes, stating that the impact of the change is unclear. A commenter noted that there may be modifications to the ICD–10–CM sepsis code set to better align with ICD–11 conventions and recommended that CMS avoid implementing changes to ICD–10–CM at this time.

Response: We note that individual ICD–10 codes are more specific than HCCs. By re-specifying the risk models with individual ICD–10 codes, we improve the performance of the risk adjustment models for our condition specific measures.

We appreciate commenters' observations regarding potential future modifications to ICD–10–CM sepsis coding and the possibility of future alignment with ICD–11 conventions. We recognize that diagnosis coding systems evolve over time to reflect advances in clinical knowledge and classification standards. However, the possibility of future coding revisions does not diminish the validity of the current measure or the appropriateness of the current coding framework for identifying sepsis hospitalizations. We routinely update quality measures to account for coding changes, clinical advances, and evolving evidence. Should future revisions to ICD–10–CM or other coding systems materially affect measure specifications or performance, we would evaluate those changes through the established measure maintenance and rulemaking processes.

Comment: A commenter noted differences between the proposed Sepsis Readmission measure and the emerging digital CDC/NHSN-based framework proposed for the Adult Community-Onset Sepsis Standardized Mortality Ratio measure. Another commenter stated that CMS should align the Hospital Readmissions Reduction Program, Hospital-Acquired Condition Reduction Program, and infection prevention initiatives so that preventable hospital-acquired infections are addressed proactively through targeted improvement incentives rather than indirectly penalized through readmission measures alone.

Response: We acknowledge that the Sepsis Readmission measure and the CDC's Adult Community-Onset Sepsis Standardized Mortality Ratio measure serve different purposes and therefore employ different methodologies. The Adult Community-Onset Sepsis Standardized Mortality Ratio measure is intended as a mortality measure that relies on clinical surveillance methodologies and electronic clinical data, whereas the proposed Sepsis Readmission measure is a claims-based outcome measure designed to assess risk-standardized hospital readmission performance. Differences in data sources, measure objectives, and intended applications may appropriately result in differences in cohort definitions and identification methodologies. CMS will continue to evaluate opportunities for alignment across sepsis-related quality programs where feasible and appropriate while recognizing the distinct purposes served by individual measures. We refer readers to section IX.B.4. of the preamble of this final rule where we describe our request for comment on the CDC's Adult Community-Onset Sepsis Standardized Mortality Ratio measure.

Comment: Several commenters stated that the Sepsis Readmission measure is not appropriately risk adjusted and recommended that CMS incorporate socio-economic risk adjustment at the patient, hospitals, and community levels. Commenters stated that sepsis outcomes depend on factors outside the hospital control, and that the measure will penalize hospitals serving a disproportionate share of medically and socially complex patients.

Response: The Sepsis Readmission measure employs an appropriate risk-adjustment methodology that accounts for patient characteristics associated with the risk of readmission while preserving the measure's ability to identify meaningful differences in hospital performance. The measure was developed and tested using a comprehensive set of clinically relevant variables derived from Medicare administrative claims and encounter data and is intended to adjust for patient medical factors present at the time of admission that are outside the hospital's control. This approach is consistent with longstanding CMS measure-development principles and supports fair comparisons across hospitals.

We acknowledge the important role that social risk factors can play in patient outcomes and recognize that patients with sepsis frequently experience complex medical, behavioral, or social needs that may influence post-discharge recovery. To account for medically and socially complex patients, the 21st Century Cures Act amended section 1886(q) so that the Hospital Readmissions Reduction Program adjusts for social risk by peer grouping based on the hospital proportion of patients with dual eligible status prior to assignment of payment adjustment. Specifically, the peer grouping methodology accounts for differences in hospitals' proportions of beneficiaries that are dually eligible for both Medicare and full Medicaid benefits when calculating payment adjustments. This approach helps address concerns regarding differences in patient populations while preserving the measure's ability to identify potentially avoidable readmissions. We note, however, that the Sepsis Readmission measure is intended to hold all hospitals to the same standards of care quality and accountability. Adjusting for social risk factors could mask systemic differences in care quality between hospitals serving more versus fewer vulnerable patients. Nonetheless, the evidence shows that hospitals in the fourth quartile for the proportion of patients with dual eligibility (that is, hospitals with a relatively larger proportion of patients with dual eligible status) can perform as well as hospitals in the 1st–3rd quartiles (hospitals with relatively fewer patients with dual eligible status).[214] The measure is well calibrated for patients with and without dual eligible status. The specifications of this measure also align with CMS' other 30-day readmission measures in the Hospital Readmissions Reduction Program that also do not adjust for socioeconomic status.

Comment: A commenter recommended that CMS consider stratifying performance assessment and associated payment adjustment across different peer groups, such as academic medical center status and regional areas.

Response: We appreciate the suggestion that CMS stratify performance assessment and associated payment adjustments based on hospital characteristics such as academic medical center status or geographic region. However, the Hospital Readmissions Reduction Program

[214] *https://p4qm.org/measures/5275.*

statute only authorizes peer grouping based on patients' dual eligibility for Medicare and Medicaid; it does not permit stratification by other hospital characteristics for purposes of payment adjustment. We could consider whether additional stratified performance information could be included in hospitals' confidential feedback reports or public reporting in future rulemaking.

Comment: A few commenters suggested that CMS account for patients who may have planned readmissions.

Response: The Sepsis Readmission measure and all of the readmission measures used in this program incorporate the CMS Planned Readmission Algorithm to exclude planned readmissions from outcome calculations. As a result, hospitals are not held accountable for readmissions that are identified as planned according to established CMS methodology. This approach appropriately focuses the measure on unplanned readmissions that may be more reflective of care quality, discharge planning, care coordination, and post-discharge support. For additional details we refer readers to the measure methodology report, available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology.*

Comment: A commenter suggested that CMS should strengthen risk adjustment by incorporating clinical data elements as factors impacting readmissions including complications, inadequate treatment, and care-transition challenges are not fully captured in claims data. Another commenter stated that the methodology must incorporate enough clinical nuance to distinguish between readmissions for novel infections and those resulting from potential failures in the initial sepsis treatment plan.

Response: We agree that clinically detailed information can provide important insights into patient severity and outcomes. In the Hospital Inpatient Quality Reporting Program, the Hybrid Hospital-Wide All-Cause Readmission Measure (HWR) and the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM) use more than one data source for measure calculation: core clinical data elements (CCDEs), linking variables, and claims data (80 FR 49698). CCDEs are a set of clinical variables derived from electronic health records (EHRs) that can be used to risk adjust hospital outcome measures (80 FR 49699), such as vital signs and laboratory results. Linking variables are administrative data that can be used to link or merge the CCDEs and administrative claims data for measure calculation (80 FR 49703). These measures are designed to enhance risk adjustment of administrative claims-based outcome measures by utilizing patient clinical data captured in EHRs (80 FR 49698). We intend to explore options to add CCDEs for condition and procedure-specific measures such as those in the Hospital Readmissions Reduction Program in the future. In the meantime, the current claims-based methodology is also a robust approach for risk adjustment with strengths, including important advantages, including national feasibility, consistency of reporting, and broad applicability across hospitals. The measure underwent extensive testing and validation using available Medicare data sources, and the current model appropriately balances feasibility, reliability, and clinical relevance.

Comment: A commenter suggested that CMS should address challenges through shared accountability models as sepsis outcomes depend on factors outside hospital control, including skilled nursing facility quality, home health capacity, outpatient access, caregiver support, and medication affordability.

Response: We thank the commenter for their suggestion that CMS address challenges associated with sepsis care through shared accountability models. We appreciate this perspective and recognize that outcomes following sepsis hospitalization may be influenced by care delivered across multiple settings, including post-acute care providers, outpatient clinicians, caregivers, and community resources. Nevertheless, statutory authority limits the Hospital Readmissions Reduction Program to hospitals, and the purpose of the proposed measure is to assess the quality of hospital care and care-transition processes associated with the index hospitalization. We believe hospitals play a critical role in discharge planning, patient education, medication management, coordination of follow-up care, and other activities that influence readmission risk. As such, attribution of the measure to hospitals remains appropriate.

Comment: A few commenters recommended that, in addition to excluding patients from a hospital's performance if they were transferred to another hospital for their sepsis care, the measure should also exclude transfer patients from the accepting hospital's evaluation. The commenters noted that these patients tend to be too sick or too complex for the referring community hospital which may delay timely and effective care. A commenter noted that these patients are often transferred outside of their home area making treatment post discharge more challenging.

Response: With respect to the suggestion that transfer patients should be excluded from the accepting hospital's evaluation, we appreciate commenters' concerns that such patients are often clinically complex and may require care that is beyond the capabilities of the referring hospital. We agree that, in many instances, patients transferred for sepsis care are medically fragile and may require specialized resources, and we recognize that transfers may occur across geographic areas and thereby complicate post-discharge follow-up. At the same time, we do not agree that it would be appropriate to categorically exclude transfer patients from the accepting hospital's measure cohort. The accepting hospital is the entity that furnishes the inpatient care, coordinates the subsequent clinical course, and is often best positioned to influence the quality of the hospital stay, the discharge process, and the transition to the next site of care. Excluding these patients from the receiving hospital's evaluation would remove a meaningful set of cases from the measure and would not reflect the care delivered by the hospital that assumed responsibility for the patient's sepsis treatment. The measure's existing transfer-related exclusions appropriately address attribution concerns while preserving accountability for the hospital that furnishes the indexed inpatient stay.

We are also concerned that categorically excluding transfer patients could mask quality of care differences for this population, potentially disadvantaging patients, including many rural patients, who rely on transfers to access specialized sepsis care. Excluding these cases from measurement could reduce accountability for the care they receive at the accepting hospital. Finally, we note that the measure's risk-adjustment methodology already accounts for clinical complexity, including comorbid conditions, which mitigates concerns that transferred patients' greater severity would unfairly affect an accepting hospital's performance results.

Comment: Another commenter encouraged CMS to explore incorporation of patient-reported outcomes and functional recovery outcomes related to post-sepsis care. A commenter encouraged CMS to direct future development of sepsis measures to evaluate how certain data could be used to identify early deterioration and whether early detection would reduce

sepsis mortality. Another commenter suggested that CMS should focus efforts on identifying underlying causes of the initial sepsis admission and how sepsis hospitalizations can be prevented. A commenter recommended that CMS encourage hospitals to adopt evidence-based prevention strategies for hospital-acquired pneumonia and early sepsis recognition as part of a comprehensive patient safety approach. A commenter stated that CMS should clarify in measure documentation and impact analyses that the Sepsis Readmission measure includes sepsis cases arising from healthcare-associated infections, including hospital-acquired pneumonia, and acknowledge this as an important policy consideration.

Response: We appreciate commenters' suggestions regarding patient-reported outcomes, early deterioration detection, sepsis prevention, and measure documentation. The Sepsis Readmission measure is a readmission outcome measure and is intended to assess hospital performance using nationally available Medicare data. With respect to patient-reported and functional recovery measures, we agree that the concepts are valuable and will take them into consideration for future measure development and potential inclusion in other CMS quality programs. The Hospital Readmissions Reduction Program is statutorily limited to readmission outcome measures, so incorporating patient-reported or functional recovery outcomes directly into the Sepsis Readmission measure would not be appropriate at this time. The Sepsis Readmission measure complements the Severe Sepsis and Septic Shock Management Bundle (SEP–1) measure, which is currently included in the Hospital Value-Based Purchasing Program, by assessing post-discharge outcomes rather than in-hospital detection and treatment. We also note the Sepsis Readmission measure further complements the Sepsis Mortality measure RFI included in section IX.B.4. of this final rule.

We also appreciate that prevention of sepsis and identification of precipitating conditions are important public health and clinical goals. The Sepsis Readmission measure is intended to assess hospital performance after a sepsis hospitalization has occurred, particularly with respect to care transitions and readmissions, and is not intended to replace broader prevention efforts. CMS will continue to consider opportunities to support sepsis prevention through future rulemaking.

Finally, we clarify that the Sepsis Readmission measure includes sepsis cases arising from healthcare-associated infections, including hospital-acquired pneumonia. However, the measure excludes index admissions meeting certain additional exclusion criteria, including sepsis admissions already captured in the Pneumonia Readmission measure, which avoids overlap between the two measures.

Comment: A few commenters noted that CMS did not provide an impact analysis for the proposed Sepsis Readmission measure. A commenter specifically noted that the proposed rule did not provide the impact specifically for rural hospitals.

Response: We refer readers to the Regulatory Impact Analysis in the FY 2027 IPPS/LTCH PPS proposed rule, particularly section I.G.6. of Appendix A for the impact analysis of the measure, including an analysis of rural hospitals.[215] Table I.G.6.–01 in the proposed rule estimated the financial impact on hospitals by hospital characteristic.[216] This table is also reprinted at section I.G.6 of Appendix A of this final rule.

Comment: A few commenters expressed concern with the 30-day readmission timeframe of the Sepsis Readmission measure and suggested that either a 7-day or 14-day readmission measure window would better capture hospital performance and provide a more meaningful target for quality improvements. A commenter expressed concern that it is difficult to determine the timing of the onset of sepsis and thus the 30-day readmission timeframe may be difficult to determine. A commenter stated that hospital-onset sepsis lacks an objectively defined time-zero.

Response: We thank commenters for the suggestions. We maintain that a 30-day timeframe is appropriate for the Sepsis Readmission measure and is consistent with the longstanding approach used across the Hospital Readmissions Reduction Program. A 30-day outcome window captures a broader range of clinically meaningful post-discharge events while allowing sufficient opportunity to evaluate the effectiveness of hospital care, discharge planning, medication management, care coordination, and follow-up arrangements. The 30-day timeframe provides a comprehensive assessment of patient outcomes following hospitalization and supports consistency across Hospital Readmissions Reduction Program measures. We also clarify that the Sepsis Readmission measure is not limited to solely hospital-onset sepsis but rather captures beneficiaries who were discharged from the hospital with a principal diagnosis of sepsis (including post-procedural sepsis).

The validity of the 30-day, all-cause outcome is supported by several pieces of empirical evidence. First, we have shown for other readmission measures that the daily readmission rate does not return to baseline after 30 days after the index admission and is therefore temporally associated with the index admission. Furthermore, readmission risk remains elevated well after 30 days. For example, in one study of more than 40,000 sepsis survivors, 26 percent were readmitted within 30 days and 48 percent within 180 days.[217] A meta-analysis of 56 studies showed readmission rates among sepsis survivors were 21.4 percent at 30 days and 39 percent by 365 days.[218] Second, studies have shown that the reasons for readmission (principal discharge diagnoses) are clinically related to the index admission.[219] The 30-day timeframe has been in use since 2012 and by multiple countries because the first three weeks after discharge are the highest risk period for readmission, and this period provides adequate time for hospitals to implement strategies to avert readmission.

With regard to the concern that the timing of sepsis onset can be difficult to determine and therefore questioned the appropriateness of a 30-day readmission timeframe, we acknowledge that the clinical onset of sepsis may not always be precisely identifiable and that sepsis can represent a heterogeneous condition with varying clinical presentations. However, the Sepsis Readmission measure is anchored to the index hospitalization and discharge date rather than the precise onset of sepsis symptoms. Consistent with other Hospital Readmissions Reduction Program measures, the readmission outcome period begins following discharge from the qualifying hospitalization and assesses unplanned readmissions occurring within 30 days of discharge.

[215] 91 FR 19857.

[216] 91 FR 19858.

[217] Goodwin, A. J., Rice, D. A., Simpson, K. N., & Ford, D. W. (2015). Frequency, cost, and risk factors of readmissions among severe sepsis survivors. Critical care medicine, 43(4), 738–746.

[218] Shankar-Hari, M., Saha, R., Wilson, J., Prescott, H. C., Harrison, D., Rowan, K., Rubenfeld, G. D., & Adhikari, N. K. J. (2020). Rate and risk factors for rehospitalisation in sepsis survivors: systematic review and meta-analysis. *Intensive care medicine, 46*(4), 619–636.

[219] Ackermann, K., Lynch, I., Aryal, N., Westbrook, J., & Li, L. (2025). Hospital readmission after surviving sepsis: A systematic review of readmission reasons and meta-analysis of readmission rates. Journal of critical care, 85, 154925.

Comment: One commenter expressed general concern about the Hospital Readmissions Reduction Program that the literature shows that readmission measures based on administrative claims may be leading to increased mortality.

Response: We appreciate the commenter's concern regarding the Hospital Readmissions Reduction Program. We note that CMS has established complementary mortality measures for the existing conditions and procedures included in the Hospital Readmissions Reduction Program, which provide an additional check on whether readmission rates are being influenced by differences in patient mortality. We note the Sepsis Mortality measure RFI included in section IX.B.4. of this final rule, which would similarly complement the Sepsis Readmission measure. For existing Hospital Readmissions Reduction Program measures, previous study showed that risk-standardized mortality rates and readmission rates were not associated for patients admitted with an acute myocardial infarction or pneumonia and were only weakly associated, within a certain range, for patients admitted with heart failure.

With respect to the Sepsis Readmission measure specifically, we assessed whether post-discharge mortality may be introducing bias into the readmission measure. We examined the timing of post-discharge mortality by day (days 1–30) and week (weeks 1–4) following discharge from an index sepsis hospitalization, and the results showed that the proportion of patients who died following discharge remained relatively stable across the full 30-day post-discharge window, with no notable concentration of deaths in any particular day or week. This means that the risk of bias introduced by a hospital having a high number of deaths immediately post-discharge leading to lower readmission rates among a smaller pool of sepsis survivors was minimal.

Similarly, we examined the relationship between hospital-level post-discharge mortality among patients without a readmission and readmission rates by grouping hospitals into deciles based on their post-discharge mortality rate. The results showed that readmission rates were similarly consistent across hospital mortality decile groups. The correlation between hospital-level post-discharge mortality among patients without a readmission and hospital-level readmission rates was negligible (unweighted Pearson correlation coefficient is 0.005; p = 0.784; 95% CI [−0.032, 0.042] and volume-weighted analyses Pearson correlation coefficient is 0.011; p = 0.578; 95% CI [−0.027, 0.048]). Neither result was statistically significant, indicating minimal difference in readmission rates between hospitals with lower mortality rates among patients that are not readmitted, versus those with higher mortality and no readmissions. Post-discharge mortality is not meaningfully impacting readmissions in a way that would bias Sepsis Readmission measure. Furthermore, we have the RFI available for public comment on a Sepsis Mortality measure included in section IX.B.4. of this final rule, for continued tracking of Sepsis Mortality.

After consideration of the comments received, we are finalizing the proposal with modification. Specifically, we will adopt the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure as part of the Hospital Readmissions Reduction Program measure set beginning with an early look for the FY 2028 (applicable period of July 1, 2024 to June 30, 2026) and FY 2029 (applicable period of July 1, 2025 to June 30, 2027) program years. The measure will then be used in the Hospital Readmissions Reduction Program for payment adjustment beginning with the FY 2030 program year (applicable period of July 1, 2026 to June 30, 2028) and subsequent years.

J. Hospital Value-Based Purchasing Program

1. Background

a. Overview

For background on the Hospital Value-Based Purchasing Program, we refer readers to the CMS website at: *https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/hospital-value-based-purchasing.* We also refer readers to our codified requirements for the Hospital Value-Based Purchasing Program at 42 CFR 412.160 through 412.168.

b. FY 2027 Program Year Payment Details

Under section 1886(o)(7)(C)(v) of the Act, the applicable percent for the FY 2027 program year is 2.00 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2027 is approximately $1.9 billion, based on the December 2025 update of the FY 2025 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53573 through 53576), we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We published proxy value-based incentive payment adjustment factors in Table 16 associated with the FY 2027 IPPS/LTCH PPS proposed rule (which is available via the internet on the CMS website). We note that these proxy adjustment factors will not be used to adjust hospital payments. These proxy value-based incentive payment adjustment factors were calculated using historical baseline and performance periods for the FY 2026 Hospital Value-Based Purchasing Program. These proxy factors were calculated using the March 2026 update to the FY 2025 MedPAR file. The slope of the linear exchange function used to calculate these proxy factors was 3.4489188481, and the estimated amount available for value-based incentive payments to hospitals for FY 2027 is approximately $1.9 billion. We will add Table 16B to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2027 Hospital Value-Based Purchasing Program. We expect that Table 16B will be posted on the CMS website in the fall of 2026.

2. Hospital Value-Based Purchasing Program Measures

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19568 through 19574), we proposed to adopt substantive measure updates to five condition-specific and procedure-specific mortality measures, in the Clinical Outcomes domain, beginning with the July 1, 2028 through June 30, 2030 performance period for the FY 2032 program year, which we discuss further in section IX.B.2. of the preamble of this final rule. We proposed (91 FR 19568 through 19574) these updates contingent on our adoption of the same modified mortality measures in the Hospital Inpatient Quality Reporting Program beginning with the FY 2028 payment determination, which we discuss further in section IX.B.2. of the preamble of this final rule.

a. Summary of Previously Adopted Quality Measures for the Hospital Value-Based Purchasing Program

We refer readers to the FY 2026 IPPS/LTCH PPS final rule for summaries of the previously adopted measures for the FY 2027 through FY 2031 program years (90 FR 36951). We did not propose any changes to the measure set. Table V.J.1. summarizes the previously adopted

Hospital Value-Based Purchasing Program measure set for the FY 2027 program year.

TABLE V.J.1. SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2027 PROGRAM YEAR

Measure Short Name	Domain/Measure Name	CBE #
Person and Community Engagement Domain		
HCAHPS*	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition and Responsiveness of Hospital Staff dimensions)	0166 (0228)
Safety Domain		
CAUTI	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716
CDI	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717
SEP-1	Severe Sepsis and Septic Shock: Management Bundle	0500
Clinical Outcomes Domain		
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE	Hospital Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB	Medicare Spending Per Beneficiary (MSPB) Hospital	2158

*In the FY 2025 IPPS/LTCH PPS final rule, we adopted the updated HCAHPS Survey measure in the Hospital Value-Based Purchasing Program beginning with the FY 2030 program year (89 FR 69508 through 69511). The Care Transition and Responsiveness of Hospital Staff dimensions will be included in the HCAHPS Survey but not scored for FY 2027 through FY 2029, and will not be included in the HCAHPS Survey beginning with FY 2030.

Table V.J.2. summarizes the previously adopted Hospital Value-Based Purchasing Program measures for the FY 2028 through FY 2032 program years.

TABLE V.J.2. SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2028 THROUGH FY 2032 PROGRAM YEARS

Measure Short Name	Domain/Measure Name	CBE #
Person and Community Engagement Domain		
HCAHPS*	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition and Responsiveness of Hospital Staff dimensions)	0166 (0228)
Safety Domain		
CAUTI	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716
CDI	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717
SEP-1	Severe Sepsis and Septic Shock: Management Bundle	0500
Clinical Outcomes Domain		
MORT-30-AMI**	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF**	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN**	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD**	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG**	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE***	Hospital Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB	Medicare Spending Per Beneficiary (MSPB) Hospital	2158

* In the FY 2025 IPPS/LTCH PPS final rule, we adopted the updated HCAHPS Survey measure in the Hospital Value-Based Purchasing Program beginning with the FY 2030 program (89 FR 69508 through 69511). The Care Transition and Responsiveness of Hospital Staff dimensions will be included in the HCAHPS Survey but not scored for FY 2027 through FY 2029, and will not be included in the HCAHPS survey beginning with FY 2030.

** In this final rule, we are finalizing modifications to the MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD, and the MORT–30–CABG measures beginning with the FY 2032 program year. We refer readers to section IX.B.2. of the preamble of this final rule for more detailed discussion.

*** In the FY 2026 IPPS/LTCH PPS final rule, we finalized modifications to the COMP-HIP-KNEE measure in the Hospital Value-Based Purchasing Program beginning with the FY 2033 program year (90 FR 36943 through 36948). The updated COMP-HIP-KNEE measure will include Medicare Advantage beneficiaries in the measure cohort and a reduced reporting period from 3 to 2 years beginning with the FY 2033 program year.

3. Baseline and Performance Periods for the FY 2028 Through FY 2032 Program Years

a. Background

We refer readers to the FY 2026 IPPS/LTCH PPS final rule (90 FR 36951 through 36954) for previously adopted baseline and performance periods for the FY 2027 through FY 2031 program years. We also refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998) in which we finalized a schedule for all future baseline and performance periods.

b. Summary of Baseline and Performance Periods for the FY 2028 Through FY 2032 Program Years

Tables V.J.3., V.J.4., V.J.5., V.J.6., and V.J.7. summarize the baseline and performance periods that we have previously adopted.

TABLE V.J.3. BASELINE AND PERFORMANCE PERIODS FOR THE FY 2028 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2024 – December 31, 2024	January 1, 2026 – December 31, 2026
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN)	July 1, 2018 – June 30, 2021*	July 1, 2023 – June 30, 2026
COMP-HIP-KNEE	April 1, 2018 – March 31, 2021*	April 1, 2023 – March 31, 2026
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2024 – December 31, 2024	January 1, 2026 – December 31, 2026
SEP-1	January 1, 2024 – December 31, 2024	January 1, 2026 – December 31, 2026
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2024 – December 31, 2024	January 1, 2026 – December 31, 2026

* These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020) from the claims-based complication and mortality measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

TABLE V.J.4. BASELINE AND PERFORMANCE PERIODS FOR THE FY 2029 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2025 – December 31, 2025	January 1, 2027 – December 31, 2027
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN)	July 1, 2019 – June 30, 2022*	July 1, 2024 – June 30, 2027
COMP-HIP-KNEE	April 1, 2019 – March 31, 2022*	April 1, 2024 – March 31, 2027
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2025 – December 31, 2025	January 1, 2027 – December 31, 2027
SEP-1	January 1, 2025 – December 31, 2025	January 1, 2027 – December 31, 2027
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2025 – December 31, 2025	January 1, 2027 – December 31, 2027

* These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020) from the claims-based complication and mortality measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

TABLE V.J.5. BASELINE AND PERFORMANCE PERIODS FOR THE FY 2030 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2026 – December 31, 2026	January 1, 2028 – December 31, 2028
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN)	July 1, 2020 – June 30, 2023	July 1, 2025 – June 30, 2028
COMP-HIP-KNEE	April 1, 2020 – March 31, 2023*	April 1, 2025 – March 31, 2028
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2026 – December 31, 2026	January 1, 2028 – December 31, 2028
SEP-1	January 1, 2026 – December 31, 2026	January 1, 2028 – December 31, 2028
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2026 – December 31, 2026	January 1, 2028 – December 31, 2028

* This baseline period is impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculation for January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020) from the claims-based complication and mortality measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

TABLE V.J.6. BASELINE AND PERFORMANCE PERIODS FOR THE FY 2031 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2027 – December 31, 2027	January 1, 2029 – December 31, 2029
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN)	July 1, 2021 – June 30, 2024	July 1, 2026 – June 30, 2029
COMP-HIP-KNEE	April 1, 2021 – March 31, 2024	April 1, 2026 – March 31, 2029
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2027 – December 31, 2027	January 1, 2029 – December 31, 2029
SEP-1	January 1, 2027 – December 31, 2027	January 1, 2029 – December 31, 2029
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2027 – December 31, 2027	January 1, 2029 – December 31, 2029

TABLE V.J.7. BASELINE AND PERFORMANCE PERIODS FOR THE FY 2032 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2028 – December 31, 2028	January 1, 2030 – December 31, 2030
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN)	July 1, 2024 – June 30, 2026*	July 1, 2028 – June 30, 2030
COMP-HIP-KNEE	April 1, 2022 – March 31, 2025	April 1, 2027 – March 31, 2030
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2028 – December 31, 2028	January 1, 2030 – December 31, 2030
SEP-1	January 1, 2028 – December 31, 2028	January 1, 2030 – December 31, 2030
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2028 – December 31, 2028	January 1, 2030 – December 31, 2030

*In this final rule, we are finalizing modifications to the mortality measures beginning with the FY 2032 program year, including a reduced performance period from 3 to 2 years. We refer readers to section IX.B.2. of the preamble of this final rule for more detailed discussion.

4. Performance Standards for the Hospital Value-Based Purchasing Program

a. Background

We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69406 through 69407) for previously established performance standards for the FY 2027 program year. We also refer readers to the FY 2026 IPPS/LTCH PPS final rule (90 FR 36955 through 36957) for the previously established performance standards for the FY 2028 program year.

b. Previously Established and Newly Established Performance Standards for Certain Measures for the FY 2029 Through the FY 2031 Program Years

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2026 IPPS/LTCH PPS final rule (90 FR 36948 through 36950), we made technical updates to the Clinical Outcomes domain beginning with the FY 2027 program year to include COVID–19 patients in the measure data, and thus established new performance standards for the FY 2029 through the FY 2031 program years for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE). In the FY 2026 IPPS/LTCH PPS final rule (90 FR 36954 through 36955), we made technical updates to the Safety domain, such that the five National Healthcare Safety Network Healthcare–Associated Infection measures (CAUTI, CLABSI, CDI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI) would use the CY 2022 data to calculate performance standards for the FY 2029 program year and subsequent years. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69409 through 69410), we established performance standards for the FY 2029 through the FY 2030 program years for the Efficiency and Cost Reduction domain measure (MSPB Hospital). We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established performance standards for the Clinical Outcomes domain and the Efficiency and Cost Reduction domain and newly estimated performance standards for the Safety domain measures are set out in Table V.J.8. for the FY 2029 program year.

TABLE V.J.8. PREVIOUSLY ESTABLISHED AND NEWLY ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2029 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Safety Domain**		
CAUTI*	0.392	0
CLABSI*	0.478	0
CDI*	0.268	0
MRSA Bacteremia*	0.602	0
Colon and Abdominal Hysterectomy SSI*	0.707 0.848	0
SEP-1	0.664479	0.879775
Clinical Outcomes Domain♦		
MORT-30-AMI	0.873295	0.891834
MORT-30-HF	0.87976	0.906894
MORT-30-PN	0.801554	0.842898
MORT-30-COPD	0.905582	0.924775
MORT-30-CABG	0.970801	0.979861
COMP-HIP-KNEE*	0.031509	0.023706
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** We note that the numerical values for the performance standards for the HAI and SEP–1 measures in this final rule represent estimates based on CY 2025 data.

♦ Previously established performance standards.

We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69507 through 69508) where we finalized the policy to modify the scoring of the HCAHPS Survey for the FY 2027 through FY 2029 program years while updates to the survey are publicly reported under the Hospital Inpatient Quality Reporting Program. Scoring is modified to only score hospitals on the six unchanged Hospital Value-Based Purchasing Program dimensions of the HCAHPS Survey until the updates to the HCAHPS Survey have been publicly reported for 1 year. The six unchanged dimensions of the HCAHPS Survey for the Hospital Value-Based Purchasing Program are as follows:

- ''Communication with Nurses,''
- ''Communication with Doctors,''
- ''Communication about Medicines,''
- ''Discharge Information,''
- ''Cleanliness and Quietness,''
- ''Overall Rating.''

Scoring is modified such that for each of the six unchanged dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) will be calculated, the larger of which will be summed across these six dimensions to create a pre-normalized HCAHPS Base Score of 0–60 points (as compared to 0–80 points with the current eight dimensions). The pre-normalized HCAHPS Base Score will then be multiplied by ⅝ (1.3333333) and rounded according to standard rules (values of 0.5 and higher are rounded up, values below 0.5 are rounded down) to create the normalized HCAHPS Base Score. Each of the six unchanged dimensions will be of equal weight, so that, as currently scored, the normalized HCAHPS Base Score will range from 0 to 80 points. HCAHPS Consistency Points will be calculated in the same manner as the current method and will continue to range from 0 to 20 points. Like the Base Score, the Consistency Points Score will consider scores across the six unchanged dimensions of the Person and Community Engagement domain. The final element of the scoring formula, which will remain unchanged from the current formula, will be the sum of the HCAHPS Base Score and the HCAHPS Consistency Points Score for a total score that ranges from 0 to 100 points. The method for calculating the performance standards for the six dimensions will remain unchanged. We refer readers to the Hospital Inpatient Value-Based Purchasing Program final rule (76 FR 26511 through 26512) for our methodology for calculating performance standards. The estimated performance standards for the six unchanged dimensions for the FY 2029 program year are set out in Table V.J.9.

TABLE V.J.9. NEWLY ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2029 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT DOMAIN

HCAHPS Survey Dimension*[1]	Floor (minimum)	Achievement Threshold (50th percentile)	Benchmark (mean of top decile)
Communication with Nurses	55.34	77.84	86.08
Communication with Doctors	57.45	77.55	85.40
Responsiveness of Hospital Staff**	X	X	X
Communication about Medicines	39.83	59.29	69.67
Hospital Cleanliness & Quietness	36.69	62.90	75.78
Discharge Information	66.71	85.97	91.07
Care Transition**	X	X	X
Overall Rating of Hospital	36.23	68.84	82.39

[1] Includes IPPS hospitals with 100+ completed surveys from patients discharged between January 2025 and December 2025 (2,697 hospitals). Scores have been adjusted for survey mode and patient-mix.

*We note that the numerical values for the performance standards for the HCAHPS Survey in this final rule represent estimates based on the most recently available data. These estimates are based on 01/01/2025–12/31/2025 data.

** In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69507 and 69508), we finalized the policy to only score on the six unchanged dimensions of the original HCAHPS Survey for the FY 2029 program year while the updates to the survey are publicly reported in the Hospital Inpatient Quality Reporting Program for the statutorily required 1 year. Therefore, we are not reporting performance standards for the dimensions that are unscored.

The previously established performance standards for Clinical Outcomes domain and the Efficiency and Cost Reduction domain measures are set out in Table V.J.10. for the FY 2030 program year.

TABLE V.J.10. PREVIOUSLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2030 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain		
MORT-30-AMI	0.872557	0.892486
MORT-30-HF	0.87823	0.908997
MORT-30-PN	0.805539	0.849398
MORT-30-COPD	0.902955	0.924203
MORT-30-CABG	0.972039	0.981517
COMP-HIP-KNEE*	0.034757	0.024614
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

The previously established performance standards for Clinical Outcomes domain and the Efficiency and Cost Reduction domain measures are set out in Table V.J.11. for the FY 2031 program year.

TABLE V.J.11. PREVIOUSLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2031 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain		
MORT-30-AMI	0.877505	0.895401
MORT-30-HF	0.882399	0.912122
MORT-30-PN	0.831029	0.870506
MORT-30-COPD	0.90878	0.929579
MORT-30-CABG	0.974896	0.983693
COMP-HIP-KNEE*	0.036571	0.025288
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

c. Newly Established Performance Standards for Certain Measures for the FY 2032 Program Year

As discussed previously, we have adopted certain measures for the Clinical Outcomes domain (MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain (MSPB Hospital) for future program years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient Value-Based Purchasing Program final rule (76 FR 26511 through 26512), which is codified at 42 CFR 412.160, we are establishing the following performance standards for the FY 2032 program year for the Clinical Outcomes domain and the Efficiency and Cost Reduction domain. We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in Table V.J.12.

TABLE V.J.12. NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2032 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain		
MORT-30-AMI**	0.881686	0.899183
MORT-30-HF**	0.887519	0.915618
MORT-30-PN**	0.846031	0.882679
MORT-30-COPD**	0.911638	0.930897
MORT-30-CABG**	0.976958	0.984987
COMP-HIP-KNEE*	0.039655	0.028874
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** In this final rule, we are finalizing modifications to the five mortality measures in the Clinical Outcomes domain beginning with the FY 2032 program year. We note the performance standards for these measures do not yet reflect these finalized modifications, which include Medicare Advantage beneficiaries to the measures' cohorts and a shortened reporting period from 3 to 2 years. We intend to provide updated performance standards for the FY 2032 program year in the FY 2028 IPPS/LTCH PPS proposed rule to reflect these newly finalized modifications. We refer readers to section IX.B.2. of the preamble of this final rule for more detailed discussion.

K. Hospital-Acquired Condition (HAC) Reduction Program

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50709) for a general overview of the HAC Reduction Program and a detailed discussion of the statutory basis for the program. We also refer readers to 42 CFR 412.170 through 412.172 for codified HAC Reduction Program requirements. For additional information about the HAC Reduction Program measures and maintenance of technical specifications, we refer readers to the FY 2026 IPPS/LTCH PPS final rule (90 FR 36963 through 36967).

We did not make any proposals or updates for the HAC Reduction Program in the FY 2027 IPPS/LTCH proposed rule (91 FR 19546). We refer readers to section I.G.8. of Appendix A of this final rule for an updated estimate of the proportion of hospitals in the worst performing quartile of the Total HAC Scores for the FY 2027 HAC Reduction Program.

L. Rural Community Hospital Demonstration Program

1. Introduction

The Rural Community Hospital Demonstration was originally authorized by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). The demonstration has been extended three times since the original 5-year period mandated by the MMA, each time for an additional 5 years. These extensions were authorized by sections 3123 and 10313 of the Patient Protection and Affordable Care Act (ACA) (Pub. L. 111–148), section 15003 of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) enacted in 2016, and most recently, by section 128 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), which also reauthorized the RCHD for five years. Later in this section we summarize the status of the demonstration program and the current methodologies for implementation and calculating budget neutrality.

2. Background

Section 410A(a) of the MMA required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Our policy for implementing the 5-year extension period authorized by the CAA, 2021 follows upon the previous extensions under the ACA and the Cures Act. Section 410A of the MMA initially required a 5-year period of performance. Subsequently, sections 3123 and 10313 of the ACA (Pub. L. 111–148) required the Secretary to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. In addition, the ACA (Pub. L. 111–148) limited the number of hospitals participating to no more than 30. Section 15003 of the Cures Act (Pub. L. 114–255) required a 10-year extension period in place of the 5-year extension period under the ACA (Pub. L. 111–148), thereby extending the demonstration for another 5 years. Section 128 of CAA, 2021 (Pub. L. 116–260), in turn, revised the statute to indicate a 15-year extension period, instead of the 10-year extension period mandated by the Cures Act (Pub. L. 114–255). The FY 2023 IPPS proposed and final rules (87 FR 28454 through 28458, and 87 FR 49138 through 49142, respectively) describe hospitals entering into and withdrawing from the demonstration with these re-authorizations. As of March 2026, there are 27 hospitals participating in the demonstration.

2. Budget Neutrality

a. Statutory Budget Neutrality Requirement

Section 410A(c)(2) of the MMA (Pub. L. 108–173) requires that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount that the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral on its own terms; the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. We note that the payment methodology for this demonstration, that is, cost-based payments to participating small rural hospitals, made it unlikely that increased Medicare outlays would produce an offsetting reduction to Medicare expenditures elsewhere. Therefore, in the IPPS final rules spanning the period from FY 2005 through FY 2016, we have adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration program, applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. We applied a different methodology for FY 2017, with the demonstration expected to end prior to the Cures Act extension. As described in the FYs 2005 through 2017 IPPS/LTCH PPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145; 80 FR 49585; and 81 FR 57034, respectively), we believe that the statutory language of the budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

We resumed this methodology of offsetting demonstration costs against the national payment rates in the IPPS final rules from FY 2018 through FY 2026. Please see the FY 2026 IPPS/LTCH PPS final rule for a description of how we applied the budget neutrality requirement for these fiscal years (90 FR 36967 through 36969).

b. General Budget Neutrality Methodology

We have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, ''as submitted'' cost reports for the hospitals participating in that year. Updated factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the

estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. For historical development and modifications to this methodology, see 81 FR 57034 through 57037.

We note that we have calculated this difference for FYs 2005 through 2020 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

c. Budget Neutrality Methodology for the Extension Period Authorized by CAA, 2021

For the most-recently enacted extension period, under the CAA, 2021, we have continued upon the general budget neutrality methodology used in previous years, as described previously in the citations to earlier IPPS final rules.

Under the general methodology used in previous years, we have estimated the costs of the demonstration for the upcoming fiscal year, and proposed to incorporate the estimate into the budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. We are conducting this estimate for FY 2027 based on the 30 participating hospitals for cost report periods ending in CY2024. However, due to timing issues with the addition of 11 new hospitals in 2025, we are not yet able to finalize the estimated FY 2027 costs of the demonstration at this time. We anticipate that all of the historical ''as submitted'' cost reports needed to formulate estimated demonstration costs for FY 2027 and FY 2028 will be available in advance of the FY 2028 IPPS/LTCH PPS proposed rule and we will be able to finalize estimated demonstration costs for both FY 2027 and FY 2028.

As noted, in previous years we have also calculated the difference between the actual costs of the demonstration and estimated costs of the demonstration for FYs 2005 through 2020 as determined from finalized cost reports. We intend to continue with this approach and anticipate that we will be able to determine the actual costs for the demonstration for FY 2021 and FY 2022 from finalized cost reports in advance of the FY 2028 IPPS/LTCH PPS proposed rule. Consistent with our methods in previous years these differences will be applied to the estimated costs of the demonstration when determining the FY 2027 and FY 2028 budget neutrality offsets.

As we are not yet able to finalize the FY 2027 estimated costs of the demonstration at this time, we did not propose to apply a budget neutrality offset to the FY 2027 IPPS/LTCH PPS final rule. Rather, we proposed to apply budget neutrality offsets for both FY 2027 and FY 2028 to the national IPPS rates in the FY 2028 IPPS/LTCH PPS proposed rule. We will also incorporate any statutory change that might affect the methodology for determining hospital costs either with or without the demonstration. We invited public comments.

We received a few public comments, most of which were out of scope. However all of the comments we received were supportive of continuing the Rural Community Hospital Demonstration.

Comment: A commenter recommended that CMS allow RCHD hospitals whose 5-year participation agreements have expired or will be expiring under the CAA extension reenter the program until the demonstration's statutory end date of June 30, 2028.

Response: We thank the commenter for their interest and recommendation. In the absence of new authorizing legislation, it is CMS' position that we cannot extend expired participation agreements beyond the statutorily defined 5-year periods under the same reauthorization.

Comment: The parent company for two of the participating hospitals expressed support for the continuation of the Rural Community Hospital Demonstration program, but noted that it does not offer long-term financial stability needed to maintain health care access in rural areas. The commenter requests that the demonstration be made a permanent program. Furthermore, the commenter requests several technical adjustments to the administration of the demonstration that may enhance stability in the payment to the participating hospitals.

Response: We appreciate the comments. We have conducted the demonstration program in accordance with section 410A of the MMA, and there is no authority to make the demonstration a permanent program. With regard to any technical adjustments to the demonstration, we intend to work with the commenter and other rural stakeholders to examine the issues involved.

After consideration of the public comments we received, primarily requesting to extend the demonstration, we are finalizing our policy without modification.

VI. Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under § 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Payments for Hospitals Located in Puerto Rico

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061), we revised the regulations at 42 CFR 412.374 relating to the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017 to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after January 1, 2016, made by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 601 of Public Law 114–113 increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the capital Federal rate.

C. Annual Update for FY 2027

The annual update to the national capital Federal rate, as provided in 42 CFR 412.308(c), for FY 2027 is discussed in section III. of the Addendum to this FY 2027 IPPS/LTCH PPS final rule.

VII. Changes for Hospitals Excluded From the IPPS

A. Rate-of-Increase in Payments to Excluded Hospitals for FY 2027

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously. Furthermore, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (formerly classified as ''Subclause II LTCHs'') also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, and RNHCIs.

Consistent with the regulations at §§ 412.23(g) and 413.40(a)(2)(ii)(A) and (c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45207), we finalized the use of the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2022 and subsequent fiscal years. As discussed in section IV. of the preamble of the FY 2026 IPPS/LTCH PPS final rule (90 FR 36859 through 36866), we rebased and revised the IPPS operating basket to a 2023 base year. Therefore, we used the percentage increase in the 2023-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2026.

For the FY 2027 IPPS/LTCH PPS proposed rule, based on IGI's 2025 fourth quarter forecast, we estimated that the 2023-based IPPS operating market basket percentage increase for FY 2027 was 3.2 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the FY 2027 rate-of-increase percentage that would be applied to the FY 2026 target amounts in order to calculate the FY 2027 target amounts for children's hospitals, the 11 cancer hospitals,

RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa was 3.2 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we proposed that if more recent data became available for the FY 2026 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2027.

More recent data has become available. Based on IGI's second quarter 2026 forecast, we estimate that the 2023-based IPPS operating market basket percentage increase for FY 2027 is 3.2 percent (that is, the estimate of the market basket rate-of-increase). Accordingly, the FY 2027 rate-of-increase percentage that we will apply to the FY 2026 target amounts in order to calculate the FY 2027 target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 3.2 percent, which is based on IGI's second quarter 2026 forecast.

We received no comments on this proposal and therefore are finalizing this provision without modification. Incorporating more recent data available for this final rule, as we proposed, we are adopting a 3.2 percent update for FY 2027.

In addition, payment for inpatient operating costs for hospitals classified under section 1886(d)(1)(B)(vi) of the Act (which we refer to as ''extended neoplastic disease care hospitals'') for cost reporting periods beginning on or after January 1, 2015, is to be made as described in 42 CFR 412.526(c)(3), and payment for capital costs for these hospitals is to be made as described in 42 CFR 412.526(c)(4), (for additional information on these payment regulations, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38321 through 38322).) Section 412.526(c)(3) provides that the hospital's Medicare allowable net inpatient operating costs for that period are paid on a reasonable cost basis, subject to that hospital's ceiling, as determined under § 412.526(c)(1), for that period. Under § 412.526(c)(1), for each cost reporting period, the ceiling was determined by multiplying the updated target amount, as defined in § 412.526(c)(2), for that period by the number of total Medicare discharges paid during that period. Section 412.526(c)(2)(i) describes the method for determining the target amount for cost reporting periods beginning during FY 2015. Section 412.526(c)(2)(ii) specifies that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197).

For FY 2027, in accordance with §§ 412.22(i) and 412.526(c)(2)(ii) of the regulations, for cost reporting periods beginning during FY 2027, the proposed update to the target amount for extended neoplastic disease care hospitals (that is, hospitals described under § 412.22(i)) is the applicable annual rate-of-increase percentage specified in § 413.40(c)(3), which is estimated to be the proposed percentage increase in the 2023-based IPPS operating market basket (that is, the estimate of the market basket rate-of-increase). Accordingly, the proposed update to an extended neoplastic disease care hospital's target amount for FY 2027 was 3.2 percent, which was based on IGI's fourth quarter 2025 forecast. Furthermore, we proposed that if more recent data became available for the FY 2027 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the IPPS operating market basket rate of increase for FY 2027.

More recent data has become available. Based on IGI's second quarter 2026 forecast, we estimate that the 2023-based IPPS operating market basket percentage increase for FY 2027 is 3.2 percent (that is, the estimate of the market basket rate-of-increase). Accordingly, the FY 2027 rate-of-increase percentage that we will apply to the FY 2026 target amounts in order to calculate the FY 2027 target amounts for extended neoplastic disease care hospitals is 3.2 percent, which is based on IGI's second quarter 2026 forecast.

We received no comments on this proposal and therefore are finalizing this provision without modification. Incorporating more recent data available for this final rule, as we proposed, we are adopting a 3.2 percent update for FY 2027.

B. Report on Adjustment (Exception) Payments

Section 4419(b) of Public Law 105–33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment payments made to excluded hospitals and hospital units by reason of section 1886(b)(4) of the Act during the previous fiscal year.

The process of requesting, reviewing, and awarding an adjustment payment is likely to occur over a 2-year period or longer. First, generally, an excluded hospital must file its cost report for the fiscal year in accordance with § 413.24(f)(2) of the regulations. The MAC reviews the cost report and issues a notice of provider reimbursement (NPR). Once the hospital receives the NPR, if its operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment. After the MAC receives the hospital's request in accordance with applicable regulations, the MAC or CMS, depending on the type of adjustment requested, reviews the request and determines if an adjustment payment is warranted. This determination is sometimes not made until more than 180 days after the date the request is filed because there are times when the request applications are incomplete and additional information must be requested in order to have a completed request application. However, in an attempt to provide interested parties with data on the most recent adjustment payments for which we have data, we are publishing data on adjustment payments that were processed by the MAC or CMS during FY–2025.

The table that follows includes the most recent data available from the MACs and CMS on adjustment payments that were adjudicated during FY 2025. As indicated previously, the adjustments made during FY 2025 only pertain to cost reporting periods ending in years prior to FY 2025. Total adjustment payments made to IPPS-excluded hospitals during FY 2025 are $92,696,418. The table depicts for each class of hospitals, in the aggregate, the number of adjustment requests adjudicated, the excess operating costs over the ceiling, and the amount of the adjustment payments.

Class of Hospital	Number	Excess Cost Over Ceiling	Adjustment Payments
Cancer Hospitals	5	$162,316,893	$91,599,402
Children's Hospitals	8	$5,357,347	$1,097,016
Total	13	$167,674,150	$92,696,418

B. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Frontier Community Health Integration Project Demonstration

a. Introduction

The Frontier Community Health Integration Project Demonstration was originally authorized by section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275). The demonstration has been extended by section 129 of the Consolidated Appropriations Act, 2021 (Public Law 116–260) for an additional 5 years. In this final rule, we summarized the status of the demonstration program, and the ongoing methodologies for implementation and budget neutrality for the demonstration extension period.

b. Background and Overview

As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), section 123 of the Medicare Improvements for Patients and Providers Act of 2008, as amended by section 3126 of the Affordable Care Act, authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration was titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and commonly known as the Frontier Community Health Integration Project (FCHIP) Demonstration.

The authorizing statute stated the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is a Medicare Rural Hospital Flexibility Program (MRHFP) grantee under section 1820(g) of the Act (that is, a CAH); and is located in a State in which at least 65 percent of the counties in the state are counties that have 6 or less residents per square mile.

The authorizing statute stipulated several other requirements for the demonstration. In addition, section 123(g)(1)(B) of Public Law 110–275 required that the demonstration be budget neutral. Specifically, this provision stated that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275 stated that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration. CMS selected CAHs to participate in four interventions, under which specific waivers of Medicare payment rules would allow for enhanced payment for telehealth, skilled nursing facility/nursing facility beds, ambulance services, and home health services. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Section 123 of Pub L. 110–275 initially required a 3-year period of performance. The FCHIP Demonstration began on August 1, 2016, and concluded on July 31, 2019 (referred to in this section of the final rule as the ''initial period''). Subsequently, section 129 of the Consolidated Appropriations Act, 2021 (Public Law 116–260) extended the demonstration by 5 years (referred to in this section of the final rule as the ''extension period''). The Secretary is required to conduct the demonstration for an additional 5-year period. CAHs participating in the demonstration project during the extension period began such participation in their cost reporting year that began on or after January 1, 2022.

As described in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), 10 CAHs were selected for participation in the demonstration initial period. The selected CAHs were located in three states—Montana, Nevada, and North Dakota—and participated in three of the four interventions identified in the FY 2025 IPPS/LTCH PPS final rule. Each CAH was allowed to participate in more than one of the interventions. None of the selected CAHs were participants in the home health intervention, which was the fourth intervention.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS concluded that the initial period of the FCHIP Demonstration (covering the performance period of August 1, 2016, to July 31, 2019) had satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, CMS did not apply a budget neutrality payment offset policy for the initial period of the demonstration.

Section 129 of Public Law 116–260, stipulates that only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. Among the eligible CAHs, five have elected to participate in the extension period. The selected CAHs are located in two states—Montana and North Dakota—and are implementing three of the four interventions. The eligible CAH participants elected to change the number of interventions and payment waivers they would participate in during the extension period. CMS accepted and approved the CAHs intervention and payment waiver updates. For the extension period, five CAHs are participants in the telehealth intervention, three CAHs are participants in the skilled nursing facility/nursing facility bed intervention, and three CAHs are participants in the ambulance services intervention. As with the initial period, each CAH was allowed to participate in more than one of the interventions

during the extension period. None of the selected CAHs are participants in the home health intervention, which was the fourth intervention.

c. Intervention Payment and Payment Waivers

As described in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), CMS waived certain Medicare rules for CAHs participating in the demonstration initial period to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: telehealth services, ambulance services, and skilled nursing facility/nursing facility (SNF/NF) beds expansion. The payments and payment waiver provisions only apply if the CAH is a participant in the associated intervention. CMS Intervention Payment and Payment Waivers for the demonstration extension period consist of the following:

(1) Telehealth Services Intervention Payments

CMS waives section 1834(m)(2)(B) of the Act, which specifies the facility fee to the originating site for Medicare telehealth services. CMS modifies the facility fee payment specified under section 1834(m)(2)(B) of the Act to make reasonable cost-based reimbursement to the participating CAH where the participating CAH serves as the originating site for a telehealth service furnished to an eligible telehealth individual, as defined in section 1834(m)(4)(B) of the Act. CMS reimburses the participating CAH serving as the originating site at 101 percent of its reasonable costs for overhead, salaries and fringe benefits associated with telehealth services at the participating CAH. CMS does not fund or provide reimbursement to the participating CAH for the purchase of new telehealth equipment.

CMS waives section 1834(m)(2)(A) of the Act, which specifies that the payment for a telehealth service furnished by a distant site practitioner is the same as it would be if the service had been furnished in-person. CMS modifies the payment amount specified for telehealth services under section 1834(m)(2)(A) of the Act to make reasonable cost-based reimbursement to the participating CAH for telehealth services furnished by a physician or practitioner located at distant site that is a participating CAH that is billing for the physician or practitioner professional services. Whether the participating CAH has or has not elected Optional Payment Method II for outpatient services, CMS would pay the participating CAH 101 percent of reasonable costs for telehealth services when a physician or practitioner has reassigned their billing rights to the participating CAH and furnishes telehealth services from the participating CAH as a distant site practitioner. This means that participating CAHs that are billing under the Standard Method on behalf of employees who are physicians or practitioners (as defined in section 1834(m)(4)(D) and (E) of the Act, respectively) would be eligible to bill for distant site telehealth services furnished by these physicians and practitioners. Additionally, CAHs billing under the Optional Method would be reimbursed based on 101 percent of reasonable costs, rather than paid based on the Medicare physician fee schedule, for the distant site telehealth services furnished by physicians and practitioners who have reassigned their billing rights to the CAH. For distant site telehealth services furnished by physicians or practitioners who have not reassigned billing rights to a participating CAH, payment to the distant site physician or practitioner would continue to be made as usual under the Medicare physician fee schedule. Except as described herein, CMS does not waive any other provisions of section 1834(m) of the Act for purposes of the telehealth services intervention payments, including the scope of Medicare telehealth services as established under section 1834(m)(4)(F) of the Act.

(2) Ambulance Services Intervention Payments

CMS waives 42 CFR 413.70(b)(5)(i)(D) and section 1834(l)(8) of the Act, which provides that payment for ambulance services furnished by a CAH, or an entity owned and operated by a CAH, is 101 percent of the reasonable costs of the CAH or the entity in furnishing the ambulance services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals to or from the CAH. The participating CAH would be paid 101 percent of reasonable costs for its ambulance services regardless of whether there is any provider or supplier of ambulance services located within a 35-mile drive of the participating CAH or participating CAH-owned and operated entity. CMS would not make cost-based payment to the participating CAH for any new capital (for example, vehicles) associated with ambulance services. This waiver does not modify any other Medicare rules regarding or affecting the provision of ambulance services.

(3) SNF/NF Beds Expansion Intervention Payments

CMS waives 42 CFR 485.620(a), 42 CFR 485.645(a)(2), and section 1820(c)(2)(B)(iii) of the Act which limit CAHs to maintaining no more than 25 inpatient beds, including beds available for acute inpatient or swing bed services. CMS waives 1820(f) of the Act permitting designating or certifying a facility as a critical access hospital for which the facility at any time is furnishing inpatient beds which exceed more than 25 beds. Under this waiver, if the participating CAH has received swing bed approval from CMS, the participating CAH may maintain up to ten additional beds (for a total of 35 beds) available for acute inpatient or swing bed services; however, the participating CAH may only use these 10 additional beds for nursing facility or skilled nursing facility level of care. CMS would pay the participating CAH 101 percent of reasonable costs for its SNF/NF services furnished in the 10 additional beds.

d. Budget Neutrality

(1) Budget Neutrality Requirement

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), we finalized a policy to address the budget neutrality requirement for the demonstration initial period. As explained in the FY 2022 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms, meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we finalized for the demonstration initial period of performance in the FY 2022 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), we adopted the same budget neutrality policy contingency plan used during the demonstration initial period to ensure that the budget neutrality requirement in section 123 of Public Law 110 275 is

met during the demonstration extension period. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 5-year extension period are not sufficiently offset by reductions elsewhere, we would recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide.

As explained in the FY 2023 IPPS/LTCH PPS final rule, because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality for the demonstration extension period by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration extension period is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration extension period were not implemented, CMS policy is to comply with the budget neutrality requirement finalized in the FY 2023 IPPS/LTCH PPS final rule, by reducing payments to all CAHs, not just those participating in the demonstration extension period.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), we stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented and does not identify the range across which aggregate payments must be held equal.

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a policy that in the event the demonstration extension period is found not to have been budget neutral, any excess costs would be recouped within one fiscal year. We explained our belief that this policy is a more efficient timeframe for the government to conclude the demonstration operational requirements (such as analyzing claims data, cost report data or other data sources) to adjudicate the budget neutrality payment recoupment process due to any excess cost that occurred as result of the demonstration extension period.

(2) FCHIP Budget Neutrality Methodology and Analytical Approach

As explained in the FY 2022 IPPS/LTCH PPS final rule, we finalized a policy to address the demonstration budget neutrality methodology and analytical approach for the initial period of the demonstration. In the FY 2023 IPPS/LTCH PPS final rule, we finalized a policy to adopt the budget neutrality methodology and analytical approach used during the demonstration initial period to ensure budget neutrality for the extension period. The analysis of budget neutrality during the initial period of the demonstration identified both the costs related to providing the intervention services under the FCHIP Demonstration and any potential downstream effects of the intervention-related services, including any savings that may have accrued.

The budget neutrality analytical approach for the demonstration initial period incorporated two major data components: (1) Medicare cost reports; and (2) Medicare administrative claims. As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS computed the cost of the demonstration for each fiscal year of the demonstration initial period using Medicare cost reports for the participating CAHs, and Medicare administrative claims and enrollment data for beneficiaries who received demonstration intervention services.

In addition, in order to capture the full impact of the interventions, CMS developed a statistical modeling, Difference-in-Difference (DiD) regression analysis to estimate demonstration expenditures and compute the impact of expenditures on the intervention services by comparing cost data for the demonstration and non-demonstration groups using Medicare administrative claims across the demonstration period of performance under the initial period of the demonstration. The DiD regression analysis would compare the direct cost and potential downstream effects of intervention services, including any savings that may have accrued, during the baseline and performance period for both the demonstration and comparison groups.

Second, the Medicare administrative claims analysis would be reconciled using data obtained from auditing the participating CAHs' Medicare cost reports. We would estimate the costs of the demonstration using ''as submitted'' cost reports for each hospital's financial fiscal year participation within each of the demonstration extension period performance years. Each CAH has its own Medicare cost report end date applicable to the 5-year period of performance for the demonstration extension period. The cost report is structured to gather costs, revenues and statistical data on the provider's financial fiscal period. As a result, we finalized a policy in the FY 2023 IPPS/LTCH PPS final rule that we would determine the final budget neutrality results for the demonstration extension once complete data is available for each CAH for the demonstration extension period.

e. Policies for Implementing the 5-year Extension and Provisions Authorized by Section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260)

As stated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), our policy for implementing the 5-year extension period for section 129 of Public Law 116–260 follows same budget neutrality methodology and analytical approach as the demonstration initial period methodology. While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during initial period of the demonstration to assess the financial impact of the demonstration during this extension period, upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured.

f. Total Budget Neutrality Offset Amount for FY 2027

At this time, for the FY 2027 IPPS/LTCH PPS final rule, while this discussion represents our anticipated approach to assessing the financial impact of the demonstration extension period based on upon receiving data for the full demonstration extension period, we may update and/or modify the FCHIP Demonstration budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured.

Therefore, we did not propose to apply a budget neutrality payment offset to payments to CAHs in FY 2027. This policy would have no impact for any national payment system for FY 2027. We received no comments on this

proposal and therefore are finalizing this provision without modification.

VIII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2027

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act originally defined an LTCH as a hospital that has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days.

Section 1886(d)(1)(B)(iv)(II) of the Act also provided an alternative definition of LTCHs (''subclause II'' LTCHs). However, section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886 of the Act to exclude former ''subclause II'' LTCHs from being paid under the LTCH PPS and created a new category of IPPS-excluded hospitals, which we refer to as ''extended neoplastic disease care hospitals,'' to be paid as hospitals that were formally classified as ''subclause (II)'' LTCHs (82 FR 38298).

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resource use and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002, **Federal Register** (67 FR 55954), we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA. For the initial implementation of the LTCH PPS (FYs 2003 through 2007), the system used information from LTCH patient records to classify patients into distinct long-term care-diagnosis-related groups (LTCDRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity-long-term care-diagnosis related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable-cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this final rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002, final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002, final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002, final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002, final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the ''site neutral'' payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068 through 57075).

In the FY 2018 IPPS/LTCH PPS final rule, we implemented several provisions of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255) that affected the LTCH PPS. (For more information on these provisions, we refer readers to (82 FR 38299).)

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41529), we made conforming changes to our regulations to implement the provisions of section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which extends the transitional blended payment rate for site neutral payment rate cases for an additional 2 years. We refer readers to section VII.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a discussion of our final policy. In addition, in the FY 2019 IPPS/LTCH PPS final rule, we removed the 25-

percent threshold policy under 42 CFR 412.538, which was a payment adjustment that was applied to payments for Medicare patient LTCH discharges when the number of such patients originating from any single referring hospital was in excess of the applicable threshold for given cost reporting period.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439), we further revised our regulations to implement the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) that relate to the payment adjustment for discharges from LTCHs that do not maintain the requisite discharge payment percentage and the process by which such LTCHs may have the payment adjustment discontinued.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. In accordance with section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), as amended by section 15007 of Public Law 114–255, we amended our regulations to specify that Medicare Advantage plans' and site neutral payment rate discharges are excluded from the calculation of the average length of stay for all LTCHs, for discharges occurring in cost reporting period beginning on or after October 1, 2015.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1), section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b1 (note)) (Statewide-all payer systems, subject to the rate-of increase test at section 1814(b) of the Act), or section 3021 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (42 U.S.C. 1315a).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002, final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87, and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for services furnished during the days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (in accordance with § 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient coverage as a result of the remaining Medicare days, the LTCH also is currently permitted to charge the beneficiary for services delivered on those uncovered days (in accordance with § 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to expressly limit the charges that may be imposed upon beneficiaries whose LTCHs' discharges are paid at the site neutral payment rate under the LTCH PPS. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we amended the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, an LTCH's payment for discharges occurring in cost reporting periods beginning in FYs 2016 through 2019) are considered to be site neutral payment rate payments.

Comment: We received several comments outside the scope of the proposed rule.

Response: While the comments were outside the scope of this rulemaking, we will consider issues and concerns raised by the commenters for future rulemaking.

B. Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2027

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

Under both the IPPS and the LTCH PPS, the DRG-based classification system uses information on the claims for inpatient discharges to classify patients into distinct groups (for example, DRGs) based on clinical characteristics and expected resource needs. When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. We referred to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), we adopted the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O, applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. As noted previously, we adopted the same DRG patient classification system utilized at that time under the IPPS. The MS–DRG classifications are updated annually, which has resulted in the number of MS–DRGs changing over time. For FY 2027, there will be 768 MS–DRG, and by extension, MS–LTC–DRG, groupings based on the changes, as discussed in section II.C. of the preamble of this final rule.

Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA. That is, we assign an appropriate weight to the MS–LTC–DRGs to account for the differences in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCH patients.

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs) or are minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 0JBH3ZX)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis.
- Additional or secondary diagnoses.
- Surgical procedures.
- Age.
- Sex.
- Discharge status of the patient.

Currently, for claims submitted using the version ASC X12 5010 standard, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under the HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities (45 CFR 160.103) must comply with the adopted transaction standards and operating rules specified in subparts I through S of part 162. Among other requirements, on or after January 1, 2012, covered entities are required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code sets when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) and section II.E.1. of the preamble of this final rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS.*

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the preamble of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

Medicare Administrative Contractors (MACs) enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain types of cases are selected for further explanation (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the MAC determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to

establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Changes to the MS–LTC–DRGs for FY 2027

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in this final rule, as we proposed, we are updating the MS–LTC–DRG classifications effective October 1, 2026 through September 30, 2027 (FY 2027), consistent with the changes to specific MS–DRG classifications presented in section II.C. of the preamble of this final rule. Accordingly, the MS–LTC–DRGs for FY 2027 are the same as the MS–DRGs being used under the IPPS for FY 2027. In addition, because the MS–LTC–DRGs for FY 2027 are the same as the MS–DRGs for FY 2027, the other changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under GROUPER Version 44, as discussed in section II.C. of the preamble of this final rule, including the changes to the MCE software and the ICD–10–CM/PCS coding system, are also applicable under the LTCH PPS for FY 2027.

3. Development of the FY 2027 MS–LTC–DRG Relative Weights

a. General Overview of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is costlier (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment rate by the applicable relative weight in determining payment to LTCHs for each case. Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

The established methodology to develop the MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002, LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume or nonmonotonicity or both resulting from the adoption of the MS–LTC–DRGs. We also made a modification in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge). We also adopted, beginning in FY 2023, a 10-percent cap policy on the reduction in a MS–LTC–DRG's relative weight in a given year. (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and nonmonotonicity or both, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550)). For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases (or cases that would have qualified for such payment had the LTCH PPS dual payment rate structure been in effect at the time) to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). For details on our adoption of the 10-percent cap policy, we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49152 through 49154).)

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–LTC–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section in Step 3 of our methodology) and assigned the relative weight of the quintile); and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described later in this section in Step 8 of our methodology). For FY 2027, we are continuing to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2027 MS–LTC–DRG relative weights.

b. Development of the MS–LTC–DRG Relative Weights for FY 2027

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19556 through 19562), we presented our proposed methodology for determining the MS–LTC–DRG relative weights for FY 2027.

Comment: Some commenters stated that CMS should recalibrate the MS–LTC–DRG structure to improve payment accuracy. Commenters expressed that the dual-rate payment system has reshaped the LTCH industry, resulting in a significant decline in the number of standard Federal payment rate cases and a more clinically acute patient population increasingly concentrated in a narrow set of MS–LTC–DRGs. Commenters argued that the current MS–LTC–DRG structure no longer accurately captures the true cost of treating LTCH patients, as severity varies widely within individual DRGs, and that a rising share of cases now qualifies for outlier payments because of this structural misalignment. Commenters further argued that this structural misalignment is itself a contributing factor to recent rises in the fixed-loss amount. Consistent with comments submitted in prior rulemakings, commenters highlighted standard Federal payment rate cases grouped to MS–LTC–DRGs 189 and 207, which together accounted for over 40 percent of standard Federal payment rate cases in FY 2025 and are not subdivided based on the presence or absence of a complication or comorbidity (CC) or a major complication or comorbidity (MCC). Commenters requested that CMS refine certain high-volume MS–LTC–DRGs by

creating subgroups within these MS–LTC–DRGs based on the presence or absence of CCs and MCCs, which they believe would increase LTCH PPS payment accuracy and thereby reduce the outlier payments made to cases grouped to such MS–LTC–DRGs.

Response: We continue to appreciate commenters' suggestions on possible refinements to certain MS–LTC–DRGs and their thoughts on the impact the MS–LTC–DRG structure may have on LTCH PPS payment accuracy and outlier payments. In the FY 2026 IPPS/LTCH PPS final rule (90 FR 37244), we stated that we had not found evidence that the MS–LTC–DRG structure is a major driver of the recent increases to the fixed-loss amount. While we acknowledge that commenters referenced independent analyses suggesting that the concentration of cases in a small number of MS–LTC–DRGs contributes to increases in the fixed-loss amount, we do not believe that sufficient quantitative evidence has been provided to support the conclusion that the MS–LTC–DRG structure is a major contributor to payment inaccuracy or to the increases in the fixed-loss amount in recent years. (Refer to section V.D. of the Addendum of this final rule for the public comments and responses on the fixed-loss amount.) For these reasons, we are not adopting any of the changes to the MS–LTC–DRGs suggested by commenters in this final rule.

Comment: We received a comment urging CMS to adjust the proposed methodologies for determining the FY 2027 LTCH PPS rates to account for the impact of the COVID–19 pandemic on the underlying ratesetting data. A commenter expressed particular concern about the use of FY 2024 cost report data in the determination of the MS–LTC–DRG relative weights, noting that these data reflect patient acuity and cost trends unlikely to persist in FY 2027.

Response: As discussed in Step 6 of our methodology, the MS–LTC–DRG relative weights are calculated using the hospital-specific relative weights methodology, which relies on charges from historical Medicare LTCH claims data rather than data from historical cost reports. As discussed in Step 1 of our methodology, we proposed to use charge data from the FY 2025 MedPAR file. Therefore, we do not agree that a modification to our methodology for determining the relative weights is warranted.

After consideration of the comments we received, we are finalizing, without modification, our proposed methodology for determining the MS–LTC–DRG relative weights for FY 2027. In the remainder of this section, we present our finalized methodology. We first list and provide a brief description of our steps for determining the FY 2027 MS–LTC–DRG relative weights. Later in this section, we discuss in greater detail each step. We note that, as we did in FY 2026, we used our historical relative weight methodology as described in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58898 through 58907), subject to a ten percent cap as described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49162).

- *Step 1—Prepare data for MS–LTC–DRG relative weight calculation.* In this step, we select and group the applicable claims data used in the development of the MS–LTC–DRG relative weights.
- *Step 2—Remove cases with a length of stay of 7 days or less.* In this step, we trim the applicable claims data to remove cases with a length of stay of 7 days or less.
- *Step 3—Establish low-volume MS–LTC–DRG quintiles.* In this step, we employ our established quintile methodology for low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with fewer than 25 cases).
- *Step 4—Remove statistical outliers.* In this step, we trim the applicable claims data to remove statistical outlier cases.
- *Step 5—Adjust charges for the effects of Short Stay Outliers (SSOs).* In this step, we adjust the number of applicable cases in each MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases.
- *Step 6—Calculate the relative weights on an iterative basis using the hospital-specific relative weights methodology.* In this step, we use our established hospital specific relative value (HSRV) methodology, which is an iterative process, to calculate the relative weights.
- *Step 7—Adjust the relative weights to account for nonmonotonically increasing relative weights.* In this step, we make adjustments that ensure that within each base MS–LTC–DRG, the relative weights increase by MS–LTC–DRG severity.
- *Step 8—Determine a relative weight for MS–LTC–DRGs with no applicable LTCH cases.* In this step, we cross-walk each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight.
- *Step 9—Budget neutralize the uncapped relative weights.* In this step, to ensure budget neutrality in the annual update to the MS–LTC–DRG classifications and relative weights, we adjust the relative weights by a normalization factor and a budget neutrality factor that ensures estimated aggregate LTCH PPS payments will be unaffected by the updates to the MS–LTC–DRG classifications and relative weights.
- *Step 10—Apply the 10-percent cap to decreases in MS–LTC–DRG relative weights.* In this step we limit the reduction of the relative weight for a MS–LTC–DRG to 10 percent of its prior year value. This 10-percent cap does not apply to zero-volume MS–LTC–DRGs or low-volume MS–LTC–DRGs.
- *Step 11—Budget neutralize the application of the 10-percent cap policy.* In this step, to ensure budget neutrality in the application of the MS–LTC–DRG cap policy, we adjust the relative weights by a budget neutrality factor that ensures estimated aggregate LTCH PPS payments will be unaffected by our application of the cap to the MS–LTC–DRG relative weights.

We next describe each of the 11 steps for calculating the FY 2027 MS–LTC–DRG relative weights in greater detail.

Step 1—Prepare Data for MS–LTC–DRG Relative Weight Calculation

For the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19557), we obtained total charges from FY 2025 Medicare LTCH claims data from the December 2025 update of the FY 2025 MedPAR file and used proposed Version 44 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we proposed that if better data become available, we would use those data and the finalized Version 44 of the GROUPER in establishing the FY 2027 MS–LTC–DRG relative weights in the final rule. Accordingly, for this final rule, we are establishing the FY 2027 MS–LTC–DRG relative weights based on updated FY 2025 Medicare LTCH claims data from the March 2026 update of the FY 2025 MedPAR file, which is the best available data at the time of development of this final rule, and the finalized Version 44 of the GROUPER to classify LTCH cases.

To calculate the FY 2027 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, we proposed to continue to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Section 3711(b)(2) of the CARES Act provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period. The COVID–19 PHE expired on May 11, 2023. Therefore, nearly all LTCH PPS cases in FY 2025

were subject to the dual rate LTCH PPS payment structure. However, a small number of FY 2025 LTCH PPS cases (those with admission dates on or before May 11, 2023) were subject to the CARES Act waiver and were paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. Therefore, for purposes of setting rates for LTCH PPS standard Federal rate cases for FY 2027 (including MS–LTC–DRG relative weights), we proposed to identify FY 2025 cases that meet the statutory patient criteria depending on date of admission as follows. First, we proposed to use LTCH PPS cases in the FY 2025 MedPAR file with an admission date after May 11, 2023, that met the criteria for exclusion from the site neutral payment rate under § 412.522(b) and were paid the LTCH PPS standard Federal rate in FY 2025 (based on the claim payment amount). Second, we proposed to also use LTCH PPS cases in the FY 2025 MedPAR file with an admission date on or before May 11, 2023, that would have met the criteria for exclusion from the site neutral payment rate if the CARES Act waiver had not been in effect. For these cases we relied on our historical process for identifying cases that would have met the criteria for exclusion from the site neutral payment rate rather than how those cases were paid in FY 2025. This process is explained in full detail in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69425).

We did not receive any specific comments on the proposed methodology to identify FY 2025 cases that meet the statutory patient criteria, depending on the date of admission. Therefore, we are finalizing this methodology without modification.

Furthermore, consistent with our historical methodology, we excluded any claims in the resulting data set that were submitted by LTCHs that were all inclusive rate providers and LTCHs that are paid in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92603. In addition, consistent with our historical practice and our policies, we excluded any Medicare Advantage (Part C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files.

In summary, in general, we identified the claims data used in the development of the FY 2027 MS–LTC–DRG relative weights in this final rule by trimming claims data that were paid the site neutral payment rate or would have been paid the site neutral payment rate had the provisions of the CARES Act not been in effect. We trimmed the claims data of all inclusive rate providers reported in the March 2026 update of the FY 2025 MedPAR file and any Medicare Advantage claims data. There were no data from any LTCHs that are paid in accordance with a demonstration project reported in the March 2026 update of the FY 2025 MedPAR file, but had there been any, we would have trimmed the claims data from those LTCHs as well, in accordance with our established policy.

We used the remaining data (that is, the applicable LTCH data) in the subsequent steps to calculate the MS–LTC–DRG relative weights for FY 2027.

Step 2—Remove Cases With a Length of Stay of 7 Days or Less

The next step in our calculation of the FY 2027 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the FY 2027 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very short stays. Therefore, as we proposed, consistent with our existing relative weight methodology, in determining the FY 2027 MS–LTC–DRG relative weights, we removed LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 3—Establish Low-Volume MS–LTC–DRG Quintiles

To account for MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, as we proposed, we are continuing to employ the quintile methodology for low-volume MS–LTC–DRGs, such that we grouped the ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148)).

In this final rule, based on the best available data (that is, the March 2026 update of the FY 2025 MedPAR file), we identified 244 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of MS–LTC–DRGs was then divided into 1 of the 5 low-volume quintiles. We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this final rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases was not evenly divisible by 5. The quintiles each contained at least 48 MS–LTC–DRGs (244/5 = 48 with a remainder of 4). As we proposed, we employed our historical methodology of assigning each remainder low-volume MS–LTC–DRG to the low-volume quintile that contains an MS–LTC–DRG with an average charge closest to that of the remainder low-volume MS–LTC–DRG. In cases where these initial assignments of low-volume MS–LTC–DRGs to quintiles results in nonmonotonicity within a base-DRG, as we proposed, we adjusted the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in Step 7 of our methodology.

To determine the FY 2027 relative weights for the low-volume MS–LTC–DRGs, consistent with our historical practice, we used the five low-volume quintiles described previously. We determined a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology described in Step 6 of our methodology. We assigned the same relative weight and average length of stay to each of the low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low volume of applicable LTCH cases would vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

For this final rule, we are providing the list of the composition of the low volume-quintiles for low-volume MS–LTC–DRGs in a supplemental data file for public use posted via the internet on the CMS website for this final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of Table 11.

Step 4—Remove Statistical Outliers

The next step in our calculation of the FY 2027 MS–LTC–DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, as we proposed, we are continuing to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, in each set of claims, we were left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this final rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 5—Adjust Charges for the Effects of Short Stay Outliers (SSOs)

As the next step in the calculation of the FY 2027 MS–LTC–DRG relative weights, consistent with our historical approach, as we proposed, we adjusted each LTCH's charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, as we proposed, we made this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay of all cases grouped to the MS–LTC–DRG. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the FY 2027 MS–LTC–DRG relative weights would lower the relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, we are continuing to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 6—Calculate the Relative Weights on an Iterative Basis Using the Hospital-Specific Relative Value Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, in this FY 2027 IPPS/LTCH PPS final rule, as we proposed, we are continuing to use a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2027. We believe that this method removes this hospital specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we reduced the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs). In other words, by multiplying an LTCH's relative charge values by the LTCH's case-mix index, we account for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at an LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an LTCH with high average charges as less resource-intensive than they would be at an LTCH with low average charges. For example, a $10,000 charge for a case at an LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

Consistent with our historical relative weight methodology, as we proposed, we calculated the FY 2027 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. Therefore, in accordance with our established methodology, for FY 2027, we continued to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in Step 5 of our methodology) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The average adjusted charge is then multiplied by the LTCH's case-mix

index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix-index value of 1.0 for each LTCH.

For each MS–LTC–DRG, we calculated the FY 2027 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent cases from Step 5 for each MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent applicable LTCH cases from Step 5 for each MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO adjusted trimmed applicable LTCH cases (that is, it's case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) are then multiplied by the hospital-specific case-mix indexes. The hospital specific case-mix-adjusted relative charge values are then used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 7—Adjust the Relative Weights To Account for Nonmonotonically Increasing Relative Weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions may consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level-subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level-split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the FY 2027 MS–LTC–DRG relative weights, consistent with our historical methodology, as we proposed, we continued to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the FY 2027 MS–LTC–DRG relative weights by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website.

Step 8—Determine a Relative Weight for MS–LTC–DRGs With No Applicable LTCH Cases

Using the trimmed applicable LTCH cases, consistent with our historical methodology, we identified the MS–LTC–DRGs for which there were no claims in the March 2026 update of the FY 2025 MedPAR file and, therefore, for which no charge data was available for these MS–LTC–DRGs. Because patients with a number of the diagnoses under these MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assign a relative weight to each of the no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs, ''error'' MS–LTC–DRGs, and MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of the preamble of this final rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

Consistent with our existing methodology, as we proposed, we cross-walked each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight (determined in accordance with the methodology as previously described). Then, the ''no-volume'' MS–LTC–DRG is assigned the same relative weight (and average length of stay) of the MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of the preamble of this final rule).

Of the 768 MS–LTC–DRGs for FY 2027, we identified 415 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases. The 415 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases includes the 11 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed in this section of this final rule, such that we identified 387 MS–LTC–DRGs that for which, we assigned a relative weight using our existing ''no-volume'' MS–LTC–DRG methodology (that is, $415 - 11 - 2 - 15 = 387$). As we proposed, we assigned relative weights to each of the 387 no-volume MS–LTC–DRGs based on clinical similarity and relative costliness to 1 of the remaining 353 ($768 - 415 = 353$) MS–LTC–DRGs for which we calculated relative weights based on the trimmed applicable LTCH cases in the FY 2025 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the ''cross-walked'' MS–LTC–DRGs as one of the 353 MS–LTC–DRGs to which we cross-walked each of the 387 ''no-volume'' MS–LTC–DRGs.) Then, in general, we assigned the 387 no-volume MS–LTC–DRGs the relative weight of the cross-walked MS–LTC–DRG (when necessary, we made

adjustments to account for nonmonotonicity).

We cross-walked the no-volume MS–LTC–DRG to a MS–LTC–DRG for which we calculated relative weights based on the March 2026 update of the FY 2025 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume MS–LTC–DRGs in FY 2027, the relative weights assigned based on the cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

Then we assigned the relative weight of the cross-walked MS–LTC–DRG as the relative weight for the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight (and average length of stay) for FY 2027. We note that, if the cross-walked MS–LTC–DRG had 25 applicable LTCH cases or more, its relative weight (calculated using the methodology as previously described in Steps 1 through 4) is assigned to the no-volume MS–LTC–DRG as well. Similarly, if the MS–LTC–DRG to which the no-volume MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to 1 of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight for FY 2027. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume MS–LTC–DRG resulted, additional adjustments are required to maintain monotonically increasing relative weights.)

For this final rule, we are providing the list of the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs) for FY 2027 in a supplemental data file for public use posted via the internet on the CMS website for this final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of Table 11.

To illustrate this methodology for determining the relative weights for the FY 2027 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example.

Example: There were no trimmed applicable LTCH cases in the FY 2025 MedPAR file that we are using for this final rule for MS–LTC–DRG 061 (Ischemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent with MCC). We determined that MS–LTC–DRG 064 (Intracranial hemorrhage or cerebral infarction with MCC) is similar clinically and based on resource use to MS–LTC–DRG 061. Therefore, we assigned the same relative weight (and average length of stay) of MS–LTC–DRG 064 of 1.0496 for FY 2027 to MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume would vary in the future. Consistent with our historical practice, as we proposed, we used the best available claims data to identify the trimmed applicable LTCH cases from which we determined the relative weights in the final rule.

For FY 2027, consistent with our historical relative weight methodology, as we proposed, we are establishing a relative weight of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 005); Liver Transplant without MCC (MS–LTC–DRG 006); Lung Transplant (MS–LTC–DRG 007); Simultaneous Pancreas, Islet Cell and Kidney Transplant (MS–LTC–DRG 008); Simultaneous Pancreas, Islet Cell and Kidney Transplant with Hemodialysis (MS–LTC–DRG 019); Pancreas or Islet Cell Transplant (MS–LTC–DRG 010); Kidney Transplant (MS–LTC–DRG 652); Kidney Transplant with Hemodialysis with MCC (MS–LTC–DRG 650), and Kidney Transplant with Hemodialysis without MCC (MS–LTC–DRG 651). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these 11 transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, we are establishing a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

Additionally, we are establishing a relative weight of 0.0000 for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedures with Principal Diagnosis of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Intellectual Disability); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol, Drug Abuse or Dependence, Left AMA); MS–LTC–DRG 895 (Alcohol, Drug Abuse or Dependence with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol, Drug Abuse or Dependence without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol, Drug Abuse or Dependence without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). We are establishing a relative weight of 0.0000 for these 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs because the blended payment rate and temporary exceptions to the site neutral payment rate would not be applicable for any LTCH discharges occurring in FY 2027, and as such payment under the LTCH PPS would be no longer be made in part based on the LTCH PPS standard

Federal payment rate for any discharges assigned to those MS–LTC–DRGs.

Step 9—Budget Neutralize the Uncapped Relative Weights

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the FY 2008 LTCH PPS final rule (72 FR 26881 and 26882)).

To achieve budget neutrality under the requirement at § 412.517(b), under our established methodology, for each annual update the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, as we proposed, we continued to apply budget neutrality adjustments in determining the FY 2027 MS–LTC–DRG relative weights so that our update of the MS–LTC–DRG classifications and relative weights for FY 2027 are made in a budget neutral manner. For FY 2027, as we proposed, we applied two budget neutrality factors to determine the MS–LTC–DRG relative weights. In this step, we describe the determination of the budget neutrality adjustment that accounts for the update of the MS–LTC–DRG classifications and relative weights prior to the application of the ten-percent cap. In steps 10 and 11, we describe the application of the 10-percent cap policy (step 10) and the determination of the budget neutrality factor that accounts for the application of the 10-percent cap policy (step 11).

In this final rule, to ensure budget neutrality for the update to the MS–LTC–DRG classifications and relative weights prior to the application of the 10-percent cap (that is, uncapped relative weights), under § 412.517(b), we continued to use our established two-step budget neutrality methodology. Therefore, in the first step of our MS–LTC–DRG update budget neutrality methodology, for FY 2027, we calculated and applied a normalization factor to the recalibrated relative weights (the result of Steps 1 through 8 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the normalization factor for FY 2027, we used the following three steps: (1.a.) use the applicable LTCH cases from the best available data (that is, LTCH discharges from the FY 2025 MedPAR file) and group them using the FY 2027 GROUPER (that is, Version 44 for FY 2027) and the recalibrated FY 2027 MS–LTC–DRG uncapped relative weights (determined in Steps 1 through 8 discussed previously) to calculate the average case-mix index; (1.b.) group the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2026 GROUPER (Version 43) and FY 2026 MS–LTC–DRG relative weights in Table 11 of the FY 2026 IPPS/LTCH PPS final rule and calculate the average case-mix index; and (1.c.) compute the ratio of these average case-mix indexes by dividing the average case-mix index for FY 2026 (determined in Step 1.b.) by the average case-mix index for FY 2027 (determined in Step 1.a.). As a result, in determining the MS–LTC–DRG relative weights for FY 2027, each recalibrated MS–LTC–DRG uncapped relative weight is multiplied by the normalization factor of 1.27345 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produces ''normalized relative weights.''

In the second step of our MS–LTC–DRG update budget neutrality methodology, we calculated a budget neutrality adjustment factor consisting of the ratio of estimated aggregate FY 2027 LTCH PPS standard Federal payment rate payments for applicable LTCH cases before reclassification and recalibration to estimated aggregate payments for FY 2027 LTCH PPS standard Federal payment rate payments for applicable LTCH cases after reclassification and recalibration. That is, for this final rule, for FY 2027, we determined the budget neutrality adjustment factor using the following three steps: (2.a.) simulate estimated total FY 2027 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the uncapped normalized relative weights for FY 2027 and GROUPER Version 44; (2.b.) simulate estimated total FY 2027 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2026 GROUPER (Version 43) and the FY 2026 MS–LTC–DRG relative weights in Table 11 of the FY 2026 IPPS/LTCH PPS final rule; and (2.c.) calculate the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the FY 2027 MS–LTC–DRG relative weights, each uncapped normalized relative weight is then multiplied by a budget neutrality factor of 1.0055356 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology.

Step 10—Apply the 10-Percent Cap to Decreases in MS–LTC–DRG Relative Weights

To mitigate the financial impacts of significant year-to-year reductions in MS–LTC–DRGs relative weights, beginning in FY 2023, we adopted a policy that applies a budget neutral 10-percent cap on annual relative weight decreases for MS–LTC–DRGs with at least 25 applicable LTCH cases (§ 412.515(b)). Under this policy, in cases where CMS creates new MS–LTC–DRGs or modifies the MS–LTC–DRGs as part of its annual reclassifications resulting in renumbering of one or more MS–LTC–DRGs, the 10-percent cap does not apply to the relative weight for any new or renumbered MS–LTC–DRGs for the fiscal year. We refer readers to section VIII.B.3.b. of the preamble of the FY 2023 IPPS/LTCH PPS final rule with comment period for a detailed discussion on the adoption of the 10-percent cap policy (87 FR 49152 through 49154).

Applying the 10-percent cap to MS–LTC–DRGs with 25 or more cases results in more predictable and stable MS–LTC–DRG relative weights from year to year, especially for high-volume MS–LTC–DRGs that generally have the largest financial impact on an LTCH's operations. For this final rule, in cases where the relative weight for a MS–LTC–DRG with 25 or more applicable LTCH cases would decrease by more than 10-percent in FY 2027 relative to FY 2026, as we proposed, we limited the reduction to 10-percent. Under this policy, we do not apply the 10 percent cap to the low-volume MS–LTC–DRGs identified in Step 3 or the no-volume MS–LTC–DRGs identified in Step 8.

Therefore, in this step, for each FY 2027 MS–LTC–DRG with 25 or more applicable LTCH cases (excludes low-volume and zero-volume MS–LTC–DRGs) we compared its FY 2027 relative weight (after application of the normalization and budget neutrality factors determined in Step 9), to its FY 2026 MS–LTC–DRG relative weight. For any MS–LTC–DRG where the FY 2027 relative weight would otherwise have

declined more than 10 percent, we established a capped FY 2027 MS–LTC–DRG relative weight that is equal to 90 percent of that MS–LTC–DRG's FY 2026 relative weight (that is, we set the FY 2027 relative weight equal to the FY 2026 weight × 0.90).

In section II.C. of the preamble of this final rule, we discuss our changes to the MS–DRGs, and by extension the MS–LTC–DRGs, for FY 2027. As discussed previously, under our current policy, the 10-percent cap does not apply to the relative weight for any new or renumbered MS–LTC–DRGs. We did not propose any changes to this policy for FY 2027, and as such any new or renumbered MS–LTC–DRGs for FY 2027 were not eligible for the 10-percent cap.

Step 11—Budget Neutralize Application of the 10-Percent Cap Policy

Under the requirement at existing § 412.517(b) that aggregate LTCH PPS payments will be unaffected by annual changes to the MS–LTC–DRG classifications and relative weights, consistent with our established methodology, we continued to apply a budget neutrality adjustment to the MS–LTC–DRG relative weights so that the 10-percent cap on relative weight reductions (step 10) is implemented in a budget neutral manner. Therefore, we determined the budget neutrality adjustment factor for the 10-percent cap on relative weight reductions using the following three steps: (a) simulate estimated total FY 2027 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the capped relative weights for FY 2027 (determined in Step 10) and GROUPER Version 44; (b) simulate estimated total FY 2027 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the uncapped relative weights for FY 2027 (determined in Step 9) and GROUPER Version 44; and (c) calculate the ratio of these estimated total payments by dividing the value determined in step (b) by the value determined in step (a). In determining the FY 2027 MS–LTC–DRG relative weights, each capped relative weight is then multiplied by a budget neutrality factor of 0.9978875 (the value determined in step (c)) to achieve the budget neutrality requirement.

Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website, lists the MS–LTC–DRGs and their respective relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)) for FY 2027. We also are making available on the website the MS–LTC–DRG relative weights prior to the application of the 10 percent cap on MS–LTC–DRG relative weight reductions and corresponding cap budget neutrality factor.

C. Changes to the LTCH PPS Payment Rates and Other Changes to the LTCH PPS for FY 2027

1. Overview of Development of the LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal payment rates is currently set forth at 42 CFR 412.515 through 412.533 and 412.535. In this section, we discuss the factors that we used to update the LTCH PPS standard Federal payment rate for FY 2027, that is, effective for LTCH discharges occurring on or after October 1, 2026, through September 30, 2027. Under the dual rate LTCH PPS payment structure required by statute, beginning with discharges in cost reporting periods beginning in FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at 42 CFR 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

Prior to the implementation of the dual payment rate system in FY 2016, all LTCH discharges were paid similarly to those now exempt from the site neutral payment rate. That legacy payment rate was called the standard Federal rate. For details on the development of the initial standard Federal rate for FY 2003, we refer readers to the August 30, 2002, LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the standard Federal rate from FYs 2003 through 2015, and LTCH PPS standard Federal payment rate from FY 2016 through present, as implemented under 42 CFR 412.523(c)(3), we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42445 through 42446).

In this FY 2027 IPPS/LTCH PPS final rule, we present our policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2027.

The update to the LTCH PPS standard Federal payment rate for FY 2027 is presented in section V.A. of the Addendum to this final rule. The components of the annual update to the LTCH PPS standard Federal payment rate for FY 2027 are discussed in this section, including the statutory reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2027 as required by the statute (as discussed in section IX.C.2.c. of the preamble of this final rule). As we proposed, we made an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level for FY 2027 on estimated aggregate LTCH PPS payments, in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B. of the Addendum to this final rule).

2. FY 2027 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital-related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2022-based LTCH market basket for use under the LTCH PPS beginning in FY 2025. For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476), and for a complete discussion of the LTCH market basket and a description of the methodologies used to determine the operating and capital-related portions of the 2022-based LTCH market basket, we refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69435 through 69455).

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year.'' We note that, because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to

''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Annual Update to the LTCH PPS Standard Federal Payment Rate for FY 2027

As previously noted, we adopted the 2022-based LTCH market basket for use under the LTCH PPS beginning in FY 2025. The 2022-based LTCH market basket is primarily based on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of LTCHs. For additional details on the development of the 2022-based LTCH market basket, we refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69435 through 69455). We continue to believe that the 2022-based LTCH market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted its use in the FY 2025 IPPS/LTCH PPS final rule. Therefore, in this final rule, as we proposed, we used the 2022-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2027.

Section 1886(m)(3)(A) of the Act provides that, beginning in FY 2010, any annual update to the LTCH PPS standard Federal payment rate is reduced by the adjustments specified in clauses (i) and (ii) of subparagraph (A), as applicable. Clause (i) of section 1886(m)(3)(A) of the Act provides for a reduction, for FY 2012 and each subsequent rate year, by ''the productivity adjustment'' described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the U.S. economy. The productivity measure referenced in section 1886(b)(3)(B)(xi)(II) is published by BLS as private nonfarm business total factor productivity ((TFP) previously referred to as multifactor productivity).[220] We refer readers to *www.bls.gov/productivity* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.* Section 1886(m)(3)(A)(ii) of the Act provided for a reduction, for each of FYs 2010 through 2019, by the ''other adjustment'' described in section 1886(m)(4)(F) of the Act.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

c. Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under 42 CFR 412.523(c)(4). The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, requires that a 2.0 percentage points reduction be applied to any update under 42 CFR 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP under 42 CFR 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year. These requirements are codified in the regulations at 42 CFR 412.523(c)(4). (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section X.E. of the preamble of this final rule.)

d. Annual Market Basket Update Under the LTCH PPS for FY 2027

Consistent with our historical practice, we estimate the market basket percentage increase and the productivity adjustment based on IHS Global Inc.'s (IGI's) forecast using the most recent available data. Based on IGI's fourth quarter 2025 forecast, the proposed FY 2027 market basket percentage increase for the LTCH PPS using the 2022-based LTCH market basket was 3.2 percent. The proposed productivity adjustment for FY 2027 based on IGI's fourth quarter 2025 forecast was 0.8 percentage point.

For FY 2027, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment, described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we proposed to reduce the FY 2027 market basket percentage increase by the FY 2027 productivity adjustment. To determine the proposed market basket update for LTCHs for FY 2027 we subtracted the proposed FY 2027 productivity adjustment from the proposed FY 2027 market basket percentage increase. (For additional details on our established methodology for adjusting the market basket percentage increase by the productivity adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).) In addition, for FY 2027, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points.

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19564), in accordance with the statute, we proposed to reduce the proposed FY 2027 market basket percentage increase of 3.2 percent (based on IGI's fourth quarter 2025 forecast of the 2022-based LTCH market basket) by the proposed FY 2027 productivity adjustment of 0.8 percentage point (based on IGI's fourth quarter 2025 forecast). Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, consistent with 42 CFR 412.523(c)(3)(xvii), we proposed to establish an annual market basket

[220] *https://www.bls.gov/productivity/notices/2021/mfp-to-tfp-term-change.htm.*

update to the LTCH PPS standard Federal payment rate for FY 2027 of 2.4 percent (that is, the proposed LTCH PPS market basket percentage increase of 3.2 percent less the proposed productivity adjustment of 0.8 percentage point). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under 42 CFR 412.523(c)(3)(xvii) in conjunction with 42 CFR 412.523(c)(4), we proposed to further reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we proposed to establish an annual update to the LTCH PPS standard Federal payment rate of 0.4 percent (that is, the proposed 2.4 percent LTCH market basket update minus 2.0 percentage points) for FY 2027 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. Consistent with our historical practice, we proposed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19564) that if more recent data subsequently became available (for example, a more recent estimate of the market basket percentage increase and productivity adjustment), we would use such data, if appropriate, to determine the FY 2027 market basket percentage increase and productivity adjustment in the final rule. We note that, consistent with historical practice, we also proposed to adjust the FY 2027 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B.6. of the Addendum to this final rule).

Comment: A few commenters appreciated and supported the proposed rate increase for LTCHs with a commenter stating it will help hospitals meet patient needs and improve access to care. Most commenters expressed concern with the proposed 3.2 percent LTCH market basket increase and whether it adequately supports the operational and clinical demands faced by LTCHs. Commenters stated they believe the proposed payment increase is insufficient considering the current rate of inflation and escalating costs (including labor, drugs, supplies, and equipment) facing LTCHs due to health care workforce shortages and supply chain disruptions.

Commenters provided data and cited recent studies and reports regarding increasing labor costs, state minimum wage requirements, medical supply and pharmaceuticals costs, dialysis costs, total operating costs, administrative costs (including those associated with Medicare Advantage claim denials), impact of tariffs, and hourly rates for contract labor, which the commenters stated highlights the need for additional increases in payments to cover these significant increases in costs. Commenters stated that these increases in costs, combined with the reimbursement pressures on LTCHs, have resulted in a significant decline in the number of LTCHs in operation and the total number of Medicare discharges from LTCHs.

Commenters requested that CMS either modify its methodology used to determine the market basket update, provide for a special increase to the proposed market basket update, or apply a special payment adjustment to account for significantly higher labor and supply costs incurred by LTCHs in recent years and potentially in FY 2027. Another commenter urged CMS to provide a more adequate market basket update in the final rule that reflects actual inflation in the LTCH cost structure and use all available administrative flexibilities to increase the net payment update. A commenter stated that the cumulative impact of inflationary pressure coupled with the proposed Medicare payment increases for FY 2027 will continue to have negative effects on LTCH PPS operating margins.

Response: CMS has historically used a market basket to account for input price increases in the services furnished by fee-for-service providers. Since the inception of the LTCH PPS, the LTCH PPS standard Federal payment rates (with the exception of statutorily mandated updates) have been updated based on a projection of a market basket percentage increase.

The LTCH market basket (as well as other CMS market baskets) is a fixed-weight, Laspeyres type index that measures price changes over time and does not reflect increases in costs associated with changes in the volume or intensity of input goods and services until the index is rebased. As such, the LTCH market basket update reflects the prospective price pressures described by the commenters as increasing during a high inflation period (such as faster wage growth or higher energy prices) but inherently does not reflect other factors that might increase the level of costs, such as the quantity of labor used (which may be associated with intensity of services). However, the impact of changes in quantity or use of services on the market basket cost weights are captured when the market basket is rebased.

We appreciate the commenters' concern regarding inflationary pressure, including labor and supply costs, encountered by LTCHs. We would highlight that the market basket percentage increase is a forecast of the price pressures that LTCHs are expected to face in FY 2027. We also note that when developing its forecast for the various price indexes used in the LTCH market basket, IGI considers industry-specific and overall economic conditions. More specifically for the Employment Cost Index (ECI) for hospital workers, IGI considers overall labor market conditions (including the impact of wage pressures on skill mix) as well as trends in contract labor wages, which both have an impact on wage pressures for workers employed directly by the hospital.

In the FY 2027 IPPS/LTCH proposed rule (91 FR 19564), we proposed a FY 2027 LTCH market basket percentage increase of 3.2 percent. As is our general practice, we also proposed that if more recent data became available, we would use such data, if appropriate, to derive the final FY 2027 LTCH market basket increase for the final rule. For this final rule (as proposed), we are using an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy. Based on IGI's second quarter 2026 forecast with historical data through the first quarter of 2026, the projected 2022-based LTCH market basket percentage increase for FY 2027 is 3.2 percent, the same increase as in the proposed rule.

As discussed earlier, we believe the LTCH market basket percentage increase appropriately reflects the input price growth (including compensation price growth) that LTCHs incur in providing medical services. We also believe the LTCH market basket is methodologically sound and uses the best available data for FY 2027. Therefore, we disagree with the commenters that CMS should increase the market basket update or apply a ''special'' payment adjustment to the LTCH PPS rates to account for or offset higher labor and supply costs or unprecedented inflation.

Comment: A commenter expressed concern about the lack of transparency from CMS regarding the LTCH market basket and the use of the IGI data. The commenter referenced CMS' responses in the FY 2025 IPPS/LTCH final rule (89 FR 69450) regarding commenters' concerns about the lack of transparency in the market basket. The commenter stated that in the FY 2027 IPPS/LTCH proposed rule, CMS did not provide greater transparency about the IGI data used for the market basket update that CMS is proposing for FY 2027. The commenter claimed that it is still not

possible to replicate exactly how CMS is arriving at the proposed 3.2 percent market basket update for FY 2027. The commenter requested that CMS provide more transparency in the final rule regarding the IGI data that led to the proposed market basket update.

Response: As discussed in the FY 2025 IPPS/LTCH final rule (89 FR 69450) and the FY 2026 IPPS/LTCH final rule (90 FR 36987), information on the CMS market baskets can be found at the CMS website: *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.* This website provides information including but not limited to how a top-line market basket level is derived from the detailed cost categories, how a four-quarter percent change moving average is calculated, and a link to a spreadsheet containing an example of how the detailed market basket cost weights are calculated for the 2006-based IPPS market basket, which is similar to the approach followed for the LTCH market basket as well as most of the other CMS market baskets. In addition, the latest, publicly available CMS market baskets are available at the CMS website: *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-data.* We note that publicly available market baskets on the CMS website would reflect an updated forecast only after a proposed or final rule is published. Using these spreadsheets, stakeholders are able to replicate the top-line market basket index levels in the historical time period by multiplying the detailed index level for each cost category by the associated cost weight. These products (weight multiplied by index level) can then be summed up to derive the aggregate market basket index level.

In response to the commenter's request for more transparency, in this final rule, we are also providing the projected increase for FY 2027 for some of the aggregated cost categories that underlie the most recent forecast of the FY 2027 LTCH market basket increase (3.2 percent). This detail is consistent with the level of information that is published on the CMS website on a quarterly basis as described above. We note that forecasted FY 2027 prices for Compensation costs, which account for about 62 percent of the market basket are projected to increase 3.2 percent; prices for All Other Products and Services, which account for about 28 percent of the market basket are projected to increase 3.2 percent; and prices for Capital-Related costs, which account for about 8.5 percent of the LTCH market basket are projected to increase 3.5 percent. While the projected market basket increase is calculated using the aggregation of the detailed price forecasts multiplied by their respective cost weights for each of the 26 individual cost categories, we want to provide an estimate of how the broader cost categories are contributing to the overall increase. We reiterate that the price proxy forecasts that underlie the LTCH market basket percentage increase (and all CMS market baskets) are derived from proprietary data produced by IGI. Because these forecasts are proprietary to IGI, CMS cannot make the full underlying data publicly available. CMS uses independent, third-party forecasting services such as IGI specifically to ensure that the market basket projections reflect sound, objective economic analysis. We strive for transparency regarding our methods and regularly respond to questions from stakeholders regarding the market baskets via email at *cmsdnhs@cms.hhs.gov.*

Comment: As in past years, several commenters were concerned about the proposed productivity adjustment of 0.8 percentage point. A commenter again stated that the market basket update is effectively eroded by the 0.8 percentage point productivity cut—a reduction that is especially damaging for hospitals already operating on slim or negative margins. Commenters stated that they believe the productivity adjustment to be flawed, as it assumes the hospital field can mirror productivity gains achieved by private nonfarm businesses that benefit from new technologies, economies of scale, business acumen, managerial skill and changes in production, which they argue is not realistic for the health care industry where labor is the greatest cost. Commenters indicated that LTCHs have little opportunity to gain productivity when salary and benefit pressures grow year over year, and workforce numbers need to keep up with patient demand. Commenters referenced Bureau of Labor Statistics productivity data as well as a CMS Office of the Actuary memorandum that stated hospital total factor productivity (TFP) using two methodologies ranges from 0.2 percent to 0.5 percent and also indicates an assumed future rate of hospital industry productivity growth of 0.4 percent per year.

Several commenters stated they understand that the productivity adjustment is statutorily mandated but suggest CMS use its ''special exceptions and adjustments'' authority to eliminate or reduce the productivity adjustment, or to make an additional, non-budget-neutral rate adjustment to account for flaws in the calculation. A commenter further states that if CMS believes it lacks statutory authority to temporarily suspend the productivity adjustment, then it should use its broad rate setting authority to make other changes that would reduce the impact of the productivity adjustment; such as to apply an offsetting payment adjustment to reduce the productivity adjustment, in whole or in part; or to modify the data used by IGI in a manner that would reduce the amount of the productivity adjustment. A commenter requested CMS work with Congress to reduce the magnitude of the productivity adjustment.

Several commenters expressed concern that the productivity adjustment appears to be applied only when it reduces Medicare payments. They stated that in the one year (FY 2021) where productivity in the non-farm business sector did not improve and measured TFP declined, CMS set the productivity adjustment to 0.0 rather than increasing payments. A commenter stated that while section 1886(b)(3)(B)(xi)(I) of the Act states that ''such percentage increase shall be reduced by the productivity adjustment'' it does not follow that the statute necessarily requires that the productivity adjustment be a subtraction from the otherwise applicable update. The commenter believes that CMS should make this issue subject to public notice and comment rulemaking.

A commenter also requested that CMS provide more transparency about how the productivity adjustment is calculated. A commenter requested CMS conduct and publish a hospital-sector-specific analysis of productivity assumptions and to work with Congress to reassess the continued application of the productivity adjustment in light of ongoing workforce and access challenges.

Response: Section 1886(m)(3)(A)(i) of the Act requires the application of the productivity adjustment. As set forth in section 1886(b)(3)(B)(xi) of the Act, the FY 2027 productivity adjustment is derived based on the 10-year moving average growth in economy-wide private nonfarm business total factor productivity for the period ending in FY 2027. We recognize the concerns of the commenters regarding the appropriateness of the productivity adjustment; however, as we explained in response to similar comments in the FY 2023, FY 2024 FY 2025, and FY 2026 IPPS/LTCH PPS final rules, section 1886(m)(3)(A)(i) of the Act requires the application of the specific productivity adjustment described in section

1886(b)(3)(B)(xi) of the Act. Therefore, we disagree with commenters that CMS should apply a ''special'' payment adjustment to the LTCH PPS rates to offset the productivity adjustment.

In the FY 2026 IPPS/LTCH final rule (90 FR 36988 through 36989), we addressed commenter's concerns regarding transparency and provided information on how the productivity adjustment is calculated using the TFP index levels (historical and projected). In addition, as stated in the FY 2026 IPPS/LTCH final rule, we have always made available on the CMS website the general method for calculating the productivity adjustment. This includes providing a link to the most recent BLS historical TFP data (*http://www.bls.gov/productivity*), which allows interested parties to obtain historical TFP annual index levels for 1987 through 2025. We also provided the IGI projection model (*https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/tfp_methodology.pdf*) which is used to derive annual TFP growth rates for 2026 and 2027. The annual index level derived from this method is then interpolated to quarterly levels, and the FY 2027 productivity adjustment is equal to the percent change in the 40-quarter moving average projected level for the period ending September 30, 2027 relative to the 40-quarter moving average projected level for the period ending September 30, 2026. We believe our methodology for the productivity adjustment is consistent with section 1886(b)(3)(B)(xi)(II) of the Act, which states that the productivity adjustment is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

At the time of this final rule, the FY 2027 productivity adjustment reflects BLS historical TFP data through 2025 (released on March 19, 2026) and IGI's forecasted TFP growth for 2026 and 2027. The average annual growth rate of historical TFP published by BLS for 2018 through 2025 is currently 1.0 percent and IGI is projecting average TFP growth of about 0.7 percent for 2026 and 2027 based on IGI's second-quarter 2026 forecast. Combining the historical and projected TFP data over the entire 10-year time period and interpolating into quarterly index levels results in a 10-year moving average growth rate of TFP of 0.9 percent for FY 2027. The productivity adjustment (based on the 10-year period ending with FY 2027) for the FY 2027 IPPS/LTCH final rule is 0.1 percentage point higher than in the FY 2027 IPPS/LTCH proposed rule mainly due to the incorporation of updated BLS historical data.

We acknowledge the commenter's request for CMS to conduct and publish a hospital-sector-specific analysis of productivity assumptions. CMS recently updated its analysis of Hospital Multifactor productivity to reflect data through 2023 and it is available on the CMS website at *https://www.cms.gov/files/document/productivity-memo.pdf.*

In response to commenters' concerns about the productivity adjustment only being applied if it reduces the payment update, we note that the productivity adjustment was established under the Affordable Care Act with a specific policy intent to encourage efficiency improvements in healthcare delivery by linking Medicare payment updates to economy-wide productivity gains. The statutory language in section 1886(m)(3)(A)(i) of the Act requires that the Secretary reduce (not increase) the market basket percentage increase by changes in economy-wide productivity, therefore, only positive productivity adjustments are applied.

Comment: Several commenters again requested that CMS implement a one-time market basket correction to address the cumulative underpayments resulting from forecast errors in the market basket updates from FY 2021 through FY 2025, which they state has resulted in a cumulative underpayment to LTCHs of 5.1 percent, or $130 million per year. These commenters argued that the standard methodology, while appropriate in normal circumstances, failed to capture the extraordinary inflationary environment of the post-pandemic period, resulting in payment rates that have persistently lagged behind actual cost growth. Commenters expressed concern that these forecast errors will be incorporated into the LTCH PPS payment rates indefinitely because all future updates are based on the current year's payment rate.

For these reasons, commenters requested that CMS should use the most recent forecast data to apply a one-time payment adjustment to account for the differences between the FYs 2021 through 2025 market basket updates and the actual market baskets for those years. A commenter claimed that these forecast errors have improperly allowed Medicare to underpay LTCHs for years while they have been incurring significantly higher labor and supply costs in recent years and in FY 2027. A commenter recommended CMS consider adopting a forecast error correction policy for the LTCH PPS beginning with FY 2027, in the event CMS again underestimates hospital inflation in a period of economic uncertainty and instability. A commenter stated that bipartisan Congressional support exists for a retrospective payment adjustment and urged CMS to act accordingly.

Response: In responding to similar comments in the FY 2023, FY 2024, FY 2025 and FY 2026 IPPS/LTCH PPS final rules (87 FR 49165, 88 FR 59136, 89 FR 69434, and 90 FR 36989), we explained that under the law, the LTCH PPS is a per-discharge prospective payment system that uses a market basket percentage increase to set the annual update prospectively. This means that the update relies on a mix of both historical data for part of the period for which the update is calculated and forecasted data for the remainder. (For instance, the 2022-based LTCH market basket growth rate for FY 2027 in this final rule is based on IGI's second quarter 2026 forecast with historical data through the first quarter of 2026.) While there is currently no mechanism to adjust for market basket forecast error in the LTCH PPS payment update, the forecast error for a market basket update is equal to the actual market basket percentage increase for a given year less the forecasted market basket percentage increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative.

We acknowledge the commenter's concern that forecast errors may be permanently embedded in future payment rates given the prospective nature of the LTCH PPS. While the projected LTCH market basket updates for FY 2021 through FY 2025 (the last historical fiscal year) were cumulatively under forecast (actual increases less forecasted increases were positive), this was largely due to unanticipated inflation and labor market pressures as the economy emerged from the COVID–19 PHE. The forecast error of the LTCH market basket has been both positive and negative during past years, and over longer periods of time the cumulative forecast hasn't deviated significantly from the historical measures.

For these reasons, we are not adopting the commenters' requests to implement an adjustment for FY 2027 to account for the difference between the actual and forecasted LTCH market basket updates for FYs 2021 through 2025.

Comment: A commenter expressed concern about the use of the Employment Cost Index (ECI) to measure changes in labor compensation in the market basket. The commenter

stated that the use of the ECI may not be adequately capturing employment and labor cost growth and stated that they continue to stand ready to work with CMS to examine the market basket compensation indices and proxies to improve the accuracy of these measures.

Response: We believe that the ECIs for Wages and Salaries and Benefits for Hospital Workers is accurately reflecting the price change associated with the labor used to provide hospital care in LTCHs. The ECI appropriately does not reflect other factors that might affect the rate of price changes associated with labor costs, such as a shift in the occupations that may occur due to increases in case-mix or shifts in hospital purchasing decisions (for instance, to hire or to use contract labor). We believe that the prices of employed staff and contract labor are influenced by the same factors and should generally grow at similar rates.

After consideration of public comments, we are finalizing the LTCH PPS payment rate update using the most recent forecast of the 2022-based LTCH market basket percentage increase and productivity adjustment. As such, based on IGI's second quarter 2026 forecast, the FY 2027 market basket percentage increase for the LTCH PPS using the 2022-based LTCH market basket is 3.2 percent. The current estimate of the productivity adjustment for FY 2027 based on IGI's second quarter 2026 forecast is 0.9 percentage point. Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, consistent with 42 CFR 412.523(c)(3)(xvii), we are establishing an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2027 of 2.3 percent (that is, the most recent estimate of the LTCH PPS market basket percentage increase of 3.2 percent less the productivity adjustment of 0.9 percentage point). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under 42 CFR 412.523(c)(3)(xvii) in conjunction with 42 CFR 412.523(c)(4), as we proposed, we are further reducing the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 0.3 percent (that is, the 2.3 percent LTCH market basket update minus 2.0 percentage points) for FY 2027 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP.

IX. Quality Data Reporting Requirements for Specific Providers

A. Overview

In section IX. of the proposed rule, we sought comments on and proposed changes to the following Medicare quality reporting programs:

- In section IX.B. of the proposed rule, we made the following crosscutting quality program proposals or sought requests for information:

++ Adoption of the Advance Care Planning Electronic Clinical Quality Measure for use in the Hospital Inpatient Quality Reporting Program, PPS-Exempt Cancer Hospital Quality Reporting Program, and Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs) (previously known as the Medicare EHR Incentive Program).

++ Adoption and Modifications to Five Mortality Measures in the Hospital Inpatient Quality Reporting and Value-based Purchasing Programs.

++ Measuring Emergency Care Access and Timeliness in the Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs—Request for Information.

++ Potential Future Use of the Adult Community-Onset Sepsis Standardized Mortality Ratio Measure in the Hospital Inpatient Quality Reporting Program—Request for Information.

- In section IX.C. of the proposed rule, the Hospital Inpatient Quality Reporting Program.
- In section IX.D. of the proposed rule, the PPS-Exempt Cancer Hospital Quality Reporting Program.
- In section IX.E. of the proposed rule, the Long-Term Care Hospital Quality Reporting Program.
- In section IX.F. of the proposed rule, the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs.

We summarize and respond to public comments related to our proposals and provide final decisions in each of their respective sections.

B. Crosscutting Quality Program Proposals and Requests for Comment

1. Adoption of the Advance Care Planning Electronic Clinical Quality Measure in the Hospital Inpatient Quality Reporting, PPS-Exempt Cancer Hospital Quality Reporting, and Medicare Promoting Interoperability Programs

a. Background

The 1990 Patient Self-Determination Act requires hospitals to inform patients of their rights regarding medical decisions and document the execution of an advance directive in medical records.[221] In the CY 2016 Medicare Physician Fee Schedule final rule (80 FR 70955 through 70959), we authorized Medicare payment to reimburse practitioners for time devoted to advance care planning services under specific procedure codes beginning in CY 2016.[222] Despite this, engagement in advance care planning remains low.[223] [224] Among Medicare Fee-For-Service beneficiaries, the advance care planning procedure codes were billed for less than 6 percent of patients in the three years after their introduction,[225] and about 5 percent of practitioners billed them in 2021.[226]

Many patients assume that their caregivers know their preferences regarding their care, but caregivers incorrectly predict the patients' preferences one-third of the time.[227] Additionally, care preferences may change over time,[228] particularly if there are changes in an individual's health status or circumstances.[229] [230] From the

[221] Patient Self Determination Act of 1990. 42 U.S. Code §§ 1395cc(f), 1396a(w).

[222] For additional information regarding the Advance Care Planning procedure codes, refer to the Fact Sheet available at: *https://www.cms.gov/files/document/mln-advanced-care-planning.pdf.*

[223] Gelfman LP, Barnes DE, Goldstein N, Volow AM, Shi Y, Li B, Sudore R. (2023). Quality and Satisfaction with Advance Care Planning Conversations Among English- and Spanish-Speaking Older Adults. *Journal of Palliative Medicine, 26*(10), 1380–1385. Available at: *https://doi.org/10.1089/jpm.2022.0565.*

[224] Sacks OA, Murphy M, O'Malley J, Birkmeyer N, Barnato AE. (2024). A Quality Improvement Initiative for Inpatient Advance Care Planning. *JAMA Health Forum, 5*(10):e243172. Available at: *https://doi.org/10.1001/jamahealthforum.2024.3172.*

[225] Weissman JS, Gazarian P, Reich A, Tjia J, Prigerson HG, Sturgeon D, Manful A. (2020). Recent Trends in the Use of Medicare Advance Care Planning Codes. *Journal of Palliative Medicine, 23*(12), 1568–1570. Available at: *https://doi.org/10.1089/jpm.2020.0437.*

[226] Wang N., Jiang C, Paulk E, Wang T, Hu X. (2025). Physician Billing for Advance Care Planning Among Medicare Fee-For Service Beneficiaries, 2016–2021. *The Permanente Journal, 29*(3), 105–110. Available at: *https://doi.org/10.7812/TPP/24.177.*

[227] National Institute on Aging. (2022). Advance Care Planning: Advance Directives for Health Care. Available at: *https://www.nia.nih.gov/health/advance-care-planning/advance-care-planning-advance-directives-health-care.*

[228] Mastropolo R, Cernik C, Uno H, Fisher L, Xu L, Laurent CA, Cannizzaro N, Munneke J, Cooper RM, Lakin JR, Schwartz, CM, Casperson M, Altschuler A, Kushi L, Chao CR, Wiener L, Mack JW. (2024). Evolution in Documented Goals of Care at End of Life for Adolescents and Younger Adults With Cancer. *JAMA Network Open, 7*(12), e2450489. Available at: *https://doi.org/10.1001/jamanetworkopen.2024.50489.*

[229] Shah MP, Wenger NS, Glaspy J, Hays RD, Sudore RL, Rahimi M, Gibbs L, Anand S, Tseng CH, Walling AM. (2025). Patient-reported discordance between care goals and treatment intent in advanced cancer. *Cancer, 131*(17), e35976. Available at: *https://doi.org/10.1002/cncr.35976.*

patient perspective, the benefits of documenting advance care planning can include increased autonomy, reduced unwanted and unnecessary treatments, and reduced length and number of hospitalizations as well as allowing more time with family and loved ones.[231] A study among terminally ill Medicare beneficiaries also found that earlier advance care planning conversations were associated with less intensive care, including lower rates of in-hospital death, hospital admission, intensive care unit (ICU) admission, and emergency department (ED) visits.[232] These findings underscore the need for early, iterative conversations to keep care aligned with evolving patient goals and values, and for families and clinicians to have clear guidance in the event that patients are unable to convey their preferences.[233] [234] Core elements of advance care planning include identifying a trusted health care proxy or surrogate decision-maker, clarifying care priorities for quality of life, and discussing specific treatments and interventions including resuscitation, intubation, ventilation, and ICU admission.[235] Inpatient care teams routinely manage high-stakes decisions and care transitions, making hospitalization an opportune moment to initiate or update advance care planning documentation and ensure updated directives are accessible to clinicians across subsequent care settings.

[230] Young Y, Stone A, Perre T. (2022). Are Young Adults Ready to Complete Advance Directives? *American Journal of Hospice & Palliative Medicine, 39*(10), 1188–1193. Available at: *https://doi.org/10.1177/10499091211066494.*

[231] Goswami P. (2021). Advance Care Planning and End-Of-Life Communications: Practical Tips for Oncology Advanced Practitioners. *Journal of the advanced practitioner in oncology, 12*(1), 89–95. Available at: *https://doi.org/10.6004/jadpro.2021.12.1.7.*

[232] Weissman JS, Reich AJ, Prigerson HG, Gazarian P, Tjia J, Kim D, Rodgers P, Manful A. (2021). Association of Advance Care Planning Visits With Intensity of Health Care for Medicare Beneficiaries With Serious Illness at the End of Life. *JAMA Health Forum, 2*(7), e211829. Available at: *https://doi.org/10.1001/jamahealthforum.2021.1829.*

[233] Shah MP, Wenger NS, Glaspy J, Hays RD, Sudore RL, Rahimi M, Gibbs L, Anand S, Tseng CH, Walling AM. (2025). Patient-reported discordance between care goals and treatment intent in advanced cancer. *Cancer, 131*(17), e35976. Available at: *https://doi.org/10.1002/cncr.35976.*

[234] National Institute on Aging. (2022). Advance Care Planning: Advance Directives for Health Care. Available at: *https://www.nia.nih.gov/health/advance-care-planning/advance-care-planning-advance-directives-health-care.*

[235] National Institute on Aging. (2022). Advance Care Planning: Advance Directives for Health Care. Available at: *https://www.nia.nih.gov/health/advance-care-planning/advance-care-planning-advance-directives-health-care.*

b. Overview of Measure

The Advance Care Planning electronic clinical quality measure (eCQM) calculates the proportion of adult patients with one or more inpatient hospitalizations during the measurement period who, by the time of hospital discharge for at least one encounter, have an advance care planning document or documentation of an advance care planning discussion resulting in a documented decision in the patient's electronic health record (EHR). This eCQM is intended to promote timely advance care planning by encouraging communication between patients and providers to elicit and document the patient's care preferences and surrogate decision-makers, thereby supporting age-friendly and goal-concordant care. The promotion of patient-centered care and utilization of EHRs to support health information exchange are important priorities across our quality reporting programs. Standardized advance care planning documentation in an EHR furthers these priorities to keep care aligned with patients' stated preferences across the care continuum. The Advance Care Planning eCQM allows for automated extraction of patient-level data directly from the EHR. We refer readers to the Electronic Clinical Quality Improvement (eCQI) Resource Center for detailed eCQM measure specifications and implementation guidance for each reporting period: *https://ecqi.healthit.gov/eh-cah/ecqm-resources.*

c. Measure Calculation

The measure numerator includes all adult patients with one or more inpatient encounters during the measurement period who have an advance care planning document or documentation of an advance care planning discussion resulting in a documented decision in the patient's EHR by the time of hospital discharge during at least one of the inpatient encounters. At this time, the numerator comprises any one of the following: (1) advance care planning document as evidenced by the following types of documents: designated health care agent (health care proxy or medical power of attorney for health care),[236] advance directive (or living will), or a portable medical order (medical order for life sustaining treatment [MOLST] or physician order for life sustaining treatment [POLST] or do not resuscitate [DNR] orders);[237] or (2) documentation that an advance care planning discussion with a documented decision occurred during the measurement period.[238]

To be counted in the numerator, the advance care planning document must be available in the patient's EHR during any hospitalization in the measurement period. The measure does not require a date reflecting the document's origination or when it was last updated; however, we encourage hospitals to support their health care providers in discussing with the patient, or their surrogate, whether the document accurately reflects the patient's current preferences. In order to be counted as an advance care planning discussion leading to a decision, the documentation of the discussion with a decision must have a date in the EHR that occurs during an inpatient encounter in the measurement period. If a patient has multiple inpatient encounters during the measurement period, an advance care planning discussion with a decision occurring in any one of the inpatient encounters during the measurement period is counted toward the numerator.

The denominator includes all patients aged 18 years and older at the start of the measurement period who are discharged from an inpatient hospitalization during the measurement period, which is a 12-month period that would run from January 1 through December 31 of each applicable calendar year.

There are no numerator or denominator exclusions.[239] The

[236] The designated health care agent accounts for the presence of a documented health care proxy or medical power of attorney that is either already established or identified and documented during the inpatient encounter. These forms allow a patient to identify a specific person who can make an advance care planning decision on the patient's behalf. States vary in the hierarchy of advance care planning decision-making by an undesignated proxy, and these state specifics are out of scope for the measure.

[237] Some state organizations may refer to a MOLST or POLST form by other terms such as: medical orders for scope of treatment (MOST), physician orders for scope of treatment (POST), clinical orders for life-sustaining treatment (COLST), or a transportable physician orders for patient preferences (TPOPP).

[238] Documentation that an advance care planning discussion with a documented decision occurring during the measurement period includes a discussion with the patient or the surrogate. This allows discussion with a surrogate in instances where a patient is unable to participate (for example, incapacitated) without requiring prior discussion with the patient.

[239] There are no numerator or denominator exclusions as the eCQM is intended to encourage advance care planning among all adults, recognizing that serious illness or injury can occur at any time, regardless of age or baseline health. The numerator is designed to account for situations where a patient does not have capacity to engage

Continued

Advance Care Planning eCQM is calculated as a proportion by dividing the number of patients who meet the numerator criterion by the total number of eligible patients who meet the denominator criterion.

We note the PCH Quality Reporting program currently uses another measure, Documentation of Goals of Care Discussions Among Cancer Patients measure (88 FR 59222 through 59224), which has some similar aims; however, it only evaluates whether specific oncology patients at a reporting PCH had documentation related to prognosis, treatment, and goals for care. The Advance Care Planning eCQM focuses on documenting condition-agnostic medical instructions and surrogate decision-makers among all adult patients, which are intended to remain applicable across care settings.

Updated data element feasibility has been tested in two EHR systems, and measure score reliability has been tested in 43 hospitals across three health systems.[240] Testing was completed in hospitals representing a mix of urban and rural hospitals, hospital sizes, teaching statuses (for example, teaching vs. non-teaching), and trauma levels. Hospital-level performance rates are summarized in Table IX.B.1. As higher scores indicate better performance, the higher percentiles are hospitals with higher proportions of an advance care planning document or a documented advance care planning conversation with a recorded decision in the EHR.

TABLE IX.B.1. HOSPITAL PERFORMANCE IN MEASURE TESTING FOR THE ADVANCE CARE PLANNING ECQM

Performance Percentile	Measure Proportions
10th	23.2%
50th (Median)	34.7%
90th	60.5%

The wide range and variation of results indicate room for quality improvement and aligns with evidence in the literature that advance care planning remains low. Test results indicated high measure reliability and validity (including agreement between data exported from the EHR and manual review of the patient chart). For detailed information on the measure specifications, please refer to: *https://www.p4qm.org/prmr-measures/muc2025-020.* During the Technical Expert Panel (TEP) convened by the measure developer, interested parties broadly supported the measure's validity and felt it provides meaningful information to make care decisions. For more details on the TEP discussion, we refer readers to the TEP Summary Report available at: *https://mmshub.cms.gov/sites/default/files/CORE-ACP-TEP3SummaryReport-092625.pdf.*

d. Pre-Rulemaking Process and Measure Endorsements

(1) Recommendations From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement for details on the Pre-Rulemaking Measure Review process convened by the consensus-based entity (CBE), including the voting procedures used to reach consensus on measure recommendations.[241] [242] The Pre-Rulemaking Measure Review Hospital Committee, consisting of both the Pre-Rulemaking Measure Review Hospital Recommendation Group (hereafter referred to as the Recommendation Group) and Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available ''2025 Measures Under Consideration List,'' including the Advance Care Planning eCQM.[243] Table IX.B.2. summarizes the voting results for this eCQM in the Hospital Inpatient Quality Reporting, PCH Quality Reporting, and Medicare Promoting Interoperability programs. For all three programs, the Recommendation Group reached consensus to recommend adoption of the Advance Care Planning eCQM within each program.[244]

in, declines, or defers advance care planning by crediting pre-existing advance care planning documents in the EHR and advance care planning discussions with documented decisions occurring during an inpatient encounter (including those conducted with a surrogate when the patient did not have capacity and those where the patient preferred to not name a surrogate or provide an advance care plan).

[240] Partnership for Quality Measurement. Updated Measure Score Level Testing and Importance Results, Downloads, Advance Care Planning. Available at: *https://www.p4qm.org/prmr-measures/muc2025-020.*

[241] Partnership for Quality Measurement. Pre-Rulemaking Measure Review web page. Available at: *https://www.p4qm.org/prmr/about.*

[242] In 2025, the CBE updated the Pre-Rulemaking Measure Review voting process such that Recommendation Group members will vote to either ''recommend'' or ''do not recommend'' that a measure be added to the intended CMS program(s), thus, removing the ''recommend with conditions'' voting option. The threshold to reach consensus on a given measure continues to be a minimum of 75 percent agreement among members.

[243] Centers for Medicare & Medicaid Services. (December 2025). 2025 Measures Under Consideration List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview.*

[244] Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendation Group Final Meeting Summary: Hospital Committee. Available at *https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf.*

TABLE IX.B.2. PRE-RULEMAKING MEASURE REVIEW HOSPITAL RECOMMENDATION GROUP VOTING RESULTS FOR THE ADVANCE CARE PLANNING ECQM

Program	Voted to Recommend	Voted to Not Recommend	Consensus Reached	Recommendation Decision
Hospital Inpatient Quality Reporting	19 (90%)	2 (10%)	Yes	Recommend
PCH Quality Reporting	20 (95%)	1 (5%)	Yes	Recommend
Medicare Promoting Interoperability	16 (76%)	5 (24%)	Yes	Recommend

Overall, the Pre-Rulemaking Measure Review Hospital Committee largely recognized the importance of advance care planning to improve communication and documentation of patient preferences and to promote patient-centered care. However, it raised concerns that the eCQM does not capture situations when patients decline or defer advance care planning and suggested inclusion of EHR codes that capture these instances. We understand the concerns of patients declining or deferring advance care planning discussions and include EHR codes for these situations. Specifically, hospitals can code for instances where a patient did not name a surrogate or provide an advance care plan; therefore, accommodating the situation where a conversation took place but no plan or proxy was named per the patient's preference.

A few Recommendation Group members who voted to recommend adoption of the Advance Care Planning eCQM recommended adding a length of stay (LOS) requirement to ensure trust between the patient and provider and studying the measure among young adults.

We appreciate the members' recommendations to add a length of stay requirement and to study it among young adults. We considered these recommendations and have determined that revision is not appropriate at this time as the goal of this measure is to establish advance care planning as a normalized, routine part of care regardless of health status and age. For patients facing imminent death as well as those expected to recover quickly, advance care planning is a priority as circumstances can change quickly. However, we will continue to evaluate these topics as additional information, experience, or analysis develops.

A Recommendation Group member who voted not to recommend adoption of the eCQM for the programs stated it would function as a check-the-box exercise rather than meaningful integration of patient preferences into care. This member noted that hospitals already ask whether a DNR order or advance directive is in place and that care teams rarely review these documents or integrate patients' wishes into the care plan. The member stated that advance care planning should primarily occur with a primary care provider or a specialist managing the patient's chronic conditions. We appreciate this feedback, and we wish to emphasize that we consider eliciting and documenting patients' preferences for care and designation of surrogate decision-makers to be a fundamental element of providing high-quality, patient-centered, and goal-concordant care. While the eCQM assesses presence of EHR codes rather than the quality of underlying conversations, this documentation is critical for care teams to reliably locate and use advance care planning information when making clinical decisions. Furthermore, hospitalization is a critical touchpoint to initiate advance care planning or to confirm and update existing information.

Additionally, a few Recommendation Group members who voted not to recommend adoption of the eCQM for the Medicare Promoting Interoperability Program indicated that they supported implementing and evaluating the eCQM in the Hospital Inpatient Quality Reporting Program before considering it for the Medicare Promoting Interoperability Program. Another member stated that the eCQM was not sufficiently defined for use in the Medicare Promoting Interoperability Program but did not provide additional detail regarding this concern in their vote rationale.

As the measure specifications proposed for the Medicare Promoting Interoperability Program are the same as those proposed for the Hospital Inpatient Quality Reporting and PCH Quality Reporting Programs, we believe they are sufficiently defined and appropriate for use across all three programs. The eCQM underwent extensive analysis and measure specifications development required for the endorsement process. Test results indicated high measure reliability and validity (including agreement between data exported from the EHR and manual review of the patient chart).[245] We also plan to maintain alignment of eCQM reporting requirements and the eCQM measure set between the Hospital Inpatient Quality Reporting Program and the Medicare Promoting Interoperability Program. If the eCQM is finalized for one or more programs, we would continue to conduct ongoing monitoring and evaluation analyses to watch for any unintended consequences.

After taking these recommendations and concerns into consideration, we proposed to adopt the Advance Care Planning eCQM in the Hospital Inpatient Quality Reporting Program, PCH Quality Reporting Program, and the Medicare Promoting Interoperability Program (91 FR 19564 through 19568).

(2) Measure Endorsements

We refer readers to the Partnership for Quality Measurement website for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19564 through 19568), we proposed to adopt this measure into the Hospital Inpatient Quality Reporting Program and the PCH Quality Reporting Program despite the measure not being endorsed by the CBE. Section 1886(b)(3)(B)(viii)(IX)(aa) of the Act requires that each measure specified by the Secretary for use in the Hospital Inpatient Quality Reporting Program be endorsed by the entity with a contract under section 1890(a) of the Act, and section 1866(k)(3)(A) of the Act imposes the same requirement for measures specified for use in the PCH Quality Reporting Program. Sections 1886(b)(3)(B)(viii)(IX)(bb) and

[245] Partnership for Quality Measurement. MERIT Submission Form, Downloads, Advance Care Planning. Available at: *https://www.p4qm.org/prmr-measures/muc2025-020*.

1866(k)(3)(B) of the Act state, however, that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we stated the exceptions in sections 1886(b)(3)(B)(viii)(IX)(bb) and 1866(k)(3)(B) of the Act apply. Since publication of the proposed rule, we expect the Advance Care Planning eCQM will be submitted in the fall of 2026 for endorsement by the CBE.

e. Data Sources, Submission, and Public Reporting

The proposed Advance Care Planning eCQM is specified in a standard electronic format, utilizing data extracted from EHRs, which would minimize errors due to manual abstraction of data.[246] In addition, by utilizing data in the EHR, it would allow updated directives to potentially be accessible to clinicians across subsequent care settings. The measure is designed to be calculated by a hospital's or PCH's certified health IT using patient-level data and then submitted by the hospital or PCH to CMS.

Testing was performed to confirm the feasibility of the measure and data elements with manual review of EHR data against chart-abstracted data. Testing demonstrated that all critical data elements were reliably and consistently captured in the EHR.[247] Additionally, data element validity testing revealed a high level of agreement between EHR data and chart review (92 percent and above) for all data elements except Advance Directive; however, all fifteen patients with electronically identified ''Advance Directive'' documents that were not present upon chart review (that is, they did not have an advance directive document in their chart) had another advance care planning document in their chart that fulfilled the numerator criteria.[248] Finally, the measure showed high reliability, with a mean of 0.9987 and standard deviation of 0.0012.[249] These results indicate that the measure is reliable and feasible to implement.

In section IX.D.5. of this final rule, we discuss the eCQM reporting and submission requirements in the PCH Quality Reporting Program, under which PCHs would be required to use certified health IT to report and submit eCQMs. PCHs are specialized acute care settings that provide intensive inpatient oncology services. As the measure was successfully tested in a variety of inpatient hospital types and is specified using data elements expected to be available in certified EHR technology, we believe that the high level of feasibility, validity, and reliability observed in a blend of acute care hospitals is reasonably applicable to PCHs despite their specialty focus on cancer patients. Further, we would monitor implementation and measure performance in PCHs and consider refinements if setting-specific issues arise.

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19564 through 19568), we proposed to adopt the Advance Care Planning eCQM as part of the eCQM measure set beginning with the CY 2028 reporting period/FY 2030 payment determination for the Hospital Inpatient Quality Reporting Program and the Medicare Promoting Interoperability Program. A hospital can self-select eCQMs to report from the eCQM measure set to meet the eCQM reporting requirement. We refer readers to sections IX.C.8.c. and IX.F.9., respectively, of this final rule for a discussion of the eCQM form, manner, and timing of data submission and reporting requirements for these two programs. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19564 through 19568), we proposed to adopt the Advance Care Planning eCQM beginning with the CY 2028 reporting period/FY 2030 program year for the PCH Quality Reporting Program. We refer readers to section IX.D.5. of this final rule for a discussion of the eCQM form, manner, and timing of data submission and reporting requirements for the PCH Quality Reporting Program.

We proposed that if adoption of the Advance Care Planning eCQM is finalized, we would publicly report data as soon as it is feasible on CMS websites such as the Compare tool on *Medicare.gov* (*https://www.medicare.gov/care-compare/*) and the CMS Provider Data Catalog or their successor websites after a 30-day preview period.

We invited public comment on our proposal. The following comments and responses are applicable for the Hospital Inpatient Quality Reporting, PCH Quality Reporting, and Medicare Promoting Interoperability Programs unless noted otherwise.

Comment: Many commenters supported adoption of the Advance Care Planning eCQM, emphasizing that it is a foundational element of high-quality care that contributes to improved alignment of care with patient goals and values, reduction in high-cost or unwanted treatments, decreased hospital and ICU stays, enhanced patient and family experience, and more efficient use of health care resources. Commenters stated normalizing earlier and iterative discussions can ensure care continues to align with patients' preferences during serious illness, clinical deterioration, care transitions, and when family or caregivers step in to interpret or carry out these preferences.

Response: We thank commenters for their support and agree that advance care planning is an important component of patient care that is an ongoing conversation to align care with patients' preferences.

Comment: Several commenters supported the inclusion of all patients aged 18 years and older. These commenters stated that this appropriately recognizes that serious illness, unexpected injury, and complex medical decision-making are not limited to older populations and that all adults can benefit from having an advance care plan or designated health care agent.

Response: We thank commenters for their support and agree that advance care planning is relevant to adults across age ranges.

Comment: Several commenters supported the adoption of the Advance Care Planning eCQM because they support efforts to modernize hospital quality reporting programs through adopting additional eCQMs. A few commenters identified advance care planning as a clinically meaningful, patient-centered activity that is appropriate for electronic measurement and efforts to align advance care planning eCQM requirements across CMS quality programs as a positive step toward harmonizing programs, reducing duplicative reporting effort, and supporting consistent clinical

[246] Centers for Medicare & Medicaid Services. (2023). Electronic Clinical Quality Measures (eCQMs) Specification, Testing, Standards, Tools, and Community. Available at: *https://mmshub.cms.gov/sites/default/files/eCQM-Specifications-Testing-Standards-Tools-Community.pdf.*

[247] Partnership for Quality Measurement. Meaningfulness Tab, Advance Care Planning. Available at: *https://www.p4qm.org/prmr-measures/muc2025-020.*

[248] Partnership for Quality Measurement. MERIT Submission Form, Downloads, Advance Care Planning. Available at: *https://www.p4qm.org/prmr-measures/muc2025-020.*

[249] Partnership for Quality Measurement. Meaningfulness Tab, Advance Care Planning. Available at: *https://www.p4qm.org/prmr-measures/muc2025-020.*

documentation practices across inpatient settings.

Response: We thank commenters for their support and agree that CMS' goal is to advance digital quality measurement and prioritize clinically meaningful measures.

Comment: A few commenters emphasized the role that nurses already play in advance care planning, whether it be contacting the appropriate specialist, documenting updated advance directives, connecting patients to relevant at-home health supports for after discharge, ensuring patients are informed of their rights, guaranteeing that patients' decisions are respected, or even engaging in frequent conversations with patients and families.

Response: We thank commenters for their support and agree that the Advance Care Planning eCQM is a clinically meaningful measure involving a team-based approach that benefits patients.

Comment: Several commenters supported the adoption of the Advance Care Planning eCQM while encouraging CMS to clarify that advance care planning is not only about documenting preferences and should help patients and families make informed decisions that are understandable, actionable, and usable across settings. A few commenters stated the measure does not address the quality or appropriateness of the advance care planning discussions, which could inadvertently lead to advance care planning discussions occurring at inappropriate moments or with insufficiently trained clinicians.

Response: We appreciate commenters' support and agree that eliciting and documenting patients' preferences for care and designation of surrogate decision-makers to be a fundamental element of providing high-quality, patient-centered, and goal-concordant care. We encourage hospitals to support their health care providers in discussing with the patient, or their surrogate, whether existing documentation accurately reflects the patient's current advance care planning preferences and to implement the measure consistent with professional standards. This should include ensuring that the staff involved have the appropriate training and support. We note that 70 percent of voting members on the TEP agreed or strongly agreed that the measure could differentiate good from poor quality care.[250]

Comment: Several commenters recommended updating the numerator to include only patients who have documentation of their goals and preferences created or revised during the current admission to ensure that the documentation is representative of the patient's preferences or applicable to their current condition. Commenters elaborated that counting any prior documentation could reduce advance care planning to an administrative exercise rather than an ongoing, goal-concordant process integrated into interdisciplinary care planning. Some commenters suggested requiring structured fields that distinguish between new advance care planning discussions and the confirmation or revision of existing advance care planning documents to enable hospitals to track whether advance care planning is iterative over time rather than a one-time event. A few commenters suggested piloting workflows or AI-enabled platforms to prompt teams to assess whether the plan documented in the patient's chart remains relevant.

Response: We appreciate commenters' recommendations regarding ways the measure could capture the current and iterative nature of advance care planning. However, we do not agree that the numerator should be limited to documentation completed or revised during the current admission, as prior advance care planning may remain applicable and clinically relevant over time. Requiring new or revised documentation for each admission could also create unnecessary burden. Hospitals should establish the appropriate processes to review existing advance care planning documentation with the patient or surrogate to determine whether it remains current and applicable to the patient's care. We leave the determination of the best assessment and documentation tools to each hospital, as they can best evaluate what is appropriate for their population. We also note that the numerator is not limited to documentation and may be satisfied by an advance care planning discussion with a documented decision.

Comment: Several commenters stated that hospitals should be encouraged to ensure that advance care planning conversations are understandable, culturally and linguistically appropriate, and connected to practical next steps, including referrals to financial counseling, case management, and community resources when ongoing care will create foreseeable affordability challenges. A commenter recommended that CMS evaluate whether the measure performs equitably across populations facing financial hardship and other barriers to care.

Response: We agree that hospitals should ensure that advance care planning conversations are understandable, culturally and linguistically appropriate, and connected to relevant next steps. This measure does not prescribe a specific approach to advance care planning conversations, allowing hospitals and clinicians to tailor the discussion in a way that is appropriate for each patient and situation. We acknowledge the commenter's recommendation to evaluate whether the measure performs equitably across patient populations, including those that may experience barriers to care. As part of our measure maintenance process, we will conduct ongoing monitoring and evaluation analyses to evaluate measure performance and watch for any unintended consequences.

Comment: Several commenters stated that, while inpatient care is an important touchpoint, advance care planning should occur across settings, including primary, post-acute, and long-term care, as well as home health and hospice. Several commenters remarked that the measure is not appropriate for the acute inpatient setting because effective conversations depend on trust and established patient-health care provider relationships, which are more commonly developed in outpatient or primary care settings. A few commenters expressed concerns about rushing patient decision-making during a vulnerable time by expecting a patient to reach a well-considered decision during an acute care hospitalization without having adequate time to discuss preferences with family members or their primary care clinician. These commenters recommended that CMS prioritize advance care planning measurement in outpatient settings and, for inpatient care, focus on whether existing documentation of the patient's goals is accessible, reviewed, and communicated across the care team.

Response: We agree with commenters that conversations about advance care planning should be addressed across multiple settings. We note that in the clinician-focused Quality Payment Program within the Merit-based Incentive Payment System (MIPS), there is an Advance Care Plan clinical quality measure available.[251] We also note that not all patients have the same access to primary care; therefore, it is important

[250] Partnership for Quality Measurement. Meaningfulness Tab, Advance Care Planning. Available at: *https://www.p4qm.org/prmr-measures/muc2025-020.*

[251] Centers for Medicare & Medicaid Services. Advance Care Plan Measure Specifications. Available at: *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2026_Measure_047_MIPSCQM.pdf.*

to include this measure in the inpatient setting to make sure patients who do not receive regular primary care have the opportunity to discuss advance care planning. In addition, the high prevalence of patients with acute health status in the inpatient setting supports both confirmation of established advance care plans and advance care planning discussions to support real-time treatment and decision-making.

Comment: Many commenters did not support the adoption of the Advance Care Planning eCQM because they believe the denominator is too broad. Several commenters recommended that the measure is better suited to older adults, suggesting age cutoffs of 50 or 65 years and older, or to higher-risk patients, such as oncology patients, ICU patients, patients with high comorbidity scores, and patients with high readmission risk scores. Several commenters did not support applying the measure broadly across younger populations as it may result in an undue burden for a standalone episode of acute care, require a significant change in workflow, increase documentation when health care provider burnout is high, divert resources from direct patient care, and potentially result in increased anxiety for patients. A few commenters recommended refining inclusion and exclusion criteria to improve feasibility, such as applying minimum length-of-stay thresholds and excluding short-stay, clinically inappropriate encounters, and patients who declined discussion.

Response: We appreciate the suggestion to limit or narrow the denominator. We note that the TEP that was convened as part of the measure development discussed the age range and concluded that the measure was appropriate for all patients 18 years and older because serious illness and loss of decision-making capacity can occur at any age.[252] While we appreciate the comments to refine inclusion and exclusion criteria, we agree with the TEP and believe any patient who must be admitted to an acute care hospital or PCH would benefit from the assignment of a health care proxy or agent, no matter their age, the particular clinical reason for the admission, or the length of stay. We do not intend for the measure to force conversations about end-of-life care for patients who are not ready to have those conversations. To account for this possibility, the measure is designed so that if a patient does not wish to name a health care proxy or make any decisions on their advance care planning, by broaching the conversation with the patient, the hospital may satisfy the numerator.

Regarding comments related to the burden of applying this measure to a broad patient population, we note that data element feasibility testing revealed that data elements specified across numerator categories existed within hospital systems workflows and can already be routinely collected during clinical care with limited or no additional data entry from a clinician or other health care provider, and no EHR interface changes were necessary. For hospitals for which some workflow and EHR adoption are required, we believe the effort is appropriate given the clinical importance of documented advance care plan information to capture patient treatment wishes.

Comment: Many commenters remarked that advance directives are often unavailable at the point of care, particularly in emergent situations or when patients are traveling. Thus, commenters urged CMS to ensure advance care planning documents are accessible across EHR systems and care settings, retrievable in real time, and presented in a manner that supports clinical decision-making. A commenter noted that it is important to send information to advance directive registries or to share it through exchanges such as the Trusted Exchange Framework and Common Agreement (TEFCA).

Response: This measure is intended to promote advance care planning and improve the accessibility of advance care planning documents for clinical use during inpatient encounters. As an eCQM, the Advance Care Planning measure assesses the documentation of a patient's treatment wishes in the patient's medical record and promotes the real time availability of these documents during the delivery of patient care while hospitalized. Advance care planning documents within a patient's EHR, available to all providers within an EHR system, promote data interoperability among providers. However, we acknowledge commenters' concerns that the measure cannot ensure the availability of those records in every situation and at every possible point of care. State and private registries exist to support the availability and exchange of advance directives and other advance care planning forms across the care continuum, and we encourage providers to use these tools to support patients' interests. We may consider ways to encourage broader adoption if it proves necessary.

Comment: Many commenters did not support the adoption of the Advance Care Planning eCQM, stating that the measure testing was insufficient and does not provide adequate information to ensure that the required data can be captured in existing workflows. Several commenters stated that data element validity was only evaluated in one EHR and feasibility was only tested in two EHRs and suggested additional testing across more EHRs and hospitals of varying sizes, locations, and ownership types to ensure that it is reliable, fair, clinically meaningful, and feasible to report. These commenters cited issues including a lack of structured data fields to capture the advance care planning information in some EHRs, codes for advance care planning discussions being inconsistently documented, and some items (such as goals, preferences, and priorities) do not exist as standalone items in structured fields. Without clearly defined data elements or detailed technical specifications, commenters stated that there is a risk of inconsistent interpretation and reporting across hospitals.

Response: We appreciate the commenters' input regarding data element validity and feasibility assessments of this measure across a broader set of EHR vendors and hospitals. We emphasize that eCQMs, like all other measure types, undergo rigorous testing for feasibility, validity, and reliability during the measure development process. Testing to complete the eCQM feasibility scorecard supports that the data required for hospital-level calculation are available in structured fields, are collected through routine workflows, are documented using standard terminology, and are accurate for many of the data elements across tested EHR systems.[253] While some advance care planning information may be captured in unstructured fields within a hospital's EHR, this measure consists of clearly defined data elements and aims to encourage the capture of advance care planning information in structured fields. The use of these defined data fields is important not only for reporting on the Advance Care Planning eCQM, but so that advance care planning documents can be accessed during a patient's inpatient encounter. We recognize that some EHR vendors may need to invest in development,

[252] Yale CORE. Summary of Technical Expert Panel (TEP): Advance Care Planning Measure. Available at: *https://mmshub.cms.gov/sites/default/files/CORE-ACP-TEP3SummaryReport-092625.pdf.*

[253] Partnership for Quality Measurement. Feasibility, Meaningfulness Tab, Advance Care Planning. Available at: *https://www.p4qm.org/prmr-measures/muc2025-020.*

configuration, or workflow standardization to support consistent capture and reporting of these data elements. However, we believe the effort is appropriate given the clinical importance of documented advance care plan information to capture patient treatment wishes.

Comment: Several commenters did not support adoption of this measure because it has not been endorsed by a CBE.

Response: As we detailed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19568), section 1886(b)(3)(B)(viii)(IX)(bb) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure for use in the Hospital Inpatient Quality Reporting Program that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Section 1866(k)(3)(B) of the Act imposes the same requirement for measures specified for use in the PCH Quality Reporting Program. We reviewed CBE-endorsed measures and were unable to identify any CBE-endorsed measures promoting advance care planning among patients 18 years and older for the inpatient setting. Therefore, the exceptions in sections 1886(b)(3)(B)(viii)(IX)(bb) and 1866(k)(3)(B) of the Act apply and we have determined that it is appropriate to use a measure that is not endorsed by the CBE. Further, we expect the Advance Care Planning eCQM will be submitted in the fall of 2026 for endorsement by the CBE.

Comment: Several commenters remarked that the eCQM should also ensure that an individual's religious or cultural beliefs can be honored that might conflict with providing an advance directive; specifically, the measure should include an exception or guidance allowing the documentation of a discussion to account for those individuals who wish to decline for these types of personal reasons. Several commenters recommended CMS ensure that hospitals are not disadvantaged when patients decline, defer, or approach advance care planning conversations differently because of cultural, religious, emotional, cognitive, or other personal factors. Some commenters stated that hospitals serving lower-income, non-English-speaking, or underserved populations may face steeper implementation challenges.

Response: We appreciate the commenters' concerns, however, the measure numerator accommodates situations where a conversation took place but no advance care plan or proxy was documented. As documenting that a conversation took place satisfies the numerator, hospitals are not disadvantaged for purposes of this quality measure when patients decline, defer, or approach advance care planning conversations differently because of cultural, religious, or other personal factors. Conversations can also be conducted with a surrogate in instances where a patient is unable to participate (for example, the patient is incapacitated) without requiring prior discussion with the patient. The numerator credits pre-existing documentation in the EHR, which would assist clinicians in interpreting and carrying out patient's preferences if a patient is unable or declines to meaningfully engage in a discussion of their preferences.

We remind commenters that the Hospital Inpatient Quality Reporting Program is a pay-for-reporting program. Participants are only subject to a payment adjustment if they do not submit required data on quality measures as specified; their payments are not affected based on their performance on measures. We also remind hospitals that they may initially self-select to report on this eCQM in the Hospital Inpatient Quality Reporting Program; it is not a mandatory eCQM for the CY 2028 reporting period/FY 2030 payment determination. Additionally, the PCH Quality Reporting Program does not impose payment consequences on PCHs.

Comment: A few commenters stated that hospitals' implementation of this measure will also need to comply with individual state requirements, expressing concern that this might disadvantage facilities located in certain regions.

Response: We recognize that state laws differ regarding who may make advance care planning decisions when a patient has not designated a health care proxy or other surrogate. The measure does not make distinctions based on state law and does not supersede or alter state-specific requirements. We expect hospitals to ensure their staff are familiar with applicable state laws and requirements governing advance care planning and surrogate designation so that any advance care planning activities are consistent with state law. Additionally, the variety of options to satisfy the measure numerator supports applicability across states due to both the wide range of included codes and their generality.

Comment: A few commenters advised against broader adoption of the measure as it runs the risk of generating ''survey fatigue'' if patients are asked about advance care planning every time they see a new health care provider or specialist. Commenters recommended that CMS should consider the sites, circumstances, and programs that are most suitable for this measure. A few commenters noted the potential risk of conflicting advance care plan documentation if multiple health care providers create an advance care plan to meet this measure and stated that it will be challenging for clinicians to know which plan is current, with a commenter suggesting that CMS share guidance for addressing multiple plans. Another commenter stated this measure may contribute to note bloat in the EHR, as documentation will likely be copied over repeatedly in the patient's record.

Response: We thank the commenters for sharing these concerns. We note that this measure is an eCQM, not a survey measure like the HCAHPS Survey measure. We acknowledge that in order to meet the measure requirement, hospital staff will need to ask patients questions, and to that end in order to avoid survey fatigue due to repeated questions related to advance care planning, hospitals should have clearly established workflows in which the information is captured or confirmed. Additionally, an encounter would count toward the numerator based on existing advance care planning documentation, regardless of where the documentation originated, provided it is available in the patient's medical record during an inpatient encounter in the measurement period and meets the numerator criteria. Hospitals should establish guidelines to assist their health care providers in identifying the most current and appropriate advance care plan within a patient's chart to address instances of conflicting documentation.

Comment: A commenter recommended clarification on how to capture and document patients with multiple inpatient encounters.

Response: For a patient with multiple inpatient encounters during the measurement period, either (1) an advance care planning document must be available in the patient's EHR during any hospitalization in the measurement period; or (2) an advance care planning discussion with a decision must have occurred in any one of the inpatient encounters during the measurement period. Therefore, if a patient has multiple inpatient encounters in the

measurement period and does not satisfy the numerator criteria on their initial encounter, a subsequent encounter in the same measurement period that does satisfy the numerator criteria would be credited.

Comment: A few commenters did not support the Advance Care Planning eCQM because they stated that some of the practices captured by the measure are duplicative of other reporting requirements, including parts of Medicare's Conditions of Participation (CoP), or aspects of the Age-Friendly Hospital measure, which requires attestation of advance care planning activities. To avoid redundancy, commenters recommend that CMS either remove the advance care planning attestation component from the Age-Friendly Hospital measure or incorporate the Advance Care Planning eCQM into the Age-Friendly Hospital measure.

Response: We agree that generally avoiding duplication is important. We believe commenters were referring to the Medicare CoP for hospitals related to quality assessment and performance improvement programs at 42 CFR 482.21. We disagree that the Advance Care Planning eCQM is redundant to the CoPs and maintain that it is complementary to them. While the CoPs set forth minimum activities related to developing, implementing, and maintaining an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program, the Advance Care Planning eCQM requires hospitals to build upon these minimum activities to provide goal concordant care with respect to advance care planning and health care proxies for all adult patients. In addition, the public display requirements of the Hospital Inpatient Quality Reporting, PCH Quality Reporting, and Medicare Promoting Interoperability Programs mean that the results of this measure will be available to patients, consumers, family and caregivers, and other interested parties. This transparency can further incentivize quality improvement.

While there is some overlap between the Age-Friendly Hospital and Advance Care Planning measures, the Age-Friendly Hospital measure assesses hospital commitment to improving care for patients 65 years or older receiving services in the hospital, operating room, or emergency department. The Advance Care Planning eCQM includes all patients 18 years or older with an inpatient encounter during the measurement period, covering a much broader cohort with defined data points focused on the documentation of advance care plans that can be more readily shared through EHRs.

Comment: A few commenters stated that the Advance Care Planning eCQM does not require the creation of new infrastructure so much as it calls for the effective utilization and alignment of capabilities that CMS and ONC have already catalyzed. Commenters remarked that leveraging existing standards and implementation pathways will enable scalable, real-time retrieval of advance care planning information across care settings while minimizing additional burden on providers and technology developers. Specifically, a few commenters recommended aligning with the advance directive data elements already established in the United States Core Data for Interoperability (USCDI) framework, including the Care Experience Preferences and Treatment Intervention Preferences (USCDI v4), the Advance Directive Observation element (USCDI v5), and Portable Medical Orders (USCDI v6) data elements. The Post-Acute Care Interoperability (PACIO) Project's Fast Healthcare Interoperability Resources® (FHIR®) [254] based Advance Healthcare Directive Interoperability Implementation Guide provides the technical specification for structured exchange of these data elements across care settings, including acute-to-post-acute transitions.

Response: We thank commenters for their recommendations. The Advance Care Planning eCQM was originally specified with and currently uses the Quality Data Model (QDM) 5.6 standard which defines clinical patient data and concepts for electronic quality performance measurement.[255] The measure will be specified in FHIR® via the QI–CORE standard for potential future implementation. This FHIR version will align with the suggested USCDI advance directive documentation data elements and the relevant PACIO Project Implementation Guides as the measure transitions from QDM to FHIR. The specific codes utilized in the measure were developed with extensive expert input and are designed to be comprehensive of advance care planning documentation and discussion with decision and will align across the QDM and FHIR versions. We wish to point readers to our request for information on potential FHIR timelines in the CY 2027 Physician Fee Schedule proposed rule (91 FR 44151 through 44154).

Comment: A few commenters suggested CMS should consider whether this measure belongs in the MIPS Value Pathway that addresses primary care or specialty care dealing with chronic illnesses. A commenter noted that this measure expands the measure denominator of the Advance Care Plan measure in MIPS. Another commenter recommended that CMS build on the advance care planning measure by considering additional quality measures related to communication regarding serious illnesses, symptom burden, caregiver experience, and goal-concordant transitions in addition to creating quality mechanisms, such as patient-reported outcome measures. Another commenter recommended alternative measures such as (1) the patient reporting outcome measure ''patients' experience of feeling heard and understood'' used in MIPS; (2) the proportion of patients with a surrogate decision-maker or health care proxy in the EHR; and (3) the proportion of hospital clinical staff who have successfully completed training in advanced communication skills in the context of a serious illness. A commenter encouraged CMS to align the specifications of this measure with the advance care planning measure required by the National Committee for Quality Assurance (NCQA) for Medicare Advantage plan reporting in the Healthcare Effectiveness Data and Information Set (HEDIS) for greater alignment of measures and specifications across systems to reduce regulatory burden and streamline the clinical and administrative workflows of all providers.

Response: We thank commenters for their recommendations and will consider building upon the foundation of this measure in future years. We note that the PCH Quality Reporting Program currently uses the Documentation of Goals of Care Discussions Among Cancer Patients measure, which evaluates whether specific oncology patients at a reporting PCH had documentation related to prognosis, treatment, and goals for care.[256]

Regarding alignment with other measures, such as the Advance Care Plan measure in MIPS or the NCQA's HEDIS Advance Care Planning measure,

[254] FHIR® is the registered trademark of Health Level Seven International (HL7), and its use does not constitute endorsement by HL7.

[255] Centers for Medicare & Medicaid Services, & Office of the National Coordinator for Health Information Technology. (2021, January). Quality Data Model (QDM), version 5.6: For use by measure developers creating measures using Clinical Quality Language (CQL). Available at: *https://ecqi.healthit.gov/sites/default/files/QDM-v5.6-508.pdf.*

[256] CMS QualityNet. Documentation of Goals of Care Discussions Among Cancer Patients Measure. Available at: *https://qualitynet.cms.gov/pch/measures/goals.*

the Advance Care Planning eCQM does not conflict with and expands upon the existing advance care plan measures used in other programs by widening the eligible cohort to include patients aged 18 years and older and by including additional modes of advance care planning documentation in the measure numerator.[257] Having this measure structured as an eCQM allows CMS to monitor performance of advance care planning activities at the hospital level using additional EHR data for an expanded cohort of patients 18 and older.

Comment: A commenter stated that POLST/MOLST forms should only count toward the measure numerator when a Do Not Attempt Resuscitation order is in place. Without this limitation, the commenter stated that the measure could incentivize routine completion of POLST/MOLST forms for all hospitalized adults, which is neither clinically appropriate nor consistent with best practice, as the forms are indicated for people who are at risk of a life-threatening clinical event due to a serious life-limiting medical condition.

Response: We interpret the comment to mean that the commenter does not think that POLST/MOLST forms are clinically appropriate for all hospitalized adults. We do not intend to encourage routine completion of these forms when not consistent with best practice and emphasize that the numerator may be satisfied through multiple pathways and does not require any particular document type for all patients. Rather, the Advance Care Planning eCQM encourages appropriate documentation of the advance care plan that reflects the patient's current situation and preferences.

Comment: A commenter stated that the measure should explicitly exclude in-hospital-only and temporary health care surrogate designations from qualifying as valid surrogate decision-makers, as well as surrogates identified on temporary advance directive forms at admission that are framed as identifying an emergency contact rather than a true surrogate decision-maker, as these designations may allow hospitals to receive credit for the measure without any accountability for effective advance care planning. This commenter noted that identification of a patient's surrogate decision-maker should be performed by an appropriate clinical member of the care team, and this process should include a clear discussion to ensure accurate understanding of the decision-maker's role and responsibilities.

Response: This measure aims to advance person-centered care by ensuring that hospitals provide patients and their caregivers the opportunity to discuss their goals of care and/or capture patients' existing advance care planning decisions. The measure does not require a specific duration of any documented care plan, only the presence of it during the admission. Surrogates identified on temporary advance directive forms at admission that are framed as identifying an emergency contact rather than a true surrogate decision-maker would not satisfy the numerator. It is the expectation, based on the eCQM's specified codes, that a power of attorney or healthcare surrogate are identified, not an emergency contact. We also note that each facility determines who has permission to document the information based on policy and licensure.

Comment: A commenter stated that the proposed measure only credits advance care planning discussions that result in a documented decision and recommended that CMS credit all documented advance care planning discussions. A commenter stated that the measure appears to recognize only patients with an inpatient DNR code status, which may exclude other documented code status decisions that also reflect substantive advance care planning. Another commenter stated the eCQM does not account for patients who do not have an advance care plan but do have a designated health care agent.

Response: The measure numerator includes all adult patients with one or more inpatient encounters during the measurement period who have an advance care planning document or documentation of an advance care planning discussion resulting in a documented decision in the patient's EHR by the time of hospital discharge during at least one of the inpatient encounters. The measure addresses situations where a conversation is documented without a completed plan or named proxy, allowing for situations where a patient would like additional time to consider or to consult with their primary care clinician, specialist, and family members. We clarify that a DNR code status is only one of the several elements available to satisfy the measure criteria, and that the numerator does account for patients who have a designated healthcare agent.

Comment: A few commenters suggested additional numerator components, such as mental health advance directives and CPT codes 99497 and 99498.

Response: We thank commenters for their suggestions. Our TEP concluded that mental health or psychiatric advance directives should not be included in the measure numerator as they do not reflect preferences for end-of-life care.[258] However, we acknowledge the importance of psychiatric advance directives, and note that the Transition Record with Specific Elements Received By Discharged Patients measure in the Inpatient Psychiatric Facility (IPF) Quality Reporting Program [259] includes the requirement for IPFs to indicate in the patient's transition record whether the patient has a documented psychiatric advance directive.

CPT 99497 and 99498 are not included in the final measure specifications because they represent an advance care planning discussion but do not require documentation of the discussion nor any decision that may have followed the discussion. The measure is intended to capture advance care planning discussion with a documented decision as documenting the patient's decision provides this information for care in the hospital and provides direct attestation that a conversation occurred. For example, Code 1124F is included as it represents an advance care planning discussion in which a decision was made not to identify a surrogate decision maker or make an advance care plan.

Comment: A commenter encouraged CMS to engage in broader education regarding the need to develop advance care plans and the importance of sharing their plans with their health care providers and hospitals. The commenter stated that Medicare Advantage plans should be encouraging advance care planning among their membership and that CMS should consider an agency-driven education campaign to impress upon beneficiaries the importance of advance care planning as well as the operational complexities associated with advance care planning discussions, including varying patient decisional capacity, behavioral health conditions, cultural considerations, family involvement, and differences in state law governing advance directives and surrogate decision-making.

[257] Partnership for Quality Measurement. Appropriateness of Scale Tab, Advance Care Planning. Available at: *https://www.p4qm.org/prmr-measures/muc2025-020.*

[258] Yale CORE. Summary of Technical Expert Panel (TEP): Advance Care Planning Measure. Available at: *https://mmshub.cms.gov/sites/default/files/CORE-ACP-TEP3SummaryReport-092625.pdf.*

[259] CMS QualityNet. IPF Specifications Manual v1.4: Transition Record Measure. Available at: *https://qualitynet.cms.gov/files/686bd1fde1b47e03cd8451ae?filename=2c_TranitionRec_v1.4.pdf.*

Response: We appreciate the commenter's suggestion and will consider it as part of our education and outreach during implementation of this measure. We agree that broader communication about the importance of sharing care preferences with health care providers and hospitals would support our goals to normalize advance care planning conversations and promote goal-concordant care. With respect to Medicare Advantage plans encouraging advance care planning conversations, we note that NCQA's Health Plan Ratings for Medicare include a measure, Advance Care Planning, as part of the HEDIS measure set.[260]

Comment: Many commenters stated that hospitals need time to modify EHR templates and workflows, train clinicians and quality staff, and devote additional administrative resources to ensure standardized documentation and accurate reporting. Several commenters suggested that new eCQMs, including the Advance Care Planning eCQM, be delayed to allow EHR vendors and hospitals sufficient lead time to make the necessary changes, especially in consideration of the overall pace and scope of updated eCQM reporting requirements in the Hospital Inpatient Quality Reporting Program.

Response: We carefully consider both the benefits and the burden of adopting new measures and transitioning to eCQMs. The shift toward digital quality measures will ultimately decrease the burden for hospitals because eCQMs use electronic standards, which help reduce the burden of manual abstraction and reporting. We note that hospitals participating in the Hospital Inpatient Quality Reporting Program and the Medicare Promoting Interoperability Program would have the option to self-select whether to report on this measure, which provides flexibility for those hospitals that may need more time for successful implementation. We refer readers to sections IX.C.8.c. and IX.F.9. for more detailed discussion of our modifications to the reporting and submission requirements for eCQMs in the Hospital Inpatient Quality Reporting Program and Medicare Promoting Interoperability Program, respectively.

For implementation guidance, we refer readers to the eCQI Resource Center website, available at: *https://ecqi.healthit.gov,* for more details on the measure specifications and other resources. We acknowledge that many quality measures can require adjustments to existing practices but believe the ultimate benefits to both individual patients and overall health outcomes from promoting advance care planning are worth the effort.

Comment: Commenters supported the transition to digital and FHIR®-based quality measurement in the PCH Quality Reporting Program but were concerned about introducing and operationalizing eCQMs beginning with mandatory reporting with the CY 2028 reporting period/FY 2030 program year. These commenters suggested that CMS delay the implementation of the policy for PCHs or do a phased introduction with an initial voluntary, confidential reporting period.

Response: As these concerns also relate to our proposal to adopt the Malnutrition Care Score eCQM in the PCH Quality Reporting Program, we refer readers to section IX.D.2.a. of this final rule for our responses to concerns specific to implementing eCQMs in the PCH Quality Reporting Program and where we describe our decision to finalize a modification of our proposal for the PCH Quality Reporting Program. Specifically, after consideration of the public comments we received on the proposed timeline for introducing eCQMs in the PCH Quality Reporting Program, we recognize that PCHs and their vendors may need additional time to operationalize eCQM reporting and submission requirements since eCQMs would be an entirely new measure type in the PCH Quality Reporting Program.

Therefore, we are finalizing our proposal to adopt the Advance Care Planning eCQM into the PCH Quality Reporting Program with a modification to provide an initial voluntary reporting period for the CY 2028 reporting period/FY 2030 program year followed by mandatory reporting of a full year's data beginning with the CY 2029 reporting period/FY 2031 program year. For the CY 2028 reporting period/FY 2030 program year voluntary period, PCHs will receive confidential data through the Hospital Quality Reporting System to provide opportunities to identify and address deficiencies before public display. We will then publicly report measure information beginning with the CY 2029 reporting period/FY 2031 program year data as soon as it is feasible on CMS websites such as the Compare tool on *Medicare.gov* and the CMS Provider Data Catalog, or their successor websites, after a 30-day preview period.

After consideration of public comments received, we are finalizing our proposal to adopt the Advance Care Planning eCQM as a self-selected eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination for the Hospital Inpatient Quality Reporting Program and Medicare Promoting Interoperability Program. We refer readers to section IX.F.9. of this final rule for a discussion of finalizing adoption of this eCQM in the Medicare Promoting Interoperability Program.

2. Adoption and Modifications to Five Mortality Measures in the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs

a. Background

In the CY 2007 OPPS/ASC final rule (71 FR 68205 through 68206), we began adopting condition-specific and procedure-specific mortality measures into the Hospital Inpatient Quality Reporting Program to more fully reflect patient outcomes following hospitalization. Beginning with the FY 2014 program year, we adopted mortality measures into the Hospital Value-Based Purchasing Program, under the Clinical Outcomes domain, specifically:

- Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization (MORT–30–AMI) measure (76 FR 26495 through 26511);
- Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization (MORT–30–HF) measure (76 FR 26495 through 26511);
- Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN) measure (adopted at 76 FR 26495 through 26511; modified at 81 FR 56994 through 56996);
- Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (MORT–30–COPD) measure (80 FR 49557 through 49558); and
- Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (MORT–30–CABG) measure (81 FR 56996 through 56998).

For more details on these five mortality measures, we refer readers to the condition-specific and the procedure-specific mortality measures updates and specifications reports available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology.*

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41556 through 41558), after adopting these measures into a pay-for-performance program, the Hospital Value-Based Purchasing Program, we

[260] National Committee for Quality Assurance. NCQA's Health Plan Ratings 2027. Available at: *https://www.ncqa.org/hedis/reports-and-research/ncqas-health-plan-ratings-2027/.*

removed them from the Hospital Inpatient Quality Reporting Program, a pay-for-reporting program, under removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We subsequently removed these measures from the Hospital Inpatient Quality Reporting Program, while maintaining them in the Hospital Value-Based Purchasing Program, as a part of our ongoing effort to move the programs forward in the least burdensome manner possible, while maintaining parsimonious sets of quality measures and continuing to incentivize improvement in the quality of care provided to patients. These five mortality measures continue to provide meaningful information for patients on the quality and value of care provided at a hospital and continue to be included in the calculation of incentive payment adjustments for the Hospital Value-Based Purchasing Program. Table IX.B.3. summarizes our previously finalized policies for these five mortality measures in the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs.

TABLE IX.B.3. SUMMARY OF FIVE MORTALITY MEASURES INITIAL AND FINAL PAYMENT DETERMINATION OR PROGRAM YEARS IN THE HOSPITAL INPATIENT QUALITY REPORTING AND VALUE-BASED PURCHASING PROGRAMS

Measure Name	First Payment Determination in Hospital Inpatient Quality Reporting program	First Program Year in Hospital Value-Based Purchasing Program	Last Payment Determination in Hospital Inpatient Quality Reporting program
MORT–30–AMI	FY 2008 (71 FR 68205 through 68206)	FY 2014 (76 FR 26495 through 26511)	FY 2020 (83 FR 41556 through 41558)
MORT–30–HF	FY 2008 (71 FR 68205 through 68206)	FY 2014 (76 FR 26495 through 26511)	FY 2020 (83 FR 41556 through 41558)
MORT–30–PN	FY 2009 (72 FR 47348 through 47351)	FY 2014 (76 FR 26495 through 26511)	FY 2021 (83 FR 41556 through 41558)
MORT–30–COPD	FY 2016 (78 FR 50792 through 50794)	FY 2021 (80 FR 49557 through 49558)	FY 2021 (83 FR 41556 through 41558)
MORT–30–CABG	FY 2017 (79 FR 50224 through 50227)	FY 2022 (81 FR 56996 through 56998)	FY 2022 (83 FR 41556 through 41558)

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19569), we proposed to adopt the modified versions of the MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD, and the MORT–30–CABG measures in the Hospital Inpatient Quality Reporting Program beginning with the FY 2028 payment determination. We would also modify these measures in the Hospital Value-Based Purchasing Program and remove them from the Hospital Inpatient Quality Reporting Program beginning with the FY 2032 payment determination. When these five mortality measures were previously adopted into the Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Programs, they only included Medicare Fee-For-Service beneficiaries in the measure cohorts. Since the initial adoption of these measures, the proportion of Medicare Advantage beneficiaries has increased from 35 percent of the Medicare population to approximately 50 percent.[261] If finalized as proposed, the modified mortality measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD, and MORT–30–CABG) will have been publicly reported in the Hospital Inpatient Quality Reporting Program for at least 1 year in accordance with the statutory and regulatory requirements of section 1886(o)(2)(C)(i) of the Act and 42 CFR 412.164(b), before adoption into the Hospital Value-Based Purchasing program.

b. Overview of Updates

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19569 through 19570), we proposed two substantive modifications to these five mortality measures: (1) expand the measure inclusion criteria to include Medicare Advantage beneficiaries; and (2) shorten the performance period from 3 to 2 years. Medicare fee-for-service only cohorts now omit a large portion of the Medicare population, and Medicare Advantage inclusion improves representativeness, reliability of measure scores, transparency, and beneficiary decision-making. In addition, inclusion of Medicare Advantage beneficiaries leads to more hospitals receiving results, and increases the chance of identifying meaningful differences in quality for some low-volume hospitals. Based on our analysis that included Medicare Advantage beneficiaries in addition to the Medicare Fee-For-Service measure cohort, we found that the measures could achieve a satisfactory level of reliability with a 2-year reporting period.[262] The mean reliability for each of the modified mortality measures exceeded the CBE-established minimum threshold of 0.6.[263] We therefore proposed to shorten the reporting period from 3 to 2 years for the modified mortality measures. Table IX.B.4. summarizes our reliability estimates for the five modified mortality measures using a 2 year reporting period (CY 2022 and CY 2023) and inclusion of Medicare Advantage beneficiaries:

[261] Centers for Medicare & Medicaid Services. (2025). Medicare Enrollment Dashboard. Available at: *https://data.cms.gov/tools/medicare-enrollment-dashboard.*

[262] Partnership for Quality Measurement. (December 2025). 2025 Pre-Rulemaking Measure Review Preliminary Assessment. Available at: *https://p4qm.org/prmr-measures/muc2025-036* (MORT–30–AMI); *https://p4qm.org/prmr-measures/muc2025-037* (MORT–30–HF); *https://p4qm.org/prmr-measures/muc2025-044* (MORT–30–PN); *https://p4qm.org/prmr-measures/muc2025-040* (MORT–30–COPD); and *https://p4qm.org/prmr-measures/muc2025-046* (MORT–30–CABG).

[263] For more details on reliability guidance, we refer readers to the Reliability Guidance for the Endorsement and Maintenance of Clinical Quality Measures Document available at: *https://p4qm.org/em/resources.*

TABLE IX.B.4. MORTALITY MEASURES RELIABILITY ESTIMATES USING A 2-YEAR REPORTING PERIOD

Measure Title	Mean (SD)	Min-Max	25th Percentile	50th Percentile	75th Percentile
MORT–30–AMI	0.772 (0.009)	0.739-0.788	0.765	0.771	0.779
MORT–30–HF	0.712 (0.009)	0.686-0.730	0.705	0.712	0.719
MORT–30–PN	0.900 (0.065)	0.264-0.911	0.905	0.907	0.909
MORT–30–COPD	0.771 (0.009)	0.729-0.786	0.766	0.771	0.778
MORT–30–CABG	0.726 (0.024)	0.633-0.768	0.715	0.729	0.744

Table IX.B.5. summarizes the proposed new performance periods for the Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program, beginning with the FY 2028 payment determination. We refer readers to section V.J.3. for more details on the baseline and performance periods in the Hospital Value-Based Purchasing Program for the FY 2032 program year and subsequent years.

TABLE IX.B.5. SUMMARY OF PROPOSED PERFORMANCE PERIODS FOR FIVE MODIFIED MORTALITY MEASURES IN THE HOSPITAL INPATIENT QUALITY REPORTING AND VALUE-BASED PURCHASING PROGRAMS

Measure Title	Proposed Initial Performance Period and Payment Determination in the Hospital Inpatient Quality Reporting Program		Proposed Final Performance Period and Payment Determination in the Hospital Inpatient Quality Reporting Program		Proposed Initial Performance Period and Program Year in the Hospital Value-Based Purchasing Program	
MORT–30–AMI MORT-30-HF MORT-30-PN MORT-30-COPD MORT-30-CABG	July 1, 2024 – June 30, 2026	FY 2028	July 1, 2027 – June 30, 2029	FY 2031	July 1, 2028 – June 30, 2030	FY 2032

For more details on the measure refinement methodology and results for these measures, we refer readers to the condition-specific and procedure-specific mortality measures updates and specifications reports available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology.*

c. Measure Calculation

The outcomes for the modified mortality measures, MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD, and MORT–30–CABG, would continue to measure 30-day, all-cause mortality.

The measures are calculated by first determining the ratio of the number of ''predicted'' deaths (the adjusted number of deaths at a specific hospital based on its patient population) to the number of ''expected'' deaths (the number of deaths if an average quality hospital treated the same patients) for each hospital and then multiplies the ratio by the national observed mortality rate. The ratio of predicted to expected deaths is greater than one for a hospital that has more deaths than would be expected for an average hospital with similar cases and less than one if the hospital has fewer deaths than would be expected for an average hospital with similar cases. This allows for a comparison of a particular hospital's performance to an average hospital's performance with the same case mix. This approach is analogous to a ratio of an ''observed'' or ''crude'' rate to an ''expected'' or risk-adjusted rate used in other similar types of statistical analyses.

(1) Numerator

The numerator for this measure is 30-day, all-cause mortality. We define mortality as death from any cause within 30 days of the start of the index admission, including in-hospital death.

(2) Denominator

The cohort includes admissions for patients that meet all of the following inclusion criteria:

- Discharged from the hospital with a principal discharge diagnosis of AMI, HF, COPD, pneumonia, or a qualifying CABG procedure;
- Enrolled in Medicare Fee-For-Service Part A and Part B or Medicare Advantage for the first 12 months prior to the date of admission and enrolled in Part A or Medicare Advantage during the index admission; [264]
- Aged 65 or older; and
- Not transferred from another acute care facility.

If a patient has more than one eligible AMI, HF, COPD, pneumonia, or CABG procedure hospitalization during the reporting period, then we randomly select one admission, or eligible

[264] This requirement is not applicable to Veterans Health Administration (VHA) beneficiaries hospitalized in VHA hospitals, who are eligible for inclusion in the cohort regardless of their Medicare enrollment status. VHA beneficiaries hospitalized in non-VHA hospitals must be concurrently enrolled in Medicare Fee-For-Service Part A or Medicare Advantage at the time of the index admission to be eligible for cohort inclusion.

procedure,[265] per year for inclusion in the measure cohort.[266]

For more information regarding measure specifications, including denominator exclusion criteria, we refer readers to condition-specific and procedure-specific mortality measures methodology reports at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology.*

d. Pre-Rulemaking Process and Measure Endorsements

(1) Recommendations From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement for details on the Pre-Rulemaking Measure Review process convened by the CBE, including the voting procedures used to reach consensus on measure recommendations.[267] [268] The Pre-Rulemaking Measure Review Hospital Committee, consisting of both the Pre-Rulemaking Measure Review Hospital Recommendation Group (hereafter referred to as the Recommendation Group) and Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available ''2025 Measures Under Consideration List,'' including the MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD, and the MORT–30–CABG measures.[269] Table IX.B.6. summarizes the voting results for measure recommendations for these measures in the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs.

TABLE IX.B.6. PRE-RULEMAKING MEASURE REVIEW HOSPITAL RECOMMENDATION GROUP VOTING RESULTS

Measure	MUC ID	Voted to Recommend	Voted to Not Recommend	Consensus Reached	Recommendation Decision
Hospital Inpatient Quality Reporting Program					
MORT-30-AMI	MUC2025-036	17 (81%)	4 (19%)	Yes	Recommend
MORT-30-HF	MUC2025-037	17 (81%)	4 (19%)	Yes	Recommend
MORT-30-PN	MUC2025-044	16 (80%)	4 (20%)	Yes	Recommend
MORT-30-COPD	MUC2025-040	16 (80%)	4 (20%)	Yes	Recommend
MORT-30-CABG	MUC2025-046	17 (85%)	3 (15%)	Yes	Recommend
Hospital Value-Based Purchasing Program					
MORT-30-AMI	MUC2025-036	16 (76%)	5 (24%)	Yes	Recommend
MORT-30-HF	MUC2025-037	15 (75%)	5 (25%)	Yes	Recommend
MORT-30-PN	MUC2025-044	15 (75%)	5 (25%)	Yes	Recommend
MORT-30-COPD	MUC2025-040	15 (75%)	5 (25%)	Yes	Recommend
MORT-30-CABG	MUC2025-046	15 (71%)	6 (29%)	No	Majority of the Recommendation Group expressed some support.

For the Hospital Inpatient Quality Reporting Program, the Recommendation Group reached consensus and recommended the five modified mortality measures for adoption into the program. For the Hospital Value-Based Purchasing Program, the Recommendation Group reached consensus for four of the five modified mortality measures, the MORT–30–AMI, MORT–30–HF, MORT–30–PN, and MORT–30–COPD measures, and thus, recommended these measures for adoption into the Hospital Value-Based Purchasing Program. The Recommendation Group did not reach consensus to recommend the MORT–30–CABG measure for the Hospital Value-Based Purchasing Program, although the majority of the Recommendation Group did express some support.[270]

The Recommendation Group largely supported the addition of Medicare Advantage beneficiaries to the measures' cohorts and underscored the importance of enhancing transparency and facilitating meaningful comparisons and high-quality care by including this population. The Recommendation

[265] A qualifying isolated CABG surgery is defined as a procedure performed without the following concomitant valve or other major cardiac, vascular, or thoracic procedures: valve procedures; atrial and/or ventricular septal defects; congenital anomalies; other open cardiac procedures; heart transplants; aorta or other non-cardiac arterial bypass procedures; head, neck, intracranial vascular procedures; or other chest and thoracic procedure.

[266] Centers for Medicare & Medicaid Services. (December 2025). 2025 Measures Under Consideration List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview.*

[267] Partnership for Quality Measurement. Pre-Rulemaking Measure Review web page. Available at: *https://www.p4qm.org/prmr/about.*

[268] We note the Pre-Rulemaking Measure Review voting process was updated in 2025. We refer readers to the corresponding footnote in section IX.B.1.d.(1) of this final rule for more details on the updated Pre-Rulemaking Measure Review voting process.

[269] Centers for Medicare & Medicaid Services. (December 2025). 2025 Measures Under Consideration List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview.*

[270] Partnership for Quality Measurement. (February 2026). PRMR 2025–2026 Pre-Rulemaking Measure Review Recommendation Group Final Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf.*

Group also generally agreed that shortening the reporting period from 3 to 2 years would lead to more actionable insights. Some members recommended further analysis to ensure the effects of including Medicare Advantage beneficiaries to the measures' cohorts are understood. Some members that did not vote to recommend these measures emphasized the need to understand the impacts of including Medicare Advantage beneficiaries in hospital performance in the Hospital Value-Based Purchasing Program prior to implementation. We appreciate the member's recommendation to ensure the impacts of including Medicare Advantage beneficiaries in the measures' cohorts are understood and we wish to emphasize that, based on our analysis, the variation between the two cohorts did not vary significantly for mortality rates, and the reliability estimate for the modified measures showed satisfactory results.[271] Therefore, the inclusion of Medicare Advantage beneficiaries does not raise concerns regarding potential variation between the Fee-For-Service and Medicare Advantage cohorts for these measures, or unintended consequences on hospital performance. We note that as a part of routine measure maintenance, we conduct ongoing monitoring and evaluation analyses to watch for any unintended consequences. Table IX.B.7. shows the results for observed 30-day mortality rates for the Medicare Fee-For-Service, Medicare Advantage, and combined cohorts, as well as the difference between the Medicare Fee-For-Service and Medicare Advantage cohorts for the proposed modified mortality measures. Further, based on our analysis, we found that the mean reliability estimates for the modified mortality measures, using two years of data (CY 2022 and CY 2023), and the updated cohort, all exceeded the CBE-established minimum threshold of 0.6.[272] We refer readers to Table IX.B.4., in section IX.B.2.b., for a description of our reliability estimates for the modified mortality measures, which includes estimates with the updated cohorts.

TABLE IX.B.7. MORTALITY RATES FOR MEDICARE FEE-FOR-SERVICE, MEDICARE ADVANTAGE FOR PROPOSED MODIFIED MORTALITY MEASURES, CY 2022

Measure Name	Medicare Advantage and Fee-For-Service Combined Cohort	Fee-For-Service Only Cohort	Medicare Advantage Only Cohort	Difference Between Fee-For-Service and Medicare Advantage Cohorts
MORT-30-AMI	12.3%	12.5%	12.1%	0.4%
MORT-30-HF	11.5%	12.2%	10.7%	1.4%
MORT-30-PN	16.8%	17.3%	16.2%	1.1%
MORT-30-COPD	8.9%	9.4%	8.4%	1.0%
MORT-30-CABG	2.8%	2.7%	2.9%	-0.2%

Some Recommendation Group members who recommended adopting the modified mortality measures for the Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs also provided considerations for strengthening the measures. Many of these recommendations included considerations for improving the risk adjustment model. Specifically, some members recommended adjusting for socioeconomic status in the risk model for all mortality measures. Some members that voted to recommend this measure suggested considering including the cause of death in the risk model to improve accuracy. Other members voted not to recommend these measures for the two programs, citing that additional evaluation of the updated risk model is needed.

Regarding the recommendation to add socioeconomic status factors to the risk adjustment model, we note that our analysis found that including these factors showed minimal impact to measure performance. This analysis also found that including these factors could result in negative impacts to vulnerable populations by lowering the expected mortality for these groups, and we decided to exclude these factors from our risk adjustment model. Regarding the recommendation to include the cause of death to improve the risk model, we thank the Recommendation Group members for this recommendation and will consider this in our routine measure maintenance. Regarding the recommendation for additional evaluation of the updated risk model, we wish to emphasize that we have conducted extensive evaluation and based on our analysis using the updated risk adjustment methodology, the ability of the updated risk adjustment model to account for condition-specific or procedure-specific severity improved significantly. We refer readers to section IX.B.2.f. for a detailed discussion of our updates to our risk adjustment methodology and summary of our analysis comparing the results of the modified measures using the two risk adjustment methodologies.

Recommendation Group members emphasized that the modified measures should be re-submitted for endorsement, prior to implementation as a rationale for not voting to recommend this measure for the Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs. Other key reasons cited for not recommending these modified mortality measures included recommending a phased implementation approach for the measure modifications, as well as confidential reporting to ensure a clear understanding of measure impacts. Some members expressed concerns about whether small or rural hospitals would be able to meet volume

[271] Partnership for Quality Measurement. (March 2024). 2024 Condition- and Procedure-Specific Mortality/Complication Measures Supplemental Methodology Report. Available at: *https://p4qm.org/prmr-measures/muc2025-036.*

[272] For more details on reliability guidance, we refer readers to the Reliability Guidance for the Endorsement and Maintenance of Clinical Quality Measures Document available at: *https://p4qm.org/em/resources.*

thresholds for these measures with the reduced reporting period.

Regarding members' recommendation to re-submit the modified measures for endorsement, these measures are currently endorsed by the CBE and have been re-submitted for endorsement review with these measure modifications for the Spring 2028 cycle. We note that in the FY 2027 IPPS/LTCH PPS proposed rule, we stated that these measures were next going through CBE endorsement and maintenance review in the Spring 2026 review cycle, which has since been updated to the Spring 2028 review cycle (91 FR 19573). In response to the members that recommended a phased implementation of the measures modifications as well as confidential reports, we note that we intend to provide hospitals with measure performance data with the expanded patient cohort based on data collected while the modified versions of these measures are in use in the Hospital Inpatient Quality Reporting Program via annual confidential hospital-specific reports beginning with the FY 2028 program year, as well as via annual Provider Participation Summary Reports under the Hospital Value-Based Purchasing Program beginning with the FY 2032 program year. Further, we proposed the modified mortality measures take effect for the Hospital Value-Based Purchasing Program beginning with the FY 2032 program year, which will provide time and data to monitor for any unintended consequences. In addition, the FY 2032 Hospital Value-Based Purchasing Program performance standards for this measure would be published at least 60 days prior to the beginning of each applicable performance period as required by section 1886(o)(3)(C) of the Act. Regarding the concern about whether small or rural hospitals would be unduly burdened by the shortening of the reporting period from 3 to 2 years, we wish to note that the decrease in cohort size is largely offset with the addition of Medicare Advantage beneficiaries to measure cohorts; thus, we do not anticipate small or rural hospitals to be unduly burdened by this update.

Specifically for the MORT–30–CABG measure, one member cited the potential for unintended consequences for hospitals to refuse care for patients with complex co-morbidities as their rationale for not recommending this measure for either the Hospital Inpatient Quality Reporting Program or the Hospital Value-Based Purchasing Program. We appreciate the Recommendation Group member's concern about unintended consequences. Based on our analysis with the current risk adjustment methodology, which includes risk adjustment for patient frailty, we do not anticipate hospitals to be unfairly penalized for treating patients who may be more complex. We refer readers to Table IX.B.4., in section IX.B.2.b., and Table IX.B.9., in section IX.B.2.f., for more details on our analysis of measure reliability and the risk adjustment methodology. Further, as a part of routine measure maintenance, we conduct ongoing monitoring and evaluation analyses to watch for any unintended consequences.

After taking these recommendations and concerns into consideration, we proposed to adopt the modified mortality measures in the Hospital Inpatient Quality Reporting Program beginning with the FY 2028 payment determination and subsequently modify the mortality measures in Hospital Value-Based Purchasing Program beginning with the FY 2032 program year (91 FR 19568 through 19574).

(2) Measures Endorsements

We refer readers to the Partnership for Quality Measurement website for details on the measure Endorsement and Maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. Table IX.B.8. summarizes the most recent endorsement status and the next planned Endorsement and Maintenance review for five modified mortality measures:

TABLE IX.B.8. FIVE MORTALITY MEASURES ENDORSEMENT STATUS

Measure Title	CBE#	Most Recent Endorsement	Next Endorsement and Maintenance Review*
MORT–30–AMI	0230	Fall 2020	Spring 2028
MORT–30–HF	0229	Fall 2020	Spring 2028
MORT–30–PN	0468	Fall 2020	Spring 2028
MORT–30–COPD	1893	Fall 2020	Spring 2028
MORT–30–CABG	2558	Fall 2022	Spring 2028

* We note that in the FY 2027 IPPS/LTCH PPS proposed rule, we stated that these measures were next going through CBE endorsement and maintenance review in the Spring 2026 review cycle, which has since been updated to the Spring 2028 review cycle (91 FR 19573).

e. Data Source, Submission, and Public Reporting

These measures would be calculated using administrative data from Medicare Fee-For-Service claims or hospital-submitted Medicare Advantage claims, and Medicare Advantage organization-submitted encounter data. These data are routinely generated by hospitals or Medicare Advantage organizations, and submitted to CMS for all Medicare beneficiaries, which includes Medicare Advantage and Medicare Fee-For-Service beneficiaries. Therefore, a hospital would not be required to report any additional data for this measure. The addition of Medicare Advantage beneficiaries increases cohort size, supports more precise hospital-level estimates, and allows more hospitals, including some lower-volume hospitals, to meet minimum reporting thresholds. Enrollment status would be obtained from the Medicare Enrollment Database which contains beneficiary demographic, benefit/coverage, and vital status information.

The proposed modified mortality measures would be calculated and publicly reported on an annual basis using a rolling 24 months of prior data for the measurement period, consistent with the approach currently used for the MORT–30–STK measure, the COMP–HIP–KNEE measure, and the Thirty-day Risk-Standardized Death Rate Among Surgical Inpatients with Complications measure currently reported in the

Hospital Inpatient Quality Reporting Program (90 FR 36997 through 37002, 90 FR 37002 through 37008, and 89 FR 69545 through 69552). We would then publicly report the measures results on the Compare tool, currently available at: *https://www.medicare.gov/care-compare/,* beginning in July 2027 or as soon as feasible for the Hospital Inpatient Quality Reporting Program, which would enable us to post data for at least 1 year before adopting the modifications into the Hospital Value-Based Purchasing Program, as required by section 1886(o)(2)(C)(i) of the Act. For the Hospital Value-Based Purchasing Program, we also proposed that the performance standards calculation methodology for the modified mortality measures would be the same as that which we currently use for the mortality measures. The performance standards for the modified measures for FY 2032 are not yet available.

We invited public comment on our proposals to adopt five modified mortality measures, MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD, and the MORT–30–CABG, into the Hospital Inpatient Quality Reporting Program from the FY 2028 payment determination through the FY 2031 payment determination, and subsequently remove these measures from the Hospital Inpatient Quality Reporting Program beginning with the FY 2032 payment determination, as a step towards substantively modifying them in the Hospital Value-Based Purchasing Program. We also invited public comment on our proposal to modify these five mortality measures in the Hospital Value-Based Purchasing Program beginning with the FY 2032 program year, contingent on our adoption of these changes in the Hospital Inpatient Quality Reporting Program.

Comment: Many commenters supported our proposal to adopt five modified mortality measures into the Hospital Inpatient Quality Reporting Program and subsequently modifying them in the Hospital Value-Based Purchasing Program. These commenters agreed that the proposed modifications, specifically expanding the cohorts to include Medicare Advantage beneficiaries and shortening the reporting period to 2 years, would improve the measures' reliability and the accuracy of performance data. Many commenters agreed on the importance of including Medicare Advantage beneficiaries given the growing proportion of this population to the overall Medicare population and that this change would be more representative of hospitals' patient populations and help inform care by creating a more accurate picture of hospital performance. Many commenters supported reducing the reporting period from 3 to 2 years for these measures, stating that this update to the measures would provide more timely quality data and may better support organizational learning and responsiveness to emerging safety concerns.

Response: We thank commenters for their support and agree that these updates to the measures will provide hospitals with more reliable, accurate, and timely performance data. We agree that the inclusion of Medicare Advantage beneficiaries is critical given these beneficiaries make up over half the overall Medicare population.

Comment: Many commenters did not support adopting these measures into the Hospital Inpatient Quality Reporting Program and subsequently modifying them in the Hospital Value-Based Purchasing Program due to concerns about the challenges of data collection and reporting with the proposed addition of Medicare Advantage beneficiaries to the measures' cohorts. Many commenters expressed concerns about Medicare Advantage data reliability, consistency, completeness, and the variation between Medicare Advantage and Medicare Fee-For-Service reporting practices. A commenter stated concerns that hospitals are not subject to shadow claims performance assessment prior to formal inclusion in Hospital Value-Based Purchasing Program. Commenters recommended addressing these data collection challenges by conducting additional analysis before the modified mortality measures are implemented, emphasizing the importance of transparency regarding the inclusion of Medicare Advantage populations to ensure Medicare Advantage data meet the same reliability and completeness standards as Medicare Fee-For-Service data.

Response: We acknowledge commenters' concerns regarding the inclusion of Medicare Advantage beneficiaries and the potential for challenges around data reliability, consistency, and completeness. However, we respectfully disagree that Medicare Advantage data completeness creates a significant concern regarding measure reliability, and recent data suggest improved timeliness, completeness, and accuracy of Medicare Advantage encounter data. We direct readers to the Announcement of Calendar Year 2022 Medicare Advantage Capitation Rates and Part C and Part D Payment Policies,[273] in which CMS described its efforts to improve the completeness and validity of encounter data and its transition to calculating 100 percent of the risk score using diagnoses from encounter data and Fee-For-Service claims.

CMS has been assessing Medicare Advantage data for use in quality measurement since 2017, and recent CMS policies have focused on improving the timeliness, completeness, and accuracy of Medicare Advantage data. Hospital-submitted Medicare Advantage claims data are already used in Disproportionate Share Hospital and Graduate Medical Education payment calculations, and Medicare Advantage organization-submitted encounter data are used to calculate Medicare Advantage beneficiary risk scores.

For the Hybrid Hospital-Wide All-Cause Readmission measure and the Hybrid Hospital-Wide All-Cause Risk-Standardized Mortality measure in the Hospital Inpatient Quality Reporting Program, CMS specifies that, for each Medicare Advantage admission, the measure calculation would use either the hospital-submitted information-only Medicare Advantage claim or the Medicare Advantage organization-submitted encounter data record, depending on which source is available. When Medicare Advantage admission information for a patient is available from both sources, CMS would use the hospital-submitted information-only Medicare Advantage claim because it is more timely and is already linked to the applicable hospital's CMS Certification Number.

More broadly, CMS has found that including Medicare Advantage patient data in measures improves measure reliability, narrows confidence intervals for measure scores, and increases the number of hospitals and beneficiaries included in the measures. Based on internal analyses of Medicare Advantage data submitted to CMS by hospitals and Medicare Advantage organizations for 2017 through 2021, CMS determined that incorporating Medicare Advantage admissions into CMS hospital outcome measures is feasible.

Hospitals and Medicare Advantage organizations submit these data on a schedule that will allow their use in measure calculation. Inpatient Medicare Advantage encounter data in CMS'

[273] Centers for Medicare & Medicaid Services. Advance Notice of Methodological Changes for Calendar Year 2022 for Medicare Advantage Capitation Rates and Part C and Part D Payment Policies (the Advance Notice). Accessed March 5, 2023. Available at: *https://www.cms.gov/files/document/2022-advance-notice-part-i.pdf.*

Integrated Data Repository include National Provider Identifiers that can be matched to hospitals' CMS Certification Numbers, which are currently used to identify hospitals in CMS outcome measures. Based on an analysis to include Medicare Advantage beneficiaries into outcome measures, a high percentage of Medicare Advantage encounter data were submitted within the three-month timeframe needed for hospital measure reporting, and submission timeliness has improved over time, increasing from 90.3 percent in 2018 to 95.2 percent in 2021 for inpatient encounters at acute care and critical access hospitals.[274]

CMS' internal analysis also found a high rate of matching diagnoses between Medicare Advantage organization-submitted Medicare Advantage encounter data and hospital-submitted Medicare Advantage claims. This finding supports the use of either data source for a given admission in measure calculation. As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19568 through 19574), we have studied whether there are key differences between the Medicare Advantage and Medicare Fee-For-Service populations and found that there were not significant differences between the two populations. Further, we found that incorporating Medicare Advantage beneficiaries into measures' cohorts improved the measures' reliability. Using 2 years of data (CY 2022 and CY 2023), we found that the mean reliability estimates all exceeded the CBE established minimum threshold of 0.6, with results ranging from 0.712 for the MORT–30–HF measure to 0.900 for the MORT–30–PN measure. Further, we examined the differences in mortality rates between Medicare Advantage and Medicare Fee-For-Service populations and found the observed mortality rates ranged from −0.2 percent for the MORT–30–CABG measure to 1.4 percent for the MORT–30–HF measure. Because the measures also adjust for Medicare Advantage versus Fee-For-Service enrollment status in the risk model, we concluded these measures do not reflect any meaningful bias due to differing proportions of Medicare Advantage patients across hospitals. We refer readers to sections IX.B.2.b. and IX.B.2.d. for detailed results on these findings.

We agree that transparency is important for both patients and providers, and we provide hospitals with annual confidential feedback reports on their measure performance, as well as making our routine measure evaluation reports publicly available through QualityNet on our website at: *https://qualitynet.cms.gov/,* or on a successor website. We note that our annual measure re-evaluations are conducted to ensure that the risk-standardized mortality model is continually assessed and remains valid, given possible changes in clinical practice and coding standards over time. Modifications made to the measure cohort, risk model, and outcomes are informed by review of the most recent literature related to measure conditions or outcomes, feedback from various stakeholders, empirical analyses, and assessment of coding trends that reveal shifts in clinical practice or billing patterns. For the complete measure methodology report and measure risk adjustment model, we specifically refer readers to QualityNet on our website at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology* and the Partnership for Quality Measurement's website at: *https://p4qm.org/prmr-measures.*

Comment: Many commenters did not support modification of the mortality measures in the Hospital Value-Based Purchasing Program due to concerns about how the inclusion of Medicare Advantage data would affect measure performance, hospital scores, or payment adjustments. Several commenters recommended providing data showing performance shifts, specifically in the Hospital Value-Based Purchasing Program, to ensure that the results can be used to drive further improvement in patient care. Several commenters expressed concerns that payment adjustment modeling has not been made publicly available for the Hospital Value-Based Purchasing Program. A commenter recommended that CMS make the results of hospital-specific analyses publicly available before implementing the modified measures in the Hospital Value-Based Purchasing Program to show the impact including Medicare Advantage beneficiaries has on individual hospital scores and payment adjustments across different market types.

Response: We understand commenters' concerns regarding impacts on measure performance, and therefore total program performance, due to potential differences in Medicare Advantage populations and Medicare Advantage plan designs. To evaluate hospital performance with the addition of Medicare Advantage beneficiaries, we examined shifts in risk-standardized mortality rates by quintiles of the proportion of hospital Medicare Advantage admissions and by quintiles of overall hospital volume, comparing the Medicare Fee-For-Service only cohort with the original Hierarchical Condition Categories-based risk model factors and the combined Medicare Advantage and Medicare Fee-For-Service cohort with the reselected ICD–10-based risk model factors. This analysis found that overall, hospitals shifted by no more than one quintile between 71.7 percent (MORT–30–CABG measure) of the time to 79.8 percent (MORT–30–HF measure) of the time.[275] For the complete measure performance results, we specifically refer readers to QualityNet on our website at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology.*

Regarding payment adjustment modeling and providing hospital-specific feedback reports, we intend to provide hospitals with measure performance data with the expanded measures' patient cohort based on data collected while the modified mortality measures are in use in the Hospital Inpatient Quality Reporting Program via annual confidential hospital-specific reports beginning with the FY 2028 payment determination, as well as via annual Provider Participation Summary Reports under the Hospital Value-Based Purchasing Program beginning with the FY 2032 program year. As previously discussed, we will make routine measure evaluation reports publicly available through QualityNet on our website at: *https://qualitynet.cms.gov/.* In addition, Hospital Value-Based Purchasing Program performance standards for this measure will be published at least 60 days prior to the beginning of each applicable performance period as required by section 1886(o)(3)(C) of the Act.

Comment: Many commenters stated concerns about the risk of being unfairly penalized for factors outside their control, such as Medicare Advantage plan prior authorization delays, network adequacy limitations, and denials of post-acute services, noting these are observed adverse practices by some Medicare Advantage plans that could negatively impact health outcomes like mortality. Several commenters raised concerns about the potential for increased administrative burden with the addition of Medicare Advantage beneficiaries, noting that the prior authorization process used by Medicare

[274] Kyanko KA, Sahay KM, Wang Y, et al. (2024). Processing and validation of inpatient Medicare Advantage data for use in hospital outcome measures. *Health Serv Res,* 59(6):e14350. Available at: *https://doi.org/10.1111/1475-6773.14350.*

[275] Centers for Medicare & Medicaid Services. 2024 Condition- and Procedure-Specific Mortality/Complication Measures Supplemental Methodology Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology.*

Advantage plans places a significant administrative burden on both acute care hospitals and post-acute care providers, which requires excessive documentation for medical necessity.

Response: We acknowledge commenters' concerns regarding health plan benefit design differences between Medicare Advantage plans and Medicare Fee-For-Service plans and the impact the potential effect of those differences on patient outcomes. Further, we recognize that Medicare Advantage payment policies are not the same as Medicare Fee-For-Service payment policies, and by design, Medicare Advantage organizations are given more flexibility in benefit and provider reimbursement design. We note that mortality is an adverse outcome irrespective of benefit or payment policies. From the patient perspective, it is important to measure and provide transparency as to mortality rates for all Medicare beneficiaries. Using 2 years of data (CY 2022 and CY 2023), internal analyses showed no statistical difference in the average risk-standardized mortality rates across the condition- and procedure-specific measures for the Medicare Fee-For-Service-only and Medicare Advantage-only beneficiaries. Therefore, CMS does not believe that inclusion of MA beneficiaries in the measure cohort would materially increase hospitals' risk of adverse performance results based on differences between the Medicare FFS and MA populations. Based on the available sample, the measures' do not demonstrate meaningful variation in mortality rates between the Medicare Fee-For-Service and Medicare Advantage cohorts. Accordingly, we believe that combining Medicare Fee-For-Service and Medicare Advantage beneficiaries for purposes of measure calculation is appropriate and will preserve a larger measure cohort, thereby increasing hospital case volume and supporting more precise and reliable hospital-level measure scores.

While we understand that Medicare Advantage beneficiaries are subject to different benefits design and payment approaches than Medicare Fee-For-Service enrollees, we do not agree that these differences mean that improving clinical outcomes are completely beyond the hospital's control. In addition, Medicare Advantage payment amounts, plan denials, and plan-specific payment rules are not used to calculate the mortality measures. We continue to encourage hospitals to work closely with insurers, including Medicare Advantage plans, to coordinate the highest quality care for their patients.

Comment: Many commenters did not support this proposal due to the timing of the proposed changes, citing concerns that the implementation timeline of the methodological re-specifications to the mortality measures was too compressed and did not provide a meaningful transition period. Commenters recommended delaying modifications or taking a phased approach to modifying these measures in the Hospital Value-Based Purchasing Program to ensure that hospitals have had adequate time to evaluate the impacts of the revised methodology before holding them financially accountable. A few commenters recommended delaying implementation of these mortality measures until there is a clearer understanding of the impact of including Medicare Advantage beneficiaries into measure cohorts and confidence that inclusion does not result in any unintended consequences. A commenter expressed concern about the rapid pace of re-specifications to these measures and recommended providing dry-run reports incorporating these changes before implementation in any program to assist hospitals to meaningfully improve outcomes.

Response: We understand commenters' concerns about the impacts of implementing multiple changes to the mortality measures. We note that the current approach to adopt the modified mortality measures into the Hospital Inpatient Quality Reporting Program beginning with the FY 2028 payment determination, per section 1886(o)(2)(C)(i) of the Act, followed by adoption into the Hospital Value-Based Purchasing Program beginning with the FY 2032 program year, is a phased implementation approach. This phased approach allows hospitals to have about 4 years to assess the impact of Medicare Advantage beneficiary inclusion before payment adjustments would take effect.

Comment: Many commenters stated concerns about whether the existing risk adjustment methodologies adequately account for differences in patient complexity, clinical severity, Medicare Advantage-specific coding patterns, and social risk factors across patient populations that may influence patient outcomes and provider performance. A few commenters recommended providing additional analysis and detail on the statistical methods, reliability across hospital types, and safety-net status and case mix before the modified measures are fully incorporated into payment programs.

Response: We note that the updated risk adjustment model accounts for case mix in both Medicare Fee-For-Service and Medicare Advantage cohorts. The clinical variables included in the updated risk adjustment model were selected based on analyses of a combined Medicare Fee-For-Service and Medicare Advantage cohort. This approach ensures that the model captures the key risk factors relevant to the combined population. The model includes an indicator variable for Medicare Fee-For-Service and Medicare Advantage enrollment status, which accounts for any potential differences in risk between these groups. We found that the prevalence of clinical risk factors and their associations with mortality risk were similar across Medicare Fee-For-Service and Medicare Advantage populations. We refer readers to section IX.B.2.f. where we discuss details of technical updates to the mortality measures' risk adjustment methodology.

Comment: A few commenters recommended providing additional analysis and detail showing the results of socioeconomic status factors before the modified measures are fully incorporated into payment programs. A commenter expressed concerns that these measures do not account for social risk factors, which could disproportionately impact facilities serving the most vulnerable patients.

Response: Internal analyses found that the impact of any socioeconomic status factors is small to negligible on model performance and hospital-level results. Given these results, and that all patients deserve the same quality of care regardless of social risk, we do not support risk adjusting for these factors. This analysis also found that including these factors could result in negative impacts to vulnerable populations by lowering the expected mortality rate for these groups, therefore, we excluded these factors from our risk adjustment model.

Comment: A commenter recommended that CMS publish an interim report evaluating the impact across hospitals and commit to annual testing and analysis to monitor changes and recalibrate risk adjustment as needed.

Response: We thank commenters for their recommendation to publish an interim report evaluating the impacts of the measure modifications, but we note we annually publish measure evaluation reports. These evaluations ensure that the risk-standardized mortality models are continually assessed and remain valid, given possible changes in clinical practice and coding standards over time.[276] Modifications made to the

[276] Centers for Medicare & Medicaid Services. 2024 Condition- and Procedure-Specific Mortality/

measure cohort, risk model, and outcomes are informed by review of the most recent literature related to measure conditions or outcomes, feedback from various stakeholders, empirical analyses, and assessment of coding trends that reveal shifts in clinical practice or billing patterns. We make our routine measure evaluation reports publicly available through QualityNet on our website at: *https://qualitynet.cms.gov/.* For the complete measure methodology report and measure risk adjustment model, we specifically refer readers to QualityNet on our website at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology.*

Comment: Several commenters raised concerns about the potential for increased administrative burden with the addition of Medicare Advantage beneficiaries, noting that the prior authorization process used by Medicare Advantage plans places a significant administrative burden on both acute care hospitals and post-acute care providers, which requires excessive documentation for medical necessity. A few commenters highlighted concerns that changes to these measures could potentially place disproportionate administrative burdens on rural hospitals with limited staffing and IT resources, emphasizing these burdens may divert critical resources away from patient care. A commenter recommended closely monitoring the impacts of changes to the measures on rural and lower-volume hospitals to ensure that reliability thresholds, case minimums, and reporting approaches do not inadvertently disadvantage these providers.

Response: We would like to clarify that the inclusion of hospital-submitted information-only Medicare Advantage claim or Medicare Advantage organization-submitted encounter data into the mortality measures' cohorts does not require any additional data collection or submission from hospitals. As we discussed in the proposed rule (91 FR 19753 through 19755), the inclusion of Medicare Advantage encounter data in these measures uses readily available claim-level data elements routinely generated and submitted to CMS for Medicare Advantage beneficiaries. Specifically, the Medicare Advantage encounter data used for this measure are submitted by Medicare Advantage organizations to CMS. Similarly, Medicare Fee-For-Service claims are submitted through existing hospital billing processes. As such, the proposed modifications do not impose additional data submission burden on hospitals. We refer readers to sections XII.B.2. and XII.B.4.c. for additional details on our information collection burden estimate for the proposal to adopt the modified mortality measures. In addition, hospitals have been preparing for the addition of Medicare Advantage data to several Hospital Inpatient Quality Reporting Program measures, including the MORT–30–STK measure, the COMP–HIP–KNEE measure, and the Thirty-day Risk-Standardized Death Rate Among Surgical Inpatients with Complications measure currently reported in the Hospital Inpatient Quality Reporting Program (90 FR 36997 through 37002, 90 FR 37002 through 37008, and 89 FR 69545 through 69552).

Comment: A commenter recommended providing technical assistance and funding support targeted to rural providers.

Response: While we will not be providing additional funding support for rural providers, we do note that we have outreach and education information, including detailed information related to the measure specifications, located at: *https://qualitynet.cms.gov/inpatient/iqr.*

Comment: A commenter requested that CMS clarify the use of the data collected under the Hospital Inpatient Quality Reporting Program to inform future Hospital Value-Based Purchasing Program scoring, as well as how hospitals should interpret performance results during this interim phase, noting the transition is not intuitive.

Response: To transition these mortality measures from the Hospital Inpatient Quality Reporting Program to the Hospital Value-Based Purchasing Program, we would first adopt the modified mortality measures into the Hospital Inpatient Quality Reporting Program beginning with the FY 2028 payment determination, per section 1886(o)(2)(C)(i) of the Act, followed by adoption into the Hospital Value-Based Purchasing Program beginning with the FY 2032 program year.

We intend to provide hospitals with measure performance data with the expanded measures' patient cohort based on data collected while the modified mortality measures are in use in the Hospital Inpatient Quality Reporting Program via annual confidential hospital-specific reports beginning with the FY 2028 payment determination, as well as via annual Provider Participation Summary Reports under the Hospital Value-Based Purchasing Program beginning with the FY 2032 program year. We will make routine measure evaluation reports publicly available through QualityNet on our website at: *https://qualitynet.cms.gov/.* We will continue working with hospitals to provide information regarding the effects these changes may have on their publicly reported data under the Hospital Inpatient Quality Reporting Program and potential impacts on their Hospital Value-Based Purchasing Program performance.

Comment: A few commenters recommended providing stratified analyses or supplemental reporting that allows stakeholders to better understand any differences across Medicare Advantage and Medicare Fee-For-Service performance results. A few commenters recommended separate reporting for Medicare Advantage and Medicare Fee-For-Service populations in both public reporting and confidential feedback, citing concerns that combining these populations would obscure meaningful differences. Conversely, a few commenters recommended that these measures should not be publicly reported by plan type, emphasizing that doing so would contradict the intended purpose of measuring hospital quality and outcomes and improve validity and reliability, rather than imply plan-level quality comparisons.

Response: We thank commenters for their recommendation to provide stratified measure results, as well as comments recommending that we do not provide stratified measure results. We considered both options and note that the measures' risk models include an indicator variable for Medicare Fee-For-Service and Medicare Advantage enrollment status, which accounts for any potential differences between these groups. We found that stratifying the models by Medicare Fee-For-Service and Medicare Advantage did not yield meaningful improvements in performance, supporting the decision to model them together with an indicator variable. By keeping Medicare Fee-For-Service and Medicare Advantage patients together for purposes of these measures' calculation and display in public reporting will keep the hospitals' total volume higher for more precise measure scores. We note that while we will publicly report aggregated data, confidential feedback reports to hospitals will include patient-level payer information. We will continue to monitor the measures and evaluate whether future stratifications are warranted in public reporting.

Comment: A commenter supported inclusion of the modified mortality

Complication Measures Supplemental Methodology Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology.*

measures in the Hospital Inpatient Quality Reporting Program, but expressed concern about modifying them in the Hospital Value-Based Purchasing Program as Medicare Advantage plans may have their own value-based purchasing and alternative payment model arrangements that assess performance for their own enrolled populations, which could potentially lead to counting the same event twice, which could disproportionately impact hospitals serving the most vulnerable patients.

Response: We understand commenters' concerns regarding the potential for the same event being counted by multiple programs and recognize that Medicare Advantage organizations may operate their own quality programs or value-based arrangements. Those arrangements are contracts between a Medicare Advantage organization and its network providers. The modified mortality measures assess hospital-level, condition- or procedure-specific outcomes for Medicare beneficiaries treated at the hospital. Including the same patient outcome in different accountability contexts does not convert the mortality measure into a plan-level quality measure. We remain concerned that omitting Medicare Advantage beneficiaries from the mortality measures does not provide a complete picture of the quality of care provided to Medicare beneficiaries by participating hospitals. We maintain that all patients deserve the same quality of care regardless of payer or status and therefore intend to include all Medicare Advantage beneficiaries in these measures. We intend to monitor for potential differences between the Medicare Advantage and Medicare Fee-For-Service populations on these measures and will watch for any unintended consequences.

Comment: A commenter did not support this proposal for the Hospital Inpatient Quality Reporting Program because the proposed performance period is already underway, expressing concern about the performance period for the measures starting prior to the requirements being finalized in rulemaking and recommending that CMS delay the timeline.

Response: We acknowledge the commenter's concern that finalizing these measures for the Hospital Inpatient Quality Reporting Program beginning with the FY 2028 payment determination would result in public reporting of measure results that include the July 1, 2024 through June 30, 2026 performance period, which will have ended by the time of publication of this final rule. We note the Hospital Inpatient Quality Reporting Program is a pay-for-reporting program and hospital payment is not affected by performance on these measures. As long as hospitals report the required measure data in accordance with the form, manner, and timing policies specified by the Secretary, they would not be subject to a financial penalty under this program. Further, delaying adoption of the modified mortality measures to apply only to future performance periods would unnecessarily delay our efforts to improve transparency regarding hospital performance for the combined Medicare Advantage and Medicare Fee-For-Service populations. We note that, beginning with the FY 2028 payment determination, hospitals will be able to preview their data on these measures in the Hospital Inpatient Quality Reporting Program prior to it being publicly reported via annual confidential hospital-specific reports. Further, the mortality measures would not impact payment adjustments until the FY 2032 program year, when the modified measures would begin to be reported in the Hospital Value-Based Purchasing Program. This phased approach allows hospitals to have about 4 years to assess the impact of Medicare Advantage beneficiary inclusion before being subject to any potential payment adjustments.

Comment: A commenter requested that we clarify that the modifications to these measures are fundamentally re-specified measures with newly calculated benchmarks and performance baselines and not a continuation of the existing measures in the Hospital Value-Based Purchasing Program.

Response: We disagree that these are fundamentally re-specified, but do note that because there are substantive modifications to the measures, we proposed them for adoption in the Hospital Inpatient Quality Reporting Program from the FY 2028 payment determination through the FY 2031 payment determination, prior to implementing the modified measures in the Hospital Value-Based Purchasing Program beginning with the FY 2032 program year, in accordance with statutory requirements. We note the newly calculated benchmarks and performance baselines for the FY 2032 program year for the modified mortality measures will be updated in the FY 2028 proposed rule.

Comment: A commenter did not support adoption of the MORT–30–PN measure into the Hospital Inpatient Quality Reporting Program, citing concerns that the measure minimum reliability achieved with 25 admissions was too low with the shortened 2-year reporting period.

Response: We understand concerns about ensuring measures meet an acceptable level of reliability. We note the measure developer conducted rigorous testing using 2 years of data (CY 2022 and CY 2023) from 3,741 facilities with at least 25 admissions and concluded that the addition of Medicare Advantage beneficiaries to the measure's cohort, in conjunction with the performance period changes, resulted in over 75 percent of hospitals exceeding a 0.6 reliability score, with a mean score of 0.900.[277] When at least 70 percent of hospitals have a reliability above 0.6, the measure is capable of differentiating hospitals' quality of performance, and considered acceptable for use for quality reporting.[278] This demonstrates the proposed measure updates balance a focus of using more recent data with a sufficiently reliable measure score that reflects the quality of care provided by hospitals.

Comment: A few commenters requested that we remove the mortality measures from the Hospital Inpatient Quality Reporting Program after they have been adopted into the Hospital Value-Based Purchasing Program, emphasizing this aligns with the Meaningful Measure framework and de-duplication efforts across quality reporting programs.

Response: As proposed, we would adopt the mortality measures into the Hospital Inpatient Quality Reporting Program for the FY 2028 payment determination through the FY 2031 payment determination, removing them from the program beginning with the FY 2032 payment determination. The mortality measures would be modified in the Hospital Value-Based Purchasing Program beginning with the FY 2032 program year, after meeting statutory requirements to publicly report these measures in the Hospital Inpatient Quality Reporting Program for one year.

Comment: A few commenters recommended ensuring different names for the modified mortality measures in confidential feedback reports and when they are publicly reported to avoid confusion. Commenters also recommended providing additional education about the differences in the

[277] Partnership for Quality Measurement. Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia (PN) Hospitalization, Reliability Tab, under the Meaningfulness Tab. Available at: *https://p4qm.org/prmr-measures/muc2025-044.*

[278] For more details on reliability guidance, we refer readers to the Reliability Guidance for the Endorsement and Maintenance of Clinical Quality Measures Document. Available at: *https://p4qm.org/em/resources.*

quality measures reported across the two programs.

Response: We intend to ensure that the names of modified measures are clearly indicated as such in confidential feedback reports and when publicly reported to avoid any confusion about the two versions of these measures being reported across different programs simultaneously. Technical specifications of the mortality measures are provided on our website under the Measure Methodology Reports section, available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology*. We will continue working with hospitals to ensure that they fully understand any effects these changes may have on their publicly reported data under the Hospital Inpatient Quality Reporting Program and potential impacts on their Hospital Value-Based Purchasing Program performance.

Comment: A commenter requested clarification on whether similar cohort expansions would also apply to other Medicare populations, such as beneficiaries with End-Stage Renal Disease or individuals eligible for Medicare due to long-term disabilities, given the potential for higher clinical complexity, greater comorbidity burden, and elevated baseline mortality risk that could influence observed mortality rates following CABG surgery.

Response: We interpret the comment as a request for clarification regarding whether beneficiaries eligible for Medicare due to end-stage renal disease or long-term disabilities will be included in the measures' cohorts. Beneficiaries with end-stage renal disease can choose either Medicare Fee-For-Service or Medicare Advantage coverage.[279] We note that the measures' patient populations include Medicare Fee-For-Service and Medicare Advantage beneficiaries 65 years and older so beneficiaries with end-stage renal disease under either would be included. For the full measure specifications, including discussion of cohort inclusion and exclusion criteria, we refer readers to: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology.*

Comment: A few commenters recommended that CMS improve quality measurement to drive mortality reduction in the hospital inpatient setting. A commenter recommended development of measures that recognize the full spectrum of mortality reduction efforts, including clinical assessment, risk stratification, and diagnostic-informed decision-making, including the use of in vitro diagnostics to strengthen quality measurement. A commenter recommended developing metrics or other mechanisms that more directly recognize and reward hospitals that implement targeted plans to improve care for high-risk patient populations.

Response: While we are not updating the measures to include the use of in-vitro diagnostics or incentives for implementing targeted plans for improving care at this time, we encourage hospitals to actively engage in quality improvement efforts that improve care for all patients.

After consideration of the public comments received we are finalizing our proposal as proposed, such that we are finalizing adoption of the five modified mortality measures, MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD, and MORT–30–CABG, into the Hospital Inpatient Quality Reporting Program from the FY 2028 payment determination through the FY 2031 payment determination, and removing these measures from the Hospital Inpatient Quality Reporting Program beginning with the FY 2032 payment determination, and modifying them in the Hospital Value-Based Purchasing Program beginning with the FY 2032 program year. We refer readers to section IX.B.2.b. for details on the substantive modifications to the five modified mortality measures.

f. Technical Updates

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19574), we also notified the public of technical updates to the risk adjustment methodology for the five modified mortality measures' proposed for adoption in the Hospital Inpatient Quality Reporting Program, beginning with the FY 2028 payment determination, and for modification in the Hospital Value-Based Purchasing Program, beginning with the FY 2032 program year, to use individual International Classification of Diseases (ICD–10) codes instead of hierarchical condition categories (HCC) to improve the measure's risk adjustment methodology. The risk adjustment strategy currently in use involves grouping ICD–10 diagnosis codes from CMS's HCC system into clinically relevant categories (76 FR 26495 through 26511, 80 FR 49557 through 49558, and 81 FR 56994 through 56996). We then evaluate the HCCs for statistical association with the measures' outcomes. To better leverage the data and analytical advances since the measure was initially developed, we created a new approach to use individual ICD–10 codes for risk adjustment. Research has indicated that using individual ICD–10 codes in place of HCCs could significantly improve the model performance of the mortality measures. With this new approach, the ability of the risk adjustment model to account for condition-specific or procedure-specific severity was significantly better. See Table IX.B.9. for a summary of improvements to the risk adjustment models' performance for the five modified mortality measures.[280]

[279] *https://www.medicare.gov/basics/end-stage-renal-disease.*

[280] Partnership for Quality Measurement. (March 2024). 2024 Condition- and Procedure-Specific Mortality/Complication Measures Supplemental Methodology Report. Available at: *https://p4qm.org/prmr-measures/muc2025-036.*

TABLE IX.B.9. RISK ADJUSTMENT MODEL PERFORMANCE COMPARISON USING CALENDAR YEAR 2022 DATA

Measure Title	Fee-For-Service-only cohort with HCC-based Risk Variables		Fee-For-Service and Medicare Advantage cohort with ICD-10-based Risk Variables	
	C-statistic (predictive ability %)	Signal-to-Noise Reliability Median (Q1, Q3)	C-statistic (predictive ability %)	Signal-to-Noise Reliability Median (Q1, Q3)
MORT–30–AMI	0.79 (1.2 – 41.6)	0.51 (0.4, 0.6)	0.86 (1.0 – 63.3)	0.73 (0.6, 0.8)
MORT–30–HF	0.69 (2.5 – 27.3)	0.67 (0.5, 0.8)	0.83 (1.1 – 51.4)	0.9 (0.8, 0.9)
MORT–30–PN	0.73 (2.8 – 41.3)	0.63 (0.5, 0.7)	0.85 (1.2 – 69.2)	0.89 (0.8, 0.9)
MORT–30–COPD	0.74 (1.2 – 26.0)	0.54 (0.5, 0.6)	0.85 (0.7 – 45.9)	0.74 (0.6, 0.8)
MORT–30–CABG	0.79 (0.2 – 11.9)	0.82 (0.8, 0.9)	0.85 (0.4 – 16.2)	0.88 (0.8, 0.9)

We received several comments on this technical update.

Comment: Several commenters supported the notice of the technical updates to the risk adjustment model to transition to ICD–10 codes instead of HCCs. Commenters agreed that updating the risk adjustment methodology will enhance the specificity and clinical relevance of the model. A commenter supported the more granular ICD–10–based modeling, noting that ensuring that mortality measures adequately account for patient complexity is critical, particularly for cardiovascular conditions such as heart failure and for procedures such as CABG that often involve high-risk patients.

Response: We thank commenters for their support and agree the updated risk methodology will enhance specificity and clinical relevance, supporting more granular modeling. We agree that ensuring that these measures adequately account for patient complexity is critical for all patients, especially for high-risk patients.

Comment: A few commenters raised concerns about the abrupt nature of the transition to ICD–10 codes coinciding with the other measure modifications, recommending extensive testing to ensure accuracy and reliability. A commenter shared concerns that updating the risk model to use ICD–10 codes could result in unintended consequences due to variations in coding intensity rather than true patient complexity.

Response: We understand commenters' concerns regarding the change from HCCs to ICD–10 code-based risk models and ensuring that this update results in measures that are accurate and reliable. As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19574), we developed this approach to risk adjustment to better leverage data and analytic advances and found this new approach could significantly improve the model performance and reliability of the mortality measures. For example, the predictive ability of the MORT–30–HF measure improved from 0.69 to 0.83 with the combined Medicare Advantage and Medicare Fee-For-Service and ICD–10-based risk variables, and the MORT–30–AMI measure signal-to-noise reliability improved from 0.51 to 0.73.

We note the measure developers conduct annual measure re-evaluations to ensure the risk-standardized mortality rate model is continually assessed and remains valid, given possible changes in clinical practice and coding standards over time. Modifications made to the measure cohort, risk model, and outcomes are informed by review of the most recent literature related to measure conditions or outcomes, feedback from various stakeholders, empirical analyses, and assessment of coding trends that reveal shifts in clinical practice or billing patterns. We refer readers to Table IX.B.9. for our results. For the complete measure methodology report and measure risk adjustment model, we specifically refer readers to QualityNet on our website at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology.* We also refer readers to QualityNet: *https://qualitynet.cms.gov/,* where we make our technical measure specifications reports and measure evaluation reports publicly available.

3. Measuring Emergency Care Access and Timeliness in the Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs—Request for Information

a. Background

Occupancy and boarding rates in EDs continue to worsen and exceed pre-pandemic levels. ED boarding, defined as holding a patient in the ED after the patient is admitted or placed into observation status at a hospital, is an outcome of misaligned incentives to deploy care delivery resources in a particular way,[281] often resulting in shortages of inpatient beds and staff. ED boarding contributes to ED crowding, leading to safety risks for patients and stressful working conditions for healthcare personnel.[282] [283] [284] A recent report from the Agency for Healthcare Research and Quality (AHRQ) characterized patient ED boarding as a growing public health crisis and engaged interested parties to address the strain on the United States healthcare system.[285]

Recent studies indicate that delays in the timeliness of ED care are associated with patient harm.[286] [287] Long ED wait

[281] Michael, S.S., Bruna, S., Sessums, L.L. (2025). Building a public-private partnership to confront the emergency department boarding crisis, *Health Affairs Scholar, 3*(4). Available at: *https://doi.org/10.1093/haschl/qxaf014.*

[282] Morley, C., Unwin, M., Peterson, G.M., Stankovich, J., Kinsman, L. (2018). Emergency department crowding: A systematic review of causes, consequences and solutions. *PLoS One, 13*(8):e0203316. Available at: *https://doi.org/10.1371/journal.pone.0203316.*

[283] Moore, C. & Heckmann, R. (2025). Hospital Boarding In The ED: Federal, State, And Other Approaches. *Health Affairs Forefront.* Available at: *https://www.healthaffairs.org/content/forefront/hospital-boarding-ed-federal-state-and-other-approaches.*

[284] Rizk, D. (2025). *Systemic solutions to emergency department boarding: The hospitalist's perspective.* Health Affairs Scholar, 3(9). Available at: *https://academic.oup.com/healthaffairsscholar/article/3/9/qxaf168/8241101.*

[285] Agency for Healthcare Research and Quality. (2025). Technical Report: AHRQ Summit To Address Emergency Department Boarding. Available at: *https://www.ahrq.gov/sites/default/files/wysiwyg/topics/ed-boarding-summit-report.pdf.*

[286] Gaieski, D.F., Agarwal, A.K., Mikkelsen, M.E., Drumheller, B., Cham Sante, S., Shofer, F.S., Goyal, M., & Pines, J.M. (2017). The impact of ED crowding on early interventions and mortality in patients with severe sepsis. *The American Journal of Emergency Medicine, 35*(7), 953–960. Available at: *https://doi.org/10.1016/j.ajem.2017.01.061.*

[287] Laam L.A., Wary A.A., Strony R.S., Fitzpatrick M.H., & Kraus C.K. (2021). Quantifying the impact of patient boarding on emergency department length of stay: All admitted patients are negatively

times are also one of the most cited reasons for patients leaving an ED without being evaluated by a clinician.[288] Increased ED LOS is also a strong predictor of poor timeliness of care and is significantly impacted by ED boarding. One study of several EDs within a single health system found that for every patient boarded, the median ED LOS for all admitted patients increased by at least 12 minutes.[289] Other evidence indicates that prolonged boarding is concentrated among older adults and is associated with downstream impacts that extend beyond the ED encounter.[290] Furthermore, ED boarding and crowding have been associated with poor patient outcomes, such as increased mortality,[291] delays in needed care,[292] and negative patient and staff experiences.[293] [294] [295] For instance, evidence shows that ED crowding can harm patients with sepsis by delaying administration of lifesaving intravenous (IV) fluids and antibiotics.[296] Additionally, there may be additional operational and financial burdens associated with ED boarding, underscoring its relevance to inpatient capacity management and hospital performance.[297]

Studies have documented a significantly higher likelihood of boarding when hospital occupancy rates exceed 85 percent.[298] [299] These dynamics became more pronounced during the COVID–19 public health emergency, when national hospital occupancy increased by 11 percentage points, while staffed hospital beds declined by roughly 16 percent.[300] Data such as these have supported the argument made by a number of emergency medicine clinicians and researchers that ED efficiency and patient throughput are closely tied to a broad collection of hospital-wide operational processes beyond those just occurring in the ED, including but not limited to inpatient bed management, staffing and procedure scheduling, discharge planning and post-acute care access, and diagnostic and consult turnaround.[301]

In line with this perspective, evidence suggests that hospitals which perform better on metrics related to ED boarding are more likely to adopt cross-departmental initiatives (for example, ED, radiology, laboratory services, hospitalist, surgery, housekeeping, nursing) to alleviate crowding.[302] Hence, hospital administrators, individual departments, and associated staff can collectively participate in a variety of processes and interventions that can contribute to lower levels of boarding in the ED. Actions that make discharges earlier, more predictable, and daily (for example, identifying ''next-day discharges'' during afternoon rounds, using expected date of discharge documented on admission when possible, performing early morning discharge rounds, enabling weekend and holiday discharges, pre-completing discharge paperwork and medication reconciliation) can free beds in preparation of future peaks in ED utilization.[303] [304] ''Smoothing'' the surgical schedule to ensure a steady, predictable demand for inpatient beds throughout the week can eliminate artificial peaks and valleys in bed demand that could otherwise contribute to boarding.[305] Employing real-time monitoring and other predictive capabilities within health information technology systems can also identify new efficiencies in triaging and staffing that can result in better rates of bed turnover.[306] [307] Other examples of interventions that have been considered to address this issue include care transitions, point-of-care testing, observation units, streaming, short-stay units, strengthening triage and ED teams, creating new care zones, use of capacity protocols, and other

affected by boarding. *Journal of American College Emergency Physicians, 2*(2):e12401. Available at: *https://doi.org/10.1002/emp2.12401.*

[288] Janke, A.T., Melnick, E.R., & Venkatesh, A.K. (2022). Monthly Rates of Patients Who Left Before Accessing Care in US Emergency Departments, 2017–2021. *JAMA,* 5(9), e2233708. Available at: *https://doi.org/10.1001/jamanetworkopen.2022.33708.*

[289] Laam L.A., Wary A.A., Strony R.S., Fitzpatrick M.H., & Kraus C.K. (2021). Quantifying the impact of patient boarding on emergency department length of stay: All admitted patients are negatively affected by boarding. *Journal of American College Emergency Physicians,* 2(2):e12401. Available at: *https://doi.org/10.1002/emp2.12401.*

[290] Sifnugel, N., et al. (2025). An analysis of boarding trends in older adults in the United States. *Health Affairs Scholar,* 3(10). Available at: *https://doi.org/10.1093/haschl/qxaf187.*

[291] Hsuan, C., Segel, J.E., Hsia, R.Y., Wang, Y., & Rogowski, J. (2023). Association of emergency department crowding with inpatient outcomes. *Health Services Research,* 58(4), 828–843. Available at: *https://doi.org/10.1111/1475-6773.14076.*

[292] Gaieski, D.F., Agarwal, A.K., Mikkelsen, M.E., Drumheller, B., Cham Sante, S., Shofer, F.S., Goyal, M., & Pines, J.M. (2017). The impact of ED crowding on early interventions and mortality in patients with severe sepsis. *The American Journal of Emergency Medicine,* 35(7), 953–960. Available at: *https://doi.org/10.1016/j.ajem.2017.01.061.*

[293] Reznek, M.A., Larkin, C.M., Scheulen, J.J., Harbertson, C.A., & Michael, S.S. (2021). Operational factors associated with emergency department patient satisfaction: Analysis of the Academy of Administrators of Emergency Medicine/Association of Academic Chairs of Emergency Medicine national survey. *Academic Emergency Medicine: Official Journal of the Society for Academic Emergency Medicine,* 28(7), 753–760. Available at: *https://doi.org/10.1111/acem.14278.*

[294] Loke, D.E., Green, K.A., Wessling, E.G., Stulpin, E.T., & Fant, A.L. (2023). Clinicians' Insights on Emergency Department Boarding: An Explanatory Mixed Methods Study Evaluating Patient Care and Clinician Well-Being. *Joint Commission Journal on Quality and Patient Safety,* 49(12), 663–670. Available at: *https://doi.org/10.1016/j.jcjq.2023.06.017.*

[295] Norton, V., Schreyer, K.E., Kuhn, D. (2025). Workforce impact of emergency department boarding, *Health Affairs Scholar,* 3(8). Available at: *https://doi.org/10.1093/haschl/qxaf134.*

[296] Gaieski, D.F., Agarwal, A.K., Mikkelsen, M.E., Drumheller, B., Cham Sante, S., Shofer, F.S., Goyal, M., & Pines, J.M. (2017). The impact of ED crowding on early interventions and mortality in patients with severe sepsis. *The American Journal of Emergency Medicine,* 35(7), 953–960. Available at: *https://doi.org/10.1016/j.ajem.2017.01.061.*

[297] Canellas, M.M., et al. (2024). *Measurement of cost of boarding in the emergency department.* Annals of Emergency Medicine. Available at: *https://doi.org/10.1016/j.annemergmed.2024.04.012.*

[298] Kelen, G.D., Wolfe, R., D'Onofrio, G., Mills, A.M., Diercks, D., Stern, S.A., . . . & Sokolove, P.E. (2021). Emergency department crowding: the canary in the health care system. *NEJM Catalyst Innovations in Care Delivery,* 2(5). Available at: *https://catalyst.nejm.org/doi/abs/10.1056/CAT.21.0217.*

[299] Janke, A.T., Melnick, E.R., & Venkatesh, A.K. (2022). Hospital occupancy and emergency department boarding during the COVID–19 pandemic. *JAMA Network Open,* 5(9), e2233964–e2233964. Available at: *https://pmc.ncbi.nlm.nih.gov/articles/PMC9526134/.*

[300] Leuchter, R.K., Delarmente, B.A., Vangala, S., Tsugawa, Y., Sarkisian, C.A. (2025). Health care staffing shortages and potential national hospital bed shortage. *JAMA Netw Open,* 8(2):e2460645. Available at: *https://doi.org/10.1001/jamanetworkopen.2024.60645.*

[301] Rizk, D. (2025). Systemic solutions to emergency department boarding: The hospitalist's perspective. *Health Affairs Scholar,* 3(9). Available at: *https://academic.oup.com/healthaffairsscholar/article/3/9/qxaf168/8241101.*

[302] Chang, A.M., Cohen, D.J., Lin, A., Augustine, J., Handel, D.A., Howell, E., . . . & Sun, B.C. (2018). Hospital strategies for reducing emergency department crowding: a mixed-methods study. *Annals of emergency medicine,* 71(4), 497–505. Available at: *https://pmc.ncbi.nlm.nih.gov/articles/PMC5828915/.*

[303] Bechir, G., & Bechir, A. (2025). Start With the End: Early Hospital Discharge Planning as a Day-One Priority. *Cureus,* 17(6). Available at: *https://pmc.ncbi.nlm.nih.gov/articles/PMC12308768/.*

[304] The Hospitalist. ''Tips for Improving Early Discharge Rates.'' Published May 29, 2016. Available at: *https://www.the-hospitalist.org/hospitalist/article/121668/patient-safety/tips-improving-early-discharge-rates/.*

[305] Rathlev, N.K., Chessare, J., & Litvak, E. (2018). Redesigning the surgical schedule to enhance productivity in the operating room. *J Emerg Med Trauma Surg Care,* 5, 023. Available at: *https://www.heraldopenaccess.us/openaccess/redesigning-the-surgical-schedule-to-enhance-productivity-in-the-operating-room.*

[306] Sinsical, A. (2025). 171 Streamlining Inpatient Discharge Processes to Reduce Emergency Department Boarding. *Annals of Emergency Medicine,* 86(3), S73–S74. Available at: *https://www.annemergmed.com/article/S0196-0644(25)00566-9/fulltext.*

[307] Boland, R. (2025). ''4 strategies to reduce ED overcrowding.'' *Healthcare Financial Management Association.* Available at: *https://www.hfma.org/operations-management/4-strategies-to-reduce-ed-overcrowding/.*

administrative or organizational improvements.[308] [309] [310] [311]

Notably, the breadth and variation in these strategies makes it clear that no single intervention will solve the ED boarding crisis, particularly when considering the effectiveness of these actions is likely to vary across patient populations, health status and comorbidities, and case-mix. As such, it is important for throughput and patient flow to be viewed as a shared responsibility within the healthcare delivery system. To that end, quality measures should reflect and promote a culture of accountability.

b. Overview of Measure

The Emergency Care Access & Timeliness eCQM is currently specified for the hospital setting and calculates the proportion of four outcome metrics that quantify access to and timeliness of care in a hospital ED setting against specified thresholds, including: (1) patient wait time—1 hour; (2) whether the patient left the ED without being evaluated; (3) patient boarding time in the ED (as defined by a Decision to Admit (order) to ED departure for admitted patients)—4 hours; and (4) patient ED LOS (time from ED arrival to ED physical departure, as defined by the ED departure timestamp)—8 hours. Measure testing for the Emergency Care Access & Timeliness eCQM was conducted by the measure developer across 32 hospital-based EDs, representing a diverse mix of geographic regions, rurality, hospital size, teaching status, trauma level, and EHR vendors, demonstrating that the measure is reliable, valid, and feasible for all required data elements.[312] Measure testing results showed a wide range in overall scores, and across all strata, indicating variation in performance and implying room for quality improvement.[313]

(1) Numerator

The measure numerator includes any ED encounter in the denominator where the patient experiences any one of the following: (1) the patient waited longer than 1 hour after arrival to the ED to be placed in a treatment room or dedicated treatment area that allows for audiovisual privacy during history-taking and physical examination; (2) the patient left the ED without being evaluated; (3) the patient boarded in the ED for longer than 4 hours; and (4) the patient had an ED LOS of longer than 8 hours.[314] An encounter is considered part of the numerator if it includes any one of the four numerator events, with events not being mutually exclusive and each contributing only once to the numerator. ED encounters with ED observation stays [315] are excluded from components (3) and (4) but are included in the denominator. Patients who have a ''decision to admit'' after an ED observation stay remain excluded from criteria (3) calculations.[316]

These four outcomes were selected based on published literature demonstrating that each numerator component is associated with patient harm, as well as input from clinical experts including ED experts and statistical and methodological experts and a TEP that was convened by the measure developer.[317] A Patient and Family Engagement Work Group provided feedback on experiences with emergency care, noting long wait times to be seen by a provider, long wait times to be transferred, and gaps in the discharge processes.

The numerator thresholds were developed according to evidence and consensus-based clinical guidelines for ED time thresholds, including guidelines developed by The Joint Commission (TJC), the American College of Emergency Physicians (ACEP), and the Emergency Department Benchmarking Alliance as well as input from a TEP, literature reviews, and environmental scans. For example, the 4-hour threshold for numerator component (3), boarding time, was developed according to recommendations from TJC and ACEP.[318] [319] This threshold reflects delays that are influenced by inpatient bed availability, hospital capacity, and admission processes.

(2) Denominator

The measure denominator includes all ED encounters associated with patients of all ages, for all-payers, during a 12-month period of performance. Patients can have multiple encounters during a period of performance, and each encounter is eligible to contribute to the calculation of the measure.[320]

(3) Measure Calculation

The measure score is first calculated at the individual ED level as the proportion of ED encounters where any one of the four outcomes occurred. Raw measure scores are then standardized by ED case volume using z-scores. The z-score, or standard score, indicates how many standard deviations a data point is from the mean of a normal distribution. It is calculated by subtracting the mean from a data point, then dividing the result by the standard deviation. For the Emergency Care Access & Timeliness eCQM, a volume-adjusted z-score shows how an ED's performance compares to the average for similar-volume EDs, addressing differences in patient population in hospital outpatient departments (HOPD) and ensuring fair ''like to like'' comparisons between EDs of similar size. ED volume strata are defined in volume bands of 20,000 ED visits, and each ED is assigned to only one volume stratum. For CMS Certification Numbers (CCNs) with more than one ED, volume-

[308] Austin, E.E., Blakely, B., Tufanaru, C. et al. (2020). Strategies to measure and improve emergency department performance: a scoping review. *Scand J Trauma Resusc Emerg Med,* 28, 55. Available at: *https://doi.org/10.1186/s13049-020-00749-2.*

[309] De Freitas, L., Goodacre, S., O'Hara, R., Thokala, P., Hariharan, S. (2018). Interventions to improve patient flow in emergency departments: an umbrella review. *Emerg Med J,* 35(10):626–637. Available at: *https://doi.org/10.1136/emermed-2017-207263.*

[310] Burns T.A., Kaufman B, Stone R.M. (2022). An EMS Transport Destination Officer is Associated with Reductions in Simultaneous Emergency Department Arrivals. *Prehosp Emerg Care.* Available at: *https://doi.org/10.1080/10903127.2022.2107126.*

[311] Bittencourt, R.J., Stevanato, A.M., Bragança, C,T,N,M., Gottems, L.B.D., O'Dwyer, G. (2020). Interventions in overcrowding of emergency departments: an overview of systematic reviews. *Rev Saude Publica.* 54:66. Available at: *http://doi.org/10.11606/s1518-8787.2020054002342.*

[312] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at: *https://www.p4qm.org/measures/4625e.*

[313] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at: *https://www.p4qm.org/measures/4625e.*

[314] For proposed measure specifications, we refer readers to the eCQI Resource Center at *https://ecqi.healthit.gov/ecqm/hosp-outpt/2027/cms1244v1,* or the CMS QualityNet Hospital Outpatient Quality Reporting program website at: *https://qualitynet.cms.gov/outpatient.*

[315] ED observations stays are defined as an observation encounter where the patient remains physically in an area under control of the ED and under the care of an ED clinician inclusive of observation in a hospital bed. Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at: *https://p4qm.org/measures/4625e.*

[316] Specific codes required to calculate the numerator are outlined in the value set data dictionary and eCQM package (Quality Data Model—QDM output). Please refer to the ''Measure Calculation'' Section for information at: *https://p4qm.org/measures/4625e.*

[317] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at: *https://p4qm.org/measures/4625e.*

[318] The Joint Commission. (2012). Approved: Standards revisions addressing patient flow through the emergency department. Joint Commission perspectives. *Joint Commission on Accreditation of Healthcare Organizations, 32*(7), 1–5.

[319] American College of Emergency Physicians. (2024). Emergency Department Boarding and Crowding. Available at: *https://www.acep.org/administration/crowding--boarding.*

[320] For proposed measure specifications, we refer readers to the eCQI Resource Center at *https://ecqi.healthit.gov/ecqm/hosp-outpt/2027/cms1244v1,* or the CMS QualityNet Hospital Outpatient Quality Reporting program website at *https://qualitynet.cms.gov/outpatient.*

adjusted z-scores are then combined as a weighted average for that CCN.[321]

The results of the Emergency Care Access & Timeliness eCQM are stratified into four groups, two by age (18 years and older, and under 18 years) and two by mental health diagnoses (with, and without).[322] Testing results during the measure development process indicates that the stratification of results by age and mental health diagnosis, as well as standardization of measure performance scores by volume, was sufficient to account for differences between HOPDs; however, we are seeking feedback on whether additional stratification or risk adjustment would be appropriate if the measure were considered for inclusion in the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs.

We refer readers to the CY 2026 OPPS/ASC final rule, where the Emergency Care Access & Timeliness eCQM was adopted into the Hospital Outpatient Quality Reporting [323] and Rural Emergency Hospital (REH) Quality Reporting [324] programs (90 FR 53925 through 53934; 90 FR 53945 through 53951). Further information and resources are available at the CMS QualityNet Hospital Outpatient Quality Reporting Program website at *https://qualitynet.cms.gov/outpatient,* which also takes readers to the electronic specifications available at the eCQI Resource Center: *https://ecqi.healthit.gov/ecqm/hosp-outpt/2027/cms1244v1.*

c. Request for Comment on Potential Future Use in the Hospital Inpatient Quality Reporting and the Hospital Value-Based Purchasing Programs

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19577), we sought input on how to best measure care access and timeliness among hospitals participating in its quality reporting and value-based purchasing programs. We recognize that this issue is not specific to one particular setting (that is, inpatient or outpatient), and that a higher-level approach may instead be needed. However, as currently designed, CMS's quality reporting programs are divided to separately monitor inpatient and outpatient settings. If proposed for future rulemaking, we could consider adopting the existing outpatient measure into the Hospital Inpatient Quality Reporting Program as currently specified, or we could make adjustments to tailor it more specifically for inpatient use. Such enhancements could include modifying specific numerator components or the overall denominator to be more applicable for the inpatient setting. However, this more targeted approach to inpatient quality measurement may be at odds with aligning access and timeliness at a systems-level as noted above.

We invited public comment on the potential use of the Emergency Care Access & Timeliness eCQM into the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs, in addition to the following questions:

- What are some of the key barriers and challenges faced by inpatient providers in supporting process changes that improve bed availability and reduce ED boarding?
- What are the best practices for providers within inpatient departments to actively engage with colleagues in other departments, as well as other settings that impact bed availability (for example, post-acute care facilities)? What barriers do providers face, especially rural providers, in establishing protocols for bi-directional communication?
- Are there any elements of this measure that are not applicable (for example, numerator components, denominator, exclusions, etc.) to inpatient care, or for which an inpatient hospital should not be held accountable, which would warrant removal or modification if the measure is proposed in the Hospital Inpatient Quality Reporting Program?

++ For example, numerator components (1), (2), and (4) of the measure can occur for care provided entirely outside of an inpatient setting. This may lead to concerns that hospital inpatient processes are being evaluated based on the care and outcomes of patients who are not admitted during their stay.

++ On the other hand, as discussed above, ED boarding resulting from processes within the inpatient department impacts the throughput of *all ED patients,* which is reflected in numerator components (1), (2) and (4). Therefore, there are concerns that limiting the inpatient Emergency Care Access & Timeliness eCQM to those admitted or boarded may be insufficient to truly address access and timeliness issues.

- Given the overlap in patient cohort with the measure recently adopted for the Hospital Outpatient Quality Reporting program, do stakeholders have concerns related to duplication of encounters in quality measures? Given the shared responsibility across units within the hospital, is it beneficial for the cohort (or a subset of the cohort) to be tracked across similar measures in both programs?

++ For example, we could consider developing separate measures for each program, where a version for use in inpatient quality reporting tracks access and timeliness amongst patients that were admitted during their stay, while an outpatient quality reporting measure version tracks those not admitted.

- Should CMS consider including this measure in the Hospital Value-Based Purchasing Program? If so, would it be beneficial to keep the current measure specifications as is, particularly as these programs may be better suited to capture broader, system-wide processes?
- Are there any potential unintended consequences CMS should be aware of related to introducing this measure into the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs?
- Are there other measure development/re-specification ideas or opportunities CMS should consider for how inpatient departments can address ED boarding and better measure patient outcomes, such as harm from delays to inpatient care?

We received public comments on this RFI. The following is a summary of the comments we received:

Comment: Many commenters expressed concerns related to the expansion of the Emergency Care Access and Timeliness eCQM into the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs. Commenters stated that many of the reasons for prolonged emergency department wait times are outside of a hospital's control, citing availability of inpatient beds, delays in prior authorization, and a shortage of behavioral medicine and post-acute care beds. Many commenters recommended that CMS refine the measure to account for system-level drivers of performance, recognize alternative care delivery models, and incorporate safeguards that align with patient-centered clinical practice. Commenters also stated that time-based metrics may not fully reflect

[321] For proposed measure specifications, we refer readers to the CMS QualityNet Hospital Outpatient Quality Reporting program website at *https://qualitynet.cms.gov/outpatient.*

[322] The principal diagnosis (first listed diagnosis at ED discharge) will be used to define strata inclusion. For this measure's purpose, mental health diagnoses do not include substance use disorder diagnoses. Mental health refers to mental health diagnoses, life stressors and crises, and stress-related physical symptoms.

[323] Available at: *https://www.federalregister.gov/d/2025-20907/p-3744.*

[324] Available at: *https://www.federalregister.gov/d/2025-20907/p-3956.* Notably, the specifications for several components in the REH Quality Reporting program measure differ slightly from the Outpatient Quality Reporting specifications to reflect the fact that REHs do not have inpatient beds. The version of the measure being considered for inpatient reporting matches the Hospital Outpatient Quality Reporting specifications.

the patient safety risks associated with boarding in the emergency department and encouraged CMS to evaluate more clinically meaningful measurement options. Other commenters suggested stratification by patient type to accurately reflect acuity and severity. Another commenter suggested reporting each of the four underlying measures along with the composite performance.

A few commenters expressed concern that the measure needed further technical and conceptual development, noting unclear definitions, a lack of evidence-based guidelines, and a failure to adequately account for differences in case mix and volumes. A few commenters expressed concern that the Emergency Care Access and Timeliness eCQM does not account for variability across different types of facilities, noting that the measure may not capture the challenges faced by different types of hospitals or factors specific to the care provided to different patient demographics, such as pediatric care at children's hospitals, hospitals with specialized patient populations, high-acuity referral centers, safety-net providers, and rural hospitals. A commenter also expressed concern that testing the measure at only 9 sites insufficiently captures the variability in facilities and EHR platforms.

Some commenters supported the inclusion of the Emergency Care Access and Timeliness eCQM in the inpatient reporting programs, stating that factors such as inpatient staffing, bed availability, and scheduling are outside of the control of emergency department staff and continuity of the measure across settings will help address the root causes of boarding. Commenters emphasized that the 4-hour maximum timeframe for patients admitted from the emergency department should remain a strict limit and that time in the emergency department should never exceed 8 hours and stated that it is critical to avoid changes that would weaken accountability if the measure must be modified for adoption in the inpatient settings. A few commenters observed that including this measure in the inpatient quality reporting programs would complement the current Age Friendly Hospital measure.

Many commenters identified many barriers and challenges related to improving bed availability and reducing emergency department boarding, including workforce shortages, behavioral health capacity constraints, inpatient bed occupancy, post-acute care bed availability, challenges in finding placement for medically complex patients, and laborious prior authorization requirements. Commenters noted that hospitals continue to strengthen their ability to undertake cross-disciplinary improvement initiatives and to continue to build the operational analytics and capacity management capabilities necessary for system redesign and stated that CMS should allow hospitals additional time to develop these capabilities. Several commenters emphasized the challenges faced in placing behavioral medicine patients due to significant shortages in inpatient psychiatric facility beds and staff as well as reimbursement and coverage limitations. A few commenters stated that the problems in emergency departments are exacerbated by a shortage of primary care providers and an ongoing loss of insurance coverage, leading many to delay care and use the emergency department as a primary care provider. A commenter explained that prior authorization requirements for advanced medical imaging in urgent care and outpatient settings result in patients presenting to the emergency department for timely care, straining emergency department capacity. A few commenters focused on the additional challenges faced in rural settings such as a lack of round-the-clock specialty care, case management, and social workers as well as a lack of geographically close nursing homes or other post-discharge care settings, making hospital throughput and discharges particularly difficult and time intensive.

Several commenters discussed their best practices for encouraging collaboration and engagement across departments and care settings. Examples included EHR interoperability, automated treatment capacity trackers, triage hospitalists, identification of appropriate alternatives to admission, trained social workers and case managers to help expedite placement and transfer, specialists embedded in the emergency department for consultations, and a clear escalation path for questions and disputes. Commenters stated that the exclusion of behavioral healthcare providers from the financial incentives of the Health Information Technology for Economic and Clinical Health Act resulted in a gap in capabilities, and that this gap negatively impacts the exchange of data and delays the acceptance and transfer of patients.

Commenters stated that multiple elements are not applicable to inpatient care or are factors that the hospital should not be held accountable or penalized for. Some commenters reiterated that the Emergency Care Access and Timeliness eCQM is not suitable for the inpatient environment. Other commenters stated that psychiatric units, patients who left without being seen, and hospice patients should be excluded from the measure. Another commenter suggested that patient volume, hospital classification, and provider access should be considered when evaluating performance on the measure. A commenter suggested that a measure of time from consult order to consult completion be added to the measure, while another commenter suggested that socioeconomic status and social determinants of health should be accounted for. Several commenters voiced concerns with aspects of the measure for inpatient or outpatient settings, specifically the ''dedicated treatment area with audiovisual privacy,'' noting that the concept is unclear and not represented in the structured data elements. A commenter suggested that focusing an inpatient measure on patients with a decision to be admitted would be more appropriate than including all emergency department patients in the denominator.

Many commenters stated that adding the Emergency Care Access and Timeliness eCQM to inpatient quality reporting programs would be duplicative, increase administrative burden, increase the risk of payment adjustments for the same measure, and add complexity. Commenters stated that delays in the emergency department are often driven by factors outside of the control of the hospital and that CMS should invest in infrastructure and community-based services to address these issues. Commenters encouraged CMS to invest in more clinically significant emergency department measures or evaluate whether existing Hospital Outpatient Quality Reporting Program measures can be enhanced to address identified gaps. Many commenters expressed concern with adding the Emergency Care Access and Timeliness eCQM to additional programs before reporting data is available, encouraging CMS to collect sufficient data from the outpatient programs to identify unintended consequences first. Commenters supporting the adoption of the Emergency Care Access and Timeliness eCQM in the inpatient programs stressed the importance of prioritizing alignment across programs and clear guidance regarding the interpretation of results.

Commenters were largely opposed to including the Emergency Care Access and Timeliness eCQM in the Hospital Value-Based Purchasing Program due to the complexity and the influence of

factors outside the control of the hospital such as behavioral health patients awaiting placement, patients who cannot be discharged for lack of post-acute or supportive housing options, and non-deferrable trauma volume. Commenters emphasized that, if the measure must be added to the Hospital Value-Based Purchasing Program, it needs to be evaluated and reported in the Hospital Inpatient Quality Reporting Program for at least two years, and all components have been clearly and consistently defined. Many commenters stated that the measure is inappropriate for the Hospital Value-Based Purchasing Program.

Many commenters expressed concerns regarding unintended consequences of adopting the Emergency Care Access and Timeliness eCQM into the inpatient programs, such as incentivizing hospitals to convert patients to observation status to avoid poor scores. Commenters also expressed concerns that the measure could result in inpatient units being disincentivized to accept direct admissions from other facilities, an increase in provider burnout, less time spent on thorough patient exams, premature disposition or discharge of patients, and an increase in patient diversion. A commenter stated that the measure does not account for modern care delivery models, including triage-based evaluation and waiting room treatment models, and another commenter expressed concerns about variability in documentation and timestamp capture that would impact data accuracy. A commenter cautioned CMS to avoid a pattern of adopting, then sunsetting, key emergency care measures, as this has limited the ability to track boarding trends and weakened enforcement initiatives.

Commenters recommended options to address emergency department boarding, such as phasing in complementary metrics to provide a more complete picture, modifying the emergency services CoP to add a readiness component, creating metrics for Medicare Advantage plans related to the timeliness of prior authorizations, improving access to post-acute care for Medicare Fee-For-Service beneficiaries, and encouraging direct inpatient admissions from outpatient settings. A commenter also suggested analyzing hospitals that do not have the staffing capacity to support their inpatient capacity. Another commenter suggested that CMS prioritize policies impacting the flow of patients to the most appropriate care setting, such as addressing issues with prior authorization, inpatient psychiatric bed availability, and inadequate community resources.

Response: We appreciate all the comments and interest in this topic. While we are not responding to specific comments in response to the RFI in this final rule, we acknowledge that this input is very valuable and will continue to take all concerns, comments, and suggestions into account for future development and consideration of this measure for the Hospital Inpatient Quality Reporting Program and the Hospital Value-Based Purchasing Program.

4. Potential Future Use of the Adult Community-Onset Sepsis Standardized Mortality Ratio Measure in the Hospital Inpatient Quality Reporting Program—Request for Information

a. Background

Sepsis is a life-threatening condition that results from the body's dysregulated response to infection and is a leading cause of mortality, hospitalization, and readmission in the United States.[325] It is the most frequent principal diagnosis among non-maternal, non-neonatal inpatients, with over 2.2 million hospitalizations reported in 2018.[326] Of the 1.7 million adults diagnosed with sepsis annually, approximately 20 percent die.[327] [328] [329] [330]

Accurate tracking of sepsis incidence and outcomes can be challenging due to the lack of a definitive diagnostic test and wide variation in diagnosis and coding practices.[331] There are limitations to using claims data only, for example reporting delays and incomplete data for non-Medicare/Medicaid patients. Increased screening and coding for sepsis have led to more cases being identified, often inflating case counts and lowering reported mortality rates.[332] A measure assessing the community-onset sepsis standardized mortality ratio is essential for producing timely, consistent, and clinically meaningful comparisons across hospitals.[333]

For the past several years, we have been working together with the CDC's National Healthcare Safety Network (NHSN) team to advance CMS's digital strategy through the use of digital quality measures (dQMs).[334] Through this collaboration, we have been exploring leveraging CDC's NHSNLink application programming interface (API) that would allow hospitals to exchange data and report digital quality measures to NHSN in a hands-free, fully automated manner, using the FHIR® standard for exchanging healthcare information electronically between information systems.[335] FHIR is a foundational, standards-based specification developed for secure and scalable electronic health information exchange. Using FHIR, data are represented based on nationally recognized standards across EHR vendors, facilities, and agencies. Through CDC's NHSNLink API, EHR data can be pulled from a facility, making real-time patient-level, risk-adjusted surveillance feasible, while at the same time, it can also provide the data needed to calculate hospital quality measures for CMS quality programs,

[325] An Assessment of Sepsis in the United States and its Burden on Hospital Care. Rockville, MD: Agency for Healthcare Research and Quality; 2024. AHRQ Pub No. 24–0087. Available at: *https://hcup-us.ahrq.gov/reports/SepsisUSBurdenHospitalCare.pdf.*

[326] McDermott KW, Roemer M. (2021). Most Frequent Principal Diagnoses for Inpatient Stays in U.S. Hospitals, 2018. Healthcare Cost and Utilization Project (HCUP) Statistical Brief #277. Available at: *https://pubmed.ncbi.nlm.nih.gov/34428003/.*

[327] Centers for Disease Control and Prevention. About Sepsis. August 2025. Available at: *https://www.cdc.gov/sepsis/about/index.html.*

[328] U.S. Department of Health and Human Services. Agency for Healthcare Research and Quality. Report to Congress: An Assessment of Sepsis in the United States and its Burden on Hospital Care. 2024. Available at: *https://www.ahrq.gov/sites/default/files/publications2/files/sepsis-report-to-congress_0.pdf.*

[329] Page B, Klompas M, Chan C, Filbin MR, Dutta S, McEvoy DS, Clark R, Leibowitz M, Rhee C. (2021). Surveillance for healthcare-associated infections: hospital-onset adult sepsis events versus current reportable conditions. *Clin Infect Dis, 73*(6):1013–1019. Available at: *https://doi.org/10.1093/cid/ciab217.*

[330] Rhee C, Dantes R, Epstein L, Murphy DJ, Seymour CW, Iwashyna TJ, Kadri SS, Angus DC, Danner RL, Fiore AE, Jernigan JA, Martin GS, Septimus E, Warren DK, Karcz A, Chan C, Menchaca JT, Wang R, Gruber S, Klompas M; CDC Prevention Epicenter Program. (2017). Incidence and Trends of Sepsis in US Hospitals Using Clinical vs Claims Data, 2009–2014. *JAMA,318*(13):1241–1249. Available at: *https://doi.org/10.1001/jama.2017.13836.*

[331] Rhee C, Kadri SS, Danner RL, Suffredini AF, Massaro AF, Kitch BT, Lee G, Klompas M. (2016). Diagnosing sepsis is subjective and highly variable: a survey of intensivists using case vignettes. *Crit Care, 20*,89. Available at: *https://doi.org/10.1186/s13054-016-1266-9.*

[332] Epstein L, Dantes R, Magill S, Fiore A. Varying estimates of sepsis mortality using death certificates and administrative codes—United States, 1999–2014. *MMWR Morb Mortal Wkly Rep, 65*(12),342–345. Available at: *https://doi.org/10.15585/mmwr.mm6513a2.*

[333] Prescott HC, Heath M, Jayaprakash N, Dantes RB, Rhee C, Posa PJ, Flanders SA. (2025). Concordance of 30-Day Mortality and In-Hospital Mortality or Hospice Discharge After Sepsis. *JAMA, 333*(19), 1724–1726. Available at: *https://doi.org/10.1001/jama.2025.2526.*

[334] Centers for Disease Control and Prevention. NHSN Digital Quality Measures (dQMs). Available at: *https://www.cdc.gov/nhsn/fhirportal/.*

[335] Centers for Disease Control and Prevention. NHSN Digital Quality Measures (dQMs). Available at: *https://www.cdc.gov/nhsn/fhirportal/.*

thus significantly reducing reporting burden for facilities. This enables different systems, such as EHRs and applications, to exchange information in a consistent, structured, and reusable format. CMS has already integrated the FHIR standard, and signaled the use of FHIR, in some of our interoperability requirements in our quality reporting modernization. CDC has implementation guides that describe the CDC NHSN's approach to digital data and the technical specifications for reporting to NHSN. We refer readers to these resources for additional detail on the electronic reporting of NHSN digital quality measures: *https://hl7.org/fhir/us/nhsn-dqm/* and *https://www.cdc.gov/nhsn/fhirportal/dqm/ig/*. CDC is currently partnering with 19 hospitals and health systems across the United States who are working to pilot, implement, and validate NHSN dQMs. This network of hospitals will be the foundation for advancing new healthcare data exchange approaches like FHIR® and will provide valuable insights and lessons learned for implementing FHIR-based dQMs that can be shared with all United States hospitals as they build their FHIR capabilities.

CMS and CDC are collaborating on the development of several FHIR-based dQMs which may be adopted into CMS hospital quality programs in the coming years. Of these, we have identified the Adult Community-Onset Sepsis Standardized Mortality Ratio measure as a high priority due to high sepsis mortality and morbidity. This measure was reviewed in the 2025 Pre-Rulemaking Measure Review process and is currently being tested as a pilot with NHSN partner hospitals (more information available at: *https://www.cdc.gov/nhsn/nhsncolab/index.html*).[336] These partners are submitting EHR FHIR data to NHSN as well as data from claims.

b. Overview of Measure

The Adult Community-Onset Sepsis Standardized Mortality Ratio measure provides hospitals with a nationally benchmarked metric of community-onset sepsis mortality outcomes, which can be used to measure their progress on improving the care of patients with sepsis. The measure uses data from the EHR in combination with claims data to provide robust risk-adjustment. All data elements are in defined fields in electronic sources and align with United States Core Data for Interoperability (USCDI)[337] and USCDI+ Quality[338] standards.

Empiric validity of the measure was tested by comparing hospital-level adult community-onset sepsis standardized mortality ratios (SMRs) to hospital-level process measures that are typically considered to reflect best practices for sepsis care in the first 3–6 hours (Severe Sepsis and Septic Shock Management Bundle [SEP–1]), Hospital 30-day, All-cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (pneumonia mortality), and the CMS Overall Hospital Star Rating. SMRs correlated with pneumonia mortality ($\rho = 0.27$, $p < 0.001$) and quality star ratings ($\rho = -0.29$, $p = 0.001$). The results support the rationale for the Adult Community-Onset Sepsis Standardized Mortality Ratio measure that encourages hospitals to focus on the full breadth of sepsis care, from presentation through discharge, and foster innovation in identifying additional measures that meaningfully impact sepsis outcomes. The CDC calculated signal-to-noise reliability across 433,065 persons from 265 hospitals and reported a median reliability of 0.921.

(1) Measure Description

The measure assesses the annual risk-adjusted standardized mortality ratio (SMR) of adult inpatients with community-onset sepsis who died during their hospitalization or were discharged to hospice. The SMR is reported annually and is calculated by dividing the number of observed community-onset sepsis deaths by the number of predicted community-onset sepsis deaths.

(2) Numerator

The measure numerator is the number of annually observed adults with community-onset sepsis who died during hospitalization or were discharged to hospice. The following are excluded from the numerator:

- Patients <18 years of age
- Length of hospitalization >120 days
- Patients with prior enrollment in hospice
- Patients that transferred to another acute care hospital

(3) Denominator

The measure denominator is the number of annually predicted adults with community-onset sepsis who died during hospitalization or were discharged to hospice.

(4) Measure Calculation

Hospital-level Standardized Mortality Ratio = (observed adult community-onset sepsis in-hospital mortality & discharge to hospice)/(predicted community-onset sepsis in-hospital mortality & discharge to hospice).

(5) Risk-Adjustment

This measure utilizes a risk-adjustment model incorporating baseline patient characteristics (age, sex), comorbidities, and detailed clinical data (including vital signs, laboratory values, positive blood cultures and COVID–19 tests, body mass index, and infection source per ICD–10 codes).

We refer readers to the NHSN digital Quality Measure Resource Center at *https://www.cdc.gov/nhsn/fhirportal/dqm/ach-dQMs.html* for more details on the measure specifications.

(6) Data Sources

Data are from EHRs that would be submitted via the FHIR-based NHSNLink API and augmented by claims data (specifically, ICD–10 codes) for specific components of the sepsis definition, certain exclusions, and part of the risk adjustment. Hospitals' claims data could be submitted directly to NHSN by uploading .csv files or through a third party vendor on a hospital's behalf and would be similar in process to how facilities currently report claims data for the NHSN Surgical Site Infection measures.

c. Pre-Rulemaking Process and Measure Endorsement

(1) Recommendations From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement for details on the Pre-Rulemaking Measure Review process convened by the CBE, including the voting procedures used to reach consensus on measure recommendations.[339] [340] The Pre Rulemaking Measure Review Hospital Committee, consisting of both the Pre-

[336] Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendation Group Final Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf.*

[337] Office of the National Coordinator for Health IT. United States Core Data for Interoperability (USCDI). Available at: *https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi.*

[338] Office of the National Coordinator for Health IT. USCDI+. Available at: *https://www.healthit.gov/topic/interoperability/uscdi-plus.*

[339] Partnership for Quality Measurement. Pre-Rulemaking Measure Review web page. Available at: *https://www.p4qm.org/prmr/about.*

[340] We note the Pre-Rulemaking Measure Review voting process was updated in 2025. We refer readers to the corresponding footnote in section IX.B.1.d.(1) of this final rule for more details on the updated Pre-Rulemaking Measure Review voting process.

Rulemaking Measure Review Hospital Recommendation Group (hereafter referred to as the Recommendation Group) and Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available ''2025 Measures Under Consideration List,'' including the Adult Community-Onset Sepsis Standardized Mortality Ratio measure.[341] Table IX.B.10. summarizes the voting results for this measure in the Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs. The Recommendation Group reached consensus to recommend adoption of the Adult Community-Onset Sepsis Standardized Mortality Ratio measure in the Hospital Inpatient Quality Reporting Program but did not reach consensus on the use of the measure in the Hospital Value-Based Purchasing Program.[342]

TABLE IX.B.10. PRE-RULEMAKING MEASURE REVIEW HOSPITAL RECOMMENDATION GROUP VOTING RESULTS FOR THE ADULT COMMUNITY-ONSET SEPSIS STANDARDIZED MORTALITY RATIO MEASURE

Program	Voted to Recommend	Voted to Not Recommend	Consensus Reached	Recommendation Decision
Hospital Inpatient Quality Reporting Program	17 (81%)	4 (19%)	Yes	Recommend
Hospital Value-Based Purchasing Program	12 (57%)	9 (43%)	No	Majority of the Recommendation Group expressed some support.

(2) Measure Endorsement

We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69458 through 69459) for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. The Adult Community-Onset Sepsis Standardized Mortality Ratio measure will be submitted in a future cycle for endorsement by the CBE. Section 1886(b)(3)(B)(viii)(IX)(bb) of the Act provides an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under Section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures that specifically measure sepsis mortality, therefore we believe the exception in Section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

d. Request for Comment on Potential Future Use in the Hospital Inpatient Quality Reporting Program

We invited public input on the potential use of the Adult Community-Onset Sepsis Standardized Mortality Ratio measure, in addition to the following questions:

Operational Considerations

- How feasible would it be for hospitals, especially those in rural areas, to implement and report on this measure using existing data and workflows? What data, workflow, or resource challenges do you anticipate? What is the single most important change you would recommend, if any?
- Do EHRs receive reconciled claims codes from payers or billing systems? Do EHR data reflect the claims-adjudicated codes or does it remain unchanged after claims are submitted? Are there any time lags or any other considerations for using the claims codes for sepsis surveillance and measure calculation as described above? If EHRs do receive reconciled claims from the billing systems, are they able to be represented in FHIR APIs?
- Do third-party vendors reconcile the claim codes? If so, how do these vendors receive data and submit data, what standards are used, and what is the frequency and cadence of data flow? Please consider third-party vendors such as quality measurement vendors, health information exchanges, aggregators, EHR intermediaries, etc. who may normalize or reconcile claims (ICD–10, CPT, HCPCS) with clinical or FHIR-based data for reporting purposes.
- What are anticipated challenges in mapping EHR data to the specified Sepsis measure FHIR profiles and value sets? Please focus on data elements that may be unstructured (for example, are in narrative form), may be represented in local codes, or exist outside of commonly used documents that map to FHIR profiles (for example, flowsheets and provider orders). We refer readers to the NHSN digital quality measure information available at: *https://hl7.org/fhir/us/nhsn-dqm/* and *https://www.cdc.gov/nhsn/fhirportal/dqm/ig/*.
- Are there any additional anticipated challenges or burden related to: (1) making the required EHR data available in FHIR, (2) accessing and linking claims data needed for exclusions and risk adjustment, or (3) working with vendors or NHSN to implement the dQM specifications referenced above? Please provide details.

Additional Policy Options

- To what extent do you believe this measure allows for fair comparison across hospitals? What adjustments or stratifications, if any, would improve fairness?
- To what extent do you agree this measure meaningfully reflects quality/value of care such that CMS should consider including this measure in a pay-for-performance program, such as

[341] Centers for Medicare & Medicaid Services. (December 2025). 2025 Measures Under Consideration List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview*.

[342] Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendation Group Final Meeting Summary. Available at: *https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf*.

the Hospital Value-Based Purchasing Program?

• Are there any potential unintended effects of using this measure for payment adjustment (for example, risk variable selection, reduced access to care, documentation burden)? If yes or not sure, please describe.

We received public comments on this RFI. The following is a summary of the comments we received:

Comment: Many commenters expressed support for the transition from process measures to outcome-based measures. Some commenters expressed concern regarding the Adult Community-Onset Sepsis Standardized Mortality Ratio measure, noting that further pilot testing and stakeholder engagement were needed in order to ensure that the pilot organizations represent a meaningful cross-section of hospitals and vendors. Commenters requested that CMS carefully define the sepsis population and consider stratification by severity. Some commenters requested that CMS provide clear technical specifications, as well as further information regarding the methodology used to calculate the standardized mortality ratio, including risk adjustment, patient attribution, and inclusion and exclusion criteria. A commenter expressed concern regarding the overlap between the measure specifications and Food and Drug Administration's guidance for medical devices, in which clinical decision support for sepsis is a Medical Device requiring 510(k) clearance.

Many commenters encouraged CMS to move beyond the current Severe Sepsis and Septic Shock: Management Bundle (SEP–1), stating that it is out of date and no longer reflects best practice or provides meaningful information. Other commenters encouraged CMS to evaluate the appropriateness of sepsis measures in pay-for-performance programs, noting that meaningful improvements in sepsis outcomes will also require greater emphasis on community-based prevention, early recognition, care access, and post-discharge support. A commenter recommended that CMS retire SEP–1 and pursue a smaller, well-tested set of sepsis measures. Other commenters encouraged CMS to explore measures targeting early identification of sepsis, address inaccurate diagnosis of sepsis, address the prevalence of contaminated blood cultures, and recognize the importance of in vitro diagnostics in improving outcomes.

Commenters expressed concerns regarding the measure's feasibility and implementation burden, particularly for rural hospitals, and cautioned against adding a new sepsis measure that could increase burden without improving outcomes. Many commenters noted that there are significant variations across hospitals due to differences in rural access, transfer patterns, patient acuity, limited specialty resources, and baseline mortality risk, stating that current risk adjustment models may not fully capture these nuances. Commenters also noted that factors beyond the control of the inpatient facility have a significant impact on sepsis outcomes, and urged CMS to account for the impact of social determinants of health variables (such as delayed access to care, transportation barriers, health literacy, and limited primary care access) within risk adjustment models as well as risk adjustment based on a clinical illness severity score. Another commenter encouraged CMS to consider the challenges faced by rural hospitals, specifically resource constraints and patients that tend to be older, have less contact with the healthcare system, and are often sicker when they arrive at the hospital. A commenter encouraged CMS to provide hospitals access to mortality data for deaths that occur outside of the hospital by providing information from the Social Security Death Index. Commenters stated that measures should include clinically appropriate exclusions so that reporting does not penalize clinician judgment and individualized care, which may create adverse incentives potentially resulting in harmful, non-individualized care.

Other commenters raised ongoing concerns regarding attribution, reliance on present-on-admission coding, transfer patients, variability in defining community-onset cases, and stated that these considerations impact the ability to compare outcomes across hospitals. A commenter expressed concern that limited interoperability and visibility across EHR platforms placed hospitals in areas with multiple healthcare systems at a disadvantage. Commenters stated that it is important to adjust for risk value selection, the appropriate classification of sepsis, code status on admission, and access to care to improve comparability across hospitals.

Although commenters recognized that the measure criteria reflect a meaningful effort to standardize the capture of data relevant to sepsis events and supported the goal of incentivizing the timely and accurate identification of sepsis, they also expressed concern that the resources to implement, maintain, and monitor this measure would be substantial. Some commenters stated that the current one-time early preview of measure results is not sufficient and suggested that CMS provide a 3-year implementation timeline for reporting new measures with additional post-reporting time to review results and adjust documentation and workflows accordingly.

Some commenters encouraged CMS to pursue CBE endorsement as soon as is feasible and prior to including the measure in a quality reporting program. A commenter recommended that CMS defer to the measure specifications instead of codifying the measure in the rule text, citing complications related to the divergence between the regulatory text and the measure specification as the measure evolves.

Commenters recommended changes to the measure, including: a case minimum that is high enough to ensure a valid reliability score; clear definitions of elements such as sepsis categorization, inclusion and exclusion criteria, and risk adjustment; and the exclusion of transfer patients, hospice patients, and patients who refuse care. Commenters supported approaches that limit reliance on billing codes or claims-based processes, stating that risk-adjustment that relies on claims-adjudicated ICD–10 codes result is not compatible with a time-critical measure, and that there is a great deal of inconsistency in the way that adjudicated claims data are received, stored, and integrated. Several commenters stated that the transition to digital quality measurement using data from the EHR instead of relying on claims-based methods is the right approach. Commenters also expressed concerns that claims-based approaches lend themselves to deceptive coding practices and are more reflective of administrative coding practices than clinical care provided. A commenter stated that fragmentation across settings makes it challenging to meet reporting thresholds, and dependencies such as adjudicated claims feeds add delays and burden. Another commenter noted that the term ''reconciled claims data'' is not defined for the measure and requested clarification, also requesting that CMS avoid using dual submission methodologies for a single measure. A commenter suggested that CMS encourage the use of the Patient Access and Provider Access APIs as a source for adjudicated claims data.

Many commenters expressed concerns about including the Adult Community-Onset Sepsis Standardized Mortality Ratio measure in the Hospital Value-Based Purchasing Program. Commenters were concerned that inadequate consideration of pre-hospital influences would disadvantage hospitals based on the population they serve. Others stated that the lack of a

standardized national definition of sepsis, as well as the presence of SEP–1 in the program, would create unnecessary burden and that the measures do not allow for comparison across systems. A commenter believed that sepsis measures in the Hospital Inpatient Quality Reporting, Hospital Value-Based Purchasing, and Hospital Readmission Reduction Programs would result in hospitals experiencing compound penalties driven by a single patient population. Commenters that did not oppose inclusion of the measure in the Hospital Value-Based Purchasing Program urged CMS to thoroughly test it in the Hospital Inpatient Quality Reporting Program and allow sufficient time for hospitals with smaller EHRs to adapt workflows and reporting systems.

Many commenters expressed concern that using this measure for payment adjustment may result in unintended consequences, such as disincentivizing palliative care and hospice, increasing antimicrobial resistance by incentivizing the use of broad-spectrum antibiotics, and penalizing hospitals that care for the sickest and most medically complex patients.

Many commenters provided feedback regarding additional challenges or burden related to using FHIR for reporting the Adult Community-Onset Sepsis Standardized Mortality Ratio measure. Commenters emphasized the need for: robust pilot testing; demonstrations of feasibility across diverse EHRs, hospitals, and clinical settings; detailed specifications; and confidential feedback reports for multiple reporting periods. Several commenters expressed concerns about the use of unstructured or narrative data, and many commenters stressed that the build, mapping, and workflow challenges inherent in moving to FHIR will be substantial. While some commenters believed that the use of FHIR would eventually be less burdensome than current reporting methods, many commenters stated that small and under-resourced hospitals would be at a disadvantage during the transition due to the increased burden and lack of access to resources. Commenters also expressed concerns about the cost of upgrades and services related to the transition to FHIR. Many commenters stated that CMS needs to provide adequate time for the workflow modifications, infrastructure updates, and reconfigurations that will be necessary to move to FHIR-based reporting. A few commenters suggested a phased, pilot-based implementation pathway.

Several commenters supported the transition to FHIR but encouraged CMS to proceed with caution and consider the challenges with prior interoperability and quality reporting initiatives as well as the hybrid readmission and mortality measures. A commenter stated that additional data endpoints are needed to capture the data required in the measure and recommended a targeted expansion of the USCDI rather than modifications to the measure. Another commenter stated that FHIR mapping must realistically reflect the diverse settings in which a patient is provided care for sepsis, while other commenters expressed concerns regarding the challenges related to interoperability and data exchange. A few commenters encouraged CMS to invest in submission models that utilize FHIR APIs and bulk-data exports, and to evaluate opportunities to provide FHIR-based reporting pathways from the earliest stages of measure adoption and implementation. A few commenters requested further clarification regarding the long-term certification plans and transition strategies for current quality reporting measures, another expressed concerns regarding the lack of alignment between the approaches CMS and the CDC are taking to develop dQMs.

Response: We appreciate all the comments and interest in this topic. While we are not responding to specific comments in response to the RFI in this final rule, we acknowledge that this input is very valuable and will continue to take all concerns, comments, and suggestions into account for future development and consideration of this measure for the Hospital Inpatient Quality Reporting Program and the Hospital Value-Based Purchasing Program.

C. Requirements for and Changes to the Hospital Inpatient Quality Reporting Program

1. Background and History of the Hospital Inpatient Quality Reporting Program

The Hospital Inpatient Quality Reporting Program is a pay-for-reporting program intended to measure the quality of hospital inpatient services, improve the quality of care provided to Medicare beneficiaries, and facilitate public transparency. Section 1886(b)(3)(B)(viii) of the Social Security Act (the Act) states that subsection (d) hospitals participating in the Hospital Inpatient Quality Reporting Program that do not submit data required for measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0 percentage point reduction to their annual payment update for the applicable fiscal year. We refer readers to our previous final rules for detailed discussions of the history of the Hospital Inpatient Quality Reporting Program, including statutory history, and for the measures we have previously adopted for the Hospital Inpatient Quality Reporting Program measure set.[343] We also refer readers to 42 Code of Federal Regulations (CFR) 412.140 for the Hospital Inpatient Quality Reporting Program regulations. We note that in the FY 2026 IPPS/LTCH PPS proposed rule, we discontinued the practice of retaining all subsections of the preamble every year where there are no proposed changes.

2. Considerations in Expanding and Updating Quality Measures

(a) Background

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148), in which we describe the Meaningful Measures Framework. In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, addressing a wide variety of settings, interested parties, and measure requirements.[344]

There are statutory requirements that the Secretary of HHS make public certain quality and efficiency measures that the Secretary is considering for adoption through rulemaking under Medicare.[345] To comply with those requirements, the consensus-based entity (CBE), currently Battelle, convenes the Partnership for Quality Measurement, which is comprised of

[343] These rules are: the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861); the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181); the FY 2012 IPPS/LTCH PPS final rule (76 FR 51605 through 51653); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50775 through 50837); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609); the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509); the FY 2021 IPPS/LTCH PPS final rule (85 FR 58926 through 58959); the FY 2022 IPPS/LTCH PPS final rule (86 FR 45360 through 45426); the FY 2023 IPPS/LTCH PPS final rule (87 FR 49190 through 49310); the FY 2024 IPPS/LTCH PPS final rule (88 FR 59144 through 59203); the FY 2025 IPPS/LTCH PPS final rule (89 FR 69515 through 69577); and the FY 2026 IPPS/LTCH PPS final rule (90 FR 36996 through 37027).

[344] Centers for Medicare & Medicaid Services. (2025). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/medicare/quality/cms-national-quality-strategy/meaningful-measures-20-moving-measure-reduction-modernization.*

[345] See section 1890A(a)(2) of the Social Security Act (42 U.S.C. 1395aaa–1(a)(2)).

clinicians, patients, measure experts, and health information technology specialists, to participate in the pre-rulemaking process and the measure endorsement process. We refer readers to the Partnership for Quality Measurement website [346] for a more detailed discussion on the updated Pre-Rulemaking Measure Review process, as well as the endorsement and maintenance process.

3. New Measures for the Hospital Inpatient Quality Reporting Program Measure Set

In the FY 2027 IPPS/LTCH PPS proposed rule, we proposed to adopt eight measures into the Hospital Inpatient Quality Reporting Program, three new measures (91 FR 19581 through 19588), and five modified mortality measures (91 FR 19568 through 19574) as a step towards substantively modifying the mortality measures currently used in the Hospital Value-Based Purchasing Program: (1) Excess Days in Acute Care After Hospitalization for Diabetes measure beginning with the July 1, 2025 through June 30, 2027 performance period, associated with the FY 2029 payment determination; (2) Advance Care Planning electronic clinical quality measure (eCQM) beginning with the CY 2028 reporting period/FY 2030 payment determination; (3) Hospital Harm—Postoperative Venous Thromboembolism eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination; (4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization measure beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination; (5) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization measure beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination; (6) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization measure beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination; (7) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease Hospitalization measure beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination; and (8) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft Surgery measure beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination. We provide more details on the Excess Days in Acute Care After Hospitalization for Diabetes and the Hospital Harm—Postoperative Venous Thromboembolism eCQM in the subsequent sections of the preamble. Details on the Advance Care Planning eCQM measure are in section IX.B.1., and details on the five modified mortality measures are in section IX.B.2.

a. Adoption of the Excess Days in Acute Care After Hospitalization for Diabetes Measure

(1) Background

An estimated one in every three Americans 65 years or older has diabetes.[347] The American Diabetes Association estimated that in 2022, health care expenditures attributable to diabetes for individuals aged 65 years or older in the United States included $67.7 billion for hospital inpatient stays and $7.2 billion for emergency department (ED) visits.[348] Diabetes is one of the most expensive conditions billed to Medicare,[349] with wide variation in inpatient utilization among hospitals.[350] For Medicare beneficiaries, diabetes with complications is a leading Medicare principal discharge diagnosis and among the top five principal diagnoses for 30-day all-cause hospital readmissions.[351] [352] Post-discharge ED visits and observation stays are also common and costly for patients with diabetes,[353] often reflecting gaps in discharge coordination, patient education, medication management, and standardized post-discharge support.[354]

Hospitals can improve diabetes care quality with evidence-based, guideline-driven interventions. The American Diabetes Association recommends multiple key strategies as part of structured discharge planning, including diabetes self-management education, medication reconciliation, and scheduling follow-up appointments before the patient is discharged.[355] A review of interventions aimed at reducing readmissions for patients with type 2 diabetes concluded that diabetes management interventions that start at the index admission are highly effective.[356] Common strategies associated with effective interventions include multidisciplinary input, dedicated care transition teams, certified diabetes educator appointments post-discharge, and hospital-initiated discharge protocol development and implementation, among others.[357] Other recommended interventions include the use of dedicated inpatient diabetes teams and multi-component programs combining education, transition support, and outpatient follow-up.[358] [359] Hospitals

[346] Battelle, Partnership for Quality Measurement website. Available at: *https://p4qm.org.*

[347] Centers for Disease Control and Prevention (CDC). (May 15, 2024). National Diabetes Statistics Report. Available at: *https://www.cdc.gov/diabetes/php/data-research/index.html.*

[348] Parker, E.D., Lin, J., Mahoney, T., et al. (2024). Economic Costs of Diabetes in the U.S. in 2022. *Diabetes care, 47*(1), 26–43. Available at: *https://doi.org/10.2337/dci23-0085.*

[349] Liang, L. (AHRQ), Moore, B. (IBM Watson Health), Soni, A. (AHRQ). (July 2020). National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2017. HCUP Statistical Brief #261. Agency for Healthcare Research and Quality. Available at: *www.hcup-us.ahrq.gov/reports/statbriefs/sb261-Most-Expensive-Hospital-Conditions-2017.pdf.*

[350] Rubin, D.J., & Shah, A.A. (2021). Predicting and Preventing Acute Care Re-Utilization by Patients with Diabetes. Current Diabetes Reports, 21(9), 34. Available at: *https://doi.org/10.1007/s11892-021-01402-7.*

[351] Agency for Healthcare Research and Quality (AHRQ). Healthcare Cost and Utilization Project (HCUPnet). Available at: *https://datatools.ahrq.gov/hcupnet/.*

[352] Jiang, H.J., & Barrett M.L. (April 2024). Clinical Conditions With Frequent, Costly Hospital Readmissions by Payer, 2020. Healthcare Cost and Utilization Project (HCUP) Statistical Brief #307. Agency for Healthcare Research and Quality. Available at: *https://hcup-us.ahrq.gov/reports/statbriefs/SB307-508.pdf.*

[353] Rubin, D.J., & Shah, A.A. (2021). Predicting and Preventing Acute Care Re-Utilization by Patients with Diabetes. Current Diabetes Reports, 21(9), 34. Available at: *https://doi.org/10.1007/s11892-021-01402-7.*

[354] Cai, J. & Islam, M.S. (2023). Interventions incorporating a multi-disciplinary team approach and a dedicated care team can help reduce preventable hospital readmissions of people with type 2 diabetes mellitus: A scoping review of current literature. Diabetic Medicine 40(1), e14957. Available at: *https://doi.org/10.1111/dme.14957.*

[355] American Diabetes Association Professional Practice Committee. Recommendation 16.16 (structured discharge plan). Chapter 16. Diabetes Care in the Hospital: Standards of Care in Diabetes—2025. Diabetes Care 2025;48 (Suppl. 1):S321–S334. Available at: *https://doi.org/10.2337/dc25-S016.*

[356] Cai, J. & Islam, M.S. (2023). Interventions incorporating a multi-disciplinary team approach and a dedicated care team can help reduce preventable hospital readmissions of people with type 2 diabetes mellitus: A scoping review of current literature. Diabetic Medicine 40(1), e14957. Available at *https://doi.org/10.1111/dme.14957.*

[357] Cai, J. & Islam, M.S. (2023). Interventions incorporating a multi-disciplinary team approach and a dedicated care team can help reduce preventable hospital readmissions of people with type 2 diabetes mellitus: A scoping review of current literature. Diabetic Medicine 40(1), e14957. Available at: *https://doi.org/10.1111/dme.14957.*

[358] Demidowich, A.P., Batty, K., Love, T., et al. (2021). Effects of a Dedicated Inpatient Diabetes Management Service on Glycemic Control in a Community Hospital Setting. *Journal of diabetes*

that practice these interventions help to reduce post-discharge acute care utilization and other diabetes-related costs.[360]

There are currently no publicly reported measures of post-discharge care utilization for patients hospitalized for diabetes in the Hospital Inpatient Quality Reporting Program. Given the prevalence, care burden, and cost of diabetes, as well as the availability of effective interventions,[361] we proposed (91 FR 19581 through 19585) to adopt the Excess Days in Acute Care After Hospitalization for Diabetes (Diabetes EDAC) measure into the Hospital Inpatient Quality Reporting Program beginning with the July 1, 2025 to June 30, 2027 performance period, associated with the FY 2029 payment determination. The Diabetes EDAC measure supports the CMS and HHS priority to address chronic illness while aiming to improve disease-specific outcomes, reduce avoidable acute-care utilization, and improve care transitions.[362]

(2) Overview of Measure

The Diabetes EDAC measure is a risk adjusted outcome measure that assesses the number of days a patient spends in acute care within 30 days of discharge from an inpatient hospitalization for a diagnosis of diabetes mellitus with complications. The measure is intended to improve the quality of care transitions provided to patients hospitalized for diabetes by collectively measuring different types of returns to the hospital (ED visits, observation stays, and unplanned readmissions), which are all adverse acute care outcomes that can occur at any time within 30 days of discharge.[363] We tested the proposed Diabetes EDAC measure using the most recent Medicare inpatient hospital discharge data from 4,193 hospitals with at least 25 eligible discharges from January 1, 2022, through December 31, 2023. Hospital-level performance rates are depicted in Table IX.C.1., and demonstrate there is meaningful variation in the distribution of the measure scores.[364] Similarly to the existing EDAC measures in the Hospital Inpatient Quality Reporting Program for patients admitted for pneumonia, heart failure, or acute myocardial infarction, which calculate final risk adjusted measure scores as the difference (''excess'') between a hospital's ''predicted days'' and ''expected days,'' per 100 discharges, lower scores (including negative numbers) indicate better performance. Thus, the lower performance percentiles are better performing hospitals than those in the higher percentiles (for example, the hospitals in the tenth percentile are the best performing hospitals). We note that in Table IX.C.1. negative numbers indicate fewer days than predicted in acute care. The interquartile range is 69.5 excess days in acute care per 100 discharges, and the difference between the 10th and 90th percentiles is 142.8 excess days in acute care per 100 discharges, occurring within 30 days of discharge from an inpatient hospitalization for diabetes.[365] For more details on the risk adjustment model, we refer readers to section IX.C.3.a.

TABLE IX.C.1. HOSPITAL PERFORMANCE IN MEASURE TESTING FOR THE DIABETES EDAC MEASURE

Performance Percentile	Risk-Adjusted Excess Days in Acute Care per 100 Discharges
10th Percentile	-55.1
25th Percentile	-29.5
50th Percentile (median)	1.6
75th Percentile	40.3
90th Percentile	87.7

Further, test results indicated measure reliability that meets accepted standards of reliability for a publicly reported measure.[366] In testing this measure, we observed a significant association with the expected strength and in the expected direction with measures in the same causal pathway, which supports the validity of the Diabetes EDAC measure.[367] The Diabetes EDAC measure was designed with stakeholder feedback from a diverse Technical Expert Panel (TEP).[368] During measure development, the TEP evaluated the measure's face validity and expressed overall support, indicating that the Diabetes EDAC measure is a meaningful indicator of hospital quality.[369]

science and technology, 15(3), 546–552. Available at: *https://doi.org/10.1177/1932296821993198.*

[359] Bhalodkar, A., Sonmez, H., Lesser, M., et al. (2020). The Effects of a Comprehensive Multidisciplinary Outpatient Diabetes Program on Hospital Readmission Rates in Patients with Diabetes: A Randomized Controlled Prospective Study. *Endocr Pract., 26*(11), 1331–1336. Available at: *https://doi.org/10.4158/EP-2020-0261.*

[360] American Diabetes Association Professional Practice Committee. (2025). Chapter 16. Diabetes care in the hospital: Standards of care in diabetes—2025. Diabetes Care, 48(Supplement 1). Available at: *https://doi.org/10.2337/dc25-S016.*

[361] American Diabetes Association Professional Practice Committee. (2025). Chapter 16. Diabetes care in the hospital: Standards of care in diabetes—2025. Diabetes Care, 48(Supplement 1). Available at: *https://doi.org/10.2337/dc25-S016.*

[362] U.S. Department of Health & Human Services. (2025). HHS Priorities. Available at: *https://www.hhs.gov/about/priorities/index.html.*

[363] QualityNet. Excess Days in Acute Care Measures Methodology. Available at: *https://qualitynet.cms.gov/inpatient/measures/edac/methodology.*

[364] Partnership for Quality Measurement. Diabetes EDAC Empiric Validity and Evidence of Performance Gap. Excess Days in Acute Care (EDAC) After Hospitalization for Diabetes. Available at: *https://www.p4qm.org/prmr-measures/muc2025-053.*

[365] Centers for Medicare & Medicaid Services. Diabetes EDAC Empiric Validity and Evidence of Performance Gap. Available at: *https://www.p4qm.org/sites/default/files/2025-12/MUC2025-053.zip.*

[366] Partnership for Quality Measurement. (Oct. 2025). National Consensus Development and Strategic Planning for Health Care Quality Measurement. Endorsement and Maintenance Guidebook. Available at: *https://www.p4qm.org/sites/default/files/2025-11/Del-3-6-Endorsement-and-Maintenance-Guidebook-OP2-508.pdf.*

[367] Partnership for Quality Measurement. Diabetes EDAC Empiric Validity and Evidence of Performance Gap. Excess Days in Acute Care (EDAC) After Hospitalization for Diabetes. Available at: *https://www.p4qm.org/prmr-measures/muc2025-053.*

[368] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation. (Oct. 2024). Summary of Technical Expert Panel (TEP) Diabetes Excess Days in Acute Care (EDAC). Available at: *https://mmshub.cms.gov/sites/default/files/Diabetes-EDAC-TEP-Meetings-Summary-Report.pdf.*

[369] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation. (Oct. 2024). Summary of Technical Expert Panel (TEP) Diabetes Excess Days in Acute Care (EDAC). Available at: *https://mmshub.cms.gov/sites/default/files/Diabetes-EDAC-TEP-Meetings-Summary-Report.pdf.*

(3) Measure Calculation

The final risk adjusted Diabetes EDAC measure score is calculated as the difference, or ''excess'' days, between a hospital's ''predicted'' days (that is, the average number of days a patient spent in acute care after adjusting for the risk factors) and ''expected'' days (that is, the average number of risk adjusted days in acute care a patient would have been expected to spend if discharged from an average-performing hospital with the same case mix), per 100 discharges. The measure result is multiplied by 100, such that the final Diabetes EDAC measure score would represent excess days in acute care per 100 discharges and is reported as a rate.

(a) Numerator

The numerator for the proposed Diabetes EDAC measure is defined as the number of days a patient spends in acute care for any cause, within 30 days of discharge from the index hospitalization for diabetes. Days in acute care are defined as time spent in: ED visits without an associated admission, observation stays, and unplanned readmissions.[370] Utilization is measured in days; each ED visit counts as one full day, regardless of duration or whether it spans more than one calendar date. Observation stays are measured in hours and rounded up to the nearest whole day; for example, a 28-hour observation stay counts as two full days. Unplanned readmissions are counted in days based on length of the hospital stay. All eligible encounters occurring within the 30-day period are counted, even if repeated. For example, an unplanned readmission with a length of stay of 7 days and an ED visit without an associated admission, both within 30 days of discharge, would contribute 8 days toward the EDAC numerator. Planned readmissions, such as scheduled follow-up visits, elective surgeries, or chemotherapy, are excluded. Consistent with existing EDAC measures, a planned readmission algorithm identifies admissions typically scheduled within 30 days of discharge.

(b) Denominator

This measure denominator includes index admissions for patients who meet all of the following criteria:

- Principal discharge diagnosis of diabetes;
- Enrolled in Medicare Fee-For-Service or Medicare Advantage for the 12 months prior to the date of admission and during the index admission;
- Aged 65 or over;
- Discharged alive from a non-federal short-term acute care hospital; and
- Not transferred to another acute care facility.

The measure excludes the following index admissions from the measure cohort: (1) hospitalizations without at least 30 days of post-discharge enrollment in Medicare Fee-For-Service or Medicare Advantage; (2) discharged against medical advice; or (3) diabetes admissions within 30 days of discharge from a prior diabetes index admission. These exclusion criteria are similar to those of the existing EDAC measures in the Hospital Inpatient Quality Reporting Program.

(c) Risk-Adjustment

To account for differences in case mix among hospitals, the measure risk adjusts for age, comorbidities, severity of illness, and frailty based on clinical status at the index admission. The measure's risk adjustment includes comorbidities present at admission or within the prior 12 months, excludes complications arising during hospitalization, and accounts for survival times shorter than 30 days post discharge to accurately reflect hospital performance.

(4) Pre-Rulemaking Process and Measure Endorsement

(a) Recommendation From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement for details on the Pre-Rulemaking Measure Review process convened by the CBE, including the voting procedures used to reach consensus on measure recommendations.[371] [372] The Pre-Rulemaking Measure Review Hospital Committee, consisting of both the Pre-Rulemaking Measure Review Hospital Recommendation Group (hereafter referred to as the Recommendation Group) and Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available ''2025 Measures Under Consideration List,'' including the Diabetes EDAC measure (MUC2025–053).[373]

The voting results of the Recommendation Group for the proposed inclusion of the Diabetes EDAC measure in the Hospital Inpatient Quality Reporting Program were: 15 members (68 percent) recommended adopting the measure into the Hospital Inpatient Quality Reporting Program; 7 members (32 percent) voted not to recommend the measure for adoption.[374] With 68 percent of the votes for recommend, consensus was not reached, but the majority of the Recommendation Group expressed some support for use of the measure in the Hospital Inpatient Quality Reporting Program.

Recommendation Group members who voted to recommend the measure for inclusion in the Hospital Inpatient Quality Reporting Program emphasized its importance for patients hospitalized for diabetes. Some Recommendation Group members provided considerations along with their vote to recommend this measure. Considerations included improved discharge planning and shortening the accountability window to a 7-day post-discharge period. Another member recommended adding sociodemographic risk factors to the risk adjustment model. Members also recommended expanding the measure to a hospital-wide approach, rather than a condition-specific approach.

Recommendation Group members who voted not to recommend the measure for inclusion in the Hospital Inpatient Quality Reporting Program provided the following rationales: (1) hospitals have limited control over outpatient access or follow-up care; (2) the 30-day post-discharge period may not be appropriate; (3) the risk adjustment should be evaluated to ensure it is sufficient; (4) the measure should undergo additional testing and have clearer specifications; and (5) the measure should be submitted for endorsement.

Regarding concerns related to hospitals' limited control over

[370] Partnership for Quality Measurement. Excess Days in Acute Care (EDAC) After Hospitalization for Diabetes. Available at: *https://www.p4qm.org/prmr-measures/muc2025-053.*

[371] Partnership for Quality Measurement. Pre-Rulemaking Measure Review web page. Available at: *https://p4qm.org/prmr/about.*

[372] In 2025, the CBE updated the Pre-Rulemaking Measure Review voting process such that Recommendation Group members will vote to either ''recommend'' or ''do not recommend'' that a measure be added to the intended CMS program(s), thus, removing the ''recommend with conditions'' voting option. The threshold to reach consensus on a given measure continues to be a minimum of 75 percent agreement among members. Recommendation Group members can provide considerations for CMS to review prior to implementation.

[373] Centers for Medicare & Medicaid Services. (2025). 2025 Measures Under Consideration List. Available at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[374] Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendations Group Final Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf.*

outpatient access or follow-up care, we wish to emphasize that an effective strategy for improving avoidable post-discharge acute-care utilization is to connect patients to resources as part of discharge planning. For example, one of the key strategies recommended by the American Diabetes Association is scheduling follow-up appointments before the patient is discharged.[375] We consider these types of activities to be an important part of providing high quality care for patients with diabetes and note that a goal of this measure is to incentivize hospitals to ensure these types of activities are standard practices. Through detailed, confidential, hospital-specific reports, hospitals would be provided with data to show where there are opportunities for improvement.

Regarding concerns and considerations related to the post-discharge period for accountability, the measure's 30-day timeframe is consistent with the existing 30-day readmission and EDAC measures in the Hospital Inpatient Quality Reporting Program, which have been endorsed by a CBE and publicly reported. The 30-day timeframe allows for a more complete reflection of the hospital's full discharge plan, including follow-up, care coordination, and self-management education.

Regarding concerns about the sufficiency of the measure's risk adjustment model, measure testing supported the current risk adjustment model. The Diabetes EDAC measure is risk adjusted for clinically relevant factors including patient functional status (frailty indicator), patient-level demographics (age), and patient-level health status and clinical conditions (case-mix adjustment, comorbidities, and severity of illness).[376] The risk adjustment model testing results indicate adequate controls for differences in patient characteristics (case mix), with a c-statistic [377] of 0.68, and 0.70 in the validation sample. The predictive ability [378] ranged from 1.66 percent to 13.23 percent, and 1.22 percent to 14.43 percent in the validation sample.[379] These testing results demonstrate the risk adjustment model effectively differentiates excess days in acute care after hospitalization for diabetes, thus adequately adjusting for differences in patient characteristics.[380] Regarding the recommendation to include sociodemographic risk factors, we tested model performance using dual-eligible status. Overall, the results indicate that the impact of dual-eligible status on measures scores is minimal and did not meaningfully change hospital scores. This informed our decision not to adjust for dual-eligible status in the risk adjustment model.[381]

Regarding concerns about additional testing, a recommendation for clearer specifications, and concerns about lack of endorsement, we note that the measure underwent the same extensive analysis and measure specifications development needed for the endorsement process, and that the measure will be submitted to the CBE for endorsement review for the Spring 2026 review cycle.

Regarding the consideration to expand this measure to a hospital-wide approach, rather than a condition-specific approach, we thank the Recommendation Group for this consideration and will consider it for future measures.

After taking these recommendations and concerns into consideration, we proposed (91 FR 19581 through 19585) to adopt the Diabetes EDAC measure into the Hospital Inpatient Quality Reporting Program beginning with the July 1, 2025 to June 30, 2027 performance period, associated with the FY 2029 payment determination.

(b) Measure Endorsement

We refer readers to the Partnership for Quality Measurement website for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. The Diabetes EDAC measure will be submitted to the CBE for endorsement review for the Spring 2026 cycle. Section 1886(b)(3)(B)(viii)(IX)(aa) of the Social Security Act (Act) generally requires that measures specified by the Secretary for use in the Hospital Inpatient Quality Reporting Program be endorsed by the entity with a contract under section 1890(a) of the Act. However, section 1886(b)(3)(B)(viii)(IX)(bb) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any CBE-endorsed hospital inpatient measures addressing post-discharge care utilization for patients hospitalized for diabetes. Therefore, the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

(5) Data Sources, Submission, and Public Reporting

The proposed Diabetes EDAC measure uses claims data from Medicare Fee-For-Service and Medicare Advantage encounter data which are routinely generated by hospitals and Medicare Advantage plans and submitted to CMS. Therefore, hospitals would not be required to report any additional data for this measure. Enrollment status would be obtained from the Medicare Enrollment Database which contains beneficiary demographic, benefit/coverage, and vital status information.

While the existing EDAC measures in the Hospital Inpatient Quality Reporting Program currently use a 3-year performance period, in the FY 2027 IPPS/LTCH PPS proposed rule, we proposed (91 FR 19590 through 19593) to add Medicare Advantage

[375] American Diabetes Association Professional Practice Committee. Recommendation 16.16 (structured discharge plan). Chapter 16. Diabetes Care in the Hospital: Standards of Care in Diabetes—2025. Diabetes Care 2025;48 (Suppl. 1):S321–S334. Available at: *https://doi.org/10.2337/dc25-S016.*

[376] Centers for Medicare & Medicaid Services. (2025). Diabetes EDAC Risk Adjustment and Model Performance Testing. Available at: *https://www.p4qm.org/sites/default/files/2025-12/MUC2025-053.zip.*

[377] The c-statistic is an indicator of the model's discriminant ability or ability to correctly classify those patients who have and have not had a qualifying event within 30 days. Potential values range from 0.5, meaning no better than chance, to 1.0, an indication of perfect prediction. The CBE has determined that for readmission-type measures, a c-statistic of 0.68 is considered an effective model of discriminant ability. We refer readers to the ''Diabetes EDAC Risk Adjustment and Model Performance Testing'' available at: *https://p4qm.org/prmr-measures/muc2025-053* for more details.

[378] Predictive ability measures the ability to distinguish high-risk subjects from low-risk subjects. A model with good predictive ability would see a wide range in observed outcomes between lowest and highest deciles of predicted outcomes. We have calculated the range of mean observed hospital ratios between the lowest and highest deciles of hospital visit probabilities. We refer readers to the ''Diabetes EDAC Risk Adjustment and Model Performance Testing'' available at: *https://p4qm.org/prmr-measures/muc2025-053* for more details.

[379] Centers for Medicare & Medicaid Services. (2025). Diabetes EDAC Risk Adjustment and Model Performance Testing. Available at: *https://www.p4qm.org/sites/default/files/2025-12/MUC2025-053.zip.*

[380] Centers for Medicare & Medicaid Services. (2025). Diabetes EDAC Risk Adjustment and Model Performance Testing. Available at: *https://www.p4qm.org/sites/default/files/2025-12/MUC2025-053.zip.*

[381] Centers for Medicare & Medicaid Services. (2025). Diabetes EDAC Risk Adjustment and Model Performance Testing. Available at: *https://www.p4qm.org/sites/default/files/2025-12/MUC2025-053.zip.*

beneficiaries to the measure cohorts and shorten the performance period to 2 years. To align with these proposed updates, we proposed that the Diabetes EDAC measure would also use a 2-year performance period. For example, for the FY 2029 payment determination, the performance period would comprise of data for index admissions that occurred between July 1, 2025 to June 30, 2027. The measure would be publicly reported through the Compare tool, currently available at: *https://www.medicare.gov/care-compare/,* or successor CMS website, for the first time in July 2028, or as soon as feasible. The measure would be calculated and publicly reported on an annual basis using a rolling 24-months performance period data.

We invited public comment on our proposal to adopt the Diabetes EDAC measure into the Hospital Inpatient Quality Reporting Program beginning with the July 1, 2025 to June 30, 2027 performance period, associated with the FY 2029 payment determination.

Comment: Many commenters supported the adoption of the Diabetes EDAC measure into the Hospital Inpatient Quality Reporting Program, stating that it improves inpatient diabetes management, discharge planning, patient outcomes, adherence to guideline-based care, patient education, and access to diabetes support. Many commenters stated that the measure strengthens care transition planning and effectiveness. A few commenters stated that longitudinal measures better reflect patients' real-world experiences after hospitalization. These commenters stated that this measure broadens healthcare utilization to more than readmissions by including ED visits and observation stays, noting that it identifies opportunities to improve discharge readiness, medication management, and follow-up care. A few commenters stated that the measure increases post-discharge accountability, and a commenter stated this measure would provide meaningful insight into the effectiveness of care transitions, post-acute management, and chronic disease management for longitudinal outcomes.

A few commenters stated that given the prevalence, care burden, and cost of diabetes, as well as the availability of effective interventions, it is appropriate to include a publicly reported measure of post-discharge care utilization for patients hospitalized for diabetes. A few commenters supported adoption of the measure because reducing post-discharge acute care utilization and complications can lower costs.

A few commenters specifically noted a gap in adherence to American Diabetes Association clinical guidelines in hospital settings and expressed the importance of this measure in encouraging a greater focus on highly vulnerable patients and driving the system-wide accountability needed to close that gap. A commenter stated the importance of hospitals connecting patients to resources and follow-up services as part of discharge planning, as the American Diabetes Association recommends. A few commenters appreciated CMS's recognition of diabetes self-management training as an evidence-based, guideline-driven intervention.

A commenter supported adoption of the Diabetes EDAC measure and stated that it could encourage hospitals to improve inpatient diabetes management through innovative care delivery tools and workflows, including evidence-based insulin management support and clinical software platforms that help standardize protocols, reduce hypoglycemia and hyperglycemia events, and minimize clinician burden. The commenter also encouraged CMS to continue engaging providers, health systems, and health care technology developers as the measure evolves to ensure implementation reflects real-world clinical workflows and advances in diabetes technology. A commenter stated that the use of post-discharge acute care utilization measures can help reinforce secondary and tertiary prevention-oriented approaches to chronic disease management and recommended that CMS explore how similar approaches might be applied to other chronic conditions.

Response: We thank the commenters for their support. We agree that adopting the Diabetes EDAC measure into the Hospital Inpatient Quality Reporting Program will help address a gap in publicly reported measures of post-discharge care utilization for patients hospitalized for diabetes. We also agree that the measure will provide important information to inform care delivery, discharge planning, and connection of patients to community resources.

Comment: A commenter recommended implementing the measure in CY 2028 rather than CY 2027 in order to allow for 18 months before implementation of eCQMs.

Response: We note that the Diabetes EDAC measure is not an eCQM; the measure uses Medicare Fee-For-Service claims and Medicare Advantage encounter data that are routinely generated and submitted to CMS, and hospitals would not be required to report additional data for this measure. We would also like to clarify that this measure is proposed for adoption beginning with the July 1, 2025 to June 30, 2027 performance period, associated with the FY 2029 payment determination.

Comment: A commenter recommended CMS report the measure in the aggregate, meaning not stratified by Medicare Fee-For-Service and Medicare Advantage. Another commenter recommended stratifying Medicare Advantage and Medicare Fee-For-Service cohorts in measure reporting.

Response: We acknowledge commenters' recommendations to provide stratified measure results, as well as comments recommending that we do not provide stratified measure results. We considered both options and at this time we will publicly report aggregated data, but note that confidential feedback reports to hospitals will include payer information on a patient level. By keeping Medicare Fee-For-Service and Medicare Advantage patients together for purposes of this measure's calculation and display in public reporting, hospitals' total volume will remain higher for more precise measure scores. We will continue to monitor the measure and evaluate whether future stratifications are warranted in public reporting.

Comment: Many commenters expressed concerns related to the inclusion of Medicare Advantage beneficiaries in EDAC measures.

Response: We note that these concerns were applicable to both the proposed adoption of the Diabetes EDAC measure and the proposal to include Medicare Advantage beneficiaries in our three current EDAC measures. We refer readers to section IX.C.5. of this final rule in which we respond to these concerns for the expanded cohort of current EDAC measures.

Comment: A few commenters stated that EDAC measures are uniquely sensitive to Medicare Advantage encounter data integrity compared to readmission measures, because Medicare Advantage plans report ED and observation encounters inconsistently and through downstream entities.

Response: We note that we have previously conducted analyses assessing the availability, completeness, and comparability of data elements used to define the EDAC outcome. These analyses found that the data elements necessary to identify ED visits and observation stays are available within Medicare Advantage encounter data,

and that Medicare Advantage encounter data latency is comparable to Medicare Fee-For-Service claims for inpatient and outpatient settings. Generally, within 3 months following the close of the measurement period, more than 97 percent of ED and observation claims are available in both data sources. The relative distribution of EDAC outcome components, including inpatient readmissions, ED visits, and observation stays, is comparable between Medicare Advantage encounter data and Medicare Fee-For-Service claims, supporting the use of Medicare Advantage encounter data for reliable EDAC outcome measurement.

Comment: A commenter urged CMS to explore alternative methodologies that can maintain stability and reliability with smaller denominators rather than continuing to depend on Medicare Advantage data to improve the scientific properties of the measure.

Response: We note that inclusion of Medicare Advantage beneficiaries in the measure cohort is not only important for measure reliability, but that it is also important to provide a more complete assessment of care transitions and acute care use following hospitalization. The proportion of Medicare Advantage beneficiaries has increased to over half of the Medicare population and therefore omitting Medicare Advantage beneficiaries leaves a critical gap in assessing quality of care for a large population of Medicare beneficiaries. A primary purpose of including Medicare Advantage beneficiaries in the measure cohort is to assess quality of care for these Medicare beneficiaries.

Comment: A commenter expressed concern that adding Medicare Advantage beneficiaries to penalty programs, such as the Hospital Value-Based Purchasing Program, could lead to double-counting events given that Medicare Advantage plans have their own value-based purchasing arrangements that assess performance for enrolled populations. The commenter encouraged CMS to address the risk of double-counting events should the agency choose to use this measure in a value-based care program in the future.

Response: We understand commenters' concerns regarding the potential for the same event being counted by multiple programs and recognize that Medicare Advantage plans have their own quality program. While we are not adopting the Diabetes EDAC measure into any value-based purchasing programs at this time, we maintain that all patients deserve the same quality of care regardless of payer or status.

Comment: Many commenters recommended delaying adoption of the Diabetes EDAC measure until the measure can be tested to ensure that the risk adjustment model properly accounts for differences in patient characteristics. Some commenters specifically recommended an analysis to ensure that Medicare Advantage data can be used with Medicare Fee-For-Service without an impact on performance.

Response: Measure testing supported the current risk adjustment model and demonstrated adequate controls for differences in patient characteristics (case mix). The Diabetes EDAC model c-statistic is 0.68, indicating good model discrimination. Predictive ability results show a wide range between the lowest decile and highest decile, indicating the ability to distinguish high-risk subjects from low-risk subjects. In addition, higher deciles of the predicted outcomes are associated with higher observed outcomes, indicating good calibration of the model for all admissions, as well as admissions stratified by payer (Medicare Advantage vs. Medicare Fee-For-Service). Interpreted together, our diagnostic results demonstrate the risk adjustment model adequately controls differences in patient characteristics.

Good measure score reliability provides additional support that adding Medicare Advantage admissions will not adversely impact measure performance. For hospitals with at least 25 admissions, the split-half reliability was 0.79, and the minimum entity-level signal-to-noise reliability was 0.668 with a median of 0.904, meeting the CBE reliability threshold of 70 percent of measured entities being greater than or equal to 0.6. For more details on measure testing results we refer readers to *https://qualitynet.cms.gov/inpatient/iqr/proposedmeasures.*

Comment: Many commenters expressed concerns about the risk adjustment approach. A few commenters stated that Pre-Rulemaking Measure Review Hospital Committee members raised concerns regarding whether the risk adjustment was sufficient. A few commenters recommended including demographic and social risk factors in addition to age. These commenters stated that sociodemographic risk adjustments are essential to ensuring that hospitals serving large populations of low-income or uninsured patients are not unfairly penalized.

Response: The Diabetes EDAC measure's risk adjustment approach was based on a rigorous empirical approach that identified variables that are significantly associated with the outcome. The risk adjustment model is intended to adjust for case-mix differences across hospitals by including more than 40 clinically relevant factors such as patient age, comorbidities, severity of illness, and indicators of patient frailty. The risk adjustment model uses comorbidities present at admission or in the 12 months prior to the index admission and excludes complications that arise during hospitalization to support fair comparisons across hospitals.

Measure testing supported the current risk adjustment approach. The model demonstrated adequate controls for differences in patient characteristics, with a c-statistic of 0.68 in the development sample and 0.70 in the validation sample. The predictive ability ranged from 1.66 percent to 13.23 percent in the development sample and 1.22 percent to 14.43 percent in the validation sample. The calibration results also demonstrated good alignment between predicted and observed outcomes, indicating that the model provides accurate probability estimates across the full range of predictions.

We note that we tested dual-eligible status as a surrogate marker for economic disadvantage. Although patients with dual eligibility had higher unadjusted days in acute care than patients without dual eligibility, adding dual-eligible status to the risk model had minimal impact on measure scores. Measure scores calculated with and without dual eligibility were highly correlated at greater than 0.999, and the distribution of measure scores across hospitals grouped by the proportion of patients with dual eligibility largely overlapped. We also found that the risk model is well calibrated for admissions for patients with, and without, the dual eligibility variable. These empiric results did not support adjusting the measure for dual eligibility. We will continue to monitor the measure's performance, including its performance for hospitals serving higher proportions of patients with economic disadvantage, as part of routine measure monitoring and evaluation activities.

Comment: A few commenters expressed concern that smaller hospitals will not be able to meet minimum volume thresholds and therefore would be unable to report the measure. A commenter specifically stated that a 2-year performance period would be difficult for hospitals with smaller diabetes volumes, while another commenter expressed concern that reliability and validity data for the 2-year performance period was not provided. A commenter expressed

concern that small case volumes may limit statistical reliability.

Response: We understand commenters' concern regarding the reliability and validity data for the 2-year performance period. We note that measure testing results for reliability and validity were made publicly available in March 2026. The Diabetes EDAC measure was tested using a 2-year (CY 2022 to 2023) dataset. The final cohort included 370,594 index admissions across 4,193 hospitals.[382] Among hospitals with at least one diabetes index admission, the median hospital volume was 37 admissions over the 2-year testing period. For purposes of public reporting, the measure uses a minimum case threshold of at least 25 admissions to help ensure that publicly reported results are sufficiently reliable. For hospitals meeting this minimum case threshold, split-half reliability was 0.79, and the minimum entity-level signal-to-noise reliability was 0.668 with a median of 0.904, meeting the CBE reliability threshold of 70 percent of measured hospitals with reliability greater than or equal to 0.6. The measure testing also demonstrated evidence supporting validity, including face validity and empiric validity testing. We acknowledge that some smaller-volume hospitals may not meet the minimum case threshold. However, hospitals that do not meet the minimum case threshold would not have measure results publicly reported for this measure but would receive their own results as part of confidential reporting. For the complete measure methodology report, we specifically refer readers to QualityNet on our website at: *https://qualitynet.cms.gov/inpatient/iqr/proposedmeasures* and the Partnership for Quality Measurement's website at: *https://p4qm.org/prmr-measures.*

Comment: A few commenters urged CMS to incorporate enhanced risk adjustment, stratification, or exclusion criteria for patients over age 80 because national guidelines emphasize that diabetes management in adults aged 80 and older should be highly individualized due to the fact that this population is often marked by multimorbidity, frailty, and limited life expectancy with frequent health care utilization.

Response: We agree that diabetes management for older adults may be clinically complex and individualized. The Diabetes EDAC measure risk adjusts for age, comorbidities, severity of illness, and indicators of frailty, which are intended to account for differences in patient clinical complexity across hospitals. We will continue to monitor the measure's performance, including for older adults and other clinically complex patient populations, as part of routine measure monitoring and evaluation activities.

Comment: A few commenters recommended CMS define the measure using only a primary diagnosis of diabetes and exclude cases captured through secondary diagnoses, which may reflect more complex underlying clinical circumstances and reduce the measure's specificity. A few commenters expressed concerns regarding the 30-day measure window and whether it is appropriate for the measure. A commenter stated that it incorporates excess days beyond the reasonable control of a hospital and suggested a shorter 7-day window.

Response: The Diabetes EDAC measure cohort is defined using a principal discharge diagnosis of diabetes. This approach is intended to identify patients hospitalized for diabetes, support a more clinically specific cohort, and avoid overlap with other existing EDAC measure cohorts. Regarding concerns about the 30-day measure window, the 30-day timeframe is consistent with existing 30-day readmission and EDAC measures in the Hospital Inpatient Quality Reporting Program which have been endorsed by a CBE and publicly reported. The 30-day timeframe allows for a more complete reflection of the hospital's discharge plan, including follow-up, care coordination, and self-management education. In addition, data during testing has shown that following an admission for diabetes, post-discharge hospital visits continue beyond 30 days, and do not reach baseline until about 80 days.

Comment: A few commenters requested that CMS clarify the measure specifications, with another commenter expressing concern regarding the lack of clarification outlining what will constitute ''excess days'' as opposed to an appropriate length of stay for diabetic persons in acute care, and upon what criteria that determination will be made. The commenter cautioned that applying a limitation on the length of stay for a patient with diabetes may present challenges for individuals who have chronic and comorbid conditions and stated that limited lengths of stay could lead to further complications that may have been prevented with treatment that was provided within an adequate timeframe.

Response: The measure does not establish a limitation on the appropriate length of an inpatient stay for patients with diabetes. The measure specifically looks at patients returning to acute care settings following discharge from an index admission. The measure calculates ''excess days'' as the difference between a hospital's predicted days and expected days in acute care within 30 days of discharge, per 100 discharges. Days in acute care include ED visits, observation stays, and unplanned readmissions after the index hospitalization. Detailed technical specifications that clarify what constitutes ''excess days'' and the full measure methodology are available in the Diabetes EDAC Measure Methodology Report available at: *https://qualitynet.cms.gov/inpatient/iqr/proposedmeasures.*

Comment: A few commenters stated the need for additional testing, validation, and stakeholder review before this new measure is considered for use in the Hospital Inpatient Quality Reporting Program. A commenter highlighted the TEP members' suggestion for additional refinement and testing to ensure the measure's validity and reliability.

Response: The measure was developed with input from clinical and methodological experts, a Technical Expert Panel, and other stakeholders, and was tested using Medicare Fee-For-Service claims and Medicare Advantage encounter data. Measure testing demonstrated good model performance, strong reliability, and evidence supporting validity. We note that TEP feedback informed the measure specifications and that face validity testing indicated support for the validity of the measure. For the complete measure methodology report, we specifically refer readers to QualityNet on our website at: *https://qualitynet.cms.gov/inpatient/iqr/proposedmeasures,* and to the Partnership for Quality Measurement's website at: *https://p4qm.org/prmr-measures,* for additional measure details.

Comment: Several commenters who did not support the measure raised concerns that the measure outcomes are heavily influenced by factors beyond hospital control, such as access to outpatient care, medication affordability, community resources, caregiver support, and patient adherence. The commenters stated that the measure may not accurately reflect hospital performance and could create unintended consequences.

Response: We wish to emphasize that an important strategy for improving

[382] Centers for Medicare & Medicaid Services. (March 2026). Excess Days in Acute Care (EDAC) After Hospitalization for Diabetes: Measure Methodology Report. Available at: *https://qualitynet.cms.gov/inpatient/iqr/proposedmeasures.*

avoidable post-discharge acute-care utilization is to connect patients to resources as part of discharge planning. Hospitals play an important role in discharge planning, medication reconciliation, patient education, care coordination, and arranging timely follow-up care, including scheduling follow-up appointments before discharge. We consider these types of activities to be an important part of providing high quality care for patients with diabetes and a goal of this measure is to incentivize hospitals to ensure these types of activities are standard practices. Through detailed, confidential, hospital-specific reports, hospitals would be provided with data to show where there are opportunities for improvement.

Comment: A few commenters expressed concerns about potential unintended consequences to patients that may result from measures that include readmissions, noting a study that analyzed Hospital Readmissions Reduction Program measures that showed that the 30-day readmission measures may lead to increased mortality. The study raised several potential concerns around gaming, including the potential to incentivize hospitals to ''game'' the system, using strategies such as delaying admissions beyond day 30, increasing observation stays, or shifting inpatient-type care to emergency departments. A commenter specifically recommended additional analyses to examine the association between reduced readmission rates and patient mortality. A few commenters also suggested examining trends based on adjusted and unadjusted data to better understand clinical decisions and outliers.

Response: We acknowledge commenters' concerns about potential unintended consequences associated with measures that include readmissions, including concerns regarding the relationship between reduced readmissions and mortality. With respect to the concern that readmissions-focused measures may incentivize hospitals to delay admissions beyond day 30, increase observation stays, or shift care to emergency departments, we note that the Diabetes EDAC measure is not limited to readmissions but instead assesses broader post-discharge acute care utilization, including ED visits, observation stays, and unplanned readmissions within 30 days of discharge. Including broader post-discharge acute care utilization is intended to reduce the likelihood that hospitals will shift acute care to non-acute settings or delay care. We reiterate that there are many strategies that a hospital can use to reduce the risk that a patient clinically deteriorates following discharge such that they require further acute care.

We note that the Diabetes EDAC measure, like other EDAC measures, incorporates the proportion of days alive within the 30-day outcome window to account for post-discharge mortality, thereby reducing the risk of assigning better performance to hospitals with higher mortality rates.

We will continue to monitor Diabetes EDAC for potential unintended consequences as part of routine measure monitoring and evaluation activities. With respect to the recommendation to examine trends based on adjusted and unadjusted data, the measure methodology report, available at: *https://qualitynet.cms.gov/inpatient/iqr/proposedmeasures,* includes unadjusted outcome analyses, including observed days in acute care and component outcomes, as well as risk-adjusted measure testing results. Hospitals will also receive confidential hospital-specific reports that provide information on their measure performance to help identify opportunities for improvement.

Comment: A few commenters expressed concern that this measure could disproportionately impact areas with provider shortages, particularly rural areas where travel barriers may affect patients' ability to access post-discharge care despite hospital discharge planning efforts. A commenter urged CMS to evaluate the effects of the measure on rural and safety-net facilities where unique case-mix variables and access limitations may skew performance outcomes.

Response: In areas with provider shortages, it is critical that hospitals help patients identify strategies for managing symptoms and preventing clinical deterioration with an understanding of the barriers patients may face in accessing care. Hospitals play an important role in discharge planning, care coordination, patient education, medication reconciliation, and connecting patients to appropriate follow-up care and resources. We will monitor the measure for potential unintended consequences, including any disproportionate effects on rural and safety-net hospitals or areas with provider shortages, as part of routine measure monitoring and evaluation activities. In studies done with the currently implemented EDAC measures, there was no consistent association between safety net status and EDAC performance.[383]

Comment: Several commenters who did not support the measure adoption expressed concern that the Diabetes EDAC measure may not be sufficiently attributable to inpatient hospital care. A commenter stated that, compared with existing EDAC measures, the Diabetes EDAC measure may be more challenging because patients hospitalized for diabetes often have complex comorbidities, a range of complications, and care needs involving multiple specialists. A commenter expressed concern regarding the reliability of diagnosis coding for diabetes and the feasibility of accurately capturing the full range of acute care encounters for patients with diabetes.

Response: We acknowledge that patients with diabetes may have complex comorbidities, complications, and care across inpatient and outpatient settings. This further emphasizes the importance of assessing outcomes and improving quality of care for this patient population. Additionally, this measure is risk-adjusted for clinically relevant factors for patients hospitalized for diabetes. We also note that the Diabetes EDAC measure is intended to assess hospital-level variation in post-discharge acute care utilization following hospitalization for diabetes, rather than all aspects of diabetes management. Regarding concerns about the reliability of diagnosis coding for diabetes and feasibility of capturing the full range of acute care encounters for patients with diabetes, we note that the measure cohort is defined using a principal discharge diagnosis of diabetes. This approach identifies patients hospitalized for diabetes, supports a more clinically specific cohort, and helps avoid overlap with other existing EDAC measure cohorts. In addition, research has shown that coding for diabetes is highly stable.[384] Regarding the feasibility of capturing the full range of acute care encounters for patients with diabetes, the Diabetes EDAC measure uses the same approach as the existing CBE-endorsed EDAC

[383] Horwitz LI, Wang Y, Altaf FK, Wang C, Lin Z, Liu S, Grady J, Bernheim SM, Desai NR, Venkatesh AK, Herrin J. (2018). Hospital Characteristics Associated With Post-discharge Hospital Readmission, Observation, and Emergency Department Utilization. *Med Care, 56(4), 281–289.* Available at: *https://pmc.ncbi.nlm.nih.gov/articles/PMC6170884/.*

[384] Pan J, Lee S, Cheligeer C, Li B, Wu G, Eastwood CA, Xu Y, Quan H. (2025). Assessing the validity of ICD–10 administrative data in coding comorbidities. *BMJ Health Care Inform,* 32(1), e101381. Available at: *https://pmc.ncbi.nlm.nih.gov/articles/PMC12083369/.*

measures to identify post-discharge hospital utilization.

Comment: A few commenters stated that many of the factors influencing long-term outcomes occur outside the inpatient setting and that successful diabetes management often depends on outpatient medication management, patient education, access to supplies, and ongoing clinical follow-up. The commenters further expressed concern that the typical inpatient hospital stay only provides hospitals with a limited ability to influence factors that drive diabetes-related readmissions. A commenter stated that diabetes management is better aligned with the function of a primary care provider than hospitals, and another commenter suggested the measure may be better suited for an Accountable Care Organization-type environment due to the dependency on outpatient resources and post-discharge follow-up.

Response: We recognize that diabetes care extends beyond the inpatient stay. However, hospitals play an important role in discharge planning, medication reconciliation, patient education, care coordination, and connecting patients to appropriate follow-up care and resources. Standards for hospital care for patients with diabetes, including care at the peri-discharge period, are well established. The American Diabetes Association Professional Practice Committee has established recommendations to reduce readmissions for patients hospitalized for diabetes that include clear guidance for hospitals to transition patients from the hospital to an ambulatory setting to reduce future readmissions. The Diabetes EDAC measure is intended to assess hospital-level outcomes 30 days post-discharge following an inpatient hospitalization for diabetes, rather than long-term outcomes, and it is appropriate to evaluate hospitals on their patients' outcomes following discharge within the 30 days post-discharge timeframe. Analyses submitted for CBE endorsement review show that in Medicare patients the most common reason, as captured by principal discharge diagnosis, for a diabetes hospitalization after discharge is a diabetes-specific complication, suggesting that better management of diabetes in the peri-discharge period can reduce excess post-discharge acute care utilization.[385]

Comment: A commenter urged CMS to consider alternate programs for the measure's implementation, stating this hospital-level measure is not targeted towards the conditions and complications typically associated with hospitalization for diabetes, including coma, diabetic ketoacidosis, diabetic foot ulcer, and hyperosmolar hyperglycemic state. Another commenter recommended that CMS consider a more targeted post-procedural EDAC measure that is more directly attributable to inpatient care and more actionable for hospitals. A commenter recommended adopting a diabetes-related readmission measure rather than an EDAC measure due to general challenges of EDAC measures, including capturing observation stays and ED visits that may occur at another facility.

Response: We note that the Diabetes EDAC measure assesses hospital-level outcomes following an inpatient hospitalization for diabetes, focusing on acute care utilization after discharge. The measure cohort is defined using a principal diagnosis of diabetes with complications (AHRQ CCS50 codes), which is intended to identify hospitalizations where diabetes is the primary reason for admission, and includes hospitalization for diabetes, including coma, diabetic ketoacidosis, diabetic foot ulcer, and hyperosmolar hyperglycemic state, among other complications. We refer readers to Table 1 (Diabetes EDAC Cohort Inclusion) of the Diabetes EDAC Data Dictionary available at: *https://p4qm.org/sites/default/files/2026-04/5575-1.13a-Diabetes-EDAC-Data-Dictionary-Spring2026.xlsx.*

Hospitals play an important role in supporting safe care transitions at discharge. Supplementary analyses demonstrated that the most frequent principal discharge diagnoses associated with unplanned readmission after an index hospitalization for diabetes were diabetes mellitus with complications, septicemia (except in labor), and complications of surgical procedures or medical care, all of which indicate relatedness to the index hospitalization.[386] We note that the measure outcome approach provides broader information than a readmission-only measure by capturing ED visits and observation stays in addition to unplanned readmissions. We will monitor implementation of the measure and consider these recommendations in future rulemaking as we continue developing quality measures related to chronic conditions.

Comment: A commenter stated there is limited information regarding how this measure aligns with existing diabetes-related quality initiatives. The commenter recommended CMS provide information regarding the measure in the context of other diabetes-related quality measures and initiatives before finalizing the proposal. A commenter stated that hospitals already participate in outpatient diabetes quality measures.

Response: We note that the Diabetes EDAC measure is intended to address a specific gap in the Hospital Inpatient Quality Reporting Program, as there are currently no publicly reported measures of post-discharge care utilization for patients hospitalized for diabetes. The Diabetes EDAC measure is distinct from outpatient diabetes quality measures because it assesses hospital-level post-discharge acute care utilization following an inpatient hospitalization for diabetes. Additionally, variation across hospitals in Diabetes EDAC measure scores during measure testing identified an important quality gap.

Comment: A commenter stated that this measure overlaps conceptually with existing readmissions measures, as both assess 30-day post-discharge utilization with the EDAC measure capturing broader sets of encounters, including ED visits and observation stays. The commenter noted this overlap can create challenges in prioritization and performance improvement efforts, as hospitals must track and respond to multiple closely related outcome measures that reflect similar aspects of care transitions, and asked whether it has been evaluated for overlap or redundancy with existing measures.

Response: We note the Diabetes EDAC measure does not duplicate existing measures; specifically, there is no existing Diabetes readmission measure in our portfolio of quality reporting and value-based purchasing programs. The Diabetes EDAC measure is defined using a principal discharge diagnosis of diabetes, which supports a more clinically specific cohort, avoiding overlap with other existing EDAC measure cohorts. While EDAC and readmission measures both assess 30-day post-discharge utilization, the Diabetes EDAC measure captures a broader set of acute care use, including ED visits, observation stays, and unplanned readmissions.

Comment: A commenter asserted that there is a lack of clearly defined, scalable inpatient-only interventions or care bundles with strong and validated evidence that demonstrates a sustained

[385] Partnership for Quality Measurement. (2026, May). Excess days in acute care (EDAC) after hospitalization for diabetes. Available at: *https://p4qm.org/measures/5575.*

[386] Partnership for Quality Measurement. (May 2026). Excess days in acute care (EDAC) after hospitalization for diabetes. Available at: *https://p4qm.org/measures/5575.*

reduction in excess days in acute care following hospitalization for diabetes.

Response: Regarding available interventions, we recognize that no single inpatient-only intervention will address all factors affecting post-discharge acute care utilization for patients with diabetes. Outcome measures, such as Diabetes EDAC, combined with confidential hospital-specific reports, help hospitals identify specific areas of improvement for their patient population. Furthermore, there are evidence-based interventions and guideline-directed standards that have been shown to reduce post-discharge acute care use, including high-quality care transitions through diabetes self-management education, medication reconciliation, scheduling follow-up appointments before discharge, multidisciplinary input, dedicated care transition teams, certified diabetes educator appointments post-discharge, and hospital-initiated discharge protocols.

Comment: A few commenters recommended that CMS carefully balance the agency's quality measurement priorities with the substantial operational, financial, and technological burdens measure reporting places on hospitals. A commenter urged CMS to ensure new reporting requirements remain feasible for hospitals of all sizes, and provide adequate flexibility, technical assistance, and implementation timeframes, particularly for rural and resource-constrained facilities. A commenter recognized the value of expanding outcome-based measurement but noted that adding a Diabetes EDAC measure creates additional burden for hospitals by increasing the number of publicly reported performance metrics tied to post-discharge outcomes.

Response: We agree that reporting requirements should be feasible and should avoid unnecessary burden, particularly for rural, smaller, and resource-constrained hospitals. We note that the Diabetes EDAC measure uses Medicare Fee-For-Service claims and Medicare Advantage encounter data that are routinely generated and submitted to CMS. Therefore, hospitals would not be required to report any additional data for this measure. We understand that there may be some burden for hospitals to review publicly reported data to ensure accuracy and completeness, however, the use of measures generated using data already submitted to CMS should minimize this burden while providing high-value information about outcomes associated with a common clinical condition. We will continue to consider burden and feasibility as we monitor implementation of the measure.

Comment: A few commenters urged CMS to delay adoption of the measure into the Hospital Inpatient Quality Reporting Program until CBE endorsement review is completed to provide additional insight on measure performance. A commenter recommended that CMS continue to refine and evaluate the measure before it is included in the Hospital Inpatient Quality Reporting Program with respect to validity and reliability testing. A few commenters urged CMS to allow hospitals to assess performance impact, develop internal monitoring tools, and engage in meaningful quality improvement before the measure is implemented.

Response: Although the Diabetes EDAC measure will be submitted to the CBE for endorsement review for the Spring 2026 cycle, we note that the Diabetes EDAC measure is closely aligned with the existing EDAC measures in the Hospital Inpatient Quality Reporting Program, which have been CBE-endorsed and publicly reported. Further, we note section 1886(b)(3)(B)(viii)(IX)(bb) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any CBE-endorsed hospital inpatient measures addressing post-discharge care utilization for patients hospitalized for diabetes. Therefore, the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

The Diabetes EDAC measure underwent extensive analysis and specification development needed for the endorsement process. The measure testing supported the measure's performance, including reliability, validity, and meaningful variation in hospital scores. We refer readers to the Diabetes EDAC Methodology Report available at: *https://qualitynet.cms.gov/inpatient/iqr/proposedmeasures* for further details on measure testing. We note that hospitals will receive confidential hospital-specific reports to help identify opportunities for improvement.

After consideration of the public comments we received, we are finalizing adoption of the Diabetes EDAC measure as proposed beginning with the July 1, 2025 to June 30, 2027 performance period, associated with the FY 2029 payment determination.

b. Adoption of the Hospital Harm—Postoperative Venous Thromboembolism Electronic Clinical Quality Measure

(1) Background

Postoperative venous thromboembolism (VTE) includes both deep vein thrombosis (DVT), a thrombus (that is, blood clot) in the deep veins, most often in the legs, and pulmonary embolism (PE), when a thrombus travels through the venous circulation and the right side of the heart, and lodges in the lungs. VTE is considered to be a leading cause of preventable death following surgery, with as many as 70 percent of cases considered to be preventable.[387] Non-fatal postoperative VTE can lead to adverse health consequences, including chronic thromboembolic pulmonary hypertension, a potentially fatal condition. Long term complications, such as pain and swelling in the affected limb, occur among one third to one half of people who have had a DVT and one third of VTE patients will experience a recurrence of the DVT within 10 years.[388] The AHRQ Healthcare Cost and Utilization Project (HCUP) State Inpatient Database from 2020, 2021, and 2022 showed that 50,017 perioperative PE's or DVT's occurred in 15,387,213 discharges, which is a rate of 3.25 per 1,000 discharges.[389] Each postoperative VTE event generates an estimated $17,367 in additional costs,[390] suggesting a 3-year cost of $868,645,239 for the postoperative VTE events identified in the HCUP data. An analysis of 1,112,014 hospitalizations between 2013 and 2021 found a more than three times higher risk of readmission and a 63 percent

[387] Centers for Disease Control and Prevention. (2025). Data and Statistics on Venous Thromboembolism. In *Venous Thromboembolism (Blood Clots).* Available at: *https://www.cdc.gov/blood-clots/data-research/facts-stats/index.html.*

[388] Centers for Disease Control and Prevention. (2025). Data and Statistics on Venous Thromboembolism. In *Venous Thromboembolism (Blood Clots).* Available at: *https://www.cdc.gov/blood-clots/data-research/facts-stats/index.html.*

[389] Agency for Healthcare Research and Quality. Patient Safety Indicators (PSI) Benchmark Data Tables, v. 2025. AHRQ PSI Technical Documentation, Version v2025. Available at: *https://qualityindicators.ahrq.gov/measures/psi_resources.*

[390] Agency for Healthcare Research and Quality. (2020). AHRQ National Scorecard on Hospital-Acquired Conditions. Available at: *https://www.ahrq.gov/hai/pfp/index.html.*

higher risk of death for patients acquiring a hospital-associated VTE.[391]

There are established therapies that can reduce the risk of a VTE, but failure or delay in prescribing appropriate VTE prophylaxis can result in a higher risk of postoperative VTE. For example, one study found that delays or interruptions in thromboprophylaxis were associated with two to three times higher risk of VTE.[392] Hospital care processes can reduce the risk of hospital-acquired VTE through integration of evidence-based guidelines into hospital protocols and use of VTE-risk assessment and physician alerts to improve use of VTE prophylaxis.[393] Another report found evidence that combining hospital interventions, such as mechanical and pharmacological prophylaxis, can reduce the incidence of DVT among patients undergoing surgery or admitted with trauma.[394] This volume of preventable safety events shows that there are opportunities to reduce the rate of postoperative VTEs.

Preventing VTE and associated complications after hospitalization and incentivizing appropriate administration of VTE prophylaxis have been, and continue to be, important goals of the Hospital Inpatient Quality Reporting Program since the early days of the program. The current measure set contains two VTE eCQMs, Venous Thromboembolism Prophylaxis (VTE–1) eCQM and Intensive Care Unit Venous Thromboembolism Prophylaxis (VTE–2) eCQM, which were adopted as measures that hospitals could self-select beginning with the CY 2014 reporting period (78 FR 50807 through 50810). Replacing these two process measures with a single comprehensive outcome measure can reduce burden while continuing to address this consequential health care issue affecting postoperative patient outcomes.

We proposed to adopt the Hospital Harm—Postoperative Venous Thromboembolism (hereafter referred to as Hospital Harm—Postoperative VTE) eCQM (91 FR 19585 through 19588) beginning with the CY 2028 reporting period/FY 2030 payment determination. We refer readers to section IX.C.4.a. for our proposal to remove the VTE–1 and VTE–2 eCQMs contingent upon the adoption of the Hospital Harm—Postoperative VTE eCQM.

(2) Overview of Measure

The Hospital Harm—Postoperative VTE eCQM is a risk-adjusted outcome measure that assesses the proportion of inpatient hospitalizations for patients age 18 and older who have at least one surgical procedure performed inside the operating room during the admission, and who suffer the harm of a postoperative VTE during hospitalization or within 30 days after the first surgical procedure. The intent of the measure is to improve patient safety by incentivizing hospitals to implement processes to reduce the occurrence of postoperative VTE. Accurately monitoring the rate at which postoperative VTE occurs will allow hospitals to improve quality and reduce VTE harm rates.

(3) Measure Calculation

This outcome measure reports the proportion of inpatient hospitalizations for patients aged 18 years and older with a postoperative VTE within 30 days of the first surgical procedure.[395] This measure is calculated using a risk adjusted measure score, which reflects the performance of a hospital treating its patients relative to the average hospital treating patients with the same characteristics. This is calculated by:

- Dividing the number of inpatient hospitalizations in the numerator by the number of inpatient admissions in the denominator to determine the observed rate;
- Using the risk adjustment model to determine the hospital's expected VTE event rate based on the hospital's case mix; and
- Dividing the observed rate by the expected rate.

(a) Numerator

The numerator is the number of inpatient hospitalizations for adult patients who had a surgical procedure performed in the operating room during the hospitalization and experienced a VTE within 30 days of the surgical procedure. Postoperative VTE cases can be identified for inclusion in the numerator in multiple ways. For example, documentation in the medical record of a diagnosis of VTE that was not present when the patient was admitted to the hospital for an inpatient stay that included surgery would qualify the admission for the numerator. Alternatively, an inpatient admission in which a patient had surgery and subsequently had a diagnostic imaging procedure performed followed by an order for anticoagulation therapy would also qualify for the numerator. A postoperative VTE that occurs during a subsequent hospital stay within 30 days of the surgical procedure would count toward the numerator if there is documentation of a diagnosis of VTE and anticoagulation therapy ordered or prescribed during that hospital stay. We refer readers to the Partnership for Quality Measurement website (*https://p4qm.org/prmr-measures/muc2025-067*) for more details on the measure specifications, including more details on how a postoperative VTE is determined.

(b) Denominator

The denominator is the number of adult patients who had a surgical procedure performed in the operating room during an inpatient hospitalization. The cohort includes inpatient hospitalizations for patients aged 18 and older where a surgical procedure was performed inside the operating room during the encounter. The cohort excludes inpatient encounters for:

- Patients with an obstetric-related diagnosis;
- A VTE diagnosis present on admission;
- Acute brain or spinal injury or hemorrhage present on admission;
- Extracorporeal membrane oxygenation during the inpatient encounter;
- A thrombectomy procedure before or on the same day as the first surgical procedure;
- Intracranial or spinal surgery where the patient was discharged less than five days after the end of the surgery; and
- Inpatient encounters with a duration of stay less than 2 days.

[391] Neeman E, Liu V, Mishra P, et al. Trends and Risk Factors for Venous Thromboembolism Among Hospitalized Medical Patients. JAMA Net Open. 2022;5(11):e2240373. Available at: *doi:10.1001/jamanetworkopen.2022.40373.*

[392] Henke, P.K., Kahn, S.R., Pannucci, C.J., Secemksy, E.A., Evans, N.S., Khorana, A.A., Creager, M.A., & Pradhan, A.D. (2020). Call to action to prevent venous thromboembolism in hospitalized patients: A policy statement from the American Heart Association. Circulation, 141(24). Available at: *https://doi.org/10.1161/cir.0000000000000769.*

[393] Geerts, W. (2009). Prevention of venous thromboembolism: a key patient safety priority. Journal of Thrombosis and Haemostasis, 7, 1–8. Available at: *https://www.sciencedirect.com/science/article/pii/S1538783622174040.*

[394] Kakkos, S., Kirkilesis, G., Caprini, J.A., Geroulakos, G., Nicolaides, A., Stansby, G., & Reddy, D.J. (2022). Combined intermittent pneumatic leg compression and pharmacological prophylaxis for prevention of venous thromboembolism. The Cochrane database of systematic reviews, 1(1), CD005258. Available at: *https://doi.org/10.1002/14651858.CD005258.pub4.*

[395] This criterion was supported by the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP). Information about this program is available at: *https://www.surgeons.org/-/media/Project/RACS/surgeons-org/files/interest-groups-sections/surgical-directors/199778_2016-08-20_pre_bruce_hodge_nsqip.pdf?rev=ef1c0da899bf442aa5cdf711ba24155b&hash=65855EF1169A93A4C83471DA384DAF57.*

(c) Risk Adjustment

The risk adjustment model accounts for factors that affect risk of VTE, specifically age, sex, and eight clinical factors (bleeding disorders, cancer, catheter insertion, history of VTE, obesity, respiratory operations, stroke, and vascular surgeries). The risk adjustment model was developed using two consecutive years (CY 2022 through 2023) of electronic health record (EHR) data from a commercially available EHR database.[396] Testing of the risk adjustment model demonstrated the ability to discriminate between high-risk and low-risk postoperative VTE events. The risk adjustment model has been developed to ensure that hospitals that care for patients at higher risk of postoperative VTE are evaluated fairly.[397]

The sample to evaluate the risk adjustment model included 100,911 hospitalizations from 34 hospitals in six states during 2022 and 2023. Hospital-level characteristics were not available because the data uses anonymized hospital identifications. Hospitals included in the sample had hospitalizations ranging in number from 56 to 6,746 annually.[398] The risk adjusted performance scores ranged from 0.21 percent in Decile 1 to 4.21 percent in Decile 10, with a median score of 0.78 percent.[399] The difference between the best and worst performing facilities suggests there is room for improvement among facilities. In addition, the median performance score of 0.78 percent exceeds the rate of 0.35 percent found in the AHRQ HCUP State Inpatient Database.[400] The testing results using 2 years of data (CY 2022 through 2023) indicated strong measure reliability, with signal-to-noise reliability scores ranging from 0.9998 to 0.9999, and therefore this measure demonstrates high reliability using 2 years of data.[401] Data element validity testing was conducted with two hospitals and results from this testing showed strong agreement between EHR data and patient chart-abstracted data for nearly all data elements and moderate to excellent sensitivity and specificity results for classifying patients into the denominator and numerator. There was moderate to low sensitivity for classifying patients as denominator exclusions, but these findings were likely driven by specific limitations of the hospitals involved in testing rather than indicative of broader validity limitations.

(4) Pre-Rulemaking Process and Measure Endorsements

(a) Recommendations From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement website for details on the Pre-Rulemaking Measure Review process convened by the CBE, including the voting procedures used to reach consensus on measure recommendations.[402] [403] The Pre-Rulemaking Measure Review Hospital Committee, consisting of both the Pre-Rulemaking Measure Review Hospital Recommendation Group (hereafter referred to as the Recommendation Group) and Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available ''2025 Measures Under Consideration List,'' including the Hospital Harm—Postoperative VTE measure.[404]

The voting results of the Recommendation Group for the proposed adoption of the Hospital Harm—Postoperative VTE measure in the Hospital Inpatient Quality Reporting Program were: 7 members (35 percent) recommended adopting the measure into the Hospital Inpatient Quality Reporting Program, and 13 members (65 percent) voted not to recommend the measure for adoption.[405] With 65 percent of the votes not to recommend, consensus was not reached, with the majority of the Recommendation Group expressing some concern about use of the measure in the Hospital Inpatient Quality Reporting Program.

Some Recommendation Group members who voted to support adoption of the Hospital Harm—Postoperative VTE measure in the Hospital Inpatient Quality Reporting Program provided several considerations with their vote. These considerations were concerns regarding the proposed 30-day window, concern that the timeline for adoption is unclear, and a recommendation to test the measure in additional EHR systems.

Recommendation Group members who voted not to recommend provided the following rationales: (1) concerns regarding the proposed 30-day timeframe; (2) concerns regarding potential overlap with the PSI 12 measure; (3) concerns regarding potential unintended consequences; (4) recommendations for methodological refinements; (5) concerns regarding technical implementation within EHR systems; (6) lack of clarity regarding the measure's ability to meaningfully advance quality; and (7) concerns that the measure has not been endorsed by the CBE. We address each of these concerns in detail in the following paragraphs.

Regarding concerns that the timeline for adoption is unclear, we note that we proposed to adopt the Hospital Harm—Postoperative VTE measure beginning with the CY 2028 reporting period/FY 2030 payment determination as an option for self-selection. That is, participating hospitals may select the Hospital Harm—Postoperative VTE measure as one of the three self-selected eCQMs to be reported in addition to three mandatory eCQMs. We refer readers to Table IX.C.5 for the full list of eCQMs available for self-selection. In addition, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19600 through 19604), we proposed that Hospital Harm eCQMs would become mandatory after two years of being an option for self-selection. If that policy is finalized, the Hospital Harm—Postoperative VTE measure would become mandatory beginning with the CY 2030 reporting period/FY 2032 payment determination.

[396] Partnership for Quality Measurement. Measurement Data Report, Downloads, Hospital Harm—Postoperative Venous Thromboembolism. Available at: *https://p4qm.org/measures/5325e.*

[397] Partnership for Quality Measurement. Risk Adjustment, under the Scientific Acceptability Tab, Hospital Harm—Postoperative VTE. Available at: *https://p4qm.org/measures/5325e.*

[398] Partnership for Quality Measurement. Scientific Acceptability Tab, Hospital Harm—Postoperative VTE. Available at: *https://p4qm.org/measures/5325e.*

[399] Partnership for Quality Measurement. Under the Performance Gap, under Importance Tab. Available at: *https://p4qm.org/measures/5325e.*

[400] Agency for Healthcare Research and Quality. Patient Safety Indicators (PSI) Benchmark Data Tables, v. 2025. AHRQ PSI Technical Documentation, Version v2025. Available at: *https://qualityindicators.ahrq.gov/measures/psi_resources.*

[401] Partnership for Quality Measurement. Reliability web page, under the Scientific Acceptability Tab, Hospital Harm—Postoperative Venous Thromboembolism. Available at: *https://p4qm.org/measures/5325e.*

[402] Partnership for Quality Measurement. Pre-Rulemaking Measure Review web page. Available at: *https://p4qm.org/prmr/about.*

[403] We note the Pre-Rulemaking Measure Review voting process was updated in 2025. We refer readers to the corresponding footnote in section IX.C.3.a.(4)(a) of this final rule for details on the updated Pre-Rulemaking Measure Review voting process.

[404] Centers for Medicare & Medicaid Services. (2025). 2025 Measures Under Consideration List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview.*

[405] Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendation Group Final Meeting Summary: Hospital Committees. Available at: *https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf.*

Regarding the recommendation to test the measure in additional EHR systems, we used test sites collectively using four EHR systems (specifically, Epic, Allscripts, Cerner, and Meditech) which represent the majority of EHR systems in the United States.[406] We refer readers to section IX.C.3.b.(3)(c) for details on measure testing, including measure reliability and validity. If this eCQM is finalized for adoption into the Hospital Inpatient Quality Reporting Program, we note that as a part of routine measure maintenance we conduct ongoing monitoring and evaluation of our measures to identify potential unintended consequences.

With respect to the 30-day timeframe, we note that 30 days post-discharge is a common window for assessing adverse events stemming from a hospital admission. The Hospital Inpatient Quality Reporting Program includes several measures that cover the 30-day period post discharge, such as the Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications Measure and the Hybrid Hospital-Wide All-Cause Readmission Measure. With respect to using a 30-day timeframe for capturing postoperative VTE events, evidence shows that roughly one third of VTEs occur between postoperative day 14 and the end of the fourth week after surgery.[407]

We understand the concern regarding potential overlap with PSI 12, which is a claims-based measure of perioperative PE and DVT rate included in the Patient Safety and Adverse Events Composite (PSI 90 composite), and only captures care provided for Medicare beneficiaries. The Hospital Harm—Postoperative VTE measure is an all-payer eCQM, and therefore captures care provided for all patients rather than Medicare patients only. For this reason, we believe this measure has the potential to serve as a replacement for the claims-based PSI 12 measure in the future.

With respect to concerns about unintended consequences, including overtreatment and unnecessary use of anticoagulation therapies, we note that as a part of routine measure maintenance we conduct ongoing monitoring and evaluation of our measures to identify potential unintended consequences. Furthermore, we may consider adopting a measure focused on overuse of anticoagulation medication in future measure development and rulemaking.

Members of the Recommendation Group who suggested methodological refinements specifically recommended including clearer diagnostic criteria for VTE. The measure specifies that a stay must have documentation of both an imaging procedure to diagnose the VTE and initiation of anticoagulant therapy within 24 hours of the imaging procedure. The measure further requires that the anticoagulant therapy be delivered at a dose appropriate for therapeutic treatment of VTE, as opposed to a lower dose appropriate for VTE prophylaxis or maintenance therapy for atrial fibrillation. In concert, the three numerator requirements—(a) documentation of a diagnostic imaging procedure, (b) administration of anticoagulant therapy within 24 hours of the imaging procedure, and (c) for the anticoagulant to be provided at a dose consistent with VTE treatment—would minimize the chance for misclassification. We refer readers to the Electronic Clinical Quality Improvement (eCQI) Resource Center (*https://ecqi.healthit.gov/ecqm/hosp-inpt/2028/cms1061v1*) for more details on the measure specifications, including more details on how a postoperative VTE is determined.

Members of the Recommendation Group who had concerns regarding technical implementation in EHRs were concerned that hospitals in systems with a single enterprise-wide EHR may appear to perform worse on the measure because post-discharge VTE events are more likely to be captured. We note that this measure relies on capturing data regarding an imaging procedure to diagnose the VTE and initiation of anticoagulant therapy within 24 hours of the imaging procedure within the same EHR system in which the qualifying surgery was documented, which may cause systems with multiple EHRs to appear to perform better on this measure because they capture fewer post-discharge VTE events. However, given that many numerator-qualifying VTE events occur during the initial hospitalization, and approximately 75 percent of patients with post-surgical complications return to their discharging hospital,[408] [409] we expect that the vast majority of data on postoperative VTEs would be available within the reporting hospital's EHR.

With respect to questions about how the Hospital Harm—Postoperative VTE measure advances quality, adopting a measure that evaluates the frequency of postoperative VTEs incentivizes hospitals to evaluate their current procedures and implement quality improvement initiatives to reduce the occurrences of this preventable condition.

With respect to concerns raised by Recommendation Group members that the measure had not been endorsed by the CBE, the Hospital Harm—Postoperative VTE measure was submitted to the CBE for the Fall 2025 endorsement cycle. We note that the CBE had not yet met to review the Hospital Harm—Postoperative VTE measure for endorsement at the time of the Recommendation Group review, but it subsequently did so and endorsed the measure with conditions. We refer readers to section IX.C.3.b.(4)(b) of this final rule for a further discussion of the results of the CBE's endorsement decision.

After taking these recommendations and concerns into consideration, we proposed to adopt the Hospital Harm—Postoperative VTE measure in the Hospital Inpatient Quality Reporting Program beginning with the FY 2030 payment determination (91 FR 19585 through 19588).

(b) Measure Endorsement

We refer readers to the Partnership for Quality Measurement website for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. The Hospital Harm—Postoperative VTE eCQM was submitted for review in the Fall 2025 cycle. The Management of Acute and Chronic Conditions Recommendation Group reviewed the Hospital Harm—Postoperative VTE eCQM (CBE# 5325e) on February 4, 2026. The voting results of the Recommendation Group were: 2

[406] Holmgren AJ, Apathy NC. (2023). Trends in US Hospital Electronic Health Record Vendor Market Concentration, 2012–2021. J Gen Intern Med. *Journal of general internal medicine, 38*(7), 1765–1767. Available at: *https://pmc.ncbi.nlm.nih.gov/articles/PMC10212829/*.

[407] Singh, T., Lavikainen, L. I., Halme, A. L. E., Aaltonen, R., Agarwal, A., Blanker, M. H., Bolsunovskyi, K., Cartwright, R., García-Perdomo, H., Gutschon, R., Lee, Y., Pourjamal, N., Vernooij, R. W. M., Violette, P. D., Haukka, J., Guyatt, G. H., & Tikkinen, K. a. O. (2023). Timing of symptomatic venous thromboembolism after surgery: meta-analysis. *British Journal of Surgery, 110*(5), 553–561. Available at: *https://doi.org/10.1093/bjs/znad035*.

[408] Lawson, E. H., Hall, B. L., Louie, R., Ettner, S. L., Zingmond, D. S., Han, L., Rapp, M., & Ko, C. Y. (2013). Association Between Occurrence of a Postoperative Complication and Readmission: Implications for Quality Improvement and Cost Savings. *Annals of Surgery, 258*(1), 10–18. Available at: *https://doi.org/10.1097/sla.0b013e31828e3ac3*.

[409] Brooke, B. S., Goodney, P. P., Kraiss, L. W., Gottlieb, D. J., Samore, M. H., Finlayson, S. R. G. (2015). Readmission destination and risk of mortality after major surgery: an observational cohort study. In *The Lancet* (Vol. 386, pp. 884–895). Available at: *http://dx.doi.org/10.1016/S0140-6736(15)60087-3*.

members (11 percent) voted to endorse the measure; 15 members (79 percent) voted to endorse the measure with conditions; and 2 members (11 percent) voted not to endorse the measure. With more than 75 percent of members voting to endorse the measure or endorse the measure with conditions, the Recommendation Group reached consensus to endorse the measure with conditions.[410] The condition is that by the next measure maintenance review (5 years) the developer will have explored other risk factors that may impact post-discharge VTE (for example, social determinants of health). In connection with this condition, we will continue to monitor and evaluate the risk adjustment methodology to determine if changes are needed.

(5) Data Source, Submission, and Public Reporting

The Hospital Harm—Postoperative VTE eCQM uses data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' certified health IT using the patient-level data and then submitted by hospitals to CMS. All data elements necessary to calculate the measure, including the numerator and denominator as well as to apply the risk adjustment model, are defined within value sets available in the Value Set Authority Center.[411] Testing was performed to confirm the feasibility of the measure, data elements, and validity of the numerator, using clinical adjudicators who validated the EHR data compared with medical chart-abstracted data. Testing in six hospitals using three EHR systems demonstrated that all critical data elements can be reliably and consistently captured, and measure implementation is feasible.

We refer readers to section IX.C.8.c. of this final rule for discussion of previously finalized eCQM reporting and submission policies, and our modifications to establish mandatory reporting of all Hospital Harm eCQMs after an initial period of voluntary reporting in the program. Additionally, we refer readers to section IX.F.9. of this final rule for discussion of a similar policy to adopt this measure in the Medicare Promoting Interoperability Program.

We invited public comment on our proposal to adopt the Hospital Harm—Postoperative VTE eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination.

Comment: Many commenters supported adoption of the Hospital Harm—Postoperative VTE eCQM. Some commenters supported this measure because it is an eCQM, stating that eCQMs improve the timeliness of quality data. Some commenters stated VTE is an important healthcare topic and that adding an outcome measure to the portfolio of measures addressing VTE will improve the ability to evaluate hospitals for the effectiveness of care, not just the processes.

Response: We thank these commenters for their support and agree that the outcome measure will help evaluate the effectiveness of care.

Comment: A few commenters supported adoption of the Hospital Harm—Postoperative VTE eCQM and stated that this measure is a critical step towards a process measure of structured VTE risk assessment. These commenters stated that this would both address VTE prevention and concerns about anticoagulant overuse.

Response: We thank the commenters for their support of the Hospital Harm—Postoperative VTE eCQM and their recommendation to consider a process measure of structured VTE risk assessment.

Comment: Many commenters expressed concern that the measure was not recommended by the Recommendation Group and recommended that CMS address the Recommendation Group's concerns and return the measure to the Pre-Rulemaking Measure Review process and resubmitted to the Measures Under Consideration List.

Response: We understand commenters' concern that the Recommendation Group did not vote to recommend this measure for adoption into the Hospital Inpatient Quality Reporting Program. Members who voted not to recommend this measure raised the following concerns about the Hospital Harm—Postoperative VTE eCQM: (1) concerns regarding the proposed 30-day timeframe; (2) concerns regarding potential overlap with the PSI 12 measure; (3) concerns regarding potential unintended consequences; (4) recommendations for methodological refinements; (5) concerns regarding technical implementation within EHR systems; (6) concerns regarding a lack of clarity on the measure's ability to meaningfully advance quality; and (7) concerns that the measure has not been endorsed by the CBE. We addressed each of these topics in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19587 through 19588) and address them further in the subsequent comments and responses. Regarding the recommendation that we return the measure to the Measures Under Consideration List, because we have addressed each of the Recommendation Group's concerns without updates to the measure specifications, it is not necessary to return the measure to the Pre-Rulemaking Measure Review process. Doing so would delay adoption of this outcome measure that addresses an important patient safety topic.

Comment: Some commenters expressed concern regarding the 30-day post discharge attribution period. These commenters stated that many factors outside of a hospital's control, including patient adherence, post-acute care transitions, social risk factors, and outpatient follow-up, can contribute to post-discharge VTE.

Response: We would like to clarify that the measurement period includes the 30 days following the first surgical procedure, rather than ''30 days post-discharge,'' which may include some post-discharge period, but is not dependent on the date of discharge. We understand commenters' concern that post discharge outcomes are influenced by many factors, including factors outside of the hospital's control. We note that while hospitals cannot directly control elements such as patient adherence and outpatient follow-up, a hospital's responsibility is to provide education and support to help patients and their caregivers understand the importance of adhering to medical recommendations and to help prepare patients for outpatient follow-up.

Comment: A few commenters stated that there is a lack of evidence to support the 30 days as a timeframe for associating VTE events with a surgical procedure. A commenter stated that CMS had not provided evidence that a VTE which occurs after discharge is associated with the care received during the inpatient stay.

Response: We selected 30 days post-surgery because this is a period of high-risk for post-surgical VTEs. Evidence shows that roughly one third of VTEs following surgery can occur between postoperative day 14 and the end of the fourth week after surgery.[412] Because of

[410] Partnership for Quality Measurement. (April 2026). Fall 2025 Cycle Endorsement and Maintenance (E&M) Technical Report: Management of Acute Events and Chronic Conditions. Available at: *https://p4qm.org/document/6096.*

[411] To access the value sets for the measure, please visit the Value Set Authority Center, sponsored by the National Library of Medicine, at *https://vsac.nlm.nih.gov/.*

[412] Singh, T., Lavikainen, L.I., Halme, A.L.E., Aaltonen, R., Agarwal, A. Blanker, M.H., Bolsunovskyi, K., Cartwright, R., García-Perdomo, H., Gutschon, R., Lee, Y., Pourjamal, N., Vernooij, R.W.M., Violette, P.D., Haukka, J., Guyatt, G.H., & Tikkinen, K.A.O. (2023). Timing of symptomatic

Continued

the high incidence of VTEs in this period, we encourage hospitals to ensure patient education and access to appropriate VTE prophylaxis prior to discharge. This care coordination and preparation for safe discharge is an important part of inpatient care. There are established therapies that can reduce the risk of a VTE, but failure to prescribe or a delay in prescribing appropriate VTE prophylaxis can result in a higher risk of postoperative VTE. For example, one study found that delays or interruptions in thromboprophylaxis were associated with two to three times the risk of VTE compared to patients who did not experience a delay.[413] Hospital care processes can reduce the risk of hospital-acquired VTE through the integration of evidence-based guidelines into hospital protocols and the use of VTE-risk assessment and physician alerts to improve the use of VTE prophylaxis.[414] While VTE events post-discharge are not completely within a hospital's control, the timeliness of interventions taken prior to and post-surgery coupled with the role of patient education and discharge planning during the stay serve a significant role in preventing these events.

Comment: A commenter recommended mitigating the concern that VTE incidence post-discharge is outside the control of the hospital by stratifying publicly reported data for in-hospital versus post-discharge events.

Response: We thank the commenter for the recommendation to stratify publicly reported data for in-hospital versus post-discharge events. As part of our routine measure monitoring, we will consider whether trends in measure performance warrant stratifying the publicly reported data.

Comment: A few commenters stated that there is potential overlap between the Hospital Harm—Postoperative VTE eCQM and PSI 12, which is a claims-based measure of perioperative PE and DVT rate included in the PSI 90 composite. A commenter supported adoption of the Hospital Harm—Postoperative VTE eCQM, stating that this alignment reduces administrative burden for hospitals. Several commenters recommended transitioning from PSI measures to eCQMs, stating that eCQMs provide more accurate information. Some commenters specifically requested that CMS provide a plan to replace PSI 12 with the Hospital Harm—Postoperative VTE eCQM. A commenter also requested that CMS establish a plan to replace all components of the PSI 90 composite with eCQMs.

Response: We thank the commenter for the support of adopting the Hospital Harm—Postoperative VTE eCQM to align with PSI 12. We agree that there is some overlap between PSI 12 and the Hospital Harm—Postoperative VTE eCQM. We note that the Hospital Harm—Postoperative VTE eCQM is an all-payer eCQM, and therefore captures care provided for all patients whereas PSI–12 only captures data related to Medicare patients. Therefore, we believe that this measure has the potential to serve as a replacement for the claims-based PSI 12 measure in the future. However, as part of the PSI 90 composite, all hospitals are required to report the PSI 12 measure, and currently the Hospital Harm—Postoperative VTE eCQM is only available for self-selection. As we gain experience with collecting Hospital Harm eCQM data, we will consider replacing some or all components of the PSI 90 composite with these measures.

Comment: Some commenters recommended that CMS monitor for unintended consequences such as inappropriate use of anticoagulants and identify strategies to ensure that these potential unintended consequences are mitigated. Another commenter recommended additional testing for potential unintended consequences, such as delayed surgery or limits to appropriate anesthesia.

Response: We thank commenters for their recommendations. As a part of our routine monitoring and evaluation, we will watch for any unintended consequences from the adoption of the Hospital Harm—Postoperative VTE eCQM. We note that we conduct annual measure re-evaluations to confirm that the measures are performing as intended. We update the specifications and post technical release notes annually on the eCQI Resource Center, available at: *https://ecqi.healthit.gov/ecqm/hosp-inpt/2028/cms1061v1.*

Comment: A few commenters stated that the Hospital Harm—Postoperative VTE eCQM does not include clear diagnostic criteria for VTE.

Response: Postoperative VTE cases can be identified for inclusion in the numerator in multiple ways. For example, documentation in the medical record of a diagnosis of VTE that was not present when the patient was admitted to the hospital for an inpatient stay that included surgery would qualify the admission for the numerator. Alternatively, an inpatient admission in which a patient had surgery and subsequently had a diagnostic imaging procedure performed followed by an order for anticoagulation therapy would also qualify for the numerator. A postoperative VTE that occurs during a subsequent hospital stay within 30 days of the surgical procedure would count toward the numerator if there is documentation of a diagnosis of VTE and anticoagulation therapy ordered or prescribed during that hospital stay. We refer readers to the Partnership for Quality Measurement website (*https://p4qm.org/measures/5325e*) for more details on the measure specifications, including more details on how a postoperative VTE is determined. We note that the Measure Calculation page within the Measure Specs tab includes a data dictionary that provides details regarding determination of imaging studies, use of anticoagulation therapies, and diagnosis codes for VTEs.

Comment: A commenter recommended refining the Hospital Harm—Postoperative VTE eCQM prior to inclusion in the Hospital Inpatient Quality Reporting Program. Commenters specifically recommended reviewing the measure for additional clinically appropriate exclusions (such as pending surgery).

Response: This measure evaluates inpatient encounters where at least one surgical procedure was performed in the operating room, with surgery being a defining component of the measure population rather than a condition warranting exclusion. The measure evaluates VTE events in relation to the index surgical encounter, which may trigger postoperative hypercoagulability and increase VTE risk for several weeks. We recognize that patients may undergo planned or subsequent procedures, however the measure does not evaluate planned, pending, or subsequent surgeries outside of the index surgical encounter within the 30-day timeframe. We note that the measure team conducted a comprehensive environmental scan that assessed perioperative VTE in the inpatient setting, convened a series of TEP meetings, and obtained public feedback to develop the exclusion list for the measure.

Comment: A few commenters recommended that CMS continue to evaluate risk factors, including social

venous thromboembolism after surgery: meta-analysis, *BJS, 110*(5), 553–561. Available at: *https://doi.org/10.1093/bjs/znad035.*

[413] Henke, P.K., Kahn, S.R., Pannucci, C.J., Secemksy, E.A., Evans, N.S., Khorana, A.A., Creager, M.A., & Pradhan, A.D. (2020). Call to action to prevent venous thromboembolism in hospitalized patients: A policy statement from the American Heart Association. *Circulation, 141*(24). Available at: *https://doi.org/10.1161/cir.0000000000000769.*

[414] Geerts, W. (2009). Prevention of venous thromboembolism: a key patient safety priority. Journal of Thrombosis and Haemostasis, 7, 1–8. Available at: *https://www.sciencedirect.com/science/article/pii/S1538783622174040.*

risk factors, that affect post-discharge VTE outcomes. A few commenters stated that the risk-adjustment model may not fully account for patient complexity and recommended that CMS continue refining the risk-adjustment methodology to ensure fair comparisons across hospitals. A commenter recommended that CMS ensure that measures distinguish outcomes within a hospital's control versus those driven by other factors.

Response: We understand commenters' concerns that factors outside of a hospital's control may affect the patient's risk for VTE. We note that the measure developer developed a conceptual model based on input from a literature review, established risk indices, clinical experts, and our TEP. This conceptual model, which is posted as part of the risk adjustment methodology report on the eCQI Resource Center, was then empirically tested using patient level data.[415] This rigorous process, which was informed by multiple clinical experts and validated scoring indices, yielded a robust risk adjustment model. However, we acknowledge that there may be opportunities to identify additional risk factors that may influence postsurgical VTE incidence. When the CBE endorsed the Hospital Harm—Postoperative VTE eCQM, they included the condition that by the next measure maintenance review (5 years) the developer will have explored other risk factors that may impact post-discharge VTE (for example, social determinants of health). In connection with this condition, we will continue to monitor and evaluate the risk adjustment methodology to determine if changes are needed.

Comment: Some commenters expressed concern that the data element validity testing was limited to two vendor systems.

Response: We understand commenters' concern regarding data element validity testing. The testing in which we calculated the percent agreement for critical data elements using chart abstracted data to calculate percent agreement was limited to two systems, which represent over 58 percent of the United States hospital EHR market.[416] [417] We note that we collaborated with 15 hospitals, which were not limited to these two vendor systems, to complete the eCQM feasibility scorecard, which assesses whether the data required for hospital-level calculation are available in structured fields, are collected through routine workflows, are documented using standard terminology, and are accurate.[418] Both of these tests demonstrated that these data elements were feasible and valid. The testing was consistent with the requirement for eCQM testing in the Measures Management System Blueprint, which requires evidence of testing with at least two different electronic health records.[419]

Comment: A few commenters expressed concern regarding whether an eCQM can accurately and completely capture post-discharge VTEs. These commenters stated that VTEs may not be completely captured in EHR data if the VTE is recorded in another hospital or health system's EHR. Some commenters requested that CMS provide additional details regarding the workflow for collecting data subsequent to discharge. A few commenters expressed concern that because QRDA I files are specific to hospitals, VTE events may not be counted if patients seek post-discharge care at other facilities. A few commenters recommended that CMS specify this as a claims-based measure to improve data completeness. Another commenter recommended that CMS wait until the measure is available as a dQM (that is, available to report using the Fast Healthcare Interoperability Resources® (FHIR®) standard) and adopt it at that time.[420] Some commenters expressed concern regarding variability in data capture across EHR systems. A few commenters expressed concern that the measure may not be feasible to implement at hospitals without advanced technology.

Response: We note that this measure relies on capturing data regarding an imaging procedure to diagnose the VTE and initiation of anticoagulant therapy within 24 hours of the imaging procedure within the same EHR system in which the qualifying surgery was documented. We understand commenters' concerns that this may lead to some VTE events not being captured within the EHR data. However, given that many numerator-qualifying VTE events occur during the initial hospitalization, and approximately 75 percent of patients with post-surgical complications return to hospital where the surgery was performed,[421] [422] we expect that the vast majority of data on postoperative VTEs would be available within the reporting hospital's EHR. Furthermore, we worked with multiple hospitals to ensure that the data required for hospital-level calculation are available in structured fields, are collected through routine workflows, are documented using standard terminology, and are accurate.

Comment: A commenter stated that QRDA files are specific to quarters and requested that CMS clarify how the measure will be calculated if the hospitalization and VTE event are in different quarters.

Response: VTE events would be assessed within 30 days from the end of the first surgical procedure of the index hospitalization. Hospitals reporting this measure would be required to include all relevant data within a given QRDA submission, even if that data occurs during a prior quarter. For example, if a patient has a denominator-eligible surgical inpatient encounter within Q1 and a subsequent inpatient encounter in Q2 with a VTE event that meets numerator criteria, the hospital would need to submit data on both inpatient encounters as part of the Q2 QRDA data submission. We will provide hospitals with resources to support compliance with this requirement through vehicles such as Expert-to-Expert webinars.

Comment: A few commenters recommended that CMS limit the measure to admissions with a discharge date on or before November 30. These commenters stated that this would ensure the entire measurement period falls within the calendar year, which the commenters stated would provide hospitals more time to capture post-discharge events, validate data, and complete data submission.

---

[415] Partnership for Quality Measurement. Risk Adjustment, under the Scientific Acceptability Tab, Hospital Harm—Postoperative VTE. Available at: *https://p4qm.org/measures/5325e.*

[416] Partnership for Quality Measurement. Validity, under the Scientific Acceptability Tab, Hospital Harm—Postoperative VTE. Available at: *https://p4qm.org/measures/5325e.*

[417] Fierce Healthcare. (May 16, 2026). Epic grows EHR footprint among small health systems even as overall market sales decline in 2025. Available at: *https://www.fiercehealthcare.com/health-tech/epic-continues-grow-ehr-market-share-it-makes-gains-small-health-systems.*

[418] Partnership for Quality Measurement. Feasibility Tab, Hospital Harm—Postoperative VTE. Available at: *https://p4qm.org/measures/5325e.*

[419] Centers for Medicare & Medicaid Services. Blueprint Measure Lifecycle: Testing and Evaluation for Special Measures. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-testing/overview.*

[420] FHIR® is the registered trademark of Health Level Seven International (HL7), and its use does not constitute endorsement by HL7.

[421] Lawson, E.H., Hall, B.L., Louie, R., Ettner, S.L., Zingmond, D.S., Han, L., Rapp, M., & Ko, C.Y. (2013). Association Between Occurrence of a Postoperative Complication and Readmission: Implications for Quality Improvement and Cost Savings. *Annals of Surgery, 258*(1), 10–18. Available at: *https://doi.org/10.1097/sla.0b013e31828e3ac3.*

[422] Brooke, B.S., Goodney, P.P., Kraiss, L.W., Gottlieb, D.J., Samore, M.H., Finlayson, S.R.G. (2015). Readmission destination and risk of mortality after major surgery: an observational cohort study. The Lancet (Vol. 386, pp. 884–895). Available at: *http://dx.doi.org/10.1016/S0140-6736(15)60087-3.*

Response: We understand commenters' concern that including VTE events that occur up to 30 days after the first surgery will require hospitals to consider data past the end of the calendar year. The measure has been specified and tested to include surgeries occurring throughout the year, therefore we are not considering revising the measure to exclude surgeries during the last 30 days of the year. We note that for eCQMs the submission deadline is March 1. For VTE events that occur up to 30 days after December 31, this will leave hospitals at least one month after the end of the 30 day lookback period to retrieve data from their EHRs for submission to CMS. However, we will continue to assess these considerations and seek feedback from stakeholders and implementers as part of ongoing measure evaluation and maintenance activities.

Comment: A commenter expressed concern that the Hospital Harm—Postoperative VTE eCQM has not been endorsed by the CBE.

Response: The Hospital Harm—Postoperative VTE eCQM was endorsed with conditions in the Fall 2025 cycle. The Management of Acute and Chronic Conditions Recommendation Group reviewed the Hospital Harm—Postoperative VTE eCQM (CBE# 5325e) on February 4, 2026. The voting results of the Recommendation Group were: 2 members (11 percent) voted to endorse the measure; 15 members (79 percent) voted to endorse the measure with conditions; and 2 members (11 percent) voted not to endorse the measure. With more than 75 percent of members voting to endorse the measure or endorse the measure with conditions, the Recommendation Group reached consensus to endorse the measure with conditions. The condition is that by the next measure maintenance review (5 years) the developer will have explored other risk factors that may impact post-discharge VTE (for example, social determinants of health). In connection with this condition, we will continue to monitor and evaluate the risk adjustment methodology to determine if changes are needed.

Comment: A few commenters recommended that CMS delay adoption of the Hospital Harm—Postoperative VTE eCQM to allow hospitals additional time to coordinate with vendors, establish workflows, train staff and monitor measure performance. A few commenters stated that adopting multiple eCQMs across the inpatient and outpatient quality reporting programs leads to operational burden and delays in clinician engagement. A commenter requested that CMS establish a timeline for adopting the Hospital Harm—Postoperative VTE eCQM.

Response: We carefully consider the benefit of adopting new measures in relation to any burden on hospitals. The program's shift toward digital measures will ultimately decrease the burden for hospitals because eCQMs use electronic standards, which helps reduce the burden of manual abstraction and reporting for measured entities. We note that we proposed to adopt the Hospital Harm—Postoperative VTE eCQM as one of the measures that hospitals can self-select for reporting beginning with the CY 2028 reporting period. Following the finalization of this rule, hospitals would have 15 months until the beginning of the CY 2028 reporting period. Furthermore, hospitals that need additional time to prepare to report the Hospital Harm—Postoperative VTE eCQM would have an additional two years of self-selected reporting prior to mandatory reporting of this measure. We refer readers to section IX.C.8. of this final rule for additional information regarding mandatory reporting of the Hospital Harm—Postoperative VTE eCQM.

Comment: A few commenters recommended that CMS provide hospital-specific data files, technical documentation, and implementation guidance early enough that hospitals can prepare for measure reporting. A commenter recommended that CMS ensure that this guidance recognizes the team-based nature of VTE prevention, avoids undue administrative burden, and ensures hospital-level outcomes are not attributed to individual clinicians.

Response: Information about the Hospital Harm—Postoperative VTE eCQM is currently available on the Partnership for Quality Measurement website (*https://p4qm.org/measures/5325e*) and on the Value Set Authority Center, sponsored by the National Library of Medicine (*https://vsac.nlm.nih.gov*). Technical information is available on the eCQI Resource Center (*https://ecqi.healthit.gov/ecqm/hosp-inpt/2028/cms1061v1*). We agree with the commenter that VTE prevention is team based and note that this measure is calculated at the hospital level and does not attribute outcomes to individual clinicians. We have developed this measure to minimize administrative burden associated with information collection.

Comment: Several commenters recommended that CMS engage interested parties in ongoing implementation, maintenance, and quality improvement efforts for this measure.

Response: We appreciate commenters' interest in implementation, maintenance, and quality improvement efforts for this measure. To ensure transparency and engagement throughout the measure development process, a TEP provided direction and input from interested parties to the measure developer in every phase of the measure development process. The measure developer incorporated feedback from TEP upon their review of the measure testing results. We also submitted this measure through the Pre-Rulemaking Measure Review process for input from a multistakeholder group of clinicians, patients, and other interested parties.

Comment: A few commenters expressed concern regarding the Hospital Harm—Postoperative VTE eCQM's potential effects on rural and safety net providers. A commenter recommended that CMS evaluate the effects, including assessing whether unique case-mix variables or access limitations may skew performance outcomes or safety-net providers. Another commenter recommended that CMS provide hardship exceptions to rural, safety-net, and resource constrained providers.

Response: We understand commenters' concerns regarding potential effects on rural and safety-net providers. Because the measure is risk adjusted based on clinical and demographic factors that have been demonstrated to affect VTE risk, the measure accounts for hospitals that treat a disproportionate number of clinically complex or high-risk patients. We additionally note that the hospitals would initially have the option to self-select whether to report this eCQM to meet the eCQM reporting requirement for the Hospital Inpatient Quality Reporting Program, providing flexibility for those hospitals, including rural or safety net hospitals, that may need more time to prepare to report this measure.

After consideration of the public comments we received, we are finalizing the Hospital Harm—Postoperative VTE eCQM as proposed beginning with the CY 2028 reporting period/FY 2030 payment determination. We refer readers to section IX.F.9. of this final rule where we are finalizing the same eCQM for the Medicare Promoting Interoperability Program.

4. Removals in the Hospital Inpatient Quality Reporting Program Measure Set

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19588 through 19590), we proposed to remove three

measures from the Hospital Inpatient Quality Reporting Program beginning with the CY 2028 reporting period/FY 2030 payment determination: (1) Venous Thromboembolism Prophylaxis eCQM; (2) Intensive Care Unit Venous Thromboembolism Prophylaxis eCQM; and (3) Discharged on Antithrombotic Therapy eCQM. We provide more details on each of these proposals in the subsequent sections.

a. Removal of Two Venous Thromboembolism Electronic Clinical Quality Measures

We refer readers to the FY 2014 IPPS/LTCH PPS final rule where we adopted the Venous Thromboembolism Prophylaxis (VTE–1) and Intensive Care Unit Venous Thromboembolism Prophylaxis (VTE–2) eCQMs beginning with the CY 2014 reporting period/FY 2016 payment determination (78 FR 50807 through 50810). These measures were originally adopted as chart-abstracted measures and were later specified as eCQMs, which we adopted as optional measures for hospitals to self-select. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19588 through 19589), we proposed to remove the VTE–1 and VTE–2 eCQMs from the Hospital Inpatient Quality Reporting Program, beginning with the CY 2028 reporting period/FY 2030 payment determination, under our measure removal factor 5, the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic, as described at 42 CFR 412.140(g)(3)(i)(E), if the proposed Hospital Harm—Postoperative VTE eCQM is adopted.[423] The VTE–1 eCQM assesses the proportion of patients admitted to the hospital who received VTE prophylaxis or have documentation of why no VTE prophylaxis was given between the day of hospital admission to the day after admission or surgery end date. The VTE–2 eCQM measures the proportion of patients admitted or transferred to the intensive care unit (ICU) who received VTE prophylaxis or have documentation of why no VTE prophylaxis was given between the day of admission or transfer to the ICU to the day after admission or surgery end date.

Patient safety topics such as appropriate VTE prophylaxis continue to be high priority topics for quality measurement in the hospital inpatient setting. Since introducing the VTE–1 and VTE–2 eCQMs into the Hospital Inpatient Quality Reporting Program over a decade ago, we have developed an outcome-focused VTE eCQM, Hospital Harm—Postoperative VTE eCQM, as proposed for adoption in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19585 through 19588) beginning with the FY 2030 payment determination. The Hospital Harm—Postoperative VTE eCQM is an outcome measure that builds upon the existing process measures and evaluates the incidence of postoperative VTE events, assessing the success of the VTE prophylaxis strategies measured by the VTE–1 and VTE–2 eCQMs, and thus is more strongly associated with desired patient outcomes for this particular topic. It also aligns with our efforts to reduce burden and refine the Hospital Inpatient Quality Reporting Program's measure set by replacing two process measures with a single outcome measure. In addition, the VTE–1 and VTE–2 eCQMs were retired from The Joint Commission's ORYX® requirements effective CY 2026.[424] [425] We note that the proposed removal of the VTE–1 and VTE–2 eCQMs is contingent upon our finalizing the proposal to adopt the Hospital Harm—Postoperative VTE eCQM as discussed in section IX.C.3.b. of this final rule.

We note that we also proposed to remove the VTE–1 and VTE–2 eCQMs in the Medicare Promoting Interoperability Program beginning with the CY 2028 reporting period. For more information, we refer readers to section IX.F.9. of this final rule.

We invited public comment on our proposal to remove the VTE–1 and VTE–2 eCQMs beginning with the CY 2028 reporting period/FY 2030 payment determination.

Comment: Many commenters supported removal of the VTE–1 and VTE–2 eCQMs. Several commenters stated that the transition to the Hospital Harm—Postoperative VTE eCQM would reduce burden while focusing on patient outcomes. Several commenters stated that VTE–1 and VTE–2 should be removed regardless of whether the adoption of the Hospital Harm—Postoperative VTE eCQM is finalized.

Response: We thank the commenters for their support. We agree that transitioning to the Hospital Harm—Postoperative VTE eCQM would improve focus on patient outcomes and reduce administrative burden. We refer readers to section IX.C.3.b. of this final rule where we are finalizing our proposal to adopt the Hospital Harm—Postoperative VTE eCQM.

Comment: A few commenters supported removal of the VTE–1 and VTE–2 eCQMs but stated that it is important that publicly reported data consistently maintains information related to VTEs to ensure continued focus on this topic.

Response: We understand commenters' concerns regarding continual reporting of information related to VTEs. We refer readers to section IX.C.3.b. of this final rule in which we are including the Hospital Harm—Postoperative VTE eCQM as a measure available for hospitals to self-select beginning with the CY 2028 reporting period/FY 2030 payment determination. This aligns with the proposal to remove the VTE–1 and VTE–2 eCQMs from the measures available for hospitals to self-select beginning with the CY 2028 reporting period/FY 2030 payment determination so that there will continually be a measure related to VTEs available for hospitals to self-select for reporting. We further refer readers to section IX.C.8.c. of this final rule in which we are establishing a policy under which reporting Hospital Harm eCQMs becomes mandatory following 2 years of self-selected reporting. We note that under that policy data regarding the Hospital Harm—Postoperative VTE eCQM will be available for all participating hospitals beginning with the CY 2030 reporting period/FY 2032 payment determination.

Comment: Many commenters stated that retaining VTE–1 and VTE–2 would continue to provide clinical value. Many commenters stated that pairing the VTE–1 and VTE–2 process measures with the newly proposed VTE related outcome measure would provide a more complete clinical picture which could help hospitals understand systemic failures which lead to VTEs. A few commenters stated that retaining these process measures would continue to provide valuable information and facilitate longitudinal analysis. A commenter stated that VTE–1 and VTE–2 include a broader patient population than the Hospital Harm Postoperative VTE eCQM because these measures include non-surgical patients.

[423] We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital Inpatient Quality Reporting Program's removal factors. Removal factors are codified at 42 CFR 412.140(g)(2) and (3).

[424] The Joint Commission. (Oct. 2025). 2026 ORYX Performance Measurement Reporting Requirements. Available at: *https://jointcommission-ddsp.atlassian.net/wiki/spaces/DCS/pages/1030619137/2026+ORYX+Performance+Measurement+Reporting+Requirements.*

[425] The ORYX initiative integrates performance measurement data into The Joint Commission's standards-based survey and accreditation process to support hospitals in their quality improvement efforts through the continuous monitoring and evaluation. For more details on The Joint Commission's accreditation, we refer readers to: *https://www.jointcommission.org/en-us/accreditation/performance-measurement.*

Response: We understand commenters' concerns that outcomes data alone does not allow analysis of potential systemic failures that led to specific outcomes and that these process measures could continue to provide valuable clinical information. We encourage hospitals seeking to improve performance on outcome-related measures to analyze processes and workflows, such as appropriate and timely VTE prophylaxis, that contribute to adverse patient outcomes. We note that this analysis would likely include all patients with VTE risk, regardless of whether the patient had a planned surgical procedure, and therefore while the Hospital Harm—Postoperative VTE eCQM does not include non-surgical patients, efforts to improve performance on this measure would impact all patients at risk of VTEs. While we understand the importance of longitudinal analysis, we note that such analysis of measures on which hospitals can self-select to report, such as VTE–1 and VTE–2, may be impacted by an inconsistent set of reporting hospitals over time. We note that one of the goals of the Hospital Inpatient Quality Reporting Program is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. Replacing these two process measures with one outcome measure is an effective way to accomplish this goal. Our priority is a focus on measurable clinical outcomes such as the prevalence of postoperative VTEs as measured by the Hospital Harm—Postoperative VTE eCQM.

Comment: A few commenters stated that performance on the proposed Hospital Harm—Postoperative VTE eCQM is outside of a hospital's control and recommended retaining VTE–1 and VTE–2 until further refinements are made to the Hospital Harm—Postoperative VTE eCQM.

Response: We refer readers to section IX.C.3.b. of this final rule in which we discuss the adoption of the Hospital Harm—Postoperative VTE eCQM. In that section of this final rule, we discuss the risk adjustment of the Hospital Harm—Postoperative VTE eCQM and strategies that hospitals can take to reduce postoperative VTE incidence. Given the importance of VTE as a clinical outcome and the strategies available to hospitals to reduce the risk of VTE, further refinements to the Hospital Harm—Postoperative VTE eCQM are not necessary and it is appropriate to adopt this outcome eCQM while removing the associated process measures from the Hospital Inpatient Quality Reporting Program measure set.

Comment: Several commenters expressed concern that the number of eCQMs available for self-selection is becoming too small. A few of these commenters stated that transitioning to other self-selected eCQMs would require time for hospitals to build, validate, and adjust workflows to meet the requirements of newly selected eCQMs. A commenter stated that most of the operational burden associated with an eCQM is in configuring data capture, mapping value sets, and aligning workflows with the measure logic. This commenter stated that removing these eCQMs would not reduce burden for hospitals, which may continue to monitor performance on these measures to support quality improvement efforts.

Response: We recognize that the number of eCQMs available for self-selection would be reduced by the removal of these eCQMs and the transition of other eCQMs to mandatory reporting. We also understand commenters' concerns that the operational burden of eCQM reporting is largely associated with system configuration and workflow updates. However, it is important to continue to evolve the Hospital Inpatient Quality Reporting Program's measure set to address the most meaningful quality measures and continue to incentivize improvement in the quality of care provided to patients. By replacing process measures with an outcome measure we can ensure that the Hospital Inpatient Quality Reporting Program's measure set advances to improve patient safety and outcomes.

After consideration of the public comments we received, we are finalizing our proposal to remove the VTE–1 and VTE–2 eCQMs beginning with the FY 2030 payment determination. We refer readers to section IX.F.9. of this final rule where we are finalizing removal of these same eCQMs for the Medicare Promoting Interoperability Program.

b. Removal of the Discharged on Antithrombotic Therapy Electronic Clinical Quality Measure Beginning With the FY 2030 Payment Determination

We refer readers to the FY 2014 IPPS/LTCH PPS final rule where we adopted the Discharged on Antithrombotic Therapy (STK–02) eCQM into the Hospital Inpatient Quality Reporting Program eCQM measure set for self-selected reporting beginning with the CY 2014 reporting period (78 FR 50807 through 50810).[426] This measure was originally adopted as a chart-abstracted measure and was later specified as an eCQM, which we adopted as an option for hospitals to self-select (76 FR 51633 through 51634 and 78 FR 50807 through 50810).[427] The STK–02 eCQM assesses the proportion of patients hospitalized with ischemic stroke who are prescribed or continue antithrombotic therapy at the time of hospital discharge. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19589 through 19590), we proposed to remove the STK–02 eCQM from the Hospital Inpatient Quality Reporting Program, beginning with the CY 2028 reporting period/FY 2030 payment determination under measure removal factor 1, measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made, as described at 42 CFR 412.140(g)(3)(i)(A).[428]

Over four of the most recent reporting periods, hospital performance has been so high and unvarying that it meets our criteria for ''topped out'' under measure removal factor 1 (83 FR 41540 through 41544), that is, statistically indistinguishable performance at the 75th and 90th percentiles, and truncated coefficient of variation ≤0.10, see Table IX.C.2. Since the STK–02 eCQM is a self-selected eCQM, meaning that not all hospitals are required to report it, we considered that the topped out status may not reflect national performance. However, the number of hospitals reporting on this measure has remained consistently high, with approximately two-thirds of the Hospital Inpatient Quality Reporting Program-eligible hospitals reporting since FY 2023. We therefore believe that the measure results represent most hospitals' performance on this measure. Further, the CBE recently selected this measure for review for potential removal from the Hospital Inpatient Quality Reporting Program as part of the Measure Set Review process and ultimately recommended its discontinuation due to minimal variation and stable median performance across hospitals.[429] The

[426] Partnership for Quality Measurement. STK–02: Discharged on Antithrombotic Therapy. Available at: *https://p4qm.org/measures/0435e.*

[427] For more details on STK–02 specifications, we refer readers to the eCQI Resource Center available at: (*https://ecqi.healthit.gov/eh-cah*).

[428] We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital Inpatient Quality Reporting Program's removal factors. Removal factors are codified at 42 CFR 412.140(g)(2) and (3) (88 FR 59144).

[429] Partnership for Quality Measurement (2025). 2025 Measure Set Review Draft Meeting Summary.

STK–02 eCQM was also retired from The Joint Commission's ORYX® requirements effective CY 2026.[430] [431]

TABLE IX.C.2.: STK-02 DATA FROM REPORTING HOSPITALS Q1 2020 THROUGH Q4 2024

Payment Determination	Performance Period	Mean	75th Percentile	90th Percentile	Truncated COV
FY 2023	Q1 2021- Q4 2021	91.66	100.00	100.00	0.055
FY 2024	Q1 2022- Q4 2022	92.26	99.00	100.00	0.045
FY 2025	Q1 2023- Q4 2023	92.71	99.00	100.00	0.038
FY 2026	Q1 2024- Q4 2024	93.13	99.00	100.00	0.034

Stroke has been and remains a priority topic for quality measurement in the hospital inpatient setting for over a decade due to its high prevalence and substantial impact on quality of life, disability, and death (76 FR 51633 through 51634).[432] We explained in the proposed rule that if the STK–02 eCQM measure is removed from the Hospital Inpatient Quality Reporting Program, we would continue to address quality of care for stroke patients through the use of other clinical outcome measures. These measures include the Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate Following Acute Ischemic Stroke (MORT–30–STK) measure, which assesses the hospital-level, risk-standardized mortality rate after hospital admission for acute ischemic stroke (78 FR 50798 through 50802, most recently modified at 90 FR 36997 through 37001) as well as the remaining two eCQMs that are a part of the stroke measure set, including the Anticoagulation Therapy for Atrial Fibrillation (STK–03) eCQM and the Antithrombotic Therapy by the End of Hospital Day Two (STK–05) eCQM (76 FR 51633 through 51634, 78 FR 50807 through 50810).

We note that we also proposed to remove the STK–02 eCQM in the Medicare Promoting Interoperability Program beginning with the CY 2028 reporting period. For more information, we refer readers to section IX.F.9. of this final rule.

We invited public comment on our proposal to remove the STK–02 eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination.

Comment: Many commenters supported our proposal to remove the STK–02 eCQM from the Hospital Inpatient Quality Reporting Program because the measure no longer provides information that is actionable or useful given the lack of meaningful differentiation in hospital performance. Several commenters supported removal of this measure and agreed that removing lower-value or topped-out measures reduces reporting burden, allowing hospitals to focus clinical and health IT resources on newer digital measures, interoperability requirements, and reporting capabilities. A few commenters supported our continued transition toward outcome-focused eCQMs that focus on patient harm, provide greater clinical value, and reduce unnecessary administrative burden.

Response: We thank commenters for their support and agree that removing this measure will allow hospitals to focus on eCQMs that provide greater clinical value.

Comment: A commenter supported the removal of this measure and recommended developing a replacement outcome measure that would close a longstanding gap in stroke quality reporting.

Response: We agree with the commenter that outcomes for stroke patients are an important topic in the inpatient setting and will continue to evaluate additional measures related to stroke care for the inpatient quality measurement sets.

Comment: Several commenters did not support removing the STK–02 eCQM because it significantly reduces flexibility in meeting eCQM reporting requirements and recommended maintaining this measure as an option for hospitals to self-select. A few commenters stated concerns about removing this measure because it is an established, stable measure that hospitals have invested significant financial, operational, and information technology resources to successfully implement. A few commenters recommended delaying the removal of STK–02 until hospitals have adequate time to build, validate, and adjust workflows to ensure a smooth and reliable transition to meet the requirements of the other self-selected measures that would take their place.

Response: We recognize that the number of eCQMs available for self-selection would be reduced by the removal of the STK–02 eCQM and the transition of other eCQMs to mandatory reporting. We also understand commenters' concerns that the operational burden of eCQM reporting is largely associated with system configuration and workflow updates. We reiterate that over four of the most recent reporting periods, hospital performance on this measure has been so high and unvarying that this measure meets our criteria for ''topped out'' under removal factor 1 (83 FR 41540 through 41544), that is, performance is statistically indistinguishable at the 75th and 90th percentiles, and truncated coefficient of variation ≤0.10. Therefore, this measure no longer provides meaningful comparative information. By removing measures that meet our criteria for ''topped out'' we can ensure that the Hospital Inpatient Quality Reporting Program's measure set continues to address the most meaningful quality measures. While removing this eCQM would limit the available eCQMs for self-selection, we anticipate that the measure set would continue to evolve in future rulemaking,

Available at: *https://p4qm.org/sites/default/files/2025-11/Del-4-11-2025-MSR-Recommendation-Group-Meeting-Final-Summary-508.pdf.*

[430] The Joint Commission. (Oct. 2025). 2026 ORYX Performance Measurement Reporting Requirements. Available at: *https://jointcommission-ddsp.atlassian.net/wiki/spaces/DCS/pages/1030619137/2026+ORYX+Performance+Measurement+Reporting+Requirements.*

[431] The ORYX initiative integrates performance measurement data into The Joint Commission's standards-based survey and accreditation process to support hospitals in their quality improvement efforts through the continuous monitoring and evaluation. For more details on The Joint Commission's accreditation, we refer readers to: *https://www.jointcommission.org/en-us/accreditation/performance-measurement.*

[432] Department of Health and Human Services. Heart Disease and Stroke. Available at: *https://odphp.health.gov/healthypeople/objectives-and-data/browse-objectives/heart-disease-and-stroke.*

providing additional self-selection options for hospitals.

Comment: A few commenters stated concerns that removal of this measure could result in a reduction in provider performance for stroke patient outcomes. Commenters stated that this measure remains a valuable tool for clinicians and patients and recommended continuing to monitor performance to confirm that removal does not result in unintended consequences, suggesting monitoring for at least 2 years following removal to assess any changes in prescribing rates. A commenter recommended ensuring that this aspect of care remains addressed through other measures within the Hospital Inpatient Quality Reporting Program.

Response: We acknowledge commenters' concerns about removing the STK–02 eCQM from the Hospital Inpatient Quality Reporting Program. We reiterate that the CBE recently recommended the removal of the STK–02 eCQM due to minimal variation and stable median performance across hospitals.[433] Given the lack of meaningful variation in measure performance, improvements in performance can no longer be made, and thus removing this measure under removal factor 1 will allow hospitals to focus resources on eCQMs with room for further performance improvement. While we are not maintaining the STK–02 eCQM as a part of the measure set in the Hospital Inpatient Quality Reporting Program, we encourage hospitals who may still find this measure valuable to maintain this measure as a part of their own quality improvement efforts.

After consideration of the public comments we received, we are finalizing our proposal to remove the STK–02 eCQM beginning with the FY 2030 payment determination. We refer readers to section IX.F.9. of this final rule where we are finalizing removal of this same eCQM for the Medicare Promoting Interoperability Program.

5. Modifications to Current Measures in the Hospital Inpatient Quality Reporting Program Measure Set

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19590 through 19594), we proposed modifications to three measures that are currently in the Hospital Inpatient Quality Reporting Program measure set beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination: (1) Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction measure; (2) Excess Days in Acute Care after Hospitalization for Heart Failure measure; and (3) Excess Days in Acute Care after Hospitalization for Pneumonia measure.

a. Modifications to Three Excess Days in Acute Care Measures

(1) Background

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49690), we began including excess days in acute care quality measures in the Hospital Inpatient Quality Reporting Program to capture the quality of care transitions provided to discharged patients. The previously finalized EDAC measures are summarized:

- Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (AMI EDAC) measure (adopted at 80 FR 49680 through 49690; modified at 87 FR 49269 through 49272).
- Excess Days in Acute Care after Hospitalization for Heart Failure (Heart Failure EDAC) measure (adopted at 80 FR 49682 through 49690).
- Excess Days in Acute Care after Hospitalization for Pneumonia (Pneumonia EDAC) (adopted at 81 FR 57142 through 57148).

For more details on these EDAC measures, we refer readers to the EDAC measures updates and specifications reports available at: *https://qualitynet.cms.gov/inpatient/measures/edac.*

Since adoption into the Hospital Inpatient Quality Reporting Program, these EDAC measures have contributed to our assessment of care coordination and patient outcomes, providing a broader view of quality of care than can be captured by individual process-of-care measures. Safely transitioning patients from hospital to home requires a complex series of tasks which would be cumbersome to capture individually as process measures: timely and effective communication between providers, prevention of and response to complications, patient education about post-discharge care and self-management, timely follow-up, and more.[434] [435] Suboptimal transitions contribute to a variety of adverse events post-discharge that result in patients returning to the hospital.[436] When these EDAC measures were adopted into the Hospital Inpatient Quality Reporting Program measure set, they only included Medicare Fee-For-Service beneficiaries in the measure cohorts. Since the initial adoption of these measures, the proportion of Medicare Advantage beneficiaries has increased from 35 percent of the Medicare population to over 50 percent.[437] Omitting Medicare Advantage beneficiaries from quality reporting leaves a critical gap in assessing acute events, care transitions, and avoidable acute utilization among a large population of Medicare beneficiaries. Capturing care transition outcomes for all Medicare beneficiaries for these acute conditions continues to be a high priority for CMS. We note that returns to the ED, observation stays, or unplanned readmissions are disruptive to patients and caregivers, costly to the healthcare system, and put patients at additional risk of hospital-acquired infections and complications.[438] Therefore, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19590 through 19594), we proposed to adopt modifications to the AMI, Heart Failure, and Pneumonia EDAC measures beginning with the July 1, 2024 through June 30, 2026 performance period, which is associated with the FY 2028 payment determination. We also refer readers to section IX.C.3.a. of this FY 2027 IPPS/LTCH PPS final rule where we proposed to add the Diabetes EDAC measure into the Hospital Inpatient Quality Reporting Program.

(2) Overview of Proposed Updates to Measures

We proposed (91 FR 19590 through 19594) to modify the AMI, Heart Failure, and Pneumonia EDAC measures with two substantive updates: (1) expand the measure inclusion criteria to include Medicare Advantage

[433] Partnership for Quality Measurement (2025). 2025 Measure Set Review Draft Meeting Summary. Available at: *https://p4qm.org/sites/default/files/2025-11/Del-4-11-2025-MSR-Recommendation-Group-Meeting-Final-Summary-508.pdf.*

[434] Tyler, N., Hodkinson, A., Planner, C., Angelakis, I., Keyworth, C., Hall, A., Panagioti, M. (2023). Transitional care interventions from hospital to community to reduce health care use and improve patient outcomes: A systematic review and network meta-analysis. *JAMA Network Open, 6*(11), e2344825. Available at: *https://doi.org/10.1001/jamanetworkopen.2023.44825.*

[435] Balasubramanian, I., Andres, E. B., & Malhotra, C. (2025). Outpatient Follow-Up and 30-Day Readmissions: A Systematic Review and Meta-Analysis. *JAMA Network Open, 8*(11), e2541272–e2541272. Available at: *https://doi.org/10.1001/jamanetworkopen.2025.41272.*

[436] Tyler, N., Hodkinson, A., Planner, C., Angelakis, I., Keyworth, C., Hall, A., Panagioti, M. (2023). Transitional care interventions from hospital to community to reduce health care use and improve patient outcomes: A systematic review and network meta-analysis. *JAMA Network Open, 6*(11), e2344825. Available at: *https://doi.org/10.1001/jamanetworkopen.2023.44825.*

[437] Centers for Medicare & Medicaid Services. (2025). Medicare Enrollment Dashboard. Available at: *https://data.cms.gov/tools/medicare-enrollment-dashboard.*

[438] CMS QualityNet. Excess Days in Acute Care (EDAC) Measures Overview. Available at: *https://qualitynet.cms.gov/inpatient/measures/edac.*

beneficiaries; and (2) shorten the performance period from 3 years to 2 years. Inclusion of Medicare Advantage beneficiaries expands quality measurement of care coordination outcomes across all Medicare beneficiaries, enhances the reliability of the measure scores, leads to more hospitals receiving results, and increases the chance of identifying meaningful differences in quality for some low-volume hospitals. Based on our analysis that included Medicare Advantage beneficiaries in addition to the Medicare Fee-For-Service measure cohort, we found that the measures could achieve a satisfactory level of reliability with a 2-year reporting period. Table IX.C.3. summarizes the reliability scores for the three modified EDAC measures for the CY 2022 through CY 2023 reporting period with the inclusion of Medicare Advantage beneficiaries:[439]

TABLE IX.C.3. EDAC MEASURES RELIABILITY ESTIMATES USING A 2-YEAR REPORTING PERIOD

Measure	Mean (SD)	Range	25th Percentile	50th Percentile	75th Percentile
AMI EDAC	0.922 (0.049)	0.786-0.992	0.897	0.935	0.960
Heart Failure EDAC	0.863 (0.128)	0.542-0.996	0.793	0.92	0.962
Pneumonia EDAC	0.873 (0.109)	0.593-0.996	0.806	0.920	0.960

The mean reliability for each of the EDAC measures exceeds the CBE-established minimum of 0.6.[440] We therefore proposed to shorten the reporting period from 3 to 2 years for the modified EDAC measures in order to provide hospitals, consumers, and other members of the public with more recent measure information.

These measures capture the quality of care transitions provided to discharged patients hospitalized with AMI, heart failure, or pneumonia by collectively measuring different types of returns to the hospital (ED visit, observation stay, or readmission), which are all adverse acute care outcomes that can occur post-discharge. With the increase in Medicare Advantage beneficiaries to over half of all Medicare beneficiaries, these modifications would better reflect overall patient care coordination among a broader population of patients, improving measure reliability. Shortening the reporting period would allow measure results to reflect more recent hospital performance and provide more actionable insights for quality improvement.

(3) Measure Calculation

The modified AMI, Heart Failure, and Pneumonia EDAC measures would continue to assess the number of days the patient spends in acute care within 30 days post-discharge from an inpatient hospitalization with a principal diagnosis of AMI, heart failure, or pneumonia. The measures adjust for factors including patient age, comorbid diseases, and indicators of patient frailty.[441] The hospital-level 30-day all-cause EDAC for each measure is a risk adjusted calculation using a random-effects binomial model which calculates the difference, or excess days, between a hospital's predicted days (the average number of days a patient spent in acute care after adjusting for the risk factors) and expected days (the average number of risk adjusted days in acute care a patient would have been expected to spend if discharged from an average-performing hospital with the same case mix) per 100 discharges. Unplanned readmissions are defined using the planned readmission algorithm.[442]

(a) Numerator

The numerator of the measure is a count of the number of days the patient spends in acute care within 30 days of discharge from an eligible index hospitalization for AMI, heart failure, or pneumonia. We define days in acute care as days spent in an ED, an observation stay, or admitted as an unplanned readmission for any cause to a short-term acute care hospital, within 30 days from the date of discharge from the index hospitalization. ED visits are counted as one whole day, regardless of how many hours the patient spends in the ED or whether the ED visit crosses more than one calendar date. Observation stays are counted by hours and rounded up to the nearest whole day.[443]

(b) Denominator

To be included in the measure cohort, patients must meet the following inclusion criteria:

- Have a principal discharge diagnosis of AMI, heart failure, or pneumonia;
- Enrolled in Medicare Fee-For-Service Part A and Part B or Medicare Advantage for 12-months prior to the date of admission and enrolled in Part A or Medicare Advantage during the index admission;[444]
- Aged 65 or older;
- Discharged alive from a non-federal short-term acute care hospital or Veterans Health Administration hospital; and
- Not transferred to another acute care facility.

For more detailed measure specifications, including denominator exclusions for each condition, we refer readers to the EDAC measure methodology reports available at: *https://qualitynet.cms.gov/inpatient/measures/edac/methodology.*

(4) Pre-Rulemaking Process and Measure Endorsement

(a) Recommendations From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement website for details on the Pre-Rulemaking Measure Review process convened by the CBE, including

[439] 2024 Excess Days in Acute Care Measures Updates and Specifications Report. Available at: *https://www.p4qm.org/prmr-measures/muc2025-030.*

[440] For more details on reliability guidance, we refer readers to the Reliability Guidance for the Endorsement and Maintenance of Clinical Quality Measures Document. Available at: *https://p4qm.org/em/resources.*

[441] QualityNet. Excess Days in Acute Care Measures Methodology. Available at: *https://qualitynet.cms.gov/inpatient/measures/edac/methodology.*

[442] Details regarding the planned readmission algorithm can be found in a zip file on the CMS Measure Methodology site, available at: *https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/measure-methodology.*

[443] QualityNet. Excess Days in Acute Care Measures Methodology. Available at: *https://qualitynet.cms.gov/inpatient/measures/edac/methodology.*

[444] This requirement is not applicable to Veterans Health Administration (VHA) beneficiaries hospitalized in VHA hospitals, who are eligible for inclusion in the cohort regardless of their Medicare enrollment status. VHA beneficiaries hospitalized in non-VHA hospitals must be concurrently enrolled in Medicare Fee-For-Service Part A or Medicare Advantage at the time of the index admission to be eligible for cohort inclusion.

the voting procedures used to reach consensus on measure recommendations.[445] [446] The Pre-Rulemaking Measure Review Hospital Committee, consisting of both the Pre-Rulemaking Measure Review Hospital Recommendation Group (hereafter referred to as the Recommendation Group) and the Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available ''2025 Measures Under Consideration List,'' including the AMI EDAC (MUC2025–030), Heart Failure EDAC (MUC2025–031), and Pneumonia EDAC (MUC2025–039) measures.[447]

The voting results of the Recommendation Group for the proposed modifications to the AMI EDAC measure were: 18 members (86 percent) recommended adopting the measure into the Hospital Inpatient Quality Reporting Program; three members (14 percent) voted not to recommend the measure for adoption. The voting results for the proposed modifications to the Heart Failure EDAC measure were: 19 members (90 percent) recommended adopting the measure into the Hospital Inpatient Quality Reporting Program; two members (10 percent) voted not to recommend the measure for adoption. The voting results for the proposed modifications to the Pneumonia EDAC measure were: 19 members (90 percent) recommended adopting the measure into the Hospital Inpatient Quality Reporting Program; two members (10 percent) voted not to recommend the measure for adoption. Thus, the Recommendation Group reached consensus agreement to recommend the AMI EDAC, Heart Failure EDAC, and Pneumonia EDAC measures for use in the Hospital Inpatient Quality Reporting Program.[448]

Overall, the Recommendation Group supported the addition of Medicare Advantage beneficiaries and the reduction of the performance period from 3 years to 2 years, noting these changes improved the comprehensiveness and timeliness of reporting. The Recommendation Group members who recommended these measures suggested adding risk adjustment factors for medically underserved and rural areas, where limited access to post-acute services may affect readmissions beyond a hospital's control. Recommendation Group members who voted not to recommend adoption of the measure for the program provided the following rationales: (1) concerns that the 30-day post-discharge window may not be appropriate; and (2) concerns regarding AMI EDAC measure's complexity, diagnosis set, and the risk adjustment approach.

Regarding the suggestion to add additional risk adjustment factors, in alignment with other readmission measures, we do not adjust the EDAC measures for rurality or medically underserved populations. We note that Critical Access Hospitals (CAHs), which serve higher proportions of rural and medically underserved populations, are not required to report to the Hospital Inpatient Quality Reporting Program.[449] We also note that EDAC measures are risk-standardized for patient demographics and comorbidities, which helps account for varying health complexities. Further, we would continue to provide hospitals with patient-level information to help inform quality improvement efforts that can be targeted to specific patient populations. We would continue to monitor the measures' performance as part of our routine monitoring and evaluation efforts to identify potential unintended consequences.

We note that the 30-day timeframe is consistent with the existing measure specifications that have been endorsed by a CBE and publicly reported. In addition, the EDAC measures were originally designed to complement condition specific 30-day readmission measures for the same conditions and therefore the 30-day outcome window is aligned. The 30-day timeframe allows for a more complete reflection of the hospital's discharge plan which includes follow-up, care coordination, and patient self-management education.

Regarding the AMI EDAC measure specifically, Recommendation Group members expressed concerns regarding its complexity and relatively narrow diagnosis set, noting a preference for other metrics to assess AMI care. While statistically complex, the AMI EDAC risk-model was determined by the CBE to indicate an effective model discrimination for a readmission-type measure with a c-statistic[450] of 0.68, and predictive ability[451] of 1.4 percent to 10.1 percent. Further, the measure developer considered threats to validity during measure development and testing of a risk adjustment model. The measure is risk adjusted for patient functional status (frailty indicator), patient-level demographics (age), and patient-level health status and clinical conditions (case-mix adjustment, comorbidities, and severity of illness). The results of model discrimination testing and calibration using the c-statistic and examining predictive ability suggest that the model effectively differentiates excess days in acute care after hospitalization for acute myocardial infarction levels and adequately adjusts for differences in patient characteristics.[452]

Recommendation Group members highlighted potential shortcomings in the current risk adjustment approach for the AMI EDAC measure, particularly the comorbidity adjustment for non-ST-segment elevation myocardial infarction (NSTEMI) cases. The measure developer used an empirical approach for the selection of risk variables included in adjustments for hospital-level case mix. The index and history (pre-index) codes were selected based on their prevalence and the index and pre-index variables were combined based on their correlation with each other and their associations with the outcome. For AMI EDAC, ST-segment elevation myocardial infarction (STEMI) involving the right and left coronary arteries occurring in

[445] Partnership for Quality Measurement. Pre-Rulemaking Measure Review web page. Available at: *https://p4qm.org/prmr/about.*

[446] We note the Pre-Rulemaking Measure Review voting process was updated in 2025. We refer readers to the corresponding footnote in section IX.C.3.a.(4)(a) of this final rule for details on the updated Pre-Rulemaking Measure Review voting process.

[447] Centers for Medicare & Medicaid Services. (2025). 2025 Measures Under Consideration List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview.*

[448] Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendations Report. Available at: *https://p4qm.org/prmr/news-events.*

[449] CMS. Critical Access Hospitals. Available at: *https://www.cms.gov/medicare/health-safety-standards/certification-compliance/critical-access-hospitals.*

[450] The c-statistic is an indicator of the model's discriminant ability or ability to correctly classify those patients who have and have not had a qualifying event within 30 days. Potential values range from 0.5, meaning no better than chance, to 1.0, an indication of perfect prediction. The CBE has determined that for readmission-type measures, a c-statistic of 0.68 is considered an effective model of discriminant ability. We refer readers to the ''2024 Excess Days in Acute Care Measures Updates and Specifications Report,'' available at: *https://www.p4qm.org/prmr-measures/muc2025-030* for more details.

[451] Predictive ability measures the ability to distinguish high-risk subjects from low-risk subjects. A model with good predictive ability would see a wide range in observed outcomes between lowest and highest deciles of predicted outcomes. We have calculated the range of mean observed hospital ratios between the lowest and highest deciles of hospital visit probabilities. We refer readers to the ''2024 Excess Days in Acute Care Measures Updates and Specifications Report,'' available at: *https://www.p4qm.org/prmr-measures/muc2025-030* for more details.

[452] PQM. 2025 Pre-Rulemaking Measure Review Preliminary Assessment: AMI EDAC. Available at: *https://www.p4qm.org/sites/default/files/2025-12/MUC2025-030-PA.pdf.*

the 12 months prior to the index admission were identified as risk adjustment variables, while NSTEMI was not identified. Clinically, STEMI presents a more severe form of myocardial infarction for which aggressive interventions are required in a short period of time. Additionally, we wish to emphasize we have conducted extensive evaluation of the proposed updated risk adjustment methodology and the updated risk methodology shows significant improvements from the previous model. We refer readers to Table IX.C.4., in section IX.C.5.a.(6), for more details on the technical updates to the risk adjustment methodology for the three modified EDAC measures.

After taking these recommendations and concerns into consideration, we proposed (91 FR 19590 through 19594) to modify the three EDAC measures in the Hospital Inpatient Quality Reporting Program beginning with the FY 2028 payment determination.

(b) Measure Endorsements

We refer readers to the Partnership for Quality Measurement website for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. The Heart Failure EDAC (CBE #2880) and Pneumonia EDAC (CBE #2882) measures were last endorsed in the Spring 2021 CBE review cycle and are planned for maintenance review in the Fall 2027 cycle.[453] [454] The updated AMI EDAC (CBE #2881) measure, which included the addition of Medicare Advantage beneficiaries, was most recently submitted to the CBE's Endorsement and Maintenance Cost and Efficiency Committee in the Spring 2025 review cycle. The Endorsement and Maintenance Cost and Efficiency Committee voted to endorse the AMI EDAC measure with conditions. The condition imposed was for the measure developer to empirically explore the differences with outpatient visits and post-hospitalizations for Medicare Advantage beneficiaries compared to Fee-For-Service beneficiaries when the measure returns in five years for maintenance endorsement in the Spring 2030 cycle.[455] [456]

(5) Data Source, Submission, and Public Reporting

The modified EDAC measures would be calculated using administrative data from Medicare Fee-For-Service claims or Medicare Advantage encounters, or both. This data is routinely generated by hospitals and submitted to CMS for all Medicare beneficiaries, which includes Medicare Advantage and Medicare Fee-For-Service beneficiaries. Therefore, a hospital would not be required to report any additional data for this measure. Enrollment status would be obtained from the Medicare Enrollment Database which contains beneficiary demographic, benefit/coverage, and vital status information. The proposed modified EDAC measures would be calculated and publicly reported on an annual basis using 24 months of prior data for the measurement period. We would then publicly report the measures' results on the Compare tool, currently available at: *https://www.medicare.gov/care-compare/,* or successor CMS website.

We invited public comment on our proposal to modify the AMI, Heart Failure, and Pneumonia EDAC measures to include Medicare Advantage patients in the measure cohort and reduce the performance period from 3 years to 2 years, beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination.

Comment: Many commenters supported the modifications to the AMI, Heart Failure, and Pneumonia EDAC measures. Many commenters stated that including Medicare Advantage beneficiaries in the measures' cohorts will fill a significant gap in data, providing a more complete picture of quality of care for a large portion of Medicare beneficiaries, which will improve patients' and families' ability to make fully informed decisions about where to seek care. Several commenters supported the shortening of the performance period from 3 to 2 years because it provides more recent data and supports organizational learning, quality improvement, and responsiveness to emerging safety concerns. A commenter stated that the shorter performance period would reduce burden. A commenter supported technical updates to existing measures stating that this would improve aligned quality measurement across programs, reduce fragmentation, and promote more actionable, patient-centered quality reporting.

Response: We thank commenters for their support of the proposed modifications to the AMI, Heart Failure, and Pneumonia EDAC measures. We agree that including Medicare Advantage beneficiaries will provide a more complete assessment of hospital performance across the Medicare population. We also agree that shortening the performance period from 3 to 2 years will provide more recent and actionable information. We appreciate commenters' support for the EDAC measures and for the technical updates to the risk adjustment methodology.

Comment: A few commenters stated that a combination of multiple modifications could create volatile and unreliable performance scores, which would drive penalty exposure without improving the quality of care delivered to patients. A commenter specifically stated that shortening the performance period could increase year-to-year volatility.

Response: As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19590 through 19594), we analyzed the modified EDAC measures with Medicare Advantage beneficiaries included in the measures' cohorts and found that the measures achieved satisfactory reliability using a 2-year reporting period. The inclusion of Medicare Advantage beneficiaries both increases measure cohort size and improves reliability, while the shortened performance period allows measure results to reflect more recent hospital performance. This approach balances the need for reliable measure results with the goal of providing more timely and actionable information for quality improvement. We refer readers to section IX.C.5.a.(2) for detailed measure testing reliability results. We also refer readers to the Excess Days in Acute Care Methodology Reports available at: *https://qualitynet.cms.gov/inpatient/measures/edac/methodology* for further details on the measure testing methodology. We also recognize the importance of ensuring that measure results are stable, meaningful, and useful for quality improvement. We will continue monitoring the performance of the EDAC measures, including reliability, validity, and year-to-year variation, as part of routine monitoring and evaluation.

Comment: Many commenters expressed concern that including Medicare Advantage beneficiaries in the cohorts for the EDAC measures would

[453] Battelle. PQM. Excess days in acute care (EDAC) after hospitalization for pneumonia. Available at: *https://www.p4qm.org/measures/2882.*

[454] Battelle. PQM. Excess days in acute care (EDAC) after hospitalization for heart failure (HF). Available at: *https://www.p4qm.org/measures/2880.*

[455] Battelle. Excess days in acute care (EDAC) after hospitalization for acute myocardial infarction (AMI). Available at: *https://www.p4qm.org/measures/2881.*

[456] Battelle. (November 2025). Draft Spring 2025 Cycle Endorsement and Maintenance Technical Report: Cost and Efficiency. Available at: *https://p4qm.org/sites/default/files/Cost%20and%20Efficiency/material/Cost-Efficiency-Spring-2025-Technical-Report.pdf.*

affect comparability and reliability due to concerns about the completeness and consistency of Medicare Advantage encounter data. Several commenters recommended delaying the inclusion of Medicare Advantage beneficiaries until further testing and analyses can be done to ensure Medicare Advantage encounter data is accurate and comparable.

Response: We understand commenters' concerns regarding the inclusion of Medicare Advantage beneficiaries and the potential for challenges around data reliability, comparability, and completeness. As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19590 through 19593), we have studied whether there are key differences between the Medicare Advantage and Medicare Fee-For-Service populations and found that there were not significant differences between the two populations. We also note that the risk adjustment models are aligned with the existing readmission measures, and include a Medicare Advantage indicator to account for differences between Medicare Advantage and Medicare Fee-For-Service beneficiaries and adjust for the prevalence of comorbidities in the Medicare Advantage cohort, especially among the pre-index variables that were derived from services in the outpatient setting (for example, physician visits). We note the inclusion of Medicare Advantage beneficiaries has several important benefits for the reliability of these EDAC measures. The increased size of the measures' cohorts leads to more hospitals reaching the minimum threshold for reporting and receiving results, thereby increasing the opportunity to identify meaningful differences in quality for some low-volume hospitals. Further, we found that incorporating Medicare Advantage beneficiaries into the measures' cohorts improved the measures' reliability. Using 2 years of data (CY 2022 to CY 2023), we found that the mean reliability estimates all exceeded the CBE established minimum threshold of 0.6, with results showing 0.922, 0.863, and 0.873, for the AMI EDAC measure, Heart Failure EDAC measure, and Pneumonia EDAC measure, respectively. Therefore, we concluded inclusion of Medicare Advantage beneficiaries into these measures' cohorts does not raise concerns about data comparability between the two populations across hospitals.

We have previously assessed the availability, completeness, and comparability of data elements used to define the EDAC outcome. These analyses found that the data elements necessary to identify ED visits and observation stays are available within Medicare Advantage encounter data, and that Medicare Advantage encounter data latency is comparable to Medicare Fee-For-Service claims for inpatient and outpatient settings. Generally, within 3 months following the close of the measurement period, more than 97 percent of ED and observation claims are available in both data sources. The relative distribution of EDAC outcome components, including inpatient readmissions, ED visits, and observation stays, is comparable between Medicare Advantage encounter data and Medicare Fee-For-Service claims, supporting the use of Medicare Advantage encounter data for reliable EDAC outcome measurement.[457]

We note that with over half of the Medicare population now receiving benefits through the Medicare Advantage program, continuing to include this population into quality measures in the Hospital Inpatient Quality Reporting Program supports quality improvement goals of high-quality, safe care for all Medicare beneficiaries and patients. We refer readers to section IX.C.5.a.(2) for detailed results on these findings. We also refer readers to the Excess Days in Acute Care Methodology Reports available at: *https://qualitynet.cms.gov/inpatient/measures/edac/methodology* for additional details on the measure testing results including the observed days of post-discharge events per 100 discharges for the EDAC measures.

Comment: Several commenters stated that utilization trends for patients with Medicare Advantage are affected by plan benefit structures, payment delays, inappropriate denials, prior authorization requirements, coding methodologies, accuracy of encounter data, care management protocols, post-acute network limitations, and differences in patient populations. A few commenters stated that these effects on utilization trends may mean that hospitals would be subject to unfair comparisons based on the markets they serve rather than on the quality of care. A few commenters stated that regional differences in Medicare Advantage penetration levels could disproportionately impact certain hospitals in areas with higher Medicare Advantage enrollment. A commenter urged CMS to ensure that the measures distinguish between factors within a hospital's control and those driven by patient, community, payer, or broader healthcare system factors.

Response: We acknowledge that some post-discharge utilization may be influenced by factors beyond a hospital's direct control including factors related to Medicare Advantage plans. Further, we recognize that Medicare Advantage payment policies are not the same as Medicare Fee-For-Service payment policies, and by design, Medicare Advantage organizations are given more flexibility in benefit and provider reimbursement design. We note that from a patient's perspective, unplanned readmissions, ED visits, and observation stays are adverse events irrespective of benefit or payment policies. It is important to measure and provide transparency on the quality of transitions in care provided to discharged patients by collectively measuring these events for all Medicare beneficiaries. These measures are intended to provide a more complete reflection of the hospital's discharge planning, including follow-up, care coordination, and patient self-management education, which are important for all patients regardless of payer. While we understand that Medicare Advantage beneficiaries are subject to different benefits design and payment approaches than Medicare Fee-For-Service enrollees, we do not agree that these differences mean that their clinical outcomes are beyond the hospital's control. We continue to encourage hospitals to work closely with insurers, including Medicare Advantage plans, to coordinate the highest quality care for their patients.

With respect to the concern that hospitals in areas with higher Medicare Advantage enrollment may be disproportionately affected, we note that the risk adjustment model includes a Medicare Advantage indicator to account for potential differences between Medicare Advantage and Medicare Fee-For-Service beneficiaries. For more details on measure testing results, we refer to *https://qualitynet.cms.gov/inpatient/measures/edac/methodology.*

Comment: A few commenters expressed concern that existing risk adjustment methodologies may not sufficiently account for differences between Medicare Advantage and traditional Medicare populations. A few commenters recommended risk adjustment for social risk, outpatient access, post-acute and specialty care availability, safety net status, rurality, and coding variation.

Response: The EDAC measures are risk adjusted for clinically relevant

[457] Centers for Medicare & Medicaid Services. (April 2025). 2025 Condition-Specific Excess Days in Acute Care Measures Updates and Specifications Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/edac/methodology.*

factors including age, comorbidities, case mix, severity of illness, and frailty. Measure testing supported the current risk adjustment model and demonstrated adequate controls for differences in patient characteristics (case mix), with a c-statistic of approximately 0.68, 0.64, and 0.67 for the AMI EDAC, Heart Failure EDAC, and Pneumonia EDAC measures, respectively. Additionally, CMS is making technical updates to the risk adjustment methodology to use individual International Classification of Diseases, Tenth Revision (ICD–10) codes rather than Hierarchical Condition Categories (HCC) categories to improve the measures' risk adjustment methodology. We refer readers to section IX.C.5.a.(6) for more details on our updates to the measures' risk methodology. We will continue to monitor measure performance, including whether future refinements to the risk adjustment methodology are warranted.

Comment: A few commenters expressed concern that the integration of Medicare Advantage data would impose disproportionate administrative burden on rural hospitals because they have limited staffing and IT resources, limited leverage with Medicare Advantage plans, and smaller patient populations which increases sensitivity to inaccurate Medicare Advantage data and variations in plan behavior. A few commenters also recommended that CMS continue monitoring for measure reliability and unintended consequences, particularly for hospitals serving medically and socially complex populations and for low-volume hospitals.

Response: We would like to clarify that the inclusion of Medicare Advantage encounter data into the EDAC measures' cohorts does not require any additional data collection or submission from hospitals. As we discussed in the proposed rule (91 FR 19593), the inclusion of Medicare Advantage encounter data in these measures uses readily available claim-level data elements routinely generated and submitted to CMS for Medicare Advantage. Specifically, the Medicare Advantage encounter data used for this measure are submitted by Medicare Advantage organizations to CMS. Similarly, Medicare Fee-For-Service claims are submitted through existing hospital billing processes. As such, the proposed modifications do not impose additional data submission burden on hospitals. We refer readers to section XII.B.4. for additional details on our information collection burden estimate for the proposal to adopt the modified EDAC measures.

Comment: A few commenters recommended that CMS stratify outcomes by payer to help identify disparities, provide visibility into Medicare Advantage and Fee-For-Service variations, and highlight emerging unintended consequences or differential patterns of preventable harm. Several commenters recommended that CMS provide hospital-specific impact analyses to allow hospitals to evaluate impacts before implementing these updates. However, a few commenters recommended that CMS not stratify outcomes by payer because the measures are designed to assess hospital quality and outcomes, rather than plan performance.

Response: We thank commenters for their recommendation to provide stratified measure results by payer to help identify disparities. We note that the measures' risk models include an indicator variable for Medicare Fee-For-Service and Medicare Advantage enrollment status, which accounts for any potential differences between these groups. We found that stratifying the risk models for the corresponding readmission measures on which these measures were based by Medicare Fee-For-Service and Medicare Advantage did not yield meaningful improvements in performance, supporting the decision to model them together with an indicator variable. Keeping Medicare Fee-For-Service and Medicare Advantage beneficiaries together for purposes of this measure's calculation will keep the hospitals' total volume higher for more precise measure scores. Any potential public reporting of stratified measure data would be proposed through future notice-and-comment rulemaking. We also note that confidential hospital-specific reports will be made available to hospitals to assess measure performance.

Comment: Several commenters urged CMS to delay the inclusion of Medicare Advantage beneficiaries until further testing and analyses can be done to ensure Medicare Advantage encounter data is accurate and comparable and can more accurately account for differences in coverage, utilization management, and data reporting. A few commenters specifically stated that when evaluating the AMI EDAC measure for endorsement, the CBE applied the condition that the developer empirically explore the differences in outpatient visits and post-hospitalization utilization for Medicare Advantage patients compared to Medicare Fee-For-Service patients prior to the next endorsement review in 5 years. These commenters stated that the CBE will likely apply the same condition to the heart failure EDAC and pneumonia EDAC measures when they undergo maintenance endorsement review in fall 2027.

Response: We note the inclusion of Medicare Advantage beneficiaries has several important benefits for the reliability of these EDAC measures. The increased size of the measures' cohorts leads to more hospitals reaching the minimum threshold for reporting and receiving results, thereby increasing the opportunity to identify meaningful differences in quality for some low-volume hospitals. As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19568 through 19574), we have studied whether there are key differences between the Medicare Advantage and Medicare Fee-For-Service populations and found that there were not significant differences between the two populations. We intend to provide hospitals with confidential hospital-specific reports on their measure performance and will continue to evaluate differences between Medicare Advantage and Medicare Fee-For-Service beneficiaries through routine measure monitoring and future measure maintenance activities consistent with the condition provided by the CBE as part of the AMI EDAC measure endorsement.

Comment: A commenter requested clarification on whether the measures are intended to capture all post-discharge utilization or only preventable utilization.

Response: The EDAC measures compare the number of days patients are predicted to spend in acute care, specifically in unplanned hospital readmissions, observation stays, and ED visits, after discharge from a hospital compared to the days expected based on their degree of illness. The measures use a risk adjustment methodology to determine the predicted post-discharge utilization. As planned inpatient readmissions are not included in the EDAC measure outcome, the measure outcome does more readily capture preventable post-discharge acute care utilization.

Comment: A few commenters expressed concern that the EDAC measures are not easily replicable using available data sources.

Response: The EDAC measures contain data that are not easily replicated because it is a measure of post-discharge outcomes and relies on claims-based data compiled from multiple healthcare settings. However, post-discharge outcomes are important

indicators of quality because they reflect the effectiveness of discharge planning, care coordination, and follow-up care and provide information that is meaningful to patients and their families when making care decisions. We note that hospital-specific reports will include patient-level information about their measure results, which may help hospitals understand their performance and identify opportunities for improvement.

Comment: Another commenter recommended evaluating whether counting each ED visit as a full day may overstate acute-care utilization, particularly for brief or low-intensity encounters.

Response: We acknowledge that ED visits vary in duration and clinical intensity. Counting each ED visit as a full day supports a standardized calculation across hospitals. Modifying the weight of ED and observation stay days helps with the production, implementation, and ongoing reevaluation of the EDAC measures and improves the performance of the statistical model. Additionally, feedback from stakeholders suggests that although the average ED treat and discharge stay is about four hours, patients often spend an entire day from the time it takes to get to the ED, the wait time in the ED for treatment, treatment in the ED, and any trips for medication or supplies after their ED visit.

Comment: A few commenters recommended that CMS delay the proposals by 1 year, use a phased approach, or conduct a dry run prior to incorporation into the Hospital Inpatient Quality Reporting Program. These commenters stated that this additional time would allow hospitals to assess potential impact and allow CMS to complete additional reliability and social risk factor testing. A commenter stated that under the proposed implementation timeline the performance period will be completed by the time the rule is finalized, leaving hospitals no opportunity to understand, operationalize, or improve performance under the new specifications.

Response: We understand commenters' concerns about the impacts of implementing multiple changes to the EDAC measures. We note that hospitals have been preparing for the addition of Medicare Advantage data to several Hospital Inpatient Quality Reporting Program measures, including the MORT–30–STK measure, the COMP–HIP–KNEE measure, and the Thirty-day Risk-Standardized Death Rate Among Surgical Inpatients with Complications measure currently reported in the Hospital Inpatient Quality Reporting Program (90 FR 36997 through 37002, 90 FR 37002 through 37008, and 89 FR 69545 through 69552). Additionally, the inclusion of Medicare Advantage encounter data into the EDAC measures' cohorts does not require any additional data collection or submission from hospitals and uses readily available claim-level data elements routinely generated and submitted to CMS by Medicare Advantage organizations. While we are not delaying our proposal to modify these measures, beginning with the FY 2028 payment determination, hospitals will be able to preview their data on this measure in the Hospital Inpatient Quality Reporting Program prior to it being publicly reported. We also note that since the Hospital Inpatient Quality Reporting Program is a pay-for-reporting program, hospitals' performance on the EDAC measures will not affect payment. As long as hospitals report the required measure data in accordance with the form, manner, and timing policies specified by the Secretary, they are not subject to a financial penalty under this program.

Regarding concerns about the risk adjustment model accounting for social risk, the risk model has been updated to account for the case mix in both Medicare Fee-For-Service and Medicare Advantage. The clinical variables included in the risk adjustment model were selected based on an analysis of a combined Medicare Fee-For-Service and Medicare Advantage cohort. This approach ensures that the model captures the key risk factors relevant to the combined population. The models include an indicator variable for Medicare Fee-For-Service and Medicare Advantage enrollment status, which accounts for any potential differences in risk between these groups. We found that the prevalence of clinical risk factors and their associations with excess days spent in acute care were similar across Medicare Fee-For-Service and Medicare Advantage populations.

Lastly, we note the measure developers conduct annual measure re-evaluations to ensure the risk adjustment model is continually assessed and remains valid, given possible changes in clinical practice and coding standards over time. Modifications made to the measure cohort, risk model, and outcomes are informed by review of the most recent literature related to measure conditions or outcomes, feedback from various stakeholders, empirical analyses, and assessment of coding trends that reveal shifts in clinical practice or billing patterns. For the complete measure methodology report and measure risk adjustment model, we specifically refer readers to QualityNet on our website at: *https://qualitynet.cms.gov/inpatient/measures/edac/methodology*. We also refer readers to QualityNet: *https://qualitynet.cms.gov/,* where we make our technical measure specifications reports and measure evaluation reports publicly available.

After consideration of the public comments we received, we are finalizing our proposal to modify the AMI, Heart Failure, and Pneumonia EDAC measures beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination.

(6) Technical Updates

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19593), we also notified the public of technical updates to the three EDAC measures' risk adjustment methodology in the Hospital Inpatient Quality Reporting Program, beginning with the FY 2028 payment determination, to use individual ICD–10 codes to improve the measure's risk adjustment methodology. The risk adjustment strategy currently in use involves grouping ICD–10 diagnosis codes from the CMS HCC system into clinically relevant categories.[458] We recently notified hospitals of the same technical update to our risk adjustment model to use individual ICD–10 codes instead of HCCs for two measures—MORT–30–STK and COMP–HIP–KNEE—in the Hospital Inpatient Quality Reporting Program to better leverage the data and analytical advances since these measures were initially developed (90 FR 36997 through 37008). With this new approach, the ability of the risk adjustment model to account for condition-specific risk improved. See Table IX.C.4. for a summary of improvements to the risk adjustment model performance for the three modified EDAC measures in the Hospital Inpatient Quality Reporting Program.[459] [460]

[458] QualityNet. 2025 Condition-Specific Excess Days in Acute Care Measures Updates and Specifications Report: AMI, HF, and Pneumonia. Available at: *https://qualitynet.cms.gov/inpatient/measures/edac/methodology*.

[459] 2024 Excess Days in Acute Care Measures Updates and Specifications Report. Available at: *https://www.p4qm.org/prmr-measures/muc2025-030*.

[460] QualityNet. 2025 Condition-Specific Excess Days in Acute Care Measures Updates and Specifications Report: AMI, HF, and Pneumonia. Available at: *https://qualitynet.cms.gov/inpatient/measures/edac/methodology*.

TABLE IX.C.4. EDAC MEASURES RISK ADJUSTMENT MODEL PERFORMANCE COMPARISON

Measure Title	Fee-For-Service-only cohort with HCC-based Risk Variables (July 1, 2022 through June 30, 2023) C-Statistic (predictive ability)	Fee-For-Service and Medicare Advantage cohort with ICD-10-based Risk Variables (January 1, 2022 through December 30, 2023) C-Statistic (predictive ability)
AMI EDAC	0.60 (85 - 123)	0.68 (59 - 261)
Heart Failure EDAC	0.59 (133 - 172)	0.64 (89 - 361)
Pneumonia EDAC	0.61 (106 - 152)	0.67 (59 - 338)

Note: The predictive ability is the range of mean observed days in acute care per 100 discharges between the lowest and highest predicted deciles.

We received a few comments on this technical update.

Comment: A few commenters supported the update to the risk adjustment methodology to use ICD–10 codes, noting it will improve alignment with contemporary clinical practice and provide a more comprehensive evaluation of hospital performance. A commenter noted it will produce more actionable risk estimates and improve validity of performance comparisons.

Response: We thank the commenters for their support and agree this update to the risk adjustment model will improve alignment with current clinical practices and result in improved validity of the measures' performance.

6. Summary of Previously Finalized and Newly Finalized Hospital Inpatient Quality Reporting Program Measures

This table IX.C.5. summarizes the previously finalized and newly finalized Hospital Inpatient Quality Reporting Program measures for the FY 2028 to FY 2031 payment determinations, which removes the STK–02, VTE–1, and VTE–2 eCQMs discussed in section IX.C.4. of this final rule; modifies three EDAC measures as discussed in section IX.C.5. of this final rule; adds the Diabetes EDAC measure and the Hospital Harm—Postoperative VTE eCQM as discussed in section IX.C.3. in this final rule; and adds the Advance Care Planning eCQM and five modified mortality measures as discussed in sections IX.B.1. and IX.B.2. of this final rule:

TABLE IX.C.5. HOSPITAL INPATIENT QUALITY REPORTING PROGRAM MEASURE SET BY DATA COLLECTION METHOD AND PAYMENT DETERMINATION (PD)

Measure Name	CBE Number	FY 2028 PD	FY 2029 PD	FY 2030 PD	FY 2031 PD
Patient Experience of Care Survey Measures					
Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)	✓	✓	✓	✓
Chart-Abstracted Clinical Process of Care Measures					
Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500	✓	✓	✓	✓
Structural Measures					
Maternal Morbidity Structural Measure	N/A	✓	✓	✓	✓
Patient Safety Structural Measure	N/A	✓	✓	✓	✓
Age Friendly Hospital Measure	N/A	✓	✓	✓	✓
Claims-Based Patient Safety Measures					
Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Inpatient Surgical Complications Rate)	4125	✓	✓	✓	✓
Claims-Based Mortality/Complications Measures					
Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate Following Acute Ischemic Stroke	N/A	✓	✓	✓	✓
Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550	✓	✓		
Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization (MORT–30–AMI)**	0230	Adopted	✓	✓	✓
Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization (MORT–30–HF)**	0229	Adopted	✓	✓	✓
Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN)**	0468	Adopted	✓	✓	✓
Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (MORT–30–COPD)**	1893	Adopted	✓	✓	✓
Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (MORT–30–CABG) measures**	2558	Adopted	✓	✓	✓
Claims-Based Coordination of Care Measures					
Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction***	2881	✓	✓	✓	✓
Excess Days in Acute Care after Hospitalization for Heart Failure***	2880	✓	✓	✓	✓
Excess Days in Acute Care after Hospitalization for Pneumonia***	2882	✓	✓	✓	✓
Excess Days in Acute Care after Hospitalization for Diabetes****	N/A		Adopted	✓	✓
National Healthcare Safety Network Measures					
HCP Influenza Vaccination	0431	✓	✓	✓	✓
Catheter- Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations	0138	✓	✓	✓	✓
Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations	0139	✓	✓	✓	✓

Measure Name	CBE Number	FY 2028 PD	FY 2029 PD	FY 2030 PD	FY 2031 PD
Claims and Electronic Data Measures					
Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502e	✓	✓	✓	✓
Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879e	✓	✓	✓	✓
Patient-Reported Outcome Performance Measures					
Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO-PM)	3559	✓	✓	✓	✓
Electronic Clinical Quality Measures					
Discharged on Antithrombotic Therapy*****	0435e	✓*	✓*	Removed	
Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e	✓*	✓*	✓*	✓*
Antithrombotic Therapy by the End of Hospital Day Two	0438e	✓*	✓*	✓*	✓*
Venous Thromboembolism Prophylaxis*****	0371e	✓*	✓*	Removed	
Intensive Care Unit Venous Thromboembolism Prophylaxis*****	0372e	✓*	✓*	Removed	
Safe Use of Opioids—Concurrent Prescribing	3316e	✓	✓	✓	✓
Hospital Harm—Opioid-Related Adverse Events	3501e	✓*	✓	✓	✓
Hospital Harm—Severe Hypoglycemia	3503e	✓	✓	✓	✓
Hospital Harm—Severe Hyperglycemia	3533e	✓	✓	✓	✓
Hospital Harm—Pressure Injury	3498e	✓*	✓*	✓	✓
Hospital Harm—Acute Kidney Injury	3713e	✓*	✓*	✓	✓
Hospital Harm—Falls with Injury******	4120e	✓*	✓*	Mandatory	✓
Hospital Harm—Postoperative Respiratory Failure******	4130e	✓*	✓*	Mandatory	✓
Hospital Harm—Postoperative Venous Thromboembolism*******	5325e			Self-selected	✓*
Cesarean Birth	0471e	✓	✓	✓	✓
Severe Obstetric Complications	3687e	✓	✓	✓	✓
Malnutrition Care Score******	3592e	✓*	✓*	Mandatory	✓
Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient)	3663e	✓*	✓*	✓*	✓*
Advance Care Planning*******	N/A			Self-Selected	✓*

✓Measure is mandatory for the specified payment determination year.

* Measure is a self-selected eCQM for the specified payment determination year. Hospitals are required to self-select three eCQMs, in addition to all mandatory eCQMs, to submit for the specified payment determination year.

** In this final rule, we are finalizing adoption of the MORT-30-AMI, MORT-30-HF, MORT-30-PN, MORT-30-COPD, and MORT-30-CABG for the FY 2028 payment determination through the FY 2031 payment determination. We refer readers to section IX.B.2. of this final rule for more detailed discussion.

*** In this final rule, we are finalizing modifications to the AMI EDAC, HF EDAC, and PN EDAC measures beginning with the FY 2028 payment determination. We refer readers to section IX.C.5. of this final rule for more detailed discussion.

**** In this final rule, we are finalizing adoption beginning with FY 2029 payment determination.

***** In this final rule, we are finalizing removal beginning with the FY 2030 payment determination.

****** In this final rule, we are finalizing modification from self-selected to mandatory reporting beginning with the FY 2030 payment determination.

******* In this final rule, we are finalizing adoption beginning with the FY 2030 payment determination. We refer readers to section IX.C.8.c. of this final rule for more detailed discussion of our modifications to the reporting and submission requirements for eCQMs. Under this modification, the Hospital Harm—Postoperative VTE eCQM will begin mandatory reporting after two years of self-selection beginning with the FY 2032 payment determination.

7. Future Considerations

We seek to develop a comprehensive set of quality measures to be widely available for informed decision-making and quality and cost improvements in the hospital inpatient setting. We have identified potential future measures that are focused on topics that are of importance to interested parties, but that are not currently included in the Hospital Inpatient Quality Reporting Program's measure set. We refer readers to section IX.B.3. for our request for comment on ''Measuring Emergency Care Access and Timeliness in Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs—Request for Information'' and section IX.B.4. for our request for comment on ''Potential Future Use of the Adult Community-Onset Sepsis Standardized Mortality

Ratio Measure in the Hospital Inpatient Quality Reporting Program—Request for Information.''

We are also soliciting comments on our anticipated approach to potential scoring methodologies for the next phase of our Birthing-Friendly Hospital designation. We will consider feedback we receive as we determine how best to further develop and refine the Hospital Inpatient Quality Reporting Program's measure set and to advance other quality improvement efforts that address important patient safety and health care quality topics.

a. Birthing-Friendly Hospital Designation Modification To Expand Designation Criteria—Request for Information

In this request for information (RFI), we sought public input on potential modifications to the Birthing-Friendly Hospital Designation which was adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49284 through 49290). In the FY 2023 IPPS/LTCH PPS final rule, we noted our intent to expand the Birthing-Friendly Hospital Designation with a more robust set of metrics in future years, and we intended for those additional metrics to potentially be derived from maternal care quality measures from the Hospital Inpatient Quality Reporting Program. This RFI aims to gather broad public input on: (1) the inclusion of the Cesarean Birth eCQM and the Severe Obstetric Complications eCQM in the criteria for awarding the Birthing-Friendly Hospital Designation; and (2) a modified scoring methodology developed for the expanded Birthing-Friendly Hospital Designation.

(1) Background

The Birthing-Friendly Hospital Designation (hereinafter referred to as ''the Designation''), was created to identify hospitals that demonstrate the delivery of high-quality maternal care and a commitment to improving maternal health outcomes (87 FR 49284 through 49290). Despite the highest rate of spending on maternity care, maternal morbidity and mortality rates in the United States are high compared to other high-income countries. Every year in the United States, approximately 700 women die of complications related to pregnancy and childbirth, and over 25,000 women experience severe complications of pregnancy (severe maternal morbidity).[461] [462] Approximately one-third of all pregnancy-related deaths occur at the time of delivery and immediately postpartum, with nearly 20 percent occurring between one and six days postpartum.[463] Yet, three out of five pregnancy-related deaths are considered preventable.[464]

We believe the Designation is an important way to advance maternal care quality for patients and families and represents our sustained commitment to improving health outcomes. Interested parties expressed support for the Designation as a meaningful step to promote transparency and improve maternal health outcomes. When we proposed the Designation in the FY 2023 IPPS/LTCH PPS proposed rule, many commenters recommended using additional data to determine which hospitals would receive the Designation, including data from the Cesarean Birth and Severe Obstetric Complications eCQMs, rather than just the Maternal Morbidity Structural measure data (87 FR 49284 through 49290).

The Designation was created to be a consumer-friendly, publicly reported display signaling a hospital's commitment to improving maternal health. Hospitals that are awarded the Designation receive a Birthing-Friendly icon on the Compare tool on *Medicare.gov*. The Designation was first displayed on the Compare tool in Fall 2023 using CY 2022 data. Geocoded information of Birthing-Friendly hospitals and health systems is available at: *https://data.cms.gov/provider-data/birthing-friendly-hospitals-and-health-systems.*

(2) Current Birthing-Friendly Hospital Designation Methodology

Currently, the Designation is comprised of the Maternal Morbidity Structural measure adopted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365). The Maternal Morbidity Structural measure is an attestation-based measure which includes one attestation, currently specified as a two-part question, that captures whether hospitals are: (1) currently participating in a structured state or national Perinatal Quality Improvement (QI) Collaborative; and (2) implementing patient safety practices or bundles as part of these QI initiatives.[465] In reporting this measure, hospitals answer ''yes,'' ''no,'' or ''not applicable (our hospital does not provide inpatient labor/delivery care)''.[466] The Designation is given to hospitals that report ''yes'' for the Maternal Morbidity Structural measure. The current version of the Maternal Morbidity Structural measure specifications is available at: *https://qualitynet.cms.gov/inpatient/iqr/measures#tab2.* We note in section IX.C.8.d.(1) of this final rule where we are updating the reporting requirements of the Maternal Morbidity Structural measure beginning with the CY 2026 reporting period/FY 2028 payment determination.

(3) Potential Modifications to the Birthing-Friendly Hospital Designation

Potential modifications to the Designation would include incorporating hospital performance on two additional maternal care quality outcome measures: (1) the Cesarean Birth eCQM and (2) the Severe Obstetric Complications eCQM. These two eCQMs aim to reduce the occurrence of cesarean deliveries and maternal complications, thereby improving maternal health outcomes and quality of life. Incorporating guidance from a TEP, we developed a potential new scoring methodology for the Designation that aggregates these two measures into a composite score to meaningfully summarize hospital maternal health performance and to determine hospital performance on the Designation.

(a) Expanding the Birthing-Friendly Hospital Designation To Include the Cesarean Birth and the Severe Obstetric Complications Electronic Clinical Quality Measures

The Cesarean Birth eCQM is an outcome measure that assesses the proportion of cesarean deliveries to

[461] Peterson EE et al. Vital Signs: Pregnancy-Related Deaths, United States, 2011–2015, and Strategies for Prevention, 13 States, 2013–2017. MMWR Morbidity and Mortality Weekly Report 2019;68:423–29.

[462] Maternal and Child Health Bureau. Federally Available Data (FAD) Resource Document. Health Resources and Services Administration. Available at: *https://mchb.tvisdata.hrsa.gov/Admin/FileUpload/DownloadContent?fileName=FadResourceDocument.pdf&isForDownload=False.*

[463] Davis N.L., Smoots A.N., and Goodman D.A. (2019). Pregnancy-Related Deaths: Data from 14 U.S. Maternal Mortality Review Committees, 2008–2017. Available at: *https://archive.cdc.gov/www_cdc_gov/reproductivehealth/maternal-mortality/erase-mm/MMR-Data-Brief_2019-h.pdf.*

[464] The Centers for Disease Control and Prevention. Pregnancy-Related Deaths in the United States. September 2021. Available at: *https://www.cdc.gov/hearher/pregnancy-related-deaths/index.html.*

[465] Centers for Medicare & Medicaid Services. Cross-Cutting Initiative: CMS Maternity Care Action Plan. 2022. Available at: *https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf.*

[466] To report on this measure, hospitals will respond to a two-part question: ''Does your hospital or health system participate in a Statewide and/or National Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery and postpartum care, and has it implemented patient safety practices or bundles related to maternal morbidity to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis?'' Further details on this measure can be found in the FY 2022 IPPS/LTCH PPS final rule at 86 FR 45361 through 45365.

nulliparous women (women giving birth for the first time) who delivered at 37 weeks' gestation or later with a live singleton baby (a single baby) in a vertex position (head-down). The hospital-level score is calculated as a proportion, for which a lower proportion is better; however, since cesarean delivery is a warranted emergency intervention in certain situations, scores are not expected, nor desired, to approach zero. For further details on the measure methodology, we refer readers to the methodology report available at: *https://manual.jointcommission.org/releases/TJC2023B/MIF0167.html.* The measure became mandatory for all hospitals participating in the Hospital Inpatient Quality Reporting and Medicare Promoting Interoperability Programs beginning with the CY 2024 reporting period (87 FR 49298 through 49302, and 87 FR 49361 through 49364).

The Severe Obstetric Complications eCQM is a risk-standardized measure that assesses severe maternal morbidity events and mortality during delivery hospitalizations for patients greater than or equal to 8 years and less than 65 years of age delivering stillborn or a live birth at greater than or equal to 20 weeks' gestation. The measure evaluates two outcomes: (1) any severe obstetric complications (as specified), and (2) severe obstetric complications excluding encounters for which blood transfusion was the only numerator event. For both outcomes, the hospital-level score is reported as a rate per 10,000 delivery hospitalizations, for which a lower score is better. For further details on the measure methodology, we refer readers to the methodology report available at: *https://ecqi.healthit.gov/sites/default/files/SevereObstetricComplications%20eCQM_Methodology%20Report%20-%20Dec%202022.pdf.* The measure became mandatory for all hospitals participating in the Hospital Inpatient Quality Reporting and Medicare Promoting Interoperability Programs beginning with the CY 2024 reporting period (87 FR 49298 through 49302; 87 FR 49361 through 49364).

(b) Potential New Scoring Methodology

Following careful assessment of various scoring approaches, we determined the composite score approach with k-means clustering to be a strong approach for calculating hospital Designation scores. The composite score approach with k-means clustering enables a tiered approach to award the Designation, thus allowing for a range of hospital performance while still recognizing high-performing hospitals. In addition, this approach allows for differential weighting, enabling more outcome related measures to have a stronger influence on the overall performance scores. This approach is similar to that used in the Overall Hospital Quality Star Rating methodology (85 FR 86193 through 86236).[467]

To be eligible for the expanded Designation, hospitals would have to attest positively to the Maternal Morbidity Structural measure and report on both maternal outcome measures (Cesarean Birth and Severe Obstetric Complications eCQMs). Positive attestation to the Maternal Morbidity Structural measure would be required for Designation eligibility and would serve as a prerequisite to obtaining the Designation. Once hospital eligibility is determined, the methodology for aggregating hospital scores for the two maternal outcome measures into a composite and scoring for the Designation would include a series of steps. First, the direction of measure scores is changed so that a higher score indicates better performance for all the measures. Second, measure scores that do not follow a normal distribution are normalized by applying a log transformation, and then the data are standardized using Z-scores[468] to enable aggregation on a common scale. Third, measure scores are multiplied by assigned weights. The Cesarean Birth eCQM is assigned a 45 percent weight. The two outcomes for the Severe Obstetric Complications eCQM are assigned weights that sum to 55 percent: 18 percent for any severe obstetric complications, and 37 percent for severe obstetric complications excluding encounters for which blood transfusion was the only numerator event. The higher weighting of the Severe Obstetric Complications eCQM was selected because it prioritizes the occurrence of severe obstetric complications and elevates attention to reducing maternal morbidity. Furthermore, the differential weighting among the two Severe Obstetric Complications eCQM outcomes was selected to prioritize the outcome excluding blood transfusion-only encounters, as these encounters may represent lesser severity than the other specified obstetric complications. Fourth, weighted measure scores are aggregated to generate the composite score for each hospital. Fifth, hospitals are grouped into four peer groups based on the delivery volume for that hospital during the performance period (less than or equal to 500 deliveries, 501 to 1000 deliveries, 1001 to 2000 deliveries, and greater than 2000 deliveries). Peer grouping by hospital delivery volume supports comparison of hospitals with obstetric units of similar scale. Sixth, a statistical clustering algorithm (k-means clustering) is applied within each peer group to assign hospitals with similar composite scores to one of three clusters representing levels of maternal care quality. For details of this potential future modified measure methodology for scoring an expanded Designation, we refer readers to the draft methodology report, available at: *https://qualitynet.cms.gov/inpatient/iqr/proposedmeasures.*

(c) Awarding the Birthing-Friendly Hospital Designation

For the current Birthing-Friendly Hospital Designation, hospitals receive the Designation for positively attesting to the Maternal Morbidity Structural measure. The potential new scoring methodology described previously would introduce a tiered approach to awarding the Designation by performance relative to other hospitals on multiple maternal quality measures, and shifts away from a binary approach that only identifies hospitals as ''Birthing-Friendly'' or, by default, as ''non-Birthing-Friendly.'' The potential new approach considers the range in maternal care performance among labor and delivery hospitals and allows for recognition of the highest-performing hospitals. As positive attestation to the Maternal Morbidity Structural measure would serve as a prerequisite to receiving the Designation, hospitals currently awarded the Designation could maintain ''Birthing-Friendly'' status.

Within delivery volume peer groups, hospitals would be assigned to one of three clusters based on composite score, where cluster three consists of hospitals with the highest level of performance (highest composite scores) and cluster one consists of hospitals with the lowest level of performance (lowest composite scores). Each cluster would be represented by a corresponding number of Birthing-Friendly icons (similar to a star rating) such that hospitals in cluster one would be identified with one Birthing-Friendly icon (identifying the lowest performing hospitals), hospitals in cluster two would be identified with two Birthing-Friendly icons, and hospitals in cluster three would be

[467] Available at: *https://data.cms.gov/provider-data/topics/hospitals/overall-hospital-quality-star-rating/.*

[468] Z-score standardization is a commonly used approach that translates hospital results into a common scale, indicating how each hospital's performance compares with the overall average. This approach helps reduce the impact of extreme values and differences in scoring methods, while supporting fair and consistent comparisons across hospitals.

identified with three Birthing-Friendly icons (identifying the top performing hospitals).

The use of peer grouping by hospital delivery volume to award the Designation allows for comparison of like hospitals, grouping facilities with obstetric units of similar scale. Other variables for peer grouping the Designation were considered, with particular attention to using Maternal Levels of Care in anticipation that hospitals providing different levels of care vary in patient case mix. The Maternal Levels of Care, a classification system developed by the American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine to support risk-appropriate maternal care delivery, is used to classify hospitals providing labor and delivery services from ''Basic Care'' (Level I) for women with low to moderate-risk pregnancies to ''Regional Perinatal Health Care Centers'' (Level IV) for women inclusive of those at low-risk to the highest-risk pregnancies.[469] However, there is currently no reliable and comprehensive source of publicly reported data on Maternal Levels of Care for all hospitals providing labor and delivery services. In this RFI, we seek further input on peer grouping considerations.

In preliminary testing of the modified Designation scoring methodology, 2,548 hospitals that reported at least one of the maternal measures for CY 2024 were identified (excluding hospitals that responded ''not applicable (our hospital does not provide inpatient labor/delivery care)'' to the Maternal Morbidity Structural measure). Among these, 1,976 hospitals were determined to have reported on all three measures and had 25 or more delivery hospitalizations during the measurement period, to align with the public reporting threshold for the maternal outcome measures. Of these hospitals, 1,920 (97.1 percent) hospitals attested positively to the Maternal Morbidity Structural measure and were included in testing of the modified Designation scoring methodology. Preliminary results indicate variation in mean composite scores for the Designation clusters across delivery volume categories (peer groups), most distinctly for the top delivery volume category (hospitals with greater than 2000 deliveries) that had a lower mean composite score within each cluster as compared to the mean composite scores of those clusters in lower delivery volume categories (see Table IX.C.6.).

TABLE IX.C.6. MEAN BIRTHING-FRIENDLY HOSPITAL DESIGNATION COMPOSITE SCORE PER CLUSTER FOR EACH DELIVERY VOLUME CATEGORY (PEER GROUP), CY 2024 TESTING DATA (N = 1920 HOSPITALS)

Delivery Volume Categories	Cluster 1 (Lowest Performing)	Cluster 2	Cluster 3 (Highest Performing)
≤ 500	-0.75	0.09	0.81
501 – 1,000	-0.66	0.13	0.85
1,001 – 2,000	-0.78	0.03	0.71
> 2,000	-0.94	-0.21	0.59

Preliminary testing results for awarding Birthing-Friendly Hospital Designation icons indicate similar distributions across delivery volume categories (peer groups) for hospitals to receive one, two, and three Birthing-Friendly icons representing lowest to highest Birthing-Friendly hospital performance (see Table IX.C.7.).

TABLE IX.C.7. DISTRIBUTION OF BIRTHING-FRIENDLY HOSPITAL DESIGNATION FOR EACH DELIVERY VOLUME CATEGORY (PEER GROUP), CY 2024 TESTING DATA (N = 1920 HOSPITALS)

Peer Groups (Delivery Volume Categories)	Cluster 1 (Lowest Performing)	Cluster 2	Cluster 3 (Highest Performing)
≤ 500	24%	44%	32%
501 – 1,000	27%	43%	30%
1,001 – 2,000	26%	45%	29%
> 2,000	28%	46%	26%

The measure developer received feedback during winter 2025 from a TEP, including patients, patient advocates, technical experts, and clinicians, supporting the expansion of criteria for the Designation and the potential new scoring methodology.[470]

(4) Solicitation of Public Comments

We sought feedback on potential modifications to the current Birthing-

[469] Available at: *https://www.acog.org/programs/lomc.*

[470] Yale CORE. (March 2026). Summary of Technical Expert Panel (TEP): Development of Birthing Friendly Hospital Designation (BFHD). Available at: *https://mmshub.cms.gov/sites/default/files/Del4-3BFHDSummaryTEPEvaluation-March2026.pdf.*

Friendly Hospital Designation. We requested input from interested parties on the following potential modifications: (1) expanding the Designation to include two maternal care quality outcome measures: Cesarean Birth eCQM and Severe Obstetric Complications eCQM; (2) the outlined scoring methodology noted previously including use of peer grouping; and (3) the accompanying tiered approach to awarding Birthing-Friendly Hospital Designation icons. Specifically, we requested feedback on the following topics:

- Do you have feedback on the potential new scoring methodology outlined in this RFI for the Designation?
- With respect to the potential new scoring methodology, do you have any special considerations for small, rural, or safety net hospitals?
- Differential measure score weighting:

++ Do you have feedback on the higher weighting of the Severe Obstetric Complications eCQM (combined scores) at 55 percent compared to weighting of the Cesarean Birth eCQM at 45 percent?

++ Do you have feedback on the differential weighting of the two Severe Obstetric Complications eCQM outcomes (any severe obstetric complication equals 18 percent, severe obstetric complications excluding encounters for which blood transfusion was the only numerator event equals 37 percent)?

- Do you have feedback on a tiered approach to awarding the Designation for identifying levels of quality/performance?
- Approaches for peer grouping:

++ Do you have feedback on using delivery volume as a peer grouping variable?

++ Would the category ''less than or equal to 500 deliveries'' represent an appropriate peer grouping for hospitals with low birth volumes, such as those in rural areas?

++ Should there be a minimum number of births required in the peer grouping, such as ''25–500 deliveries'' instead of ''less than or equal to 500 deliveries''?

++ Are there any other variables that would be appropriate for peer grouping? And if so, please provide information on data sources.

- Public reporting of the Designation results:

++ Do you have feedback on the presentation of the Designation on the Compare tool? Specifically, do you agree with using one to three Birthing-Friendly icons to represent summarized hospital performance?

++ Is the Designation easily interpreted by patients and consumers? Do you have suggestions on the messaging of the Designation on the Compare tool on *Medicare.gov?*

With these questions, we sought public input on potential modifications to the Birthing-Friendly Hospital Designation described previously, for consideration in future rulemaking.

We received public comments on these topics. The following is a summary of the comments we received:

Comment: Many commenters supported updating the Birthing-Friendly Hospital Designation because of the significant impact that the quality of obstetric care has on patients and their families. A few commenters stated that the potential updates to the Birthing-Friendly Hospital Designation would align with the Joint Commission's Outcomes-Driven Certification in Perinatal Care and stated that alignment would limit provider confusion. A commenter recommended that CMS publish updates to the Birthing-Friendly Hospital Designation, including methodology, weighting, peer grouping, and information about the public display framework through notice and comment rulemaking.

Some commenters expressed concern about the appropriateness of the available measures and did not support developing a scoring or tiering system using these measures. Some of these commenters recommended waiting until hospitals have more experience reporting and receiving feedback on these measures prior to including them in the Birthing-Friendly Hospital Designation. A commenter expressed concern that this Designation may be used to adjust hospital payments, which the commenter stated could reduce access to obstetric care.

Many commenters supported inclusion of the Cesarean Birth eCQM in the Birthing-Friendly Hospital Designation. However, many commenters expressed concerns about the Cesarean Birth eCQM. Some commenters stated that it is important to recognize that there are times when a cesarean birth is medically necessary and therefore it is not appropriate to target a zero percent score on this measure. A few commenters further stated that without a target rate of cesarean births, it will be difficult for hospitals and the public to meaningfully interpret data reported for the Cesarean Birth eCQM. A few commenters stated that this is a utilization measure that does not appropriately distinguish between medically necessary and elective cesarean births. These commenters requested that CMS provide evidence that this measure is indicative of clinical quality before incorporating it into any public facing designation. Many commenters expressed concern regarding the measure's lack of sufficient risk adjustment. These commenters recommended risk-adjusting for patient mix including age, comorbidity, payer, and clinical risk factors. However, several commenters expressed concern that clinical risk factors are sometimes documented in narrative history or scanned records.

Many commenters supported inclusion of the Severe Obstetric Complications eCQM. Some commenters recommended updates to the Severe Obstetric Complications eCQM prior to incorporation into a modified Birthing-Friendly Hospital Designation. Commenters specifically recommended incorporating risk adjustment for social and clinical risk factors, including for the most medically complex patients. A few commenters expressed concern that there have been shifts in complication rates and there is a lack of a stable national benchmark. A few commenters expressed concern about including this measure in the methodology for the Birthing-Friendly Hospital Designation because this measure tracks rare events and therefore most hospitals may not have enough cases to report.

Some commenters recommended other quality measures or quality measure concepts for inclusion in the scoring for the Birthing-Friendly Hospital Designation. The recommended measures and measure concepts are:

- Unexpected Complications in Term Newborns (PC–06)
- Elective Delivery (PC–01)
- HCAHPS, specifically the upcoming Inpatient Maternal Health Care Survey
- Timely Treatment of Severe Hypertension (ePC–08)
- Measures topics identified by the Core Quality Measures Collaborative Workgroup:
  - ++ Postpartum depression and follow-up
  - ++ Delivery types
  - ++ Unexpected complications
  - ++ Infant immunization
- Whether hospitals have adopted continuous, real-time hemodynamic monitoring capabilities
- Access to midwives
- Hemorrhage readiness and response
- Sepsis recognition
- Postpartum follow-up
- PRO–PMs
- Secure data interoperability

- Measures that reflect and address disparities in maternal health outcomes
- Quality of anesthesia care
- A measure that includes all medically unnecessary C-sections

Several commenters supported updating the scoring for the Birthing-Friendly Hospital Designation to avoid a binary scoring structure. However, several commenters expressed concern regarding the potential scoring framework described in the proposed rule. Some of these commenters specifically expressed concern regarding k-means clustering and some stated that a clustering approach may be difficult for patients to interpret and hospitals to use for quality improvement. A few commenters stated that the combined effects of k-means clustering and peer grouping could lead hospitals with higher performance to receive worse scores, or the reverse. A few commenters recommended using a z-score based methodology to improve reproducibility and ease of interpretation. A few commenters expressed concern that the scoring methodology described in the proposed rule could allow hospitals that perform poorly on the Cesarean Birth or Severe Obstetric Complications eCQMs to receive a Birthing-Friendly Hospital Designation icon. These commenters supported a scoring methodology that requires hospitals to have a positive attestation to the Maternal Morbidity structural measure or to meet a certain threshold on the two outcomes eCQMs to receive any Birthing-Friendly Hospital Designation icons. Another commenter recommended requiring a minimum Overall Star Rating score to qualify for the Birthing-Friendly Hospital Designation. A commenter recommended establishing absolute criteria to qualify for the Birthing-Friendly Hospital Designation rather than comparing hospitals to one another.

Many commenters recommended that CMS ensure any updates to the Birthing-Friendly Hospital Designation are fair for hospitals caring for medically and socially complex, rural, underserved, and historically marginalized patients. A few commenters expressed concern that establishing different methodologies based on hospital type or size may create a two-tiered standard for safety. A commenter expressed concern that updating the scoring methodology for the Birthing-Friendly Hospital Designation could strain maternal quality analytics and data systems, which could disproportionately affect safety net providers. Some commenters stated that including outcome measures could lead to a misrepresentation of the care provided at small or rural facilities.

Many commenters supported the higher weighting of the Severe Obstetric Complications eCQM because of the importance of focusing on preventable maternal morbidity. A few commenters supported weighting the Severe Obstetric Complications eCQM at 55 percent and the Cesarean Birth eCQM at 45 percent, stating that this approach has face validity because the Severe Obstetric Complications eCQM comprises two outcomes. A commenter recommended either assigning the two measures equal weight or assigning the Cesarean Birth eCQM 55 percent and the Severe Obstetric Complications eCQM 45 percent of the score because the Cesarean Birth eCQM is more established. A commenter recommended using harm-based weighting analogous to the method used in the AHRQ PSI 90 composite measure.

A few commenters supported two outcomes of the Severe Obstetric Complications eCQM that distinguish inclusion and exclusion of blood transfusion-only outcomes. A few commenters supported the tiered approach as described in the proposed rule. A few commenters recommended ensuring that the tiered approach would remain relatively stable to reduce potential confusion associated with year-to-year volatility. A few commenters stated three tiers would not provide sufficient granularity to meaningfully distinguish the quality of performance. A commenter recommended testing reliability across hospital types and delivery volumes prior to adopting any tiered designation framework.

Many commenters supported peer grouping and establishing minimum case volumes. Several commenters supported including delivery volume as a peer grouping variable. A few commenters suggested including more than two peer grouping variables to better represent hospitals' differences. A few commenters supported a minimum case volume to identify hospitals that do not regularly provide labor and delivery services. Several other commenters stated that a minimum case volume may signal that quality of care is not important at hospitals that treat small volumes of labor and delivery patients. A few commenters provided additional variables for peer grouping. Commenters specifically suggested hospital type (that is, rural, urban, critical access, or safety net), NICU level, or ACOG Maternal Level of Care.

Many commenters provided feedback on public reporting of the Birthing-Friendly Hospital Designation using one to three Birthing-Friendly icons. A few commenters stated that the use of one to three icons may be confusing and recommended providing education and outreach to show that receiving one icon does not indicate unsafe or low-quality care. A few commenters recommended aligning with Overall Hospital Star Ratings (for example by having an overall star rating and a maternal health star rating) to improve clarity when compared to introducing icons with different meanings.

Many commenters stated that the Birthing-Friendly Hospital Designation as described in the proposed rule may be hard for patients and their families to understand. Some of these commenters recommended that CMS engage with patients, families, and communities to ensure the Birthing-Friendly Hospital Designation is helpful and not overly complex. Several commenters recommended providing public-facing materials on the data used to calculate the results to improve public awareness and confidence. A few commenters recommended that CMS ensure that it is clear to patients and families how the Birthing-Friendly Hospital Designation can be interpreted in the context of Overall Star Ratings (for example, how to interpret a hospital that has a low Overall Star Rating but receives the Birthing-Friendly Hospital Designation). A few commenters stated that composite scores are not meaningful to consumers because they do not accurately reflect differences in quality of care. A commenter expressed concern that the Birthing-Friendly Hospital Designation may not be useful for most patients due to limited choice about where to receive labor and delivery services. A commenter stated that the Birthing-Friendly Hospital Designation is only helpful to patients and their families if it is regularly updated and noted that there are hospitals that no longer offer labor and delivery services that are still included as Birthing-Friendly hospitals on the Care Compare site.

Response: We appreciate all the comments and interest in this topic. While we are not responding to specific comments in response to the RFI in this final rule, we believe that this input is very valuable and will continue to take all concerns, comments, and suggestions into account for future development of the Birthing-Friendly Hospital Designation.

8. Updates to the Form, Manner, and Timing of Quality Data Submission

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19600 through 19605), we proposed changes to our

reporting and submission requirements for eCQMs and structural measures, as later discussed in this final rule.

We did not propose any changes to the following requirements: procedural requirements; data submission requirements for chart-abstracted measures; data submission and reporting requirements for hybrid measures; sampling and case thresholds for chart-abstracted measures; HCAHPS Survey administration and submission requirements; data submission and reporting requirements for CDC National Healthcare Safety Network measures; and data submission and reporting requirements for Patient-Reported Outcome-Based Performance Measures. Accordingly, these requirements were not repeated in the Form, Manner, and Timing of Quality Data Submission section. We refer readers to the QualityNet website at: *https://qualitynet.cms.gov/inpatient/iqr* (or other successor CMS designated websites) for more details on the Hospital Inpatient Quality Reporting Program data submission and procedural requirements.

a. Background

Section 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner and at a time specified by the Secretary. To successfully participate in the Hospital Inpatient Quality Reporting Program, hospitals must meet specific procedural, data collection, submission, and validation requirements.

b. Maintenance of Technical Specifications for Quality Measures

Section 412.140(c)(1) of title 42 of the CFR generally requires that a subsection (d) hospital participating in the Hospital Inpatient Quality Reporting Program must submit to CMS data on measures selected under section 1886(b)(3)(B)(viii) of the Act in a form and manner, and at a time, specified by CMS. The data submission requirements, specifications manual, measure methodology reports, and submission deadlines are posted on the QualityNet website at: *https://qualitynet.cms.gov* (or other successor CMS designated websites).

The CMS Annual Update for the Hospital Quality Reporting (HQR) Programs (Annual Update) contains the technical specifications for eCQMs. The updated measure specifications applicable to a reporting period are contained in the Annual Update issued in the year prior to the reporting period. For example, for the CY 2026 reporting period/FY 2028 payment determination, hospitals are collecting and will submit eCQM data using the May 2025 Annual Update and any applicable addenda. The Annual Update and implementation guidance documents are available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/.*

Hospitals must register and submit quality data as described at 42 CFR 412.140(a).

c. Data Submission and Reporting Requirements for Electronic Clinical Quality Measures

(1) Background

Beginning with the CY 2016 reporting period, we began requiring hospitals to report on eCQMs with the goal of progressively increasing the number of eCQMs a hospital is required to report while also being responsive to concerns about timing, readiness, and burden associated with the increased number of measures (80 FR 49693 through 49698 and 81 FR 57150 through 57157). Over time we have gradually increased the number of eCQMs that we require hospitals to report over the course of several years to allow hospitals and their vendors time to gain experience with reporting eCQMs, while providing flexibility by retaining an element of choice in allowing a hospital to self-select some eCQMs (84 FR 42503 through 42505, 85 FR 58932 through 58939, 86 FR 45417 through 45418, 87 FR 49298 through 49302, and 89 FR 69568 through 69573). In the FY 2025 IPPS/LTCH PPS final rule, we finalized a further increase in the number of mandatory eCQMs focused on improving patient safety (89 FR 69568 through 69573). Table IX.C.8. summarizes our current eCQM reporting and submission policies:

TABLE IX.C.8. PREVIOUSLY FINALIZED ECQM REPORTING AND SUBMISSION REQUIREMENTS FOR THE CY 2026 REPORTING PERIOD/FY 2028 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Reporting Period/ Payment Determination	Total Number of eCQMs Reported	eCQMs Selected by CMS to be Reported	eCQMs for Self-selection (must report 3)
CY 2026/ FY 2028	Eight	• Safe Use of Opioids—Concurrent Prescribing • Cesarean Birth • Severe Obstetric Complications • Hospital Harm—Severe Hyperglycemia • Hospital Harm—Severe Hypoglycemia	• Discharged on Antithrombotic Therapy • Anticoagulation Therapy for Atrial Fibrillation/Flutter • Antithrombotic Therapy by the End of Hospital Day Two • Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults • Venous Thromboembolism Prophylaxis • Intensive Care Unit Venous Thromboembolism Prophylaxis • Malnutrition Care Score • Hospital Harm—Opioid-Related Adverse Events • Hospital Harm—Pressure Injury • Hospital Harm—Acute Kidney Injury • Hospital Harm—Falls with Injury • Hospital Harm—Postoperative Respiratory Failure
CY 2027/ FY 2029	Nine	• Safe Use of Opioids—Concurrent Prescribing • Cesarean Birth • Severe Obstetric Complications • Hospital Harm—Severe Hyperglycemia • Hospital Harm—Severe Hypoglycemia • Hospital Harm—Opioid-Related Adverse Events	• Discharged on Antithrombotic Therapy • Anticoagulation Therapy for Atrial Fibrillation/Flutter • Antithrombotic Therapy by the End of Hospital Day Two • Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults • Venous Thromboembolism Prophylaxis • Intensive Care Unit Venous Thromboembolism Prophylaxis • Malnutrition Care Score • Hospital Harm—Pressure Injury • Hospital Harm—Acute Kidney Injury • Hospital Harm—Falls with Injury • Hospital Harm—Postoperative Respiratory Failure
CY 2028/ FY 2030 (and for subsequent years)	Eleven	• Safe Use of Opioids—Concurrent Prescribing • Cesarean Birth • Severe Obstetric Complications • Hospital Harm—Severe Hyperglycemia • Hospital Harm—Severe Hypoglycemia • Hospital Harm—Opioid-Related Adverse Events • Hospital Harm—Pressure Injury • Hospital Harm—Acute Kidney Injury	• Discharged on Antithrombotic Therapy • Anticoagulation Therapy for Atrial Fibrillation/Flutter • Antithrombotic Therapy by the End of Hospital Day Two • Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults • Venous Thromboembolism Prophylaxis • Intensive Care Unit Venous Thromboembolism Prophylaxis • Malnutrition Care Score • Hospital Harm—Falls with Injury • Hospital Harm—Postoperative Respiratory Failure

We refer readers to the QualityNet website for additional information on current and previous reporting and submission requirements for eCQMs at: *https://qualitynet.cms.gov/inpatient/measures/ecqm.*

(2) Mandatory Reporting of the Malnutrition Care Score Electronic Clinical Quality Measure

The Malnutrition Care Score eCQM was initially adopted in the FY 2023 IPPS/LTCH PPS final rule into the Hospital Inpatient Quality Reporting Program measure set from which a hospital could self-select beginning with the CY 2024 reporting period/FY 2026 payment determination (87 FR 49239 through 49246). In the FY 2025 IPPS/LTCH PPS final rule, we modified the measure to include patients 18 years old and older in the measure cohort, beginning with the CY 2026 reporting period/FY 2028 payment determination (89 FR 69557 through 69560). In the FY 2026 IPPS/LTCH PPS final rule, we summarized input we received through the public comment process in response to our RFI on measure concepts of well-being and nutrition for future years in the Hospital Inpatient Quality Reporting Program and other quality measure programs; many commenters supported the utilization of the Malnutrition Care Score eCQM, noting it plays a critical role in identifying and addressing nutritional concerns in the hospital inpatient setting, and some commenters specifically supported making the Malnutrition Care Score eCQM mandatory (90 FR 36996 through 36997).

In consideration of these public comments and in alignment with the administration's priority focus on well-being and nutrition, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR

19600 through 19604), we proposed mandatory reporting of the Malnutrition Care Score eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination. This proposal also aligns with our ongoing strategy to transition to a fully digital quality measurement landscape that promotes interoperability, reduces reporting burden, and increases the value of reporting quality measure data (90 FR 36990 through 36996). We explained in the proposed rule that if this proposal is finalized, hospitals would have an opportunity to continue to self-select this eCQM for the CY 2026 and CY 2027 reporting periods before mandatory reporting for all hospitals would begin with the CY 2028 reporting period/FY 2030 payment determination.

(3) Mandatory Reporting of the Hospital Harm Electronic Clinical Quality Measures

We previously implemented a stepwise approach to increase the number of required eCQMs in response to public comments noting the burden and resources necessary to implement new eCQMs (89 FR 69568 through 69573). This approach balances the need to prioritize more comprehensive reporting on important safety and preventable harm metrics with the need to provide hospitals and health IT vendors with time to implement new eCQMs.

Currently, in the Hospital Inpatient Quality Reporting Program, we have adopted seven eCQMs aimed at addressing different types of and various aspects of preventable hospital harms: Hospital Harm—Severe Hyperglycemia; Hospital Harm—Severe Hypoglycemia; Hospital Harm—Opioid-Related Adverse Events; Hospital Harm—Pressure Injury; Hospital Harm—Acute Kidney Injury; Hospital Harm—Falls with Injury; and Hospital Harm—Postoperative Respiratory Failure. On average, less than 10 percent of hospitals self-select to report on a given eCQM in the first year it is available, and we assume a hospital tends to self-select a given eCQM because it will perform better on that eCQM compared to other eCQMs available to self-select. Because hospital harms remain a significant source of morbidity, mortality, and cost, and because of the importance of publicly reporting these metrics to promote patient safety, we proposed to build on the stepwise approach for increasing the number of required eCQMs by modifying the eCQM reporting and submission requirements for Hospital Harm eCQMs. Specifically, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19602 through 19604), we proposed that beginning with the CY 2028 reporting period/FY 2030 payment determination, Hospital Harm eCQMs that have not yet been finalized for mandatory reporting would become mandatory in the third year of reporting.

Under this proposal, the Hospital Harm—Falls with Injury eCQM and the Hospital Harm—Postoperative Respiratory Failure eCQM would begin mandatory reporting in CY 2028 reporting period/FY 2030 payment determination. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19585 through 19588), we also proposed that the Hospital Harm—Postoperative VTE eCQM, finalized for adoption in section IX.C.3.b. of this final rule, would become mandatory to report beginning with the CY 2030 reporting period/FY 2032 payment determination, after being available for 2 years of self-selected reporting. Furthermore, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19600 through 19604 and 91 FR 19652 through 19654), we proposed that in subsequent years, newly adopted Hospital Harm eCQMs would become mandatory eCQMs for reporting after 2 years of self-selected reporting in the Hospital Inpatient Quality Reporting Program and the Medicare Promoting Interoperability Program. We did not propose changes to our previously finalized policy that progressively increases the number of mandatory eCQMs a hospital must report for the CY 2026 reporting period/FY 2028 payment determination or the CY 2027 reporting period/FY 2029 payment determination (89 FR 69568 through 69573).

TABLE IX.C.9. PROPOSED HOSPITAL HARM ECQM REPORTING AND SUBMISSION REQUIREMENTS FOR THE CY 2028 REPORTING PERIOD/FY 2030 PAYMENT DETERMINATION AND FOR SUBSEQUENT YEARS

Reporting Period/ Payment Determination	Hospital Harm eCQMs Required to be Reported
CY 2028/FY 2030	• Hospital Harm—Severe Hyperglycemia • Hospital Harm—Severe Hypoglycemia • Hospital Harm—Opioid-Related Adverse Events • Hospital Harm—Pressure Injury • Hospital Harm—Acute Kidney Injury • Hospital Harm—Falls with Injury* • Hospital Harm—Postoperative Respiratory Failure*
CY 2029/FY 2031	• Hospital Harm—Severe Hyperglycemia • Hospital Harm—Severe Hypoglycemia • Hospital Harm—Opioid-Related Adverse Events • Hospital Harm—Pressure Injury • Hospital Harm—Acute Kidney Injury • Hospital Harm—Falls with Injury* • Hospital Harm—Postoperative Respiratory Failure*
CY 2030/FY 2032 (and for subsequent years)	• Hospital Harm—Severe Hyperglycemia • Hospital Harm—Severe Hypoglycemia • Hospital Harm—Opioid-Related Adverse Events • Hospital Harm—Pressure Injury • Hospital Harm—Acute Kidney Injury • Hospital Harm—Falls with Injury* • Hospital Harm—Postoperative Respiratory Failure* • Hospital Harm—Postoperative Venous Thromboembolism**

* Proposed modification in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19600 through 19604), from self-selected to mandatory reporting beginning with the FY 2030 payment determination.

** Proposed for adoption in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19652 through 19654), as a self-selected eCQM beginning with the FY 2030 payment determination. Under this proposal the Hospital Harm—Postoperative VTE eCQM would become mandatory after 2 years of self-selected reporting beginning with the FY 2032 payment determination.

This proposal would advance the transition to a fully digital quality measure set, standardize safety data collection, and improve patient safety by having all hospitals report these measures. By the CY 2028 reporting period/FY 2030 payment determination, hospitals will have had 12 years of progressive experience reporting eCQMs. We believe hospitals have built a strong foundation of eCQM reporting through this phased ramp-up to accommodate newly adopted Hospital Harm eCQMs into the mandatory measure set for the Hospital Inpatient Quality Reporting Program and the Medicare Promoting Interoperability Program after 2 years of self-selected reporting. By making the Hospital Harm eCQMs mandatory after 2 years of self-selected reporting, we ensure that we would receive a robust national dataset for measures on these important topics, and these measures could serve as potential replacements for claims-based measures, such as those reported within the PSI 90 composite.

(4) Summary of Proposed Changes to the eCQM Reporting and Submission Requirements

We refer readers to section IX.C.6. of this final rule for the full list of eCQMs by payment determination year in the Hospital Inpatient Quality Reporting Program. If a hospital does not have patients that meet the denominator criteria for any of the eCQMs included in this proposal, the hospital would submit a zero denominator declaration. The submission of a zero denominator declaration allows a hospital to meet the reporting requirements for a particular eCQM. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 and 57170) for our previously adopted eCQM file format requirements. A QRDA Category I file with patients meeting the initial patient population of the applicable measures, a zero denominator declaration, or a case threshold exemption all count toward a successful submission for eCQMs for the Hospital Inpatient Quality Reporting Program (82 FR 38387). The following Table IX.C.10. summarizes our proposed policies:

TABLE IX.C.10. PROPOSED ECQM REPORTING AND SUBMISSION REQUIREMENTS FOR THE CY 2028 REPORTING PERIOD/FY 2030 PAYMENT DETERMINATION AND FOR SUBSEQUENT YEARS

Reporting Period/ Payment Determination	Total Number of eCQMs Reported	eCQMs Selected by CMS to be Reported	eCQMs for Self-selection (must report 3)
CY 2028/ FY 2030	Fourteen	• Safe Use of Opioids—Concurrent Prescribing • Cesarean Birth • Severe Obstetric Complications • Malnutrition Care Score* • Hospital Harm—Severe Hyperglycemia • Hospital Harm—Severe Hypoglycemia • Hospital Harm—Opioid-Related Adverse Events • Hospital Harm—Pressure Injury • Hospital Harm—Acute Kidney Injury • Hospital Harm—Falls with Injury* • Hospital Harm—Postoperative Respiratory Failure*	• Anticoagulation Therapy for Atrial Fibrillation/Flutter • Antithrombotic Therapy by the End of Hospital Day Two • Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults • Advance Care Planning** • Hospital Harm—Postoperative Venous Thromboembolism***
CY 2029/ FY 2031	Fourteen	• Safe Use of Opioids—Concurrent Prescribing • Cesarean Birth • Severe Obstetric Complications • Malnutrition Care Score* • Hospital Harm—Severe Hyperglycemia • Hospital Harm—Severe Hypoglycemia • Hospital Harm—Opioid-Related Adverse Events • Hospital Harm—Pressure Injury • Hospital Harm—Acute Kidney Injury • Hospital Harm—Falls with Injury* • Hospital Harm—Postoperative Respiratory Failure*	• Anticoagulation Therapy for Atrial Fibrillation/Flutter • Antithrombotic Therapy by the End of Hospital Day Two • Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults • Advance Care Planning** • Hospital Harm—Postoperative Venous Thromboembolism***
CY 2030/ FY 2032 (and subsequent years)	Fifteen	• Safe Use of Opioids—Concurrent Prescribing • Cesarean Birth • Severe Obstetric Complications • Malnutrition Care Score* • Hospital Harm—Severe Hyperglycemia • Hospital Harm—Severe Hypoglycemia • Hospital Harm—Opioid-Related Adverse Events • Hospital Harm—Pressure Injury • Hospital Harm—Acute Kidney Injury • Hospital Harm—Falls with Injury* • Hospital Harm—Postoperative Respiratory Failure* • Hospital Harm—Postoperative Venous Thromboembolism***	• Anticoagulation Therapy for Atrial Fibrillation/Flutter • Antithrombotic Therapy by the End of Hospital Day Two • Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults • Advance Care Planning**

* Proposed modification in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19600 through 19604), from self-selected to mandatory reporting beginning with the FY 2030 payment determination.
** Proposed for adoption in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19564 through 19568), as a self-selected eCQM beginning with the FY 2030 payment determination.
*** Proposed for adoption in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19585 through 19588), as a self-selected eCQM beginning with the FY 2030 payment determination. If this proposal and our proposal to modify the eCQM reporting requirements for Hospital Harm eCQMs are finalized, the Hospital Harm—Postoperative VTE eCQM would become mandatory after 2 years of self-selected reporting beginning with the FY 2032 payment determination.

We invited public comment on our proposals to require hospitals to report on the Malnutrition Care Score eCQM and on all current and future Hospital Harm eCQMs after 2 years of self-selected reporting beginning with the CY 2028 reporting period/FY 2030 payment determination. We refer readers to section IX.F.9. of this final rule, in which we proposed the same reporting and submission requirements for eCQMs under the Medicare Promoting Interoperability Program for eligible hospitals and CAHs.

Comment: Many commenters supported modifying eCQM reporting and submission requirements stating that this is a reasonable step in moving towards the goal to transition all quality measure reporting to digital quality measures (dQMs), which would in turn provide more real-time actionable data. These commenters recommended that CMS announce a timeline for introducing voluntary FHIR®-based dQM reporting.

Response: We thank the commenters for their support. We agree that these modifications to eCQM reporting and submission requirements are a fundamental step towards dQM transition. We note that in the FY 2022 IPPS/LTCH PPS final rule, we discussed our goal of moving to digital quality measurement for all CMS quality reporting and value-based purchasing programs (86 FR 45342). In the FY 2023 IPPS/LTCH PPS final rule, we further described our goals to transition to dQMs, which include: reducing burden of reporting; leveraging digital measures for advanced analytics to define, measure, and predict key quality issues; and employing quality measures that support development of a learning health system (87 FR 49181 through 49188). We also wish to highlight that our previously described vision for future dQMs would leverage interoperability standards to decrease mapping burden and align standards for quality measurement with interoperability standards used in other healthcare exchange methods (87 FR 49181 through 49188). We also wish to point readers to our request for information on potential FHIR® timelines in the CY 2027 Physician Fee Schedule (PFS) proposed rule (91 FR 44151 through 44154) as well as section X.E. of the preamble of this final rule where we discuss the updated standards and versions of the prior authorization FHIR® Implementation Guides.

Comment: Many commenters specifically supported transitioning the Malnutrition Care Score eCQM to mandatory reporting, noting nutrition care is a low-cost but high-impact intervention with positive implications for patient health, including improved care coordination, timely intervention, and patient satisfaction. Commenters noted that addressing malnutrition can improve patient outcomes and reduce readmissions, shorten lengths of stay, reduce complications, decrease functional decline, and lower risk of mortality. A few commenters appreciated that this measure may help close the gap between identification of and intervention for malnutrition as it is often underdiagnosed and undertreated. A commenter noted that this measure

aligns with broader federal priorities related to patient-centered care and nutrition. A few commenters noted that adopting the Malnutrition Care Score eCQM aligns with the screening and intervention for frailty and malnutrition risk component of Age-Friendly Hospital measure in the Hospital Inpatient Quality Reporting Program. Commenters encouraged CMS to continue building upon this important work by advancing additional nutrition quality measures, such as in post-acute care settings and pay-for-performance programs, to support effective care transitions upon discharge and broader implementation of evidence-based nutrition care nationwide.

Response: We thank the commenters for their support. We agree that these modifications to eCQM reporting and submission requirements to include the Malnutrition Care Score eCQM would increase the available information about malnutrition screening and therefore support increasing nutrition care which has the potential to have significant impacts on patient well-being. We agree that mandatory reporting of the Malnutrition Care Score eCQM aligns with broader HHS and CMS nutrition policies and initiatives. The January 2026 HHS fact sheet emphasizes prevention, nutrient-dense foods, and improved nutrition across federal health programs.[471]

Comment: A few commenters specifically supported the proposed implementation timeline of making Hospital Harm eCQMs mandatory because preventable harm events are among the most meaningful outcomes measures as they reflect failures that patients directly experience through injury, suffering, prolonged recovery, disability, loss of trust, and in some cases death. A few commenters supported the idea of replacing PSI 90 composite with Hospital Harm eCQMs since eCQMs provide more accurate information. A commenter encouraged CMS to formally adopt a strategy to replace all components of the PSI 90 composite with eCQMs in the near future. A few commenters encouraged CMS to maintain advancement of a continuously learning safety infrastructure to not only measure harm retrospectively but also to help health systems identify risk, recognize deterioration, strengthen communication, and prevent avoidable harm before patients are injured.

Response: We thank the commenters for their support. We agree that these modifications to Hospital Harm eCQMs reporting requirements would increase public reporting on quality and safety since they are all-payer; thus, empowering individuals to make informed decisions about their healthcare. The PSI 90 composite is a claims-based composite measure comprised of 10 patient safety indicators. We believe that the Hospital Harm eCQMs have the potential to serve as replacements for components of the PSI 90 composite, and we will consider commenters' input for future rulemaking to replace some or all components of the PSI 90 composite with these eCQMs.

Comment: Many commenters stated that the pace and scale of mandatory eCQM implementation does not leave enough time for realistic implementation of measures. A few commenters stated that EHR vendors can take several years to implement changes because of the time required to complete upgrades and programming. Many commenters recommended adopting a more phased approach to implement the new requirements to allow additional time for staff training, education, rollout, and at least a full calendar year to validate, monitor, and improve performance before mandatory reporting begins. A commenter recommended allowing more time for hospitals and EHR vendors to focus on eCQM optimization as they currently exist before adding new eCQMs which would increase administrative burden.

Response: We acknowledge commenters' concerns about the proposed timeline and the resources required for vendors to implement new eCQMs, including EHR mapping, vendor workflow updates, staff training, and ongoing monitoring to ensure accurate data is submitted. We recognize that these requirements may be particularly challenging for small and rural hospitals, including CAHs, and the proposed timeline has a short lead time to correct any issues that arise during reporting. We note that we are revising the eCQM Annual Update addendum process to expedite fixing issues in the eCQM logic as they are identified to improve vendors' ability to implement new eCQMs. Additionally, this proposal establishes a predictable timeline by providing hospitals with 2 years of self-selected reporting before a Hospital Harm eCQM becomes mandatory; thus, hospitals have advance notice and can plan accordingly. We will be monitoring for additional challenges that may warrant future attention.

Comment: Some commenters recommended offering voluntary incentivized FHIR®-based dQM reporting as an alternative to mandatory eCQM reporting. These commenters stated that increased eCQM mandates may limit hospital participation in the expected voluntary period of FHIR-based dQM reporting. A commenter recommended that CMS consider whether the proposed increase of mandatory eCQM reporting could be structured to allow FHIR-based submission as an alternative compliance pathway alongside QRDA-based eCQM submission, and to prioritize development of FHIR-native specifications for future Hospital Harm measures rather than converting Quality Data Model based specifications as the default.

Response: We thank commenters for their recommendations regarding FHIR-based dQM reporting. We understand the concern that hospitals that are updating their processes and technology to report additional eCQMs may not participate in voluntary FHIR-based dQM reporting. We will consider this input as we develop policies related to future FHIR-based dQM reporting. Because of the importance of the clinical topics addressed by the Malnutrition Care Score eCQM and the Hospital Harm eCQMs, we are prioritizing adopting mandatory reporting of these measures as we work to develop FHIR specifications. We also wish to point readers to our request for information on potential FHIR timelines in the CY 2027 PFS proposed rule (91 FR 44151 through 44154) as well as section X.E. of this final rule where we discuss the updated standards and versions of the prior authorization FHIR Implementation Guides.

Comment: Many commenters stated concerns about limited health IT resources available, particularly for small teams, stating that health IT staff in hospitals is often very limited. Commenters expressed concern that the volume of changes being implemented introduces a significant administrative burden for small and rural hospitals, including critical access hospitals (CAHs), and hospitals caring for patients who are medically complex. A few commenters noted that many hospitals, particularly small and rural hospitals, chose not to self-select Hospital Harm eCQMs as they did not have sufficient volume to report these measures. These commenters requested that CMS provide adequate guidance on minimum volumes for reporting, as well as clear language to interpret publicly reported data when minimum volumes cannot be met.

[471] Department of Health and Human Services. (2026). Fact Sheet: Trump Administration Resets U.S. Nutrition Policy, Puts Real Food Back at the Center of Health. Available at: *https://www.hhs.gov/press-room/fact-sheet-historic-reset-federal-nutrition-policy.html.*

Response: We understand concerns regarding the impact on hospitals with limited health IT resources available. We acknowledge that making additional eCQMs mandatory affects burden; however, the benefits of ensuring that all hospitals report on these critical patient safety topics outweighs that increase in burden. We understand that some hospitals do not have sufficient volume to report certain measures, including Hospital Harm eCQMs. Hospitals which document that they do not meet minimum volumes will not be penalized for not reporting these measures. We refer readers to the Quality Reporting Center for resources for the Inpatient Quality Reporting Program, including public reporting information at *https://www.qualityreportingcenter.com/en/inpatient-quality-reporting-programs/.*

Comment: Many commenters noted that hospitals have experienced a significant increase in requirements over a short period of time, noting this requires significant investments in time and staff resources. Many commenters expressed concerns that the proposal nearly doubles the number of required eCQMs. Commenters recommended various alternatives, such as extending the voluntary submission period to 3 years or assessing mandatory reporting readiness for each measure and continuing to propose mandatory reporting on a measure-by-measure basis through rulemaking rather than establishing a set policy for mandatory reporting of Hospital Harm eCQMs automatically after 2 years of voluntary reporting.

Response: A longstanding goal of the Hospital Inpatient Quality Reporting Program has been to simplify and streamline reporting through electronic reporting which improves the ability to align and harmonize measures across programs (78 FR 50807). As part of this established goal, we are increasing the number of eCQMs that we require. We understand that this requires investment in time and resources; however, we believe delaying implementation would delay our efforts to improve transparency regarding hospital performance on important safety topics. Additionally, through creating a set policy rather than an individual measure approach, we are establishing a predictable timeline by providing hospitals with 2 years of self-selected reporting before a Hospital Harm eCQM becomes mandatory; thus, hospitals have advance notice and can plan accordingly.

Comment: A few commenters requested CMS clarify its strategy for eCQM requirements, specifically recommending that CMS establish a cap for the number of mandatory eCQMs.

Response: We note that one of the goals of the Hospital Inpatient Quality Reporting Program is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. We carefully evaluate each measure that we propose to adopt for the Hospital Inpatient Quality Reporting Program to ensure that its benefits outweigh the associated burden. We also assess the cumulative burden of requirements across the program and may remove a measure when its costs outweigh the benefits of its continued use. We will continue to evaluate this balance on a case-by-case basis for the Hospital Inpatient Quality Reporting Program measure set.

Comment: Several commenters were concerned that the number of eCQMs available for self-selected eCQMs decreases too significantly as the Malnutrition Care Score and Hospital Harm eCQMs become mandatory, reducing flexibility and creating a near-mandatory reporting structure. A few commenters emphasized that self-selection is important for hospitals to report measures that are more meaningful, applicable, and representative of their specific patient populations, clinical services, and quality improvement priorities. Other commenters suggested eliminating the self-selection requirement to decrease the strain on health IT, labor, financial, and clinical resources needed to maintain those measures. Commenters stated that such efforts could be diverted to the increasing number of mandatory eCQMs. A commenter recommended that CMS change the number of self-selected eCQMs from three to two. Another recommended CMS maintain a broader portfolio of non-Hospital Harm eCQMs before implementing this proposal.

Response: We understand that increasing the number of mandatory eCQMs affects burden and reduces the list of eCQMs that hospitals can self-select. We note that the number of measures available for self-selection would be five for the CY 2028 and CY 2029 reporting periods, which allows hospitals to choose the most meaningful measures for their patient populations and quality improvement efforts. While the number of measures available for self-selection would be four beginning with the CY 2030 reporting period, the measure set may continue to evolve in future rulemaking, providing additional self-selection options for hospitals. We continually monitor and evaluate the measures and requirements of the Hospital Inpatient Quality Reporting Program, and if, in our monitoring and evaluation, we determine that the burden of maintaining a set of measures for self-selected reporting outweighs the benefit of providing this flexibility to hospitals, we will evaluate alternative approaches to our eCQM policies. We thank the commenters for recommending these alternative approaches.

Comment: A commenter requested that CMS consider aligning the deadline for validation and submission with the Merit-based Incentive Payment System (MIPS) deadline to grant hospitals additional time to report.

Response: The MIPS reporting deadline is established for CY payments to clinicians. Because hospitals are paid under the IPPS, which is a FY payment system, it is appropriate for the Hospital Inpatient Quality Reporting Program to maintain earlier reporting deadlines to prepare for payment updates that occur one calendar quarter earlier than payments made under the PFS.

Comment: A few commenters stated concerns about using Hospital Harm eCQMs in programs that directly impact reimbursement or Overall Hospital Quality Star Ratings before they have been adequately adopted, validated, and stabilized. A few commenters requested CMS limit frequent measure specifications changes, demonstrate measure stability, and consider a transition period with neutral scoring before introducing these measures in programs that impact reimbursement or public reporting. A commenter highlighted these challenges, especially for hospitals subject to state reporting requirements that rely on year-over-year eCQM outcomes. Another commenter expressed concerns that as Hospital Harm eCQMs are adopted across pay-for-reporting programs, pay-for-performance programs, and alternative payment models, hospitals are increasingly evaluated multiple times on the same underlying measures, placing substantial reliance on a relatively small set of quality measures.

Response: We thank the commenters and acknowledge their concerns about transitioning measures into programs that impact reimbursement and with public reporting that can impact Overall Hospital Quality Star Ratings or state reporting programs. We also acknowledge the request for measure stability before measures transition to performance-based programs and public reporting. By making the Hospital Harm eCQMs mandatory after 2 years of self-

selected reporting, we ensure that we will receive a robust national dataset for measures on these important topics. At this time, these eCQMs have not been proposed for adoption into a pay-for-performance program. However, as we adopt measures from the Hospital Inpatient Quality Reporting Program into pay-for-performance programs (such as the Hospital-Acquired Condition Reduction Program), we generally remove them from the Hospital Inpatient Quality Reporting Program, so we are not evaluating hospitals on the same underlying measures.

We understand commenters' concerns regarding public reporting of data on measures. To address this concern, we will publicly report data for Hospital Harm eCQMs on the more research-focused Provider Data Catalog for the first year of mandatory reporting before moving them to the consumer-focused Care Compare site, including Star Ratings, beginning with the second year of mandatory reporting. By keeping the proposed timeline, but not publicly reporting on Care Compare for an additional year after these measures become mandatory, we are able to meet our goal of advancing robust patient safety data reported, address data issues sooner, and be responsive to concerns from hospitals about potentially inaccurate data being public facing.

Comment: Several commenters expressed concerns that the timeline for mandatory reporting for the Malnutrition Care Score may be premature given ongoing data integrity concerns, measure complexity, and workflow challenges. A few commenters stated these concerns are particularly significant for hospitals without advanced EHR systems. Several commenters urged CMS to consider staffing constraints, particularly limited dietician and nutritionist resources and recommended risk adjustments for rural and resource limited hospitals. A commenter noted that for shorter lengths of stay, patients may be discharged prior to completion of a full nutrition assessment. A commenter stated that the measure promotes documentation rather than clinical improvement because outcomes are not observable during the hospital stay. A commenter recommended an evaluation of what additional resources are necessary to support successful implementation of the Malnutrition Care Score eCQM and that CMS monitor for any unintended consequences of transitioning the measure to mandatory reporting. A commenter requested a 1-year delay in mandatory reporting of the Malnutrition Care Score eCQM to allow hospitals more time to implement and validate the measure.

Response: We note that this measure uses data that is designed to be calculated by the hospital's certified health IT using data captured in structured fields, thereby reducing reporting burden and complexity. We acknowledge commenters' concerns about the availability of staff, particularly in rural hospitals, and note the measure observations can be completed at any point during the inpatient encounter, which allows flexibility for facilities that do not have a dietician on staff at all hours, and applies to patients with a length of stay equal to or greater than 24 hours. The Malnutrition Care Score eCQM measure was endorsed with conditions in the Spring 2024 review cycle, with a condition for the measure steward to review implementation data to examine whether the measure is associated with improved nutritional status or related clinical endpoints when the measure returns for maintenance review in the Spring 2029 cycle.[472] [473] The measure developer is working to collect and review hospital implementation data to assess the clinical outcomes associated with the measure by its next review cycle in Spring 2029. Because improved nutrition care has the potential to have significant impacts on patient well-being, it is appropriate to require reporting on the Malnutrition Care Score eCQM at this time. We will continue to conduct ongoing monitoring and analyses to watch for any unintended consequences of the expanded reporting for the Malnutrition Care Score eCQM.

Comment: Many commenters stated that Hospital Harm eCQMs are particularly complex to construct and validate, typically taking multiple iterations to establish EHR feasibility to ensure accurate reporting. A commenter stated the Hospital Harm—Postoperative VTE eCQM specifically has not been robustly tested enough yet for inclusion as a mandatory measure.

Response: We understand commenters' concerns regarding the complexity of reporting the Hospital Harm eCQMs. We note that these eCQMs address important patient safety topics, and therefore the benefits of reporting these data outweigh the burden of updating EHR systems. We refer readers to section IX.C.3.b.(5) of this final rule in which we discuss the testing that the Hospital Harm—Postoperative VTE eCQM underwent as part of the development and endorsement process.

After consideration of the public comments we received, we are finalizing our proposal to update the reporting requirements for the Malnutrition Care Score eCQM to begin mandatory reporting with the CY 2028 reporting period/FY 2030 payment determination. We refer readers to section IX.F.9. of the preamble of this final rule for a discussion of updating reporting requirements for this measure in the Medicare Promoting Interoperability Program.

We are finalizing our proposal to modify reporting requirements for the Hospital Harm eCQMs with modification. We are finalizing the proposed timeline to begin mandatory reporting after two years of self-selected reporting starting with the CY 2028 reporting period/FY 2030 payment determination with a modification to publicly report data on the more research-focused Provider Data Catalog for the first year of mandatory reporting before moving it to the consumer-focused Care Compare site, including Star Ratings, beginning with the second year of mandatory reporting. We refer readers to section IX.F.9. of the preamble of this final rule for a discussion of updating reporting requirements for Hospital Harm eCQMs in the Medicare Promoting Interoperability Program.

d. Data Submission and Reporting Requirements for Structural Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 and 51644) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 and 53539) for details on the data submission requirements for structural measures. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19604 through 19605), we proposed an update to the reporting and submission requirements for the Maternal Morbidity Structural measure beginning with the FY 2028 payment determination.

(1) Update to Maternal Morbidity Structural Measure Reporting

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365), we adopted the Maternal Morbidity Structural measure beginning with the FY 2023 payment determination. In this attestation-based measure, hospitals answer the following two-part question:

[472] Partnership for Quality Measurement. Malnutrition Care Score. *Available at: https://p4qm.org/measures/3592e.*

[473] Partnership for Quality Measurement. Spring 2024 Cycle Endorsement and Maintenance Technical Report Initial Recognition and Management. *Available at: https://p4qm.org/sites/default/files/Initial%20Recognition%20and%20Management/material/EM-Spring-2024-IRM-Final-Project-Report.pdf.*

Does your hospital or health system participate in a Statewide and/or National Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery and postpartum care, and has it implemented patient safety practices or bundles related to maternal morbidity to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis?[474] The answer choices are ''yes'', ''no'', or ''not applicable'' (for hospitals that do not provide inpatient labor/delivery care).

To improve the completeness and usefulness of the data collected, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19604 through 19605), we proposed updating the reporting requirements. Specifically, if a hospital answers ''yes'' to the measure as currently specified, the hospital would also need to report the name of the perinatal quality improvement collaborative program. In the HQR System, if a hospital selects ''yes'' in response to the measure, the hospital would also be prompted to report a response to the following: ''Which Statewide and/or National Perinatal Quality Improvement Collaborative Program does the hospital participate in?'' This change is intended to enhance our understanding of current practices and support targeted quality improvement efforts. This update to the reporting requirements of the measure would not impact measure performance, as the criteria for attesting ''yes'' to the measure remain the same. However, we would not consider a hospital which attested ''yes'' to the measure but did not provide the name of the perinatal quality improvement collaborative program in which they participate to have successfully reported all requirements for this measure. Therefore, such a hospital would be subject to a payment penalty. To report on this measure, hospitals would continue using the CMS-approved web-based collection tool available within the HQR System once annually, as they currently do to report for this and other Hospital Inpatient Quality Reporting Program structural measures (87 FR 49304 through 49305).

We invited public comment on our proposed update to the reporting requirements for the Maternal Morbidity Structural measure beginning with the CY 2026 reporting period/FY 2028 payment determination.

Comment: Many commenters supported our proposal to update the Maternal Morbidity Structural measure to include a sub-question for a hospital to report the name of the Statewide or national Perinatal Quality Improvement Collaborative, if a hospital answers ''yes'' to the measure. Commenters agreed this would improve completeness, transparency, and usefulness of publicly reported information, strengthening accountability for maternal safety initiatives. Commenters also recommended we continue to evolve maternal health quality reporting. A commenter supported our proposal and recommended considering the limitations that smaller, rural, and safety-net hospitals may face in accessing established collaborative networks.

Response: We thank the commenters for their support and agree it is important to continue evolving maternal health initiatives and consider this a priority topic in our quality reporting efforts in the Hospital Inpatient Quality Reporting Program. We refer readers to section IX.C.7.a.(3) of this final rule where we discuss potential scoring methodologies for the next phase of the Birthing-Friendly Hospital Designation as a part of our efforts to continue evolving maternal quality reporting. We note that the CDC maintains a list of statewide quality collaboratives at: *https://www.cdc.gov/maternal-infant-health/pqc/state-pqcs.html.* We understand the commenter's concern that smaller, rural, and safety-net hospitals may face challenges in accessing collaborative networks. However, we note that even if participation in a Statewide Perinatal Quality Improvement Collaborative is not accessible, there are a number of national Perinatal Quality Improvement Collaboratives available. Therefore, we do not anticipate hospitals being unable to access them, even if a hospital has low patient volume.

Comment: A few commenters expressed concerns that stating the name of the Perinatal Quality Improvement Collaborative would not drive clinical improvement or advance the underlying goal of the facility engaging in these initiatives. These commenters stated that hospitals should not be subject to a payment reduction for not providing the name of the perinatal collaborative initiative. A commenter expressed concern that adding descriptive reporting to this structural measure would not reflect the depth or effectiveness of its implementation, would add unnecessary burden, and would not inform consumers about quality of care provided. A commenter had concerns about the impact of this update to the Maternal Morbidity Structural measure on other state improvement reporting efforts and recommended ensuring more stability in the measure specifications given the downstream implications.

Response: Requesting hospitals to provide the name of the collaborative they are affiliated with would provide consumers and hospitals with an additional level of detail about hospitals' participation in a perinatal quality collaborative. This in turn would improve accountability and transparency of hospitals' current practices and quality improvement efforts toward addressing an important health issue like maternal morbidity. Regarding concerns about additional burden, as discussed in section XII.B.4.f. of the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19755), we estimated that the currently approved burden of five minutes is adequate for hospitals to both attest to the current two-part question and answer the additional sub-question, and therefore do not anticipate any additional burden on hospitals. We acknowledge commenter concerns about potential impacts on state reporting requirements and will monitor for unintended consequences as a part of our routine monitoring and evaluation of the Hospital Inpatient Quality Reporting Program measure set.

Comment: A few commenters made recommendations to further strengthen the Maternal Morbidity Structural measure's ability to distinguish between nominal affiliation and meaningful engagement in quality improvement activities. A few commenters recommended defining and evaluating levels of hospital engagement with the perinatal quality improvement collaborative program they are affiliated with, to consider leveraging existing perinatal quality collaborative engagement frameworks, and to incorporate an attestation to indicate the level of engagement a hospital participates in. A commenter recommended we include another prompt requesting information on what patient safety practices or bundles related to maternal morbidity are being implemented at hospitals, noting this would result in better understanding of how hospitals are utilizing certain types of patient safety bundles or activities across the country. A commenter recommending ensuring the submission process remains streamlined and

[474] CMS. QualityNet. IQR Measures—Web-Based Data Collection. Attestation Guide for the Maternal Morbidity Structural Measure. Available at: *https://qualitynet.cms.gov/inpatient/iqr/measures#tab2.*

clinically validated, avoiding excessive documentation burdens.

Response: We thank commenters for their recommendations and will consider this feedback as we continue to develop the measure in the future. While we are not updating the measure to define or evaluate a specific level of engagement or participation with a perinatal quality collaborative at this time, we encourage hospitals to meaningfully engage with the perinatal quality collaborative they are affiliated with to address this important topic and improve maternal safety.

After consideration of the public comments we received, we are finalizing our proposal to update the reporting requirements for the Maternal Morbidity Structural measure beginning with the CY 2026 reporting period/FY 2028 payment determination.

D. PPS-Exempt Cancer Hospital Quality Reporting Program

1. Background and History of the PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program

The PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program, authorized by section 1866(k) of the Act, applies to hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs''). We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53555 through 53567) for a general overview of the PCH Quality Reporting Program. We also refer readers to 42 CFR 412.24 for codified PCH Quality Reporting Program requirements.

2. New Measures for the PCH Quality Reporting Program Measure Set

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19605), we proposed to adopt two new measures into the PCH Quality Reporting Program: (1) Advance Care Planning electronic clinical quality measure (eCQM) for a full year of reporting beginning with the CY 2028 reporting period/FY 2030 program year; and (2) Malnutrition Care Score eCQM for a full year of reporting beginning with the CY 2028 reporting period/FY 2030 program year. We provide more details on the proposed adoption of the Malnutrition Care Score eCQM in section IX.D.2.a. of this final rule, while details on the proposed adoption of the Advance Care Planning eCQM measure appear in section IX.B.1. of this final rule.

a. Adoption of the Malnutrition Care Score Electronic Clinical Quality Measure

(1) Background

Malnutrition is a common and high-risk condition characterized by unbalanced nutrition, encompassing both undernutrition and overnutrition.[475] Undernutrition occurs when an individual has insufficient calories, protein, or other nutrients from inadequate intake, impaired absorption, increased metabolic demands, or increased nutrient losses. Overnutrition includes a surplus of calories, which increases risk for obesity, type 2 diabetes, heart attacks, strokes, and other chronic conditions.[476] Malnutrition can be more prevalent among hospitalized patients with cancer and is associated with increased health care costs and adverse clinical outcomes, including increased length of hospital stays, complications and readmission rates, and all-cause mortality risk.[477] Up to an estimated 80 percent of cancer patients experience malnutrition, with prevalence varying based on cancer stage, type, treatment route, and the patient's age.[478] Adult cancer patients at risk of malnutrition have a 70 percent higher risk for all-cause mortality and a 49 percent higher risk for chemotherapy-related complications compared to patients with no malnutrition risk.[479] Furthermore, the side effects of cancer treatments, such as chemotherapy and radiation therapy, can impair nutritional intake due to nausea, vomiting, early satiety, and taste changes.[480] These effects underscore the need for nutrition screening throughout cancer treatment to maintain patient health, minimize nutrition-related side effects, and ultimately ensure the ability to keep a patient on an effective treatment schedule.

PCHs have an opportunity to identify malnutrition early in the patient admission process and to address it efficiently and effectively with interventions individualized to the patient's cancer treatment plan that could optimize outcomes, including reduced complications and lengths of stay.[481] However, gaps and inconsistencies exist in nutrition care practices in the inpatient setting,[482] and malnutrition remains poorly recognized, mostly due to a lack of awareness and inadequate coordination between healthcare providers.[483] The implementation of malnutrition care including: (1) malnutrition risk screening; (2) nutrition assessment following detection of malnutrition risk; (3) malnutrition diagnosis; and (4) nutrition care plans for patients identified as malnourished improves the identification and treatment of malnourished patients.[484] Providing inpatient nutritional support saves an estimated $2,818 per patient over 6 months, largely due to fewer infections and shorter hospital stays.[485]

(2) Overview of Measure

The Malnutrition Care Score eCQM assesses the percentage of adults aged

[475] Academy of Nutrition and Dietetics. (2021). What is Malnutrition. *Available at: https://www.eatright.org/health/health-conditions/malnutrition-and-deficiencies/what-is-malnutrition.*

[476] Academy of Nutrition and Dietetics. (2022). How an RDN Can Help with Malnutrition. *Available at: https://www.eatright.org/health/health-conditions/malnutrition-and-deficiencies/how-an-rdn-can-help-with-malnutrition.*

[477] Corriveau J, Alavifard D, Gillis C. (2022). Demystifying Malnutrition to Improve Nutrition Screening and Assessment in Oncology. *Seminars in Oncology Nursing, 38*(5). *https://doi.org/10.1016/j.soncn.2022.151336.*

[478] Hoobler R, Herrera M, Woodruff K, Sanchez A, Coletta AM, Chaix A, Elizondo J, Playdon MC. (2025). Malnutrition Risk Is Associated With All-Cause Mortality and Chemotherapy Complications Among Adults Diagnosed With Diverse Cancer Types: A Retrospective Cohort Study. *Journal of the Academy of Nutrition and Dietetics, 125*(9), 1242–1255. *https://doi.org/10.1016/j.jand.2025.04.014.*

[479] Hoobler R, Herrera M, Woodruff K, Sanchez A, Coletta AM, Chaix A, Elizondo J, Playdon MC. (2025). Malnutrition Risk Is Associated With All-Cause Mortality and Chemotherapy Complications Among Adults Diagnosed With Diverse Cancer Types: A Retrospective Cohort Study. *Journal of the Academy of Nutrition and Dietetics, 125*(9), 1242–1255. *https://doi.org/10.1016/j.jand.2025.04.014.*

[480] PDQ® Supportive and Palliative Care Editorial Board. PDQ Nutrition in Cancer Care. Bethesda, MD: National Cancer Institute. Updated 09/20/2024. *Available at: https://www.cancer.gov/about-cancer/treatment/side-effects/appetite-loss/nutrition-hp-pdq.*

[481] PDQ® Supportive and Palliative Care Editorial Board. PDQ Nutrition in Cancer Care. Bethesda, MD: National Cancer Institute. Updated 09/20/2024. *Available at: https://www.cancer.gov/about-cancer/treatment/side-effects/appetite-loss/nutrition-hp-pdq.*

[482] Wills-Gallagher J, Kerr KW, Macintosh B, Valladares AF, Kilgore KM, Sulo S. (2022). Implementation of malnutrition quality improvement reveals opportunities for better nutrition care delivery for hospitalized patients. *Journal of Parenteral and Enteral Nutrition, 46*(1), 243–248. *https://doi.org/10.1002/jpen.2086.*

[483] Kabashneh S, Alkassis S, Shanah L, Ali H. (2020). A Complete Guide to Identify and Manage Malnutrition in Hospitalized Patients. *Cureus, 12*(6). *https://doi.org/10.7759/cureus.8486.*

[484] Valladares AF, Kilgore KM, Partridge J, Sulo S, Kerr KW, McCauley S. (2021). How a Malnutrition Quality Improvement Initiative Furthers Malnutrition Measurement and Care: Results From a Hospital Learning Collaborative. *Journal of Parenteral and Enteral Nutrition, 45*(2), 366–371. *https://doi.org/10.1002/jpen.1833.*

[485] Schuetz P, Sulo S, Walzer S, Vollmer L, Brunton C, Kaegi-Braun N, Stanga Z, Mueller B, Gomes F. (2021). Cost savings associated with nutritional support in medical inpatients: an economic model based on data from a systematic review of randomised trials. *BMJ Open, 11*(7), e046402. *https://doi.org/10.1136/bmjopen-2020-046402.*

18 years and older at the start of the eligible encounter, with a length of stay equal to or greater than 24 hours, who received optimal malnutrition care appropriate to the specific patient's level of malnutrition risk and severity. Best practices related to the prevention and care of malnutrition recommend that for each eligible encounter, adult inpatients are: (1) screened for malnutrition risk or for a dietitian referral order to be placed; (2) assessed by a registered dietitian (RD) or registered dietitian nutritionist (RDN) to confirm findings of malnutrition risk, and if identified with a ''moderate'' or ''severe'' malnutrition status in the current performed nutrition assessment; (3) receive a ''moderate'' or ''severe'' malnutrition diagnosis by a physician or eligible clinician as defined by CMS; and (4) have a current nutrition care plan performed by an RD/RDN.[486] [487]

To improve clinical outcomes for patients and reduce health care costs, we adopted the Malnutrition Care Score eCQM (previously known as the Global Malnutrition Composite Score eCQM) into the Hospital Inpatient Quality Reporting and Medicare Promoting Interoperability Programs as one of the eCQMs that hospitals can select to report beginning with the CY 2024 reporting period (87 FR 49239 through 49246 and 87 FR 49361 through 49365, respectively). In the FY 2025 IPPS/LTCH PPS final rule, we modified the measure to include patients 18 years old and older in the measure cohort (89 FR 69557 through 69560 and 89 FR 69621 through 69623). In this rule, we also proposed mandatory reporting of the Malnutrition Care Score eCQM in the Hospital Inpatient Quality Reporting and Medicare Promoting Interoperability Programs beginning with the CY 2028 reporting period/FY 2030 payment determination. We refer interested readers to sections IX.C.8.c.(2). and IX.F.9.c. of this final rule for further discussion of this measure in the Hospital Inpatient Quality Reporting and Medicare Promoting Interoperability Programs, respectively.

(3) Measure Calculation

The Malnutrition Care Score eCQM consists of four components, which are scored separately: (1) screening for malnutrition risk at admission; (2) completing a nutrition assessment for patients who screened for risk of malnutrition; (3) appropriate documentation of malnutrition diagnosis in the patient's medical record if a malnutrition risk of ''moderate'' or ''severe'' was indicated by the assessment findings; and (4) development of a nutrition care plan for malnourished patients including the recommended treatment plan. The malnutrition components are specified for use in electronic health records (EHRs). The Malnutrition Care Score eCQM numerator is comprised of four components that are individually scored at the encounter level for patients 18 years of age and older who are admitted to a PCH. Each eligible component is given a value of 0 if not documented, or 1 if documented, and then all values are summed to total the numerator. The measure denominator is the total eligible occurrences of the four components for patients aged 18 years and older who are admitted to a PCH. The only denominator exclusion for this measure population is patients whose length of stay is less than 24 hours. Details on the cohort for each component are specified in Table IX.D.1.

TABLE IX.D.1.: MALNUTRITION CARE SCORE ECQM COMPONENT COHORT DESCRIPTIONS

Component	Numerator	Denominator
Completion of a Malnutrition Screening	Patients in the denominator who have a malnutrition screening documented in the medical record	Patients age 18 years and older at time of admission who are admitted to a PCH
Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition	Patients in the denominator who have a nutrition assessment documented in the medical record	Patients age 18 years and older at time of admission who are admitted to a PCH and were identified as at-risk for malnutrition upon completing a malnutrition screening
Appropriate Documentation of a Malnutrition Diagnosis	Patients in the denominator with a diagnosis of malnutrition documented in the medical record	Patients age 18 years and older at time of admission who are admitted to a PCH with findings of malnutrition upon completing a nutrition assessment
Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment	Patients in the denominator who have a nutrition care plan documented in the medical record	Patients age 18 years and older at time of admission who are admitted to a PCH with findings of malnutrition upon completing a nutrition assessment.

The score for each eligible encounter is calculated by dividing the numerator by the denominator. Results range from 0 to 100 percent, with higher percentages indicating better performance. The measure specifications for the Malnutrition Care Score eCQM can be found on the Electronic Clinical Quality Improvement (eCQI) Resource Center website, available at: *https://ecqi.healthit.gov/ecqm/hosp-inpt/2028/cms0986v6.*

(4) Pre-Rulemaking Process and Measure Endorsement

(a) Recommendations From the Pre-Rulemaking Measure Review Process

We refer readers to the Partnership for Quality Measurement website for details on the Pre-Rulemaking Measure Review process convened by the consensus-

[486] Malnutrition Quality Improvement Initiative. (2024). MQii Toolkit. *Available at: https://malnutritionquality.org/mqii-toolkit/#case_malnutrition_care_hospital.*

[487] Silver HJ, Pratt KJ, Bruno M, Lynch J, Mitchell K, McCauley SM. (2018). Effectiveness of the Malnutrition Quality Improvement Initiative on Practitioner Malnutrition Knowledge and Screening, Diagnosis, and Timeliness of Malnutrition-Related Care Provided to Older Adults Admitted to a Tertiary Care Facility: A Pilot Study. *Journal of the Academy of Nutrition and Dietetics,118*(1):101–109. *https://doi.org/10.1016/j.jand.2017.08.111.*

based entity (CBE), including the voting procedures used to reach consensus on measure recommendations.[488] [489] The Pre-Rulemaking Measure Review Hospital Committee, consisting of both the Pre-Rulemaking Measure Review Hospital Recommendation Group (hereafter referred to as the Recommendation Group) and Pre-Rulemaking Measure Review Hospital Advisory Group, met on January 12 and 13, 2026, to review measures included by the Secretary on the publicly available ''2025 Measures Under Consideration List,'' including the Malnutrition Care Score eCQM (MUC2025–065).[490]

The voting results of the Recommendation Group for the proposed inclusion of the Malnutrition Care Score eCQM in the PCH Quality Reporting Program were: 19 members (95 percent) recommended adopting the measure into the PCH Quality Reporting Program, and one member (5 percent) voted not to recommend the measure for adoption.[491] With 95 percent of the votes for recommend, the Recommendation Group reached consensus agreement to recommend the Malnutrition Care Score eCQM for use in the PCH Quality Reporting Program.

The Pre-Rulemaking Measure Review Hospital Committee overall agreed that this measure is particularly relevant for cancer patients, who often experience malnutrition. The Recommendation Group member who voted not to recommend the measure expressed concerns that (1) rural hospitals often lack sufficient registered dietitian staffing, even with telemedicine, and (2) whether documenting screening leads to meaningful improvements in post-discharge outcomes.

In response to the Recommendation Group member's first concern about rural hospitals, the hospitals participating in the PCH Quality Reporting Program consist of 11 total PCHs. All PCHs are affiliated with large academic medical centers, research institutions, or standalone premier cancer centers.[492] As there are no PCHs currently designated as rural hospitals or considered to be low-resource hospitals, this concern is not relevant to our proposal to adopt the Malnutrition Care Score eCQM into the PCH Quality Reporting Program.

Regarding the Recommendation Group member's second concern about meaningful improvements, the Malnutrition Care Score eCQM measure was endorsed in the Spring 2024 review cycle with a condition for the measure steward to review implementation data to examine whether the measure is associated with improved nutritional status or related clinical endpoints when the measure returns for maintenance review in the Spring 2029 cycle.[493] [494] The measure developer is working to collect and review hospital implementation data to assess the clinical outcomes associated with the measure by its next review cycle in Spring 2029, and we will continue to evaluate the measure as more data is received.

We thank the committee for their recommendations and concerns. After taking them into consideration, we proposed to adopt the Malnutrition Care Score eCQM in the PCH Quality Reporting Program beginning with the CY 2028 reporting period/FY 2030 program year (91 FR 19605 through 19608).

(b) Measure Endorsement

We refer readers to the Partnership for Quality Measurement website for details on the measure endorsement and maintenance process, including the measure evaluation procedures the Endorsement and Maintenance Committees use to evaluate measures and whether they meet endorsement criteria. The Malnutrition Care Score eCQM was recently reviewed by the Endorsement and Maintenance Initial Recognition and Management Committee as part of measure maintenance in the Spring 2024 review cycle. The Endorsement and Maintenance committee voted to endorse with conditions. The condition was for the measure steward to review implementation data (including the recently expanded cohort of patients 18 years and older) to examine whether the measure is associated with improved nutritional status or related clinical endpoint when the measure returns for maintenance review in the Spring 2029 cycle.[495] [496] We are working with the measure steward to collect and review hospital implementation data to assess the clinical outcomes associated with the Malnutrition Care Score eCQM.

(5) Data Sources, Submission, and Reporting

The Malnutrition Care Score eCQM uses data collected through a hospital's EHR. The measure is designed to be calculated by certified health information technology (IT) using the patient-level data and then submitted by the PCH to CMS. Table IX.D.2. outlines the data specification(s) and data sources for each of the four components.

[488] Partnership for Quality Measurement. Pre-Rulemaking Measure Review web page. *Available at: https://p4qm.org/prmr/about.*

[489] In 2025, the CBE updated the Pre-Rulemaking Measure Review voting process such that committee members will vote to either ''recommend'' or ''do not recommend'' that a measure be added to the intended CMS program(s), thus removing the ''recommend with conditions'' voting option. The threshold to reach consensus on a given measure continues to be a minimum of 75 percent agreement among members. Committee members can provide considerations for CMS to review prior to implementation.

[490] Centers for Medicare & Medicaid Services. 2025 Measures Under Consideration List. *Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/overview.*

[491] Partnership for Quality Measurement. (February 2026). 2025–2026 Pre-Rulemaking Measure Review Recommendation Group Final Meeting Summary: Hospital Committee. *Available at: https://p4qm.org/sites/default/files/2026-02/PRMR-Hospital-Recommendation-Group-Meeting-Final-Summary-508.pdf.*

[492] Centers for Medicare & Medicaid Services. PPS-Exempt Cancer Hospitals. *Available at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/pps-exempt-cancer-hospitals-pchs.*

[493] Partnership for Quality Measurement. Malnutrition Care Score. *Available at: https://p4qm.org/measures/3592e.*

[494] Partnership for Quality Measurement. Spring 2024 Cycle Endorsement and Maintenance Technical Report Initial Recognition and Management. *Available at: https://p4qm.org/sites/default/files/Initial%20Recognition%20and%20Management/material/EM-Spring-2024-IRM-Final-Project-Report.pdf.*

[495] Partnership for Quality Measurement. Malnutrition Care Score. *Available at: https://p4qm.org/measures/3592e.*

[496] Partnership for Quality Measurement. Spring 2024 Cycle Endorsement and Maintenance Technical Report Initial Recognition and Management. *Available at: https://p4qm.org/sites/default/files/Initial%20Recognition%20and%20Management/material/EM-Spring-2024-IRM-Final-Project-Report.pdf.*

TABLE IX.D.2.: MALNUTRITION CARE SCORE ECQM COMPONENTS AND DATA SOURCES

Component	Description	Data Sources
Completion of a Malnutrition Screening	Patients age 18 years and older who were screened for malnutrition	- Inpatient Admission Time - Inpatient Discharge Time - Birthdate - Completed Malnutrition Screening - Completed Malnutrition Screening Time Stamp
Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition	Patients age 18 years and older identified as at-risk for malnutrition based on a malnutrition screening who have a nutrition assessment documented in the medical record	- Inpatient Admission Time - Inpatient Discharge Time - Birthdate - Completed Malnutrition Screening - Malnutrition Screening Result - Completed Nutrition Assessment - Completed Nutrition Assessment Time Stamp
Appropriate Documentation of a Malnutrition Diagnosis	Patients age 18 years and older and found to be malnourished based on a completed nutrition assessment who have documentation of a malnutrition diagnosis	- Inpatient Admission Time - Inpatient Discharge Time - Birthdate - Completed Nutrition Assessment - Nutrition Assessment Result - Malnutrition Diagnosis
Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment	Patients age 18 years and older and found to be malnourished based on a completed nutrition assessment who have a documented nutrition care plan in the medical record	- Inpatient Admission Time - Inpatient Discharge Time - Birthdate - Completed Nutrition Assessment - Nutrition Assessment Result - Documented Nutrition Care Plan

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19605 through 19608), we proposed to adopt the Malnutrition Care Score eCQM in the PCH Quality Reporting Program beginning with the CY 2028 reporting period/FY 2030 program year. We refer readers to section IX.D.5.b. of this final rule for a discussion of form, manner, and timing of data submission and reporting requirements for eCQMs in the PCH Quality Reporting Program.

Section 1866(k)(4) of the Act requires the Secretary to make quality measure information available to the public after PCHs have the opportunity to review their data. We proposed that if adoption of the Malnutrition Care Score eCQM is finalized, we would publicly report data as soon as it is feasible on CMS websites such as the Compare tool on *Medicare.gov* (*https://www.medicare.gov/care-compare/*) and the CMS Provider Data Catalog or their successor websites after a 30-day preview period.

We invited public comment on our proposal to adopt the Malnutrition Care Score eCQM into the PCH Quality Reporting Program beginning with the CY 2028 reporting period/FY 2030 program year.

Comment: Many commenters supported the proposal to adopt the Malnutrition Care Score eCQM because nutrition care is a low-cost but high-impact intervention with positive implications for patient care, including improved care coordination, timely intervention, and patient satisfaction. Commenters noted that addressing malnutrition can improve patient outcomes and reduce readmissions, length of stay, complications, and mortality. A few commenters stated that this measure may help close the gap between identification of malnutrition and actual malnutrition care provision. A commenter noted that this measure aligns with broader federal priorities related to patient-centered care and nutrition. Another commenter encouraged CMS to continue building upon this important work by advancing additional nutrition quality measures and supporting broader implementation of evidence-based nutrition care nationwide.

Response: We thank the commenters for their support. We agree that addressing nutrition is important and may consider future measure development and quality reporting activities to strengthen nutrition care across the healthcare continuum. We agree that adopting the Malnutrition Care Score eCQM aligns with broader HHS and CMS nutrition policies and initiatives. The January 2026 HHS fact sheet emphasizes prevention, nutrient-dense foods, and improved nutrition across federal health programs.[497]

Comment: Many commenters highlighted the importance of malnutrition care specifically for cancer patients, noting that malnutrition can affect a patient's ability to withstand cancer treatments and can negatively affect health outcomes. Several commenters noted the high prevalence, but underdiagnosis, of malnutrition among cancer patients. A few commenters stated that requiring the measure for PCHs would strengthen inpatient nutrition care and promote coordinated nutrition care across ambulatory and outpatient settings where many cancer patients continue to receive care. These commenters encouraged CMS to incentivize effective care transitions upon discharge and sustainable patient access to outpatient services, so nutrition diagnoses and care plans are communicated and carried out in post-acute care settings. A commenter noted that the Pre-Rulemaking Measure Review Recommendation Group overwhelmingly supported the inclusion of the Malnutrition Care Score eCQM in the PCH Quality Reporting Program.

Response: We thank the commenters for their support. We agree with commenters and the Recommendation Group that this measure would be an important addition to the PCH Quality Reporting Program as it facilitates improved care coordination and outcomes for cancer patients through timely screening and intervention for malnutrition.

[497] Department of Health and Human Services. (2026). Fact Sheet: Trump Administration Resets U.S. Nutrition Policy, Puts Real Food Back at the Center of Health. Available at: *https://www.hhs.gov/press-room/fact-sheet-historic-reset-federal-nutrition-policy.html.*

Comment: Several commenters stated concerns about implementing and operationalizing eCQMs in the PCH Quality Reporting Program beginning with the CY 2028 reporting period/FY 2030 program year as proposed. These commenters suggested that CMS delay implementation of the policy to allow sufficient time for infrastructure development, vendor alignment, workflow implementation, and data validation. Some commenters recommended an initial voluntary reporting period of up to two years or a phased approach similar to eCQM implementation policies in other CMS quality reporting programs, such as the Hospital Inpatient Quality Reporting Program, to appropriately reflect the level of effort required to ensure successful adoption and high-quality data. A few commenters questioned CMS' proposal to publicly report the eCQMs immediately following the first required reporting period, stating that the standard data preview process would not provide sufficient opportunity to validate data accuracy or ensure consistent interpretation of measure specifications prior to public display, which could misrepresent hospital performance.

A few commenters stated that the Malnutrition Care Score eCQM introduces additional complexity due to its multidisciplinary nature. They stated that successfully implementing the measure requires coordination and staff availability across clinical teams, including physicians, dietitians, and nursing staff, in addition to the efforts to initiate eCQM reporting, and stated that all of this cannot be completed within the proposed timeframe. A commenter encouraged CMS to evaluate the additional resources that are necessary to support successful implementation of the Malnutrition Care Score eCQM and monitor for any unintended consequences of the measure's required reporting, given the measure's documentation demands and workforce constraints, including the availability of nutritionists and dietitians.

Response: We appreciate the commenters' concerns about implementation of the eCQMs. We note that the measure uses data collected through hospitals' EHRs and is designed to be calculated by the hospital's certified health IT, thereby reducing reporting burden and complexity. However, we recognize that PCHs and their vendors may need additional time to operationalize eCQM reporting and submission requirements since eCQMs would be an entirely new measure type in the PCH Quality Reporting Program. We understand that additional time would help ensure the accuracy and reliability of publicly reported data and would promote implementation of more effective workflows between clinical teams seeking strong performance on both this quality measure and, more generally, the introduction of eCQMs to the PCH Quality Reporting Program. Therefore, we are finalizing our proposal with a modification; specifically, we are finalizing adoption of this measure with voluntary reporting in the PCH Quality Reporting Program for the CY 2028 reporting period/FY 2030 program year followed by mandatory reporting beginning with the CY 2029 reporting period/FY 2031 program year.

For the CY 2028 reporting period/FY 2030 program year voluntary period, PCHs will receive confidential data through the Hospital Quality Reporting System to provide opportunities to identify and address deficiencies before public display. We will then publicly report measure information beginning with the CY 2029 reporting period/FY 2031 program year data as soon as it is feasible on CMS websites such as the Compare tool on *Medicare.gov* (*https://www.medicare.gov/care-compare/*) and the CMS Provider Data Catalog or their successor websites after a 30-day preview period.

For implementation guidance, we refer readers to the measure specifications, implementation guide, and other resources, which can be found on the eCQI Resource Center website, available at: *https://ecqi.healthit.gov.* We acknowledge that many quality measures can require adjustments to existing practices but believe the ultimate benefits to both individual patients and overall health outcomes from promoting better nutrition are worth the effort. We will continue to conduct ongoing monitoring and analyses for any unintended consequences.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Malnutrition Care Score eCQM into the PCH Quality Reporting Program with a modification to start with voluntary reporting for the CY 2028 reporting period/FY 2030 program year followed by mandatory reporting of a full year's data beginning with the CY 2029 reporting period/FY 2031 program year.

3. Removal in the PCH Quality Reporting Program Measure Set

a. Removal of the COVID–19 Vaccination Coverage Among Healthcare Personnel Measure

We refer readers to the FY 2022 IPPS/LTCH PPS final rule where we adopted the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure (hereafter referred to as HCP COVID–19 Vaccination measure) into the PCH Quality Reporting Program (86 FR 45428 through 45434) and the FY 2024 IPPS/LTCH PPS final rule where we modified the HCP COVID–19 Vaccination measure to account for updated COVID–19 vaccine guidance (88 FR 59137 through 59144). The HCP COVID–19 Vaccination measure requires PCHs to report the COVID–19 vaccination status of HCP through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). PCHs must collect current vaccination status for all employees, licensed independent practitioners, adult trainees, students, and volunteers, as well as certain contract personnel one week out of each month and report these data on a quarterly basis (88 FR 59140).

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19608 through 19609), we proposed to remove the HCP COVID–19 Vaccination measure beginning with the CY 2026 reporting period/FY 2028 program year under removal factor 2, a measure does not align with current clinical guidelines or practice (§ 412.24(d)(3)(i)(B)). When we originally adopted this measure, the United States was in the midst of a Public Health Emergency (PHE) with millions of COVID–19 cases and over 550,000 COVID–19 deaths (86 FR 45428). In March 2021, when this measure was being proposed, the United States was averaging over 5,000 deaths per week. In April 2023, the last full month of the PHE, the weekly number of deaths due to COVID–19 averaged around 1,300.[498] While preventing the spread of COVID–19 remains a public health goal, the PHE ended on May 11, 2023,[499] and the COVID–19 death rate has continued to decrease. At the time we were drafting the proposed rule, weekly deaths attributed to COVID–19 ranged from 188 to 488 during the 6-

[498] Centers for Disease Control and Prevention. Provisional COVID–19 Deaths, by Week, in The United States, Reported to CDC. *Available at: https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00.*

[499] End of the Federal COVID–19 Public Health Emergency (PHE) Declaration via *https://archive.cdc.gov/www_cdc_gov/coronavirus/2019-ncov/your-health/end-of-phe.html.*

month period from the week ending August 2, 2025, through the week ending January 31, 2026.[500] Since the proposed rule was published, this figure has continued to decline; from the week ending April 4, 2026, through the week ending June 20, 2026, weekly deaths attributed to COVID–19 ranged from 16 to 172.[501]

With the end of the PHE and decrease in COVID–19 deaths, we believed the continued costs and burden to providers of reporting on this measure outweighed the benefit of continued information collection on the HCP COVID–19 Vaccination in several settings. We have already removed this measure from the Hospital Inpatient Quality Reporting Program (90 FR 37010 through 37012), the Inpatient Psychiatric Facility Quality Reporting Program (90 FR 37657 through 37658), the Inpatient Rehabilitation Facility Quality Reporting Program (90 FR 37701 through 37702), the Ambulatory Surgical Center Quality Reporting Program (90 FR 53917 through 53919), and the Hospital Outpatient Quality Reporting Program (90 FR 53917 through 53919).

Since the end of the PHE, the CDC's clinical recommendations for COVID–19 vaccination have changed. In December 2020, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should receive a complete vaccination course.[502] At the time the HCP COVID–19 Vaccination measure was adopted in August 2021, vaccination was a critical part of the nation's strategy to effectively counter the spread of COVID–19 in an effort to restore societal functioning.[503] There were well-defined parameters for receiving the COVID–19 vaccination intended to capture routine, catch-up, and risk-based immunization recommendations.

However, these parameters no longer apply, due to evolving circumstances. At the time the proposed rule was published, the latest CDC COVID–19 vaccination recommendations for the 2025–2026 season were based on shared clinical decision-making (also known as individual-based decision-making).[504] For shared clinical decision-making, there is not a default decision to vaccinate for a defined population.[505] Given that there is no single default recommendation to vaccinate a defined population, both receipt and nonreceipt of vaccination may be consistent with the application of shared clinical decision-making. This differs from the guidance in place when this measure was finalized.

On this basis, we proposed to remove the measure from the PCH Quality Reporting Program under removal Factor 2, a measure does not align with current clinical guidelines or practice, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19608 through 19609). We refer readers to section IX.E.3. of this final rule for a similar proposal to remove the HCP COVID–19 Vaccination measure in the LTCH Quality Reporting Program.

If finalized, PCHs would not be required to report CY 2026 HCP COVID–19 Vaccination measure data for purposes of the FY 2028 program year. Any CY 2026 HCP COVID–19 vaccination data received by CMS would not be used for PCH Quality Reporting Program public reporting.

We invited public comment on our proposal to remove the COVID–19 Vaccination Coverage among Healthcare Personnel measure from the PCH Quality Reporting Program beginning with the CY 2026 reporting period/FY 2028 program year.

Comment: A few commenters supported the proposed removal because they believe the HCP COVID–19 Vaccination measure no longer aligns with current clinical guidance and practice following the end of the COVID–19 PHE. These commenters stated that changing definitions of vaccination status, the transition to an endemic phase of COVID–19, and the shift towards shared clinical decision-making have reduced the measure's utility and relevance as a quality measure in the PCH setting. These commenters further stated that these changes mean the measure no longer aligns with current clinical guidelines or practice.

A few commenters supported the proposal because they believed the burden associated with collecting and reporting measure data outweighs its current value. Commenters stated that continued reporting requires staff time and resources while providing limited benefit in the current clinical environment. Some commenters also supported removal of the measure and associated reporting requirements because doing so would reduce administrative burden associated with collecting and reporting COVID–19 vaccination data.

Response: We thank the commenters for their support, and we understand that the clinical guidance has changed since the measure was first adopted and that there is confusion over the current recommendations and their applicability to HCP. When the current measure was adopted, guidance recommended routine vaccination to remain ''up to date,'' which was then revised for the 2025–2026 COVID–19 vaccination schedule based on shared clinical decision-making, also known as individual-based decision-making.[506] Unlike routine vaccination, shared clinical decision-making does not establish a standard recommendation or schedule for vaccination. Instead, the decision is made on an individual basis and may consider the available evidence, the individual's characteristics and preferences, and the health care provider's clinical judgment. Under this framework, both receipt and non-receipt of vaccination may be consistent and appropriate with current clinical guidance.[507] As a result, the measure no longer reliably reflects vaccination prevalence among HCP. Therefore, we believe removal of the measure under removal Factor 2 is appropriate. In addition, we agree with commenters about the burden reduction associated with removal of this measure and refer interested readers to sections XII.B.5.c. and XII.B.5.d. of this final rule for details on our Information Collection Burden Estimates for the removal of this measure from the PCH Quality Reporting Program.

[500] Centers for Disease Control and Prevention. Provisional COVID–19 Mortality Surveillance. *Available at: https://www.cdc.gov/nchs/nvss/vsrr/covid19/.*

[501] Centers for Disease Control and Prevention. Provisional COVID–19 Mortality Surveillance. *Available at: https://www.cdc.gov/nchs/nvss/vsrr/covid19/.*

[502] Dooling K, McClung M, Chamberland M, Marin M, Wallace M, Bell B, Lee GM, Talbot HK, Romero JR, Oliver SE. (2020). ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' *Morbidity and Mortality Weekly Report, 69*(49): 1857–1859. *http://dx.doi.org/10.15585/mmwr.mm6949e1.*

[503] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. *Available at: https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[504] Centers for Disease Control and Prevention. (2025). 2025–2026 COVID–19 Vaccination Guidance. *Available at: https://www.cdc.gov/covid/hcp/vaccine-considerations/routine-guidance.html.*

[505] Centers for Disease Control and Prevention. (2025). ACIP Shared Clinical Decision-Making Recommendations. *Available at: https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.*

[506] Centers for Disease Control and Prevention. Staying Up to Date with COVID–19 Vaccines. *Available at: https://www.cdc.gov/covid/vaccines/stay-up-to-date.html.*

[507] Centers for Disease Control and Prevention. ACIP Shared Clinical Decision-Making Recommendations. *Available at: https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.*

Comment: A few commenters opposed the proposal and stated that COVID–19 vaccination remains an important strategy for protecting cancer patients as they are highly immunocompromised and remain particularly vulnerable to increased risk of severe COVID–19 outcomes. Some commenters stated that continued visibility into HCP vaccination coverage remains important to encourage vaccine uptake, support infection prevention efforts, and protect vulnerable patients and HCP. A few commenters therefore recommended retaining the measure or exploring alternative approaches.

A few commenters opposed the proposal because they believed continued reporting of COVID–19 vaccination rates among HCP would promote transparency and accountability and expressed concern that removing the measure would reduce transparency and weaken accountability for infection prevention efforts.

Response: We acknowledge commenters' concerns regarding the increased risk for severe COVID–19 outcomes among PCH patient populations and views that continued public reporting of HCP vaccination rates may promote accountability, transparency, vaccination uptake, infection prevention efforts, and workforce protection. We also agree that preventing the spread of COVID–19 and protecting vulnerable patients remain important goals. However, we proposed removal of the measure under removal Factor 2 because the measure no longer aligns with current clinical guidelines and practice, not as a reflection of the effectiveness or importance of COVID–19 vaccination.

As stated previously, when the current measure was adopted, guidance recommended routine vaccination to remain ''up to date,'' which was then revised for the 2025–2026 COVID–19 vaccination schedule based on shared clinical decision-making.[508] Unlike routine vaccination, shared clinical decision-making does not establish a standard recommendation or schedule for vaccination. Instead, the decision is made on an individual basis and may consider the available evidence, the individual's characteristics and preferences, and the health care provider's clinical judgment. As a result, the measure is no longer reflects the prevalence of COVID–19 vaccination among HCP, as an HCP may be considered in compliance with vaccine recommendations without receiving an updated COVID–19 vaccination.

Comment: A commenter questioned whether alignment with other CMS quality reporting programs is an appropriate basis for removing the measure from the PCH Quality Reporting Program. The commenter stated that the unique characteristics of PCH patient populations warrant continued measurement of healthcare personnel vaccination coverage and suggested that alignment with other quality reporting programs should not outweigh clinical considerations specific to PCH settings.

Response: We acknowledge the commenter's concern that alignment with other CMS quality reporting programs should not, by itself, justify removal of the measure. Our decision to finalize removal of this measure is based on removal Factor 2 and our determination that the measure no longer aligns with current clinical guidelines and practice.

After consideration of the comments received, we are finalizing the removal of the COVID–19 Vaccination Coverage Among HCP measure from the PCH Quality Reporting Program beginning with the CY 2026 reporting period/FY 2028 program year as proposed.

4. Summary of Previously Finalized and Newly Finalized PCH Quality Reporting Program Measures

Table IX.D.3. summarizes the previously established and newly finalized PCH Quality Reporting Program measure set for the FY 2028 to FY 2031 program years, which removes the COVID–19 Vaccination Coverage among HCP measure as discussed in section IX.D.3.a. of this final rule, adds the Advance Care Planning eCQM as discussed in section IX.B.1. of this final rule, and adds the Malnutrition Care Score eCQM as discussed in section IX.D.2.a. of this final rule.

[508] Centers for Disease Control and Prevention. Staying Up to Date with COVID–19 Vaccines. *Available at: https://www.cdc.gov/covid/vaccines/stay-up-to-date.html.*

TABLE IX.D.3.: PCH QUALITY REPORTING PROGRAM MEASURE SET BY PROGRAM YEAR (PY)

Measure Name	CBE Number	FY 2028 PY	FY 2029 PY	FY 2030 PY	FY 2031 PY
NHSN Safety and Healthcare-Associated Infection (HAI) Measures					
NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138	✓	✓	✓	✓
NHSN Central line-associated Bloodstream Infection (CLABSI) Outcome Measure	0139	✓	✓	✓	✓
Influenza Vaccination Coverage Among Healthcare Personnel (HCP)	0431	✓	✓	✓	✓
COVID–19 Vaccination Coverage among HCP*	N/A				
American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery)	0753	✓	✓	✓	✓
NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716	✓	✓	✓	✓
NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717	✓	✓	✓	✓
Patient Safety Structural Measure	N/A	✓	✓	✓	✓
Claims-Based End-of-Life Measures					
Proportion of Patients Who Died from Cancer - Receiving Chemotherapy in the Last 14 Days of Life	0210	✓	✓	✓	✓
Proportion of Patients Who Died from Cancer - Not Admitted to Hospice	0215	✓	✓	✓	✓
Proportion of Patients Who Died from Cancer - Admitted to the ICU in the Last 30 Days of Life	0213	✓	✓	✓	✓
Proportion of Patients Who Died from Cancer - Admitted to Hospice for Less Than Three Days	0216	✓	✓	✓	✓
Patient Engagement/Experience of Care Measures					
Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey	0166	✓	✓	✓	✓
Documentation of Goals of Care Discussions Among Cancer Patients	N/A	✓	✓	✓	✓
Claims-Based Outcome Measures					
Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	N/A	✓	✓	✓	✓
30-Day Unplanned Readmissions for Cancer Patients	3188	✓	✓	✓	✓
Surgical Treatment Complications for Localized Prostate Cancer	N/A	✓	✓	✓	✓
Electronic Clinical Quality Measures					
Advance Care Planning eCQM**	N/A			Voluntary	✓
Malnutrition Care Score eCQM**	3592e			Voluntary	✓

✓Measure required for the specified program year

*Finalized for removal in this final rule beginning with the CY 2026 reporting period/FY 2028 program year.

**Finalized for adoption in this final rule beginning with voluntary reporting for the CY 2028 reporting period/FY 2030 program year followed by mandatory reporting beginning with the CY 2029 reporting period/FY 2031 program year.

We refer readers to the CMS QualityNet website at *https://qualitynet.cms.gov/pch* for additional information on the reporting periods and submission deadlines for each measure previously finalized in the PCH Quality Reporting Program.

5. Updates to the Form, Manner, and Timing of Quality Data Submission

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19610 through 19612), we proposed to update program policies for introducing eCQMs into the PCH Quality Reporting Program by establishing eCQM data submission and reporting requirements, which would apply to the proposed Advance Care Planning eCQM and Malnutrition Care Score eCQM.

a. Maintenance of Technical Specifications for Quality Measures

Section 412.24(c) of title 42 of the Code of Federal Regulations generally requires that a PCH participating in the PCH Quality Reporting Program must submit to CMS data on measures selected under section 1833(k)(3) of the Act in a form and manner, and at a time, specified by CMS. The data submission requirements, specifications manual, measure methodology reports, and submission deadlines are posted on the QualityNet website at: *https://qualitynet.cms.gov* (or other successor CMS designated websites).

In alignment with the Hospital Inpatient Quality Reporting Program, we proposed that the technical specifications for eCQMs for the PCH Quality Reporting Program would be contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update). The Annual Update and implementation guidance documents are available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/*. For eCQMs, we would generally update the measure specifications on an annual basis through the Annual Update process which includes code updates, logic

corrections, alignment with current clinical guidelines, and additional guidance for PCHs and EHR vendors to collect and submit data on eCQMs from EHRs. In addition, we would generally update related eCQM implementation guidance on an annual basis. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19610 through 19611), we proposed that PCHs would be required to use the eCQM electronic measure specifications and implementation guidance for the applicable reporting period available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/* or another website as designated by CMS.

We invited public comments on this proposal.

We did not receive public comments on this proposal; therefore, we are finalizing the policy for maintaining technical specifications for eCQMs as proposed.

b. Data Submission and Reporting Requirements for Electronic Clinical Quality Measures for the PCH Quality Reporting Program

(1) Background

Collection and reporting of data through health IT streamlines quality reporting through automated electronic extraction and reporting. Certified health IT assists facilities in a variety of ways, such as by improving coordination of care with referring providers or labs,[509] using eCQMs to improve quality and safety, and advancing a vision to eventually transition to a fully digital quality measure set.[510] We acknowledge the initial investment that the implementation of eCQMs may require for PCHs, but we expect that this investment will deliver long-term burden reduction along with more accurate and timely access to quality information to inform patient care.

We intend to transition to a fully digital quality measure (dQM) landscape, first by transitioning eCQMs to Health Level 7® Fast Healthcare Interoperability Resources® (FHIR®)-based eCQMs, to promote interoperability and increase the value of quality measure data.[511] [512] While we continue to transition our quality measurement infrastructure to dQMs, we are advancing interim improvements by expanding the use of eCQMs in our quality reporting programs. This approach will promote meaningful progress in electronic quality measurement while supporting deliberate, phased conversion to FHIR and dQMs over time. We refer readers to our most recent requests for information on the transition to digital quality measurement (90 FR 36990 through 36996) and on potential FHIR® timelines in the CY 2027 Physician Fee Schedule proposed rule (91 FR 44151 through 44154) for more information.

We refer readers to sections IX.B.1. and IX.D.2.a. of this final rule, where we finalize the adoption of the Advance Care Planning eCQM and the Malnutrition Care Score eCQM, respectively, into the PCH Quality Reporting Program measure set beginning with voluntary reporting for the CY 2028 reporting period/FY 2030 program year followed by a full year of mandatory reporting for the CY 2029 reporting period/FY 2031 program year. The Advance Care Planning eCQM and the Malnutrition Care Score eCQM are the first eCQMs in the PCH Quality Reporting Program, although CMS began providing hospitals with the opportunity to voluntarily submit eCQM data in CY 2013 before required reporting in the Hospital Inpatient Quality Reporting and Medicare Promoting Interoperability Programs in CY 2016. Additionally, eCQMs are used in the Hospital Outpatient Quality Reporting Program, Rural Emergency Hospital (REH) Quality Reporting Program, Merit-Based Incentive Payment System for clinicians, and certain CMS Innovation Center models.

Introducing eCQM reporting in the PCH Quality Reporting Program involves establishing related policies and requirements, including eCQM certification requirements, data standards and formats, submission methods, and other program-specific requirements. In the following sections, we proposed eCQM submission and reporting requirements for the PCH Quality Reporting Program that align with these other programs.

(2) eCQM Reporting and Data Submission Requirements

(a) Certification Requirements for eCQM Reporting

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69569) and the CY 2025 OPPS/ASC final rule (89 FR 94418 through 94420), we summarized our requirements with respect to using technology meeting the Office of the National Coordinator for Health Information Technology's (ONC) health IT certification criteria for reporting eCQMs in the Hospital Inpatient Quality Reporting Program and the Hospital Outpatient Quality Reporting Program, respectively. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19611), we proposed to adopt similar eCQM certification requirements in the PCH Quality Reporting Program, and to codify them by adding a new paragraph (g) ''Requirements for submission of electronic clinical quality measures (eCQMs) under the PCHQR Program'' to 42 CFR 412.24.

Under this approach, we proposed to codify at § 412.24(g)(1) the requirement for PCHs to utilize health IT certified to the ONC Health IT Certification Program certification criteria, as adopted and updated at 45 CFR 170.315(c), which cover the elements necessary for eCQM reporting under the PCH Quality Reporting Program.

We also proposed to codify at 42 CFR 412.24(g)(2) the requirement that PCHs use the certified health IT described in paragraph (g)(1) to calculate, export, and submit results for the eCQMs available to report under the PCHQR Program. Additionally, we proposed to codify at § 412.24(g)(3) the requirement that PCHs use the eCQM electronic measure specifications for the applicable reporting period available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/* or another website as designated by CMS. Further, consistent with the other programs, we proposed that health IT would not need to be recertified each time the eCQMs' specifications are updated to a more recent version. Under this proposal, this requirement would apply beginning with the CY 2028 reporting period/FY 2030 program year and for subsequent years. Any substantive changes to modernize electronic submission methods would be proposed in future rulemaking.

(b) File Format for eCQM Reporting

When EHRs and health IT systems capture data in standardized formats, the information is represented and interpreted consistently, enabling automated computation without manual interpretation. As described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49701), these standards are referred to as content exchange standards because the standards detail how data should be represented and the relationships between data elements. This allows the

[509] Office of the National Coordinator for Health IT (May 2024). Interoperable Exchange of Patient Health Information Among U.S. Hospitals: 2023. *Available at: https://www.healthit.gov/data/data-briefs/interoperable-exchange-patient-health-information-among-us-hospitals-2023.*

[510] Centers for Medicare & Medicaid Services. Electronic Clinical Quality Improvement (eCQI) Resource Center. *Available at: https://ecqi.healthit.gov/.*

[511] For more information on dQMs, visit: *https://ecqi.healthit.gov/dqm/about-dqms.*

[512] FHIR® is the registered trademark of Health Level Seven International (HL7), and its use does not constitute endorsement by HL7.

data to be exchanged across EHRs and health IT systems while retaining their meaning. At this time, the Quality Reporting Document Architecture (QRDA) standard is the standard file format used for eCQM submission in CMS quality programs that rely on QRDA-based eCQM reporting. The QRDA standard provides a document format and standard structure to electronically report quality measure data, promotes consistent representation of the data, and enables calculation of eCQM measure results.

To utilize the same file format requirements currently applied in the Hospital Inpatient Quality Reporting Program (85 FR 58940), the Hospital Outpatient Quality Reporting Program (86 FR 63869), the REH Quality Reporting Program (90 FR 53954), and the Medicare Promoting Interoperability Program (80 FR 49706), in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19611 through 19612), we proposed comparable file format requirements for the PCH Quality Reporting Program beginning with the CY 2028 reporting period/FY 2030 program year. Specifically, we proposed that a PCH: (1) must submit eCQM data via the QRDA Category I (QRDA I) file format; [513] (2) may use third parties to submit QRDA I files on their behalf; [514] and (3) may either use abstraction or pull the data from non-certified sources in order to then input these data into certified health IT for capture and reporting in the QRDA I file format. We stated under this proposal, we expect QRDA I files to reflect data for one patient per file per quarter with five key elements necessary to identify the file: (1) CCN; (2) CMS Program Name; (3) EHR Patient ID; (4) Reporting period specified in the Reporting Parameters Section; and (5) EHR Submitter ID. For technical guidance in implementing these standards for quality reporting, we referred readers to the QRDA Implementation Guides available at: *https://ecqi.healthit.gov/qrda/versions.*

PCHs could meet the eCQM reporting requirements by submitting data via QRDA I files, submitting a zero-denominator declaration, or submitting a case threshold exemption. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19611 through 19612), we discussed the zero-denominator declaration and case threshold exemptions in the subsequent sections. We also refer readers to section IX.D.5.a. of this final rule where we outline the maintenance of technical specifications including those for eCQMs.

(c) Zero Denominator Declarations

We understand there may be situations in which a PCH does not have data to report on a particular eCQM. Therefore, we proposed that if the PCH's health IT is certified to an eCQM but the PCH does not have patients that meet the denominator criteria of that eCQM, the PCH would submit a zero in the denominator for that eCQM (91 FR 19612). Submission of a zero in the denominator for such an eCQM would qualify as a successful submission for that eCQM.

(d) Case Threshold Exemptions

We understand that in some cases, a PCH may not meet the case threshold of discharges for a particular eCQM to reliably calculate performance on the measure. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19612), we proposed to align with the case threshold exemption policy from the Medicare Promoting Interoperability Program (77 FR 54080), the Hospital Inpatient Quality Reporting Program (79 FR 50323 and 50324), the Hospital Outpatient Quality Reporting Program (86 FR 63869), and the REH Quality Reporting Program (90 FR 53954). As stated for the Hospital Inpatient Quality Reporting Program, the case threshold exemption means that for each quality measure where the minimum number of patients that meet the patient population denominator criteria for the relevant reporting period is not met, a hospital could declare a ''case threshold exemption.'' We proposed a PCH using certified health IT would be exempt from reporting on that eCQM if the PCH has 5 or fewer applicable inpatient encounters or discharges per quarter or 20 or fewer applicable inpatient encounters or discharges per year (Medicare and non-Medicare combined), with applicability defined by specifications for each eCQM's denominator population. Case threshold exemptions would be entered on the Denominator Declaration screen within CMS' Hospital Quality Reporting System available during the submission period. The exemption would not have to be used, and a PCH could report those individual cases if they elect to do so. However, the measure rate would not be publicly reported if below the case threshold. We proposed to adopt the case threshold exemption for the PCH Quality Reporting Program beginning with the CY 2028 reporting period/FY 2030 program year.

(3) Submission Deadlines for eCQM Data

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57171 through 57172), the Hospital Inpatient Quality Reporting Program aligned its eCQM submission deadline with that of the Medicare Promoting Interoperability Program. The eCQM submission deadline we have established for those two programs is by the end of 2 months following the close of the calendar year reporting period.

To align with these existing programs, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19612), we proposed to require eCQM data submission for the PCH Quality Reporting Program by the end of 2 months following the close of the calendar year for the CY 2028 reporting period/FY 2030 program year and for subsequent years. We believe that by aligning with these existing programs' deadlines we can minimize burden and simplify understanding of the data reporting requirements. For example, although we are modifying our proposal to make the first year of eCQM reporting in the CY 2028 reporting period/FY 2030 program year voluntary for PCHs, a PCH participating in the one-year voluntary reporting period would be required to submit eCQM data to CMS by February 28, 2029, which is the end of 2 months following the close of the calendar year (December 31, 2028). For the CY 2029 reporting period/FY 2031 program year, when mandatory reporting begins, PCHs would be required to submit eCQM data to CMS by February 28, 2030. If this date falls on a weekend or Federal holiday, the submission deadline would be moved to the next business day under established reporting practices.

We invited public comments on these eCQM submission and reporting proposals.

Comment: A few commenters supported CMS' goals of transitioning quality reporting programs, including the PCH Quality Reporting Program, to digital quality measures and aligning requirements across programs if such measures are clinically meaningful, technically feasible, adequately tested, and implemented with appropriate pacing and support. A commenter noted that improved interoperability, digitization, and standardization of health information are essential to advancing optimal care. Another commenter remarked that CMS' proposed requirements focus on a single certification criterion for health IT, which reduces the burden for hospitals

[513] QRDA I is an individual patient-level quality report that contains quality data for one patient for one or more eCQMs. QRDA creates a standard method to report quality measure results in a structured, consistent format and can be used to exchange eCQM data between systems.

[514] The PCH remains responsible for ensuring the data submitted by a third party is true, accurate, and complete.

and avoids having to use solutions and vendors that are certified to other criteria, which may be redundant or unnecessary for participating hospitals.

Response: We thank commenters for their support. We recognize that aligned certification criteria, technical support, and sufficient lead time to establish reporting infrastructure are necessary for PCHs to begin reporting on eCQMs and ultimately reduce burden. As noted in sections IX.B.1 and IX.D.2.a. of this final rule, where we respectively adopt the Advance Care Planning and Malnutrition Care Score eCQMs, we are providing a one-year voluntary reporting period for CY 2028 before mandatory reporting begins with the CY 2029 reporting period/FY 2031 program year. This voluntary period will provide additional time for PCHs to transition to reporting eCQMs while adopting meaningful new measures and modernizing the quality reporting programs over time.

Comment: Commenters requested that CMS provide ample time for the transition to eCQMs and FHIR-based dQMs to ensure hospitals have the technical support to meet these reporting requirements. A commenter stated that introducing eCQMs to the PCH Quality Reporting Program while the broader hospital quality reporting community is moving towards FHIR® is concerning. This commenter recommended that PCHs could transition directly to a FHIR-native framework as they do not carry the legacy QRDA investment and eCQM reporting infrastructure that makes the transition to FHIR costly in other settings.

Response: While we continue to transition our quality measurement infrastructure towards FHIR-based dQMs, we are advancing interim improvements by expanding the use of digital reporting, such as eCQMs, in the quality reporting programs. A focused eCQM approach allows facilities to begin capturing clinically meaningful measures now while laying the groundwork for a future transition to FHIR-based reporting. We also wish to point readers to our request for information on potential FHIR® timelines in the CY 2027 Physician Fee Schedule proposed rule (91 FR 44151 through 44154).

After consideration of the public comments we received, we are finalizing the proposals related to the certification requirements for eCQM reporting, file format for EHR data, zero denominator declarations, case threshold exemptions, and submission deadlines as proposed.

c. Review and Corrections Period for eCQM Data Submitted to the PCH Quality Reporting Program

In alignment with the Hospital Outpatient Quality Reporting Program (86 FR 63870), in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19612), we proposed a review and corrections period for eCQM data which would run concurrently with the data submission period. The review and corrections period is from the time the submission period opens to the submission deadline. In the Hospital Quality Reporting System, providers can submit QRDA Category I test and production data files and can correct QRDA Category I test and production data files before production data are submitted for final reporting. We encourage early testing and the use of pre-submission testing tools to reduce errors and inaccurate data submissions in eCQM reporting. The Hospital Quality Reporting System does not allow data to be submitted or corrected after the annual deadline. We refer readers to the Hospital Quality Reporting System website (available at: *https://hqr.cms.gov/hqrng/support*), the eCQI Resource Center (available at: *https://ecqi.healthit.gov/*), and the CMS QualityNet website (*https://qualitynet.cms.gov/pch/public-reporting*) for more resources on eCQM reporting, submission deadlines, and program notifications for the PCH Quality Reporting Program.

We invited public comments on our proposal.

We did not receive public comments on this proposal; therefore, we are finalizing the review and corrections period for eCQM data as proposed.

E. Changes to the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background and Statutory Authority

The Long-Term Care Hospital Quality Reporting Program (LTCH QRP) is authorized by section 1886(m)(5) of the Act, and it applies to all hospitals certified by Medicare as long-term care hospitals (LTCHs). Section 1886(m)(5)(C) of the Act requires LTCHs to submit to the Secretary data on quality measures specified under section 1886(m)(5)(D) in a form and manner, and at a time, specified by the Secretary. In addition, section 1886(m)(5)(F) of the Act requires LTCHs to submit data on quality measures under section 1899B(c)(1) of the Act, resource use or other measures under section 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act. LTCHs must submit the data required under section 1886(m)(5)(F) of the Act in the form and manner, and at the time, specified by the Secretary. Section 1886(m)(5)(A) of the Act requires the Secretary to reduce by 2 percentage points the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year if the LTCH has not submitted data to the Secretary in accordance with the LTCH QRP requirements specified for that fiscal year. Section 1890A of the Act requires that the Secretary establish and follow a pre-rulemaking process, in coordination with the consensus-based entity (CBE) with a contract under section 1890(a) of the Act, to solicit input from certain groups regarding the selection of quality and efficiency measures for the LTCH QRP. We have codified our program requirements in our regulations at 42 CFR 412.560.

In this final rule, we finalize the removal of two measures, specifically the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure and the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure, beginning with the FY 2028 LTCH QRP as described in sections IX.E.3. and IX.E.4. of this final rule. In section IX.E.6.b, of this final rule, we also finalize our proposal to revise the LTCH QRP Data Submission Deadlines beginning with the FY 2029 LTCH QRP. We also provide a summary of public comments received on our Request for Information (RFI) on future measure concepts for the LTCH QRP in section IX.E.5 of this final rule.

2. General Considerations Used for the Selection of Measures for the LTCH QRP—Quality Measures Currently Adopted for the LTCH QRP

For a detailed discussion of the considerations we use for the selection of LTCH QRP quality, resource use, and other measures, we refer readers to the FY 2016 Inpatient Prospective Payment System (IPPS)/LTCH PPS final rule (*80 FR 49728*). The LTCH QRP currently has 18 adopted measures, which are set out in Table IX.E.–01. We did not propose to adopt any new measures for the LTCH QRP.

For a discussion of the factors we use to evaluate whether a measure should be removed from the LTCH QRP, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (*83 FR 41624* through *41634*) and to the regulations at § 412.560(b)(3).

TABLE IX.E.-01: QUALITY MEASURES CURRENTLY ADOPTED FOR THE LTCH QRP

Short Name	Measure Name & Data Source
LTCH CARE Data Set	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)
Change in Mobility	Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients requiring ventilator support
DRR	Drug Regimen Review Conducted with Follow-Up for Identified Issues–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
Compliance with SBT	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay
Ventilator Liberation	Ventilator Liberation Rate
TOH-Provider	Transfer of Health Information to the Provider Post-Acute Care (PAC)
TOH-Patient	Transfer of Health Information to the Patient Post-Acute Care (PAC)
DC Function	Discharge Function Score
Patient/Resident COVID-19 Vaccine	COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date
National Healthcare Safety Network (NHSN)	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure
CLABSI	National Healthcare Safety Network (NHSN) Central-Line associated Bloodstream Infection (CLABSI) Outcome Measure
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel (HCP)
HCP COVID-19 Vaccine	COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)
Claims-Based	
MSPB LTCH	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
DTC	Discharge to Community– Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)

3. Removal of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the FY 2028 LTCH QRP

We refer readers to the FY 2022 IPPS/LTCH PPS final rule where we adopted the COVID–19 Vaccination Coverage among HCP measure (HCP COVID–19 Vaccine measure) into the LTCH QRP (*86 FR 45438* through *45446*) and the FY 2024 LTCH PPS final rule where we modified the HCP COVID–19 Vaccine measure to account for updated COVID–19 vaccine guidance (*88 FR 59138* through *59144*). The HCP COVID–19 Vaccine measure requires LTCHs to report the COVID–19 vaccination status of HCP through the National Healthcare Safety Network (NHSN). LTCHs must collect current vaccination status for all employees, licensed independent practitioners, adult trainees, students, and volunteers, as well as certain contract personnel one week out of each month and report these data on a quarterly basis (*88 FR 59139*).

We proposed to remove the HCP COVID–19 Vaccine measure beginning with the FY 2028 LTCH QRP under measure removal factor 3: a measure does not align with current clinical guidelines or practice (§ 412.560(b)(3)(iii)). When we originally adopted this measure, the United States was in the midst of a Public Health Emergency (PHE) with millions of COVID–19 cases and over 550,000 COVID–19 deaths (*88 FR 59138* and *59139*). In March 2021, when this measure was being proposed, the United States was averaging over 5,000 deaths per week. In April 2023, the last full month of the PHE, the weekly number of deaths due to COVID–19 averaged around 1,300.[515] While preventing the spread of COVID–19 remains a public health goal, the PHE ended on May 11, 2023,[516] and the COVID–19 death rate has continued to decrease. At the time of the proposed rule, weekly number of deaths attributed to COVID–19 during the 6-month period from the weeks ending 8/2/25 through 1/31/26 ranged from 188 to 488.[517] Since the publication of the proposed rule more recent data show that the weekly number of deaths attributed to COVID–19 ranged from 16 to 172 during the period from the week ending in 4/4/26 through the week ending in 6/20/26.[518]

With the end of the PHE and decrease in COVID–19 deaths, we believed the continued costs and burden to LTCHs of reporting on this measure outweighed the benefit of continued information collection on the HCP COVID–19 Vaccine measure in several settings. We have already removed this measure from the Hospital Inpatient Quality Reporting Program (*90 FR 37010* through *37012*), the Inpatient Psychiatric Facility Quality Reporting Program (*90 FR 37657* through *37658*), the Ambulatory Surgical Center Quality Reporting (*90 FR 53917* through *53919*), the Hospital

[515] Provisional COVID–19 Deaths, by Week, in The United States, Reported to CDC. Accessed on March 27, 2026, via *https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00.*

[516] *https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.*

[517] Provisional COVID–19 Mortality Surveillance *https://www.cdc.gov/nchs/nvss/vsrr/covid19/.*

[518] Provisional COVID–19 Mortality Surveillance *https://www.cdc.gov/nchs/nvss/vsrr/covid19/.*

Outpatient Quality Reporting Programs (*90 FR 53917* through *53919*), and the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) (*90 FR 37700* through *37702*).

Since the end of the PHE, the CDC's clinical recommendations for COVID–19 vaccination have changed. In December 2020, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should receive a complete vaccination course.[519] At the time the HCP COVID–19 Vaccine measure was adopted in August 2021, vaccination was a critical part of the nation's strategy to effectively counter the spread of COVID–19 in an effort to restore societal functioning.[520] There were well-defined parameters for receiving the COVID–19 vaccination intended to capture routine, catch-up, and risk-based immunization recommendations.

However, these parameters no longer apply, due to evolving circumstances. The latest CDC COVID–19 vaccination recommendations for the 2025–2026 vaccine schedule recommendations, at the time of the proposed rule, were based on shared clinical decision-making (also known as individual-based decision-making).[521] For shared clinical decision-making, there is not a default decision to vaccinate for a defined population.[522] Given that there is no single default recommendation to vaccinate a defined population, both receipt and nonreceipt of vaccination may be consistent with the application of shared clinical decision-making. This differs from the guidance in place when this measure was finalized.

On this basis, we proposed to remove the measure from the LTCH QRP under removal factor 3, a measure does not align with current clinical guidelines or practice.

We proposed that LTCHs would not be required to report CY 2026 HCP COVID–19 Vaccine measure data for purposes of the FY 2028 payment determination (that is, LTCHs that do not report CY 2026 HCP COVID–19 vaccine measure data will not be penalized for FY 2028 annual payment update under the LTCH QRP). Any CY 2026 HCP COVID–19 vaccine data received by CMS will not be used for LTCH QRP compliance or public reporting.

We invited public comment on our proposal to remove the COVID–19 Vaccination Coverage among Healthcare Personnel measure from the LTCH QRP beginning with the FY 2028 LTCH QRP.

Comment: Several commenters supported CMS's proposal to remove the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure from the LTCH QRP and recommended that CMS finalize removal of the measure. Many commenters who supported removal of the measure expressed views similar to those submitted regarding the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure, which we describe in section IX.E.4 of this final rule. Several commenters stated that the measure no longer aligns with current clinical guidelines and practice following the end of the COVID–19 PHE.

Some of these commenters stated that declining COVID–19 severity and mortality, evolving vaccination recommendations, changing definitions of vaccination status, the transition to an endemic phase of COVID–19, and the shift toward shared clinical decision-making reflected in recent federal guidance have reduced the measure's utility and relevance as a standardized quality measure. These commenters further stated that these changes mean the measure no longer aligns with current clinical guidelines or practice. Commenters also supported the proposal because they believed the burden associated with collecting, tracking, and reporting HCP COVID–19 vaccination data outweighs the value of continued data collection in the current environment. Commenters noted ongoing staffing shortages, workforce challenges, and increasing operational costs and stated that resources devoted to reporting could be redirected toward patient care and other infection prevention activities.

Other commenters supported the proposal because removal of the measure would align the LTCH QRP with other CMS quality reporting programs that have already removed similar COVID–19 vaccination measures. Commenters stated that alignment with other CMS quality reporting programs would promote consistency across quality reporting programs and reduce unnecessary reporting requirements.

Several commenters emphasized that their support for removing the measure should not be interpreted as reduced support for vaccination, infection prevention activities, or public health surveillance efforts. These commenters continued to support vaccination of healthcare personnel and patients, ongoing infection prevention practices, and the maintenance of appropriate infectious disease surveillance infrastructure.

Response: We thank the commenters for their support, and we understand that the clinical guidance has changed since the measure was first adopted and that there is confusion over the current recommendations and their applicability to HCP. When the current measure was adopted, guidance recommended routine vaccination to remain ''up to date,'' which was then revised for the 2025–2026 COVID–19 vaccination schedule based on shared clinical decision-making, also known as individual-based decision-making.[523]

Unlike routine catch-up, and risk-based recommendations, individual-based decision-making does not establish a default recommendation to vaccinate. Instead, the decision is made on an individual basis and may consider the available evidence, the individual's characteristics and preferences, the health care provider's clinical judgment, and the characteristics of the vaccine. Under this framework, both receipt and nonreceipt of vaccination may be consistent with current clinical guidance.[524] We acknowledge commenters' comments about support for vaccination, infection prevention activities, or public health surveillance efforts. We acknowledge commenters' concerns regarding the burden associated with collecting and reporting data for the measure and recognize that removal of the measure will reduce reporting burden for LTCHs. However, our decision is based on our determination that the measure no longer aligns with current clinical guidelines and practice. We note that LTCHs remain subject to the infection prevention and control and antibiotic stewardship program requirements at § 482.42. Finalizing removal of this measure does not alter LTCH responsibilities under these requirements.

---

[519] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[520] Centers for Disease Control and Prevention. (2020. COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed March 6, 2026 at *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[521] ACIP Shared Clinical Decision-Making Recommendations. *https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.*

[522] *Ibid.*

[523] Centers for Disease Control and Prevention. Staying Up to Date with COVID–19 Vaccines. *Available at: https://www.cdc.gov/covid/vaccines/stay-up-to-date.html.*

[524] ACIP Shared Clinical Decision-Making Recommendations. *https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.*

Comment: A few commenters opposed the proposal to remove the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure from the LTCH QRP and recommended that CMS retain the measure. Some of these commenters stated that LTCHs serve medically complex patients with prolonged lengths of stay, serious underlying illnesses, immunocompromising conditions, and other characteristics that place them at increased risk of severe COVID–19 outcomes. These commenters stated that continued visibility into HCP vaccination coverage remains important for infection prevention, outbreak mitigation, patient safety, and protection of vulnerable LTCH patients. Commenters suggested that removing the measure could reduce CMS's ability to monitor and encourage protection of these high-risk populations.

Response: We acknowledge commenters' concerns regarding the unique characteristics of LTCH patient populations and agree that LTCHs serve medically complex patients, including patients with prolonged lengths of stay, serious underlying illnesses, immunocompromising conditions, and other factors that may place them at increased risk of severe COVID–19 outcomes. We also agree that preventing the spread of COVID–19 and protecting vulnerable patients remain important goals. However, CMS proposed removal of the measure under measure removal factor 3 because the measure no longer aligns with current clinical guidelines and practice. As discussed in the proposed rule, CDC recommendations for the 2025–2026 vaccination recommendations were based on shared clinical decision-making at the time of publication, meaning there is no longer a single default recommendation to vaccinate a defined population.[525] Under this framework, both receipt and nonreceipt of vaccination may be consistent with current clinical guidance. As a result, the measure is less useful for interpreting HCP vaccination status because an HCP may be considered up to date under this guidance without receiving an updated COVID–19 vaccine. Because the measure was adopted in a different clinical environment characterized by broadly applicable vaccination recommendations, we continue to believe that the measure no longer aligns with current clinical guidelines and practice. Removal of the measure from the LTCH QRP does not preclude LTCHs from establishing their own policies and practices related to COVID–19 vaccination or from continuing to monitor vaccination status consistent with current clinical guidance. Rather, the measure will no longer be required for purposes of the LTCH QRP. We acknowledge commenters' concerns that removing the measure could reduce CMS's ability to monitor high-risk populations. However, CMS continues to monitor quality and safety trends affecting LTCH patients, and we continue to believe that the measure no longer aligns with current clinical guidelines and practice.

Comment: Several commenters stated that HCP vaccination remains an important infection prevention strategy that helps protect patients, healthcare personnel, and visitors from COVID–19 and other vaccine-preventable diseases. Several commenters stated that healthcare personnel vaccination helps reduce disease transmission, supports patient safety efforts, and may reduce workforce absenteeism. Some commenters further stated that continued measurement and public reporting of vaccination rates promote accountability, transparency, and ongoing vaccination efforts among healthcare personnel. These commenters suggested that removing the measure could reduce attention to vaccination efforts and diminish incentives for maintaining high vaccination coverage among healthcare personnel.

Response: We acknowledge commenters' views that continued measurement and public reporting of HCP vaccination rates may promote accountability, transparency, vaccination uptake, infection prevention efforts, and workforce protection. While we recognize these potential benefits, we believe that the measure conflicts with current clinical guidance. We also acknowledge commenters' concerns that removal of the measure could reduce attention to vaccination efforts. The purpose of this proposal is not to assess the value of vaccination or infection prevention activities, but rather to evaluate whether the measure continues to be appropriate for inclusion in the LTCH QRP. As previously stated, when this measure was adopted in the LTCH QRP, COVID–19 vaccination recommendations provided specific clinical guidelines for assessing whether individuals were up to date with vaccination; in light of evolving clinical guidance, the measure no longer provides clear information on whether HCP have been vaccinated and is no longer is appropriate for inclusion in LTCH QRP.

Comment: Several commenters questioned whether alignment with other CMS quality reporting programs is an appropriate basis for removing the measure from the LTCH QRP. These commenters stated that the unique characteristics of LTCH patient populations warrant continued measurement of healthcare personnel vaccination coverage and suggested that alignment with other quality reporting programs should not outweigh clinical considerations specific to LTCH settings.

Response: We acknowledge commenters' concerns and agree that alignment with other CMS quality reporting programs should not, by itself, justify removal of the measure. While we note that similar COVID–19 vaccination measures have been removed from other CMS quality reporting programs, our decision to finalize removal of this measure is based on measure removal factor 3 that the measure no longer aligns with current clinical guidelines and practice.

After consideration of the public comments we received, we are finalizing our proposal to remove the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure beginning with the FY 2028 LTCH QRP without modification.

4. Removal of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning With the FY 2028 LTCH QRP

We refer readers to the FY 2024 IPPS/LTCH PPS final rule (*88 FR 59243* through *59250*), where we finalized the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID–19 Vaccine) measure for the FY 2026 LTCH QRP. The measure is an assessment-based process measure that reports the percent of stays in which patients in an LTCH are up to date on their COVID–19 vaccinations per the CDC's latest guidance. In the FY 2026 LTCH PPS final rule (*90 FR 37033* through *90 FR 37034*), we finalized a modification to the reporting requirements for this measure to exclude patients who expired in the LTCH beginning with the FY 2028 LTCH QRP.

We proposed to remove the Patient/Resident COVID–19 Vaccine measure from the LTCH QRP beginning with the FY 2028 LTCH QRP under removal factor 3: a measure does not align with current clinical guidelines or practice (§ 412.560(b)(3)(iii)).

When we originally adopted the Patient/Resident COVID–19 Vaccine

[525] ACIP Shared Clinical Decision-Making Recommendations | ACIP | CDC *https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.*

measure, COVID–19 continued to be a major challenge for LTCHs, with older adults at a significantly higher risk of mortality, severe disease, and death following infection (*88 FR 59243* and *59244*). In August 2023, when this measure was adopted, CDC COVID–19 vaccination guidance emphasized population-level vaccination expectations for older adults and other high-risk groups, and the evidence base focused on demonstrating broad protective benefit at the population level, as described in the FY 2024 IPPS/LTCH PPS final rule (*88 FR 59244*). CDC data at that time showed that, among adults aged 50 years and older, individuals who had received a primary vaccination series and booster dose experienced significantly lower risks of COVID–19-related hospitalization and death compared to those who were unvaccinated, and that additional booster doses, including bivalent booster formulations, further reduced the risk of severe outcomes, including hospitalization and death, in the context of emerging variants (*88 FR 59244*). These data supported an infection prevention framework under which being ''up to date'' with COVID–19 vaccination was treated as a broadly applicable expectation for high-risk populations and therefore appropriate for monitoring through a facility-level quality measure.

At the time the Patient/Resident COVID–19 Vaccine measure was adopted, it was intended to capture routine, catch-up, and risk-based immunization recommendations. Due to evolving circumstances, the latest CDC COVID–19 vaccination recommendations for the 2025–2026 vaccination recommendations were based on shared clinical decision-making (also known as individual-based decision-making).[526] For shared clinical decision-making, there is not a default decision to vaccinate for a defined population.[527] Given that there is no single default recommendation to vaccinate a defined population, both vaccination and non-vaccination may be consistent with application of shared clinical decision-making. This differs from the guidance in place when this measure was finalized.

When there were more narrow parameters for receiving the COVID–19 vaccination, the Patient/Resident COVID–19 Vaccine measure promoted consumer transparency and choice by giving consumers clear information on the number of patients in an LTCH who were vaccinated. However, these parameters no longer apply in light of current CDC clinical guidance that recommends shared clinical decision-making for COVID–19 vaccination decisions. As a result, both vaccination and non-vaccination may reflect an ''up to date'' status using the guidance of shared clinical decision-making, and the Patient/Resident COVID–19 Vaccine measure may no longer provide information on the prevalence of COVID–19 vaccination in the LTCH setting. On this basis, we proposed to remove the measure from the LTCH QRP under removal factor 3: a measure does not align with current clinical guidelines or practice.

Removing this measure will bring LTCH in to alignment with other post-acute care settings since we have already removed this measure from the Home Health Quality Reporting Program (HH QRP) (*90 FR 55416* through *55418*) and the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) (*90 FR 37702* through *37704*).

We proposed that beginning with patients discharged on or after October 1, 2026, LTCHs would no longer be required to collect and submit the Patient/Resident COVID–19 Vaccine measure data to CMS. We also proposed to remove the Patient's COVID–19 vaccination is up to date data element (O0350) from the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) as of October 1, 2028, since it is not technically feasible to remove this data element earlier. However, this data element will become voluntary and LTCHs will not be required to collect and submit Patient/Resident COVID–19 Vaccine data beginning with patients discharged on or after October 1, 2026 (FY2028 LTCH QRP, payment determination year).

We invited public comment on our proposal to remove the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure from the LTCH QRP beginning with the FY 2028 LTCH QRP.

Comment: Several commenters supported CMS's proposal to remove the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure from the LTCH QRP and recommended that CMS finalize removal of the measure. Many commenters who supported removal of the measure expressed views similar to those submitted regarding the COVID–19 Vaccination Coverage among Healthcare Personnel measure. Some commenters stated that the measure no longer aligns with current clinical guidelines and practice following the end of the COVID–19 PHE. Commenters stated that declining COVID–19 severity and mortality, evolving vaccination recommendations, the end of the COVID–19 PHE, and changes in the clinical environment have reduced the measure's utility and relevance as a standardized quality measure. Some commenters further stated that these changes mean the measure no longer represents a meaningful indicator of LTCH quality or quality performance.

Several commenters also stated that the burden associated with collecting, tracking, and reporting patient COVID–19 vaccination data outweighs the value of continued data collection in the current environment. Commenters stated that LTCHs continue to face staffing shortages, workforce challenges, and increasing operational costs and suggested that resources devoted to reporting could be redirected toward patient care and other infection prevention activities.

Several commenters further stated that removing the measure would align the LTCH QRP with other CMS quality reporting programs that have already removed similar COVID–19 vaccination measures. These commenters stated that such alignment would promote consistency across CMS quality reporting programs and reduce unnecessary reporting requirements.

Several commenters also emphasized that their support for removing the measure should not be interpreted as reduced support for vaccination, infection prevention activities, or public health surveillance efforts and continued to support vaccination of patients and healthcare personnel, infection prevention practices, and surveillance infrastructure.

Response: We thank the commenters for their support, and we understand that the clinical guidance has changed since the measure was first adopted and that there is confusion over the current recommendations and their applicability to Patients. When the current measure was adopted, guidance recommended routine vaccination to remain ''up to date,'' which was then revised for the 2025–2026 COVID–19 vaccination schedule based on shared clinical decision-making, also known as individual-based decision-making.[528] At the time of publication of the proposed rule, the definition of ''up to date'' with respect to 2025–2026 COVID–19 vaccination was based on shared

[526] 2025–2026 COVID–19 Vaccination Guidance 2025–2026 COVID–19 Vaccination Guidance | Covid | CDC.

[527] ACIP Shared Clinical Decision-Making Recommendations ACIP Shared Clinical Decision-Making Recommendations | ACIP | CDC.

[528] Centers for Disease Control and Prevention. Staying Up to Date with COVID–19 Vaccines. *Available at: https://www.cdc.gov/covid/vaccines/stay-up-to-date.html.*

clinical decision-making, also known as individual-based decision-making.[529] Unlike routine catch-up, and risk-based recommendations, individual-based decision-making does not establish a default recommendation to vaccinate. Instead, the decision is made on an individual basis and may consider the available evidence, the individual's characteristics and preferences, the health care provider's clinical judgment, and the characteristics of the vaccine. Under this framework, both receipt and nonreceipt of vaccination may be consistent with current clinical guidance.[530] As discussed in the proposed rule, we continue to believe the measure no longer aligns with current clinical guidelines under measure removal factor 3.

We acknowledge commenters' observations regarding the burden associated with collecting, tracking, and reporting patient COVID–19 vaccination data, as well as commenters' support for aligning the LTCH QRP with other CMS quality reporting programs that have removed similar COVID–19 vaccination measures. While we considered these factors, our decision is based on our determination that the measure no longer aligns with current clinical guidelines and practice.

We also acknowledge commenters' continued support for vaccination, infection prevention activities, and public health surveillance efforts. We note that LTCHs remain subject to the infection prevention and control and antibiotic stewardship program requirements at § 482.42. Finalizing removal of this measure does not alter LTCH responsibilities under these requirements.

Comment: Several commenters opposed CMS's proposal to remove the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure from the LTCH QRP and recommended that CMS retain the measure. Several commenters stated that LTCHs serve medically complex, medically fragile, and high-risk patient populations that remain vulnerable to severe COVID–19 outcomes, including serious illness, hospitalization, and death. These commenters stated that vaccination remains an important tool for protecting LTCH patients and suggested that continued measurement of patient vaccination status remains important for protecting vulnerable populations and supporting infection prevention efforts.

Response: We acknowledge commenters' concerns regarding the vulnerability of LTCH patient populations and agree that LTCHs serve medically complex patients, including older adults and patients with serious underlying illnesses increasing their risk of severe COVID–19 outcomes. However, the basis for this proposal is not a determination that COVID–19 is no longer clinically important or that vaccination is no longer beneficial. Rather, we proposed removal of the measure under measure removal factor 3 because the measure no longer aligns with current clinical guidelines and practice. We note that LTCHs may continue to monitor COVID–19 vaccination practices within their facilities and support vaccination decisions consistent with current clinical guidance and shared clinical decision-making.

Comment: A few commenters disagreed with CMS's determination that the measure no longer aligns with current clinical guidelines and practice. These commenters stated that current vaccination recommendations continue to support vaccination for populations commonly served in LTCH settings and suggested that the measure remains consistent with current clinical guidance. A commenter opposed removing the measure and cited ongoing changes to the CDC guidelines as a reason to retain this measure.

Some commenters further stated that changes in vaccination recommendations and the use of shared clinical decision-making do not diminish the value of measuring and reporting patient vaccination status. These commenters suggested that the measure continues to provide meaningful information regarding patient vaccination coverage and questioned whether shared clinical decision-making supports removal of the measure.

Response: We acknowledge commenters' views regarding current COVID–19 vaccination recommendations and their concerns that vaccination may continue to be recommended or appropriate for many patients commonly served in LTCH settings. We also acknowledge commenters' references to recent revisions to the CDC's COVID–19 vaccine recommendations. However, our proposal was based on the overall framework of current COVID–19 vaccination recommendations and the extent to which the measure continues to align with current clinical guidelines and practice. When we originally proposed this measure (*88 FR 59243* through *59250*), it was intended to capture routine, catch-up, and risk-based immunization recommendations. As discussed in the proposed rule, current COVID–19 vaccination recommendations are based on shared clinical decision-making, meaning there is no longer a single default recommendation to vaccinate a defined population. Under this framework, both receipt and nonreceipt of vaccination may be consistent with current clinical guidance.

We also acknowledge commenters' views that changes in vaccination recommendations and the use of shared clinical decision-making do not diminish the value of measuring and reporting patient vaccination status. However, because the measure assesses whether patients are ''up to date'' with COVID–19 vaccination, the evolving recommendation framework may create uncertainty in interpreting the measure for standardized quality reporting purposes. Because current clinical guidance specifies vaccination decisions are based on individual clinical circumstances and shared clinical decision-making rather than a broadly applicable recommendation for a defined population, the measure no longer aligns with current clinical guidelines and practice.[531]

Comment: Several commenters stated that the measure supports accountability, monitoring, and ongoing vaccination efforts and suggested that continued measurement of patient vaccination status remains important for encouraging vaccination uptake and maintaining attention to COVID–19 prevention efforts.

Response: We acknowledge commenters' views that continued measurement of patient vaccination status may support monitoring, accountability, and ongoing vaccination efforts. However, the purpose of this proposal is not to assess the value of vaccination or infection prevention activities generally, but rather to evaluate whether the measure continues to meet the criteria for inclusion in the LTCH QRP. For the reasons discussed in the proposed rule, including that public reporting of the measure may no longer provide information on the prevalence of COVID–19 vaccination in the LTCH setting (*91 FR 19614 and 19615*), the measure no longer aligns with current clinical guidelines and practice.

[529] Staying Up to Date with COVID–19 Vaccines *https://www.cdc.gov/covid/vaccines/stay-up-to-date.html.*

[530] ACIP Shared Clinical Decision-Making Recommendations. *https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.*

[531] ACIP Shared Clinical Decision-Making Recommendations | ACIP | CDC *https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.*

After consideration of the public comments we received, we are finalizing this proposal without modification.

5. LTCH QRP Measure Concepts Under Consideration for Future Years—Request for Information (RFI)

In the FY 2024 IPPS/LTCH PPS proposed rule (*88 FR 27150* through *27153*), we included a request for information (RFI) on a set of principles for selecting and prioritizing LTCH QRP measures, identifying measurement gaps and suitable measures for filling these gaps. We refer readers to the FY 2024 IPPS/LTCH PPS final rule (*88 FR 59250* and *59251*) for a summary of the public comments we received in response to the RFI.

We sought input on the importance, relevance, appropriateness, and applicability of the quality measure concept of advanced care planning for future years in the LTCH QRP. Advance care planning is a continuous process that supports people in understanding and communicating their goals, values, and preferences regarding future medical decisions.[532] The Patient Self Determination Act of 1990[533] supports this process by requiring healthcare facilities to inform patients of their rights regarding medical decisions, including advance directives and end of life care.[534] In post-acute care (PAC) settings, where patients recover from acute illness, injury, or major procedures, their needs and goals may evolve as their condition changes. Factors such as clinical stability, functional status, therapy tolerance, cognition function, prognosis, and personal preferences can all shift during recovery. Regular reassessment and transparent communication are essential to maintaining person-centered care, while advance care planning facilitates shared decision-making by documenting patient preferences and ensuring goal-concordant care throughout care transitions.[535]

As we review new measure concepts, we will prioritize evidence-based outcome measures that promote person-centered care practices.

The following is a summary of the public comments received on the RFI regarding the relevant aspects of advanced care planning and measures appropriate for the LTCH setting, along with our responses.

Comments: We received several comments in support of this measure concept in the LTCH QRP. A commenter appreciated that it would allow patients to have a bigger role in making medical decisions. A commenter supported the measure concept but recommended that CMS not implement a ''check box'' process measure.

CMS received several comments with recommendations for advance care planning measure specification and development. A commenter encouraged CMS to consider the role of health care agents and surrogate medical decision-makers in measure development. A few commenters recommended reporting the measure via the LCDS instead of extracting it from EHR. Other commenters stated that the measure should comply with individual state requirements and include an exception or guidance for religious or cultural refusal of these discussions. A few commenters suggested pilot testing of a potential measure in the LTCH setting. A commenter recommended that a measure should be accessible across care settings and should measure not only the presence of documentation but integration of the discussions into care workflows. A commenter recommended that the measure information be shared with advance directive registries.

A few commenters had concerns about the measure in the LTCH setting due to the clinical instability of many patients. A commenter stated that LTCH patients on medical ventilation or with cognitive impairments may be unable to participate in the advance care planning process. Another commenter did not believe that LTCHs are the appropriate accountable entity for this measure and had concerns about patient stigma associated with these discussions.

Comment: In addition to comments received on the measure concept of advance care planning, we also received comments on other future measure concepts, including patient reported outcome measures, patient-specific goal attainment, successful care transitions, and sepsis.

Response: We thank all the commenters for responding to this RFI. While we are not responding to specific comments in response to the RFI in this final rule, we will take this feedback into consideration for our future measure development efforts for the LTCH QRP.

6. Form, Manner, and Timing of Data Submission Under the LTCH QRP

a. Background

We refer readers to the regulatory text at § 412.560(b) for information regarding the current policies for reporting specified data for the LTCH QRP.

b. Revision of LTCH QRP Data Submission Deadlines Beginning With the FY 2029 LTCH QRP

(1) Background

Sections 1886(m)(5)(E), 1899B(f) and 1899B(g) of the Act require CMS to provide feedback to LTCHs and to publicly report their performance on quality and other measures specified under the LTCH QRP. More specifically, section 1899B(f)(1) of the Act requires the Secretary to provide confidential feedback reports to LTCHs on their performance on the quality, resource use, and other measures specified for the LTCH QRP. Section 1899B(f)(2) of the Act provides that, to the extent feasible, the Secretary must make these confidential feedback reports available not less frequently than on a quarterly basis, except in the case of measures reported on an annual basis, in which case the confidential feedback reports may be made available annually. Additionally, sections 1886(m)(5) and 1899B(g)(1) of the Act require the Secretary to provide for the public reporting of each LTCH's performance on the measures specified for the LTCH QRP by establishing procedures for making the performance data available to the public. Sections 1886(m)(5)(E) and 1899B(g)(2) of the Act specifically require that such procedures must ensure that LTCHs can review the data and other information before it is made public.

For LCDS assessment-based measures, in the FY 2013 IPPS/LTCH PPS final rule (*77 FR 53636* and *53637*), we finalized submission deadlines for LTCHs to submit data quarterly for each of the finalized measures in the FY 2013 rule, requiring LTCHs to submit data collected during each quarter for the FY 2015 payment determination approximately 4.5 months (135 days) after the end of the quarter. We also finalized in the FY 2013 rule that LTCHs would have a shorter data submission timeframe for each of the measures for the FY 2016 payment determination. Specifically, for each quarter in which data was collected for the FY 2016 payment determination, we finalized submission deadlines that were approximately 45 days after the

[532] McMahan, R.D., Tellez, I., & Sudore, R.L. (2021). Deconstructing the Complexities of Advance Care Planning Outcomes: What Do We Know and Where Do We Go? A Scoping Review. *Journal of the American Geriatrics Society, 69*(1), 234–244. *https://doi.org/10.1111/jgs.16801.*

[533] Public Law 101–508, sections 4206, 4751.

[534] *https://www.congress.gov/bill/101st-congress/house-bill/5835.*

[535] McMahan RD, Tellez I, Sudore RL. Deconstructing the Complexities of Advance Care Planning Outcomes: What Do We Know and Where Do We Go? A Scoping Review. J Am Geriatr Soc. 2021 Jan;69(1):234–244. doi: 10.1111/jgs.16801. Epub 2020 Sep 7. PMID: 32894787; PMCID: PMC7856112.

end of each quarter (*77 FR 53636* and *53637*). However, in the FY 2016 IPPS/LTCH PPS final rule (*80 FR 49749* through *49751*), we finalized a requirement that LTCHs submit data within 4.5 months of the end of each calendar quarter, beginning with the FY 2017 LTCH QRP, unless otherwise specified for a measure. We proposed and finalized this modification to the LTCH QRP data submission deadlines to align with the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) and Hospital Inpatient Quality Reporting (IQR) Program (*80 FR 49749* through *49751*).

We also finalized data submission deadlines for LTCH QRP measures that are submitted via the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). In the FY 2014 IPPS/LTCH PPS final rule (*78 FR 50882*), we finalized that for the NHSN Catheter Associated Urinary Tract Infection (CAUTI), the NHSN Central Line-Associated Bloodstream Infection (CLABSI) and the Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measures, each facility's data must be entered into NHSN no later than 45 days after the end of the reporting quarter. However, in the FY 2016 IPPS/LTCH PPS final rule (*80 FR 49749* through *49751*), we finalized a requirement that LTCHs submit data within 4.5 months of the end of each calendar quarter for these measures. We also finalized that the data collection period for the Influenza Vaccination Coverage among Healthcare Personnel (HCP) measure would be October 1 through March 31, with a data submission deadline of May 15th for each influenza season (*78 FR 50882* and *50883*). In the FY 2024 IPPS/LTCH PPS final rule (*88 FR 59138*), we finalized that the COVID–19 Vaccination Coverage among HCP measure would be reported to the CDC through the NHSN at least 1 week per month, with the CDC reporting data to CMS quarterly and allowing for corrections in the NHSN application in alignment with CMS data submission deadlines.

Public reporting of data collected under quality programs, such as the LTCH QRP, is designed to provide consumers and their families with the most current information to empower them to make quality-informed decisions about where to receive their care. We have identified that the time between when data on measures is submitted to us and when those data are publicly reported (approximately nine months) may be too long to provide the most accurate and up to date information for the public. For example, through technical expert panels (TEPs), we have received feedback from patient caregiver advocates that the aged data used in publicly reported quality measures diminishes their value to consumers.

Currently, the largest contributing factor to the nine-month lag between the end of the data collection period and when measures are publicly reported is the 4.5-month timeframe for data submission. Reducing the data submission timeframe from 4.5 months to 45 days could reduce this lag by up to three months, resulting in more timely public reporting of data for consumers and increasing the value of publicly reported data. Additionally, this timeframe provides LTCHs with more recent data in support of their quality improvement activities.

In the FY 2026 IPPS/LTCH PPS proposed rule, we included a request for information (RFI) on reducing the data submission deadline from 4.5 months to 45 days (*90 FR 18353*). We refer readers to the FY 2026 IPPS/LTCH PPS final rule (*90 FR 37042*) for a full summary of the public comments received.

(2) Proposal To Revise the LTCH QRP Assessment Data Submission Deadline

Beginning with the FY 2029 LTCH QRP, we proposed that LTCHs must complete their data submissions and make corrections to their assessment data where necessary no later than the 15th day of the second month after the end of the calendar quarter. However, if the 15th day of the second month falls on a Friday, weekend, or Federal holiday, the submission date is delayed until 11:59 p.m. EST on the next business day. Specifically, we proposed that LTCHs would follow the deadlines presented in Table IX.E.02 for the FY 2029 LTCH QRP. We also proposed that similar calendar year data submission deadlines would apply to future years' payment determinations.

TABLE IX.E.-02: DATA COLLECTION TIMEFRAME AND DATA SUBMISSION DEADLINES FOR LCDS DATA AFFECTING THE FY 2029 PAYMENT DETERMINATION

Calendar Year (CY) Quarter	Data Collection Timeframe	Final Data Submission Deadlines for FY 2029 Payment Determination*
CY 2027 Quarter 1	January 1–March 31, 2027	May 17, 2027
CY 2027 Quarter 2	April 1–June 30, 2027	August 16, 2027
CY 2027 Quarter 3	July 1–September 30, 2027	November 15, 2027
CY 2027 Quarter 4	October 1–December 31, 2027	February 15, 2028

* Data submission deadlines will follow a similar quarterly schedule for subsequent CYs.

We believe that requiring LTCHs to submit LCDS assessment data by the 15th day of the second month after the end of the calendar quarter is reasonable. We conducted an analysis on the potential impact of reducing the timeframe by determining how many assessments are currently being submitted by this deadline, which is approximately within 45 days of the end of the quarter. Using 2024 data, we identified that 98.36 percent of all LCDS assessments were submitted to CMS within a 45-day timeframe. Of the remaining 1.64 percent submitted beyond 45 days, 0.08 percent were submitted after the current 4.5-month data submission deadline and would not be further impacted by a change in the data submission deadline. Therefore, only 1.56 percent of LCDS assessments would be impacted by changing the data submission deadline from 4.5 months to require data submission by the 15th day of the second month after the end of the calendar quarter.

(3) Proposal To Revise the CDC NHSN Data Submission Deadlines

Beginning with the FY 2029 LTCH QRP, we proposed that LTCHs must complete their data submissions and make corrections to their CDC NHSN data where necessary no later than the 15th day of the second month after the end of the calendar quarter. However, if the 15th day of the second month falls

on a Friday, weekend, or Federal holiday, the date is delayed until 11:59 p.m. EST on the next business day. Specifically, we proposed that LTCHs would follow the deadlines presented in Table IX.E.03 for the FY 2029 LTCH QRP. We also proposed that similar calendar year data submission deadlines would apply to future years' payment determinations.

TABLE IX.E.-03: DATA COLLECTION TIMEFRAME AND DATA SUBMISSION DEADLINES FOR CDC NHSN LTCH QRP MEASURES AFFECTING THE FY 2029 PAYMENT DETERMINATION

Measure	Data Collection Timeframe	Final Data Submission Deadlines for FY 2029 Payment Determination*
CAUTI	January 1–March 31, 2027	May 17, 2027
	April 1–June 30, 2027	August 16, 2027
CLABSI	July 1–September 30, 2027	November 15, 2027
CDI **COVID-19 Vaccination Coverage among HCP****	October 1–December 31, 2027	February 15, 2028
Influenza Vaccination Coverage among HCP	October 1, 2027—March 31, 2028	May 15, 2028

* Data submission deadlines will follow a similar quarterly schedule for subsequent CYs.

** In section IX.E.3 of this final rule, we finalized our proposal to remove this measure effective with the FY2028 LTCH QRP.

We believe that requiring LTCHs to submit CDC NHSN assessment data by the 15th day of the second month after the end of the calendar quarter is reasonable. We note that there would be no change in the data submission deadline for the Influenza Vaccination Coverage among HCP measure, as the previously finalized data submission date is May 15th for each influenza season. We conducted an analysis on the potential impact of reducing the timeframe by determining how many LTCHs are currently reporting data by this deadline, which is approximately within 45 days of the end of the quarter. Using FY 2025 data, we identified that 88 percent of all LTCHs submitted CDC NHSN data within a 45-day timeframe.

On these bases, we believed revising the LTCH QRP data submission deadline for LCDS and CDC NHSN data to require LTCHs to submit CDC NHSN data by the 15th day of the second month after the end of the calendar quarter would improve the timeliness of public reporting by three months, which is beneficial to both consumers and LTCHs, with no change in burden to LTCHs.

We invited comment on this proposal to require LTCHs to submit LCDS assessment data and CDC NHSN data by the 15th day of the second month after the end of the calendar quarter beginning with the FY 2029 LTCH QRP. A summary of the comments received, along with our responses, is below.

Comment: A commenter supported the proposal, stating that it would reduce the time from reporting to public display and allow healthcare consumers to make educated decisions about where to receive care.

Response: We thank the commenter for their support and agree that this proposal would give patients and consumers more timely access to quality data.

Comment: A few commenters supported the proposal but recommended a clearer deadline, such as requiring submission on the last business day of the month, instead of the 15th day of the month. A commenter recommended extending the submission deadline to the last day of the second month after the end of the quarter and not adjusting for weekends and Federal holidays. Another commenter recommended providing 90 days after the end of the quarter.

Response: We appreciate the recommendations for alternative data submission deadlines. While we appreciate the commenters' recommendations to require submission on the last business day of the month instead of the 15th day of the month, we disagree that the proposed deadline of the 15th day of the month is unclear for providers. This format for the data submission deadline is similar to the format that has been in place for the LTCH QRP, since the current deadline of 4.5 months (or approximately 135 days) falls on or around the 15th of a given month. Also, to assist providers, CMS publishes the data submission deadlines for each program year on our website, at *https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-quality-reporting-data-submission-deadlines.*

With regard to the comment recommending a deadline that will not shift due to weekends or Federal holidays, we wish to clarify that this is not a new requirement, as our current policy already shifts the deadline for weekends and Federal holidays. We have previously heard from interested parties that flexibility around these dates is appreciated, since administrative and support staff may not be in the LTCH on those days to submit data. We also note that providers can submit the data at any time during the data submission timeframe. They do not need to alter their workflows if the deadline is moved due to a weekend or Federal holiday, if they wish to submit data earlier.

We disagree with the recommendations to adopt an alternate deadline, such as two months or 90 days after the end of the quarter, as the public reporting would fall into the same quarterly refresh that it is in currently. For example, for Q1 CY 2027, data submitted on May 17, 2027 under the proposed 45-day deadline could be published in the September 2027 Care Compare refresh on *Medicare.gov*. However, using the commenters' suggested 90-day deadline, Q1 CY 2027 data would be submitted around June 29, 2027. Adopting a two month deadline, Q1 CY 2027 data would be submitted around May 31, 2027. After allotting time for measure calculation and the 30-day provider preview period, data submitted under either of these recommended deadlines would not be published until the December 2027 Care Compare refresh on *Medicare.gov*. This

is the same 9-month lag that exists under our current data submission deadline. A longer time frame for data submission would not allow us to reach our goal of providing more timely data to consumers and LTCHs.

Comment: A commenter expressed concerns about operational challenges for LTCHs, given current clinical and administrative workflows. This commenter was concerned that the proposal would increase administrative burden and risk data inaccuracies. A few commenters were concerned that small or rural LTCHs with limited capacity and LTCHs with staffing challenges would struggle to meet shortened deadlines.

Response: We appreciate the commenters' concerns about operational and staffing challenges, especially for small or rural LTCHs. However, we are not adding any new reporting requirements to the LTCH QRP and do not believe that the proposal adds burden by changing the data submission deadline; rather, it shifts the existing workflow from 4.5 months after each quarterly data collection period to the 15th day of the second month after the end of the calendar quarter. Regarding concerns about the risk of data inaccuracies, we believe that the effective date of January 1, 2027 provides LTCHs sufficient time to address operational or staffing changes that may be required, which will allow LTCHs to confirm data accuracy prior to submission in accordance with the updated deadline. CMS does not expect that shortening the data submission timeframe would impact the accuracy of the data LTCHs submit to CMS. Historically, LTCHs have infrequently requested to modify their data submissions for the purposes of the QRP. We continue to believe that this proposed deadline modification will benefit LTCHs by allowing them to have access to more timely data for quality improvement efforts.

Comment: We received comments providing recommendations for the implementation of this policy. A few commenters recommended that CMS provide targeted outreach and assistance to LTCHs in advance of the deadlines. A few commenters suggested that CMS continue to maintain and remind LTCHs of their options for extraordinary circumstances exceptions.

Response: We appreciate commenters' input and recommendations for implementation of this proposal. We note that we currently conduct outreach by providing reminder updates for upcoming data submission deadlines as well as targeted outreach to individual LTCHs about upcoming data submission deadlines. We also provide guidance and technical manuals, data submission deadline documents, and training resources. CMS also intends to make timely updates to our outreach processes, manuals, data submission deadline documents and training resources. Regarding technical assistance and support, we list resources and several help desks on our website: *https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-quality-reporting-help.*

Regarding commenters' request to remind LTCHs about extraordinary circumstances exceptions options, CMS has an established process, described at § 412.560(c), which allows LTCHs the opportunity to request an exception or extension from the program's reporting requirements in the event they are unable to submit quality data due to extraordinary circumstances beyond their control. LTCHs affected by an extraordinary circumstance may request an exception and extension using instructions provided on our website: *https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-quality-reporting-reconsideration-and-exception-extension.*

Comment: Several commenters were opposed to the proposal, stating that it would result in additional administrative burden for LTCHs. Many of these commenters were concerned that the proposal would result in more penalties for LTCHs. A few commenters stated that a longer submission period would be beneficial in the case of a change in ownership. A commenter stated that emergency discharges or acute hospital transfers should be removed from the reporting requirements.

Response: We appreciate the commenters' concerns about administrative burden. However, we are not adding any new reporting requirements to the LTCH QRP, but instead propose shifting the time frame for this existing work, and therefore do not believe that the proposed revised data submission deadline adds burden. With regard to concerns about increased penalties for LTCHs, CMS did not propose the addition of any new or increased penalties for not meeting the proposed data submission deadline. We interpret that the commenter is referring to the requirement that LTCHs must submit required LTCH QRP data to avoid receiving a 2 percentage point reduction to the annual payment update. By proposing to implement this policy beginning in January 2027, we are giving LTCHs enough time to make any updates to IT systems and workflow operations to accommodate this change and submit data by the proposed deadline to avoid a penalty.

Regarding the request to give special consideration for change in ownership, CMS has not historically provided extended deadlines for this circumstance. CMS does not believe a change in ownership would cause an LTCH to not be able to successfully submit quality data in a timely manner as the change in ownership is a well-established process.

Regarding emergency discharges, or acute hospital transfers, we disagree that they should be removed from reporting requirements, including the proposed data submission deadline. In such cases, LTCHs would complete the unplanned discharge assessment, which requires LTCH to submit fewer data elements to CMS when a patient is having an emergency. This is an established process which reduces burden, allowing LTCHs to focus on patient care. LTCHs are required to submit admission and discharge assessments on all patients admitted to their hospital, regardless of length of stay. At the time of the emergency discharge or transfer, the LTCH may be in the process of completing or may have already completed some items of the unplanned discharge assessment, and exempting these data from reporting requirements could remove valuable information about the quality of care being provided in the LTCH from the LTCH QRP.

Comment: A few commenters were opposed to the proposal, stating that LTCHs need additional time to verify that NHSN reporting is complete and accurate and to address NHSN system problems that can delay reporting and verification.

Response: We acknowledge the commenters' concerns about having adequate time to verify that NHSN reporting is complete and accurate. However, as described in the proposed rule (91 FR 19617), our analysis showed that 88 percent of all LTCHs submitted CDC NHSN data within a 45-day timeframe, which suggests that the proposed deadline is feasible for LTCHs. The NHSN website also provides extensive training and support materials for LTCHs, available at: *https://www.cdc.gov/nhsn/cms/ltach.html.* CDC NHSN also provides a help desk that can assist with any concerns about NHSN reporting and system issues at *nhsn@cdc.gov.*

Comment: A few commenters were opposed to the proposal and recommended that the data submission period should be no less than 90 days after the end of the quarter, stating that it is impossible to collect and report all assessment information for certain

cases. Another commenter recommended a gradual transition or additional flexibility, such as an extended correction window or an extended deadline for the submission of newer measures.

Response: We disagree with the recommendations to adopt an alternate deadline, such as 90 days after the end of the quarter, because that would not allow us to close the nine-month lag between the end of the data collection period and when measures are publicly reported. A longer time frame for data submission would not allow us to reach our goal of providing more timely data to consumers and LTCHs. CMS does not expect that shortening the data submission timeframe would impact the accuracy of the data LTCHs submit to CMS. CMS expects that all data submitted for the purposes of the QRP from an LTCH is correct and the need for modifications is an infrequent occurrence. Regarding the concern that it is not possible to collect all information for certain LTCH patients, CMS reminds LTCHs that they must meet the minimum data completion threshold of no less than 85 percent of the LCDS assessments having 100 percent completion of the required data elements. This provides a buffer, allowing LTCHs flexibility in those rare cases where it is not possible to collect all quality data and submit it to CMS.

Comment: We received additional comments that were outside the scope of the proposal. Specifically, we received a comment regarding expanding the exception or extension policy to include changes of ownership.

Response: While we did not propose any changes to the exception or extension policy, we thank the commenters for bringing this issue to our attention and will take these comments into consideration for potential policy refinements.

After consideration of the public comments we received, we are finalizing our proposal to require LTCHs to submit LCDS assessment data and CDC NHSN data by the 15th day of the second month after the end of the calendar quarter beginning with the FY 2029 LTCH QRP.

7. Policies Regarding Public Display of Measure Data for the LTCH QRP

a. Background

For a more detailed discussion about our policies regarding public display of LTCH QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (*81 FR 57231* through *57236*).

b. Proposal To End the Public Display of COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure.

In the FY 2022 IPPS/LTCH PPS final rule (*86 FR 45438* through *45446*), we finalized our proposal to publicly report the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP COVID–19 Vaccine) measure beginning with the September 2022 Care Compare refresh on *Medicare.gov.* In section IX.E.3. of this final rule, we proposed to remove the HCP COVID–19 Vaccine) measure beginning with the FY 2028 LTCH QRP. If finalized as proposed, an LTCHs HCP COVID–19 measure data would be publicly reported for the last time with the September 2026 Care Compare refresh on *Medicare.gov*, based on data from Q4 of 2025. Thereafter, we would no longer display an LTCHs' HCP COVID–19 Vaccine measure data on the Care Compare tool at *Medicare.gov*.

We invited comment on our proposal to end public display of the HCP COVID–19 Vaccine measure data after the September 2026 Care Compare refresh on the Care Compare tool at *Medicare.gov.*

We received no comments on this proposal and therefore are finalizing this provision without modification.

c. Proposal To End the Public Display of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure

In the FY 2024 IPPS/LTCH PPS final rule (*88 FR 59243* through *59250*), we finalized our proposal to begin publicly displaying data for the Patient/Resident COVID–19 measure beginning with the September 2025 Care Compare refresh. In section IX.E.4. of this final rule, we proposed to remove the Patient/Resident COVID–19 Measure beginning with the FY 2028 LTCH QRP. However, if this proposal is finalized, the reporting of data for the Patient's COVID–19 vaccination is up to date data element would be voluntary effective October 1, 2026, through September 30, 2027. If finalized as proposed, we proposed that the Patient/Resident COVID–19 Vaccine measure data would be publicly reported for the last time with the September 2026 Care Compare refresh on *Medicare.gov*, based on data from Q4 of 2025.

We invited public comment on our proposal to end the public display of Patient/Resident COVID–19 Vaccine measure data after the September 2026 Care Compare refresh on *Medicare.gov.*

Comment: A few commenters opposed CMS's proposal to discontinue public reporting of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure and recommended that CMS continue publicly reporting the measure. Commenters stated that public reporting promotes transparency, accountability, and informed decision-making for patients, residents, families, and caregivers. Commenters further stated that publicly reporting patient COVID–19 vaccination rates provides important information regarding protection of vulnerable populations, supports public health surveillance and vaccination efforts, and encourages facilities to maintain focus on COVID–19 prevention activities. Some of these commenters suggested that removing the measure from Care Compare would reduce visibility into patient vaccination rates and limit information available to patients, caregivers, and families when evaluating LTCHs.

Response: We acknowledge commenters' views that public reporting may promote transparency, accountability, public health surveillance, and informed decision-making for patients, residents, families, and caregivers. We also acknowledge commenters' concerns that discontinuing public reporting of the measure may reduce visibility into patient COVID–19 vaccination rates. Because CMS is finalizing the removal of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure from the LTCH QRP as we continue to believe the measure no longer aligns with current clinical guidelines and practice, we also are finalizing our proposal to discontinue public reporting of the measure. Consistent with past practices, all previously reported and archived Patient/Resident COVID–19 vaccine measure data will remain on the Care Compare tool at *Medicare.gov* for the purposes of transparency and accountability.

After consideration of the public comments we received, we are finalizing this provision without modification.

F. Changes to the Medicare Promoting Interoperability Program

1. Statutory Authority for the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs)

Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act (as amended by the Health Information Technology for Economic and Clinical Health Act, Title

XII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 [ARRA], Pub. L. 111–5) authorize downward payment adjustments under Medicare, beginning with FY 2015 for eligible hospitals and CAHs that do not successfully demonstrate meaningful use of certified electronic health record technology (CEHRT) for the applicable electronic health record (EHR) reporting periods. Section 602 of Title VI, Division O of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) added subsection (d) hospitals in Puerto Rico as eligible hospitals under the Medicare Electronic Health Record (EHR) Incentive Program (now known as the Medicare Promoting Interoperability Program) and extended the participation timeline for these hospitals such that downward payment adjustments were authorized beginning in FY 2022 for subsection (d) Puerto Rico hospitals that do not successfully demonstrate meaningful use of CEHRT for the applicable EHR reporting periods.

2. Office of the National Coordinator for Health Information Technology (ONC) Health Information Technology (Health IT) Certification Program Updates Relevant To the Medicare Promoting Interoperability Program

a. Background

In the Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity proposed rule (90 FR 60970) (HTI–5 proposed rule), which appeared in the **Federal Register** on December 29, 2025, ONC[536] proposed a wide-ranging set of updates to the ONC Health IT Certification Program. The HTI–5 proposed rule focuses on deregulatory actions in 45 CFR part 170 (Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology) and 45 CFR part 171 (Information Blocking). The HTI–5 proposed rule seeks to reduce burden, offer flexibility to developers and health care providers, and support innovation through the removal and revision of certain certification criteria and regulatory provisions. The following summarizes proposals in the HTI–5 proposed rule that are relevant to eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

In the HTI–5 proposed rule, ONC identified 34 certification criteria for removal and 7 certification criteria for revision. ONC stated that removing or revising these criteria would reduce burden and costs for health IT developers and clinicians, partly due to the decreased necessity to maintain ongoing conformance with certification requirements (90 FR 60973).

In the FY 2027 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital Prospective Payment System (LTCH PPS) proposed rule (91 FR 19619) and this final rule, we summarized in Table IX.F.–01 the potential impact on Medicare Promoting Interoperability Program participants of the proposed certification criteria removals and revisions. Table IX.F.–01 describes how criteria that are the subject of HTI–5 proposals are incorporated into the definition of CEHRT in 42 CFR 495.4. In addition to the health IT certification criteria specified in the CEHRT definition in 42 CFR 495.4, the definition includes EHR technology certified under the ONC Health IT Certification Program that meets the Base EHR definition at 45 CFR 170.102 and technology certified to the criteria necessary to be a meaningful EHR user under the Medicare Promoting Interoperability Program. The criteria necessary to be a meaningful EHR user include criteria that are necessary to report on applicable objectives and measures under the Medicare Promoting Interoperability Program.

Several of the changes outlined in the HTI–5 proposed rule are described in further detail within this FY 2027 IPPS/LTCH PPS final rule. For more information, please see ''Updates to the Definition of Certified Electronic Health Record Technology in the Medicare Promoting Interoperability Program'' in section IX.F.2.b of this final rule and ''Removal of the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information Measures'' in section IX.F.4 of this final rule.

[536] ASTP/ONC is now referred to as ONC, pursuant to a notice published in the **Federal Register** on April 1, 2026 (91 FR 16204). Although at the time of specific references noted herein ONC was either referenced as ASTP/ONC or as ONC, for clarity all references in this document are now noted as ONC.

TABLE IX.F.-01. HTI-5 PROPOSED REMOVALS OR REVISIONS OF CERTIFICATION CRITERIA REFERENCED IN CEHRT DEFINITION FOR THE MEDICARE PROMOTING INTEROPERABILITY PROGRAM

ONC Health IT Certification Criteria as defined in the following sections of Title 45 CFR 170.315	Remove/Revise	Timing	Relevance to the CEHRT Definition for the Medicare Promoting Interoperability Program
Patient Demographics and Observations - (a)(5)	Revise	Effective date of HTI-5 final rule.	Specified in Base EHR definition.
Implantable Device List - (a)(14)	Remove	Effective date of HTI-5 final rule.	Specified in Base EHR definition.
Decision Support Interventions - (b)(11)	Revise	Effective date of HTI-5 final rule.	Specified in Base EHR definition.
Direct Project - (h)(1)	Remove	Effective date of HTI-5 final rule.	Specified in Base EHR definition.
Direct Project, Edge Protocol, and XDR/XDM - (h)(2)	Remove	Effective date of HTI-5 final rule.	Specified in Base EHR definition.
Family Health History - (a)(12)	Remove	Effective January 1, 2027.	Specified in CEHRT definition.
Patient Health Information Capture - (e)(3)	Remove	Effective January 1, 2027.	Specified in CEHRT definition.
Automated Numerator Recording - (g)(1)	Remove	Effective January 1, 2027.	Specified in CEHRT definition.
Automated Measure Calculation - (g)(2)	Remove	Effective January 1, 2027.	Specified in CEHRT definition.
Transitions of Care - (b)(1)	Revise	Effective January 1, 2027.	Specified criterion for the Support Electronic Referral Loops by Sending Health Information, Support Electronic Referral Loops by Receiving and Reconciling Health Information, HIE Bi-Directional Exchange, and Enabling Exchange Under TEFCA measures.
Clinical Information Reconciliation and Incorporation - (b)(2)	Remove	Effective January 1, 2027.	Specified criterion for the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure.
View, Download, and Transmit to 3rd Party - (e)(1)	Revise	Effective date of HTI-5 final rule.	Specified criterion for the Provide Patients Access measure.
Transmission to public health agencies - Electronic Case Reporting - (f)(5)	Revise	Effective date of HTI-5 final rule.	Specified criterion for the Electronic Case Reporting measure.
Transmission to public health agencies - Antimicrobial Use and Resistance Reporting - (f)(6)	Revise	Effective date of HTI-5 final rule.	Specified criterion for the Antimicrobial Use Surveillance and Antimicrobial Resistance Surveillance measures.
Transmission to public health agencies - Health Care Surveys - (f)(7)	Remove	Effective January 1, 2027.	Specified criterion for the Public Health Registry measure.
Application access — patient selection - (g)(7)	Remove	Effective January 1, 2027.	Specified criterion for the Provide Patients Access and HIE Bi-Directional Exchange measures.
Application Access – All Data Request - (g)(9)	Remove	Effective January 1, 2027.	Specified criterion for the Provide Patients Access and HIE Bi-Directional Exchange measures.

We stated in the proposed rule that proposed changes in the HTI–5 proposed rule would affect certification criteria referenced in the definition of CEHRT in 42 CFR 495.4 that apply to the Medicare Promoting Interoperability Program in several ways. First, several ONC proposals affect the ONC Health IT Certification Program certification criteria included within the Base EHR definition at 45 CFR 170.102, which is incorporated into the CEHRT definition at 42 CFR 495.4. Removal of these criteria from the ONC Health IT Certification Program and the Base EHR definition would therefore remove the requirement that an eligible hospital or CAH must use CEHRT that includes this functionality. ONC proposed to remove from the Base EHR definition the certification criteria at: 45 CFR 170.315(a)(14)—''implantable device list'' (90 FR 60983), 45 CFR 170.315(h)(1)—''transport methods and other protocols—direct project'' (90 FR 60998), and 45 CFR 170.315(h)(2)—''transport methods and other protocols—Direct Project, Edge Protocol, and XDR/XDM'' (90 FR 60999). ONC also proposed to revise the following criteria referenced in the Base EHR definition: 45 CFR 170.315(a)(5)—''patient demographics and observations'' (90 FR 60981 through 60982) and 45 CFR 170.315(b)(11)—''decision support interventions'' (90 FR 60986 through 60987).

ONC proposed to remove four certification criteria specified in the text

of the CEHRT definition at 42 CFR 495.4. including: 45 CFR 170.315(a)(12)—''family health history'', 45 CFR 170.315(e)(3)—''patient health information capture'', 45 CFR 170.315(g)(1)—''automated numerator recording'', and 45 CFR 170.315(g)(2)—''automated measure calculation'' (90 FR 60982, 60991, 60994, and 60995). We further discuss these criteria in section IX.F.2.b of this final rule.

ONC proposed to remove or revise other certification criteria that directly support certain Medicare Promoting Interoperability Program measures. For example, four certification criteria were identified as supporting the Provide Patients Electronic Access to Their Health Information measure: 45 CFR 170.315(e)(1), 45 CFR 170.315(g)(7), 45 CFR 170.315(g)(9), and 45 CFR 170.315(g)(10). Of these four criteria, three are impacted by the HTI–5 proposals. ONC proposed to revise 45 CFR 170.315(e)(1) (90 FR 60990 through 60991), and to remove 45 CFR 170.315(g)(7) and 45 CFR 170.315(g)(9) (90 FR 60998). If ONC finalizes these proposals, only the remaining criteria identified for the Provide Patients Electronic Access to Their Health Information measure (the revised 45 CFR 170.315(e)(1) and unaltered 45 CFR 170.315(g)(10)) would be necessary for eligible hospitals and CAHs to report the measure. Table IX.F.–07 in section IX.F.8 of the proposed rule (91 FR 19650) and this final rule contain a complete list of the Medicare Promoting Interoperability Program objectives and measures and their relevant ONC Health IT certification criteria, including the impact to individual certification criteria if the HTI–5 proposals are finalized.

Regarding the Public Health Registry Reporting measure, ONC proposed to remove the only certification criterion (45 CFR 170.315(f)(7)—''transmission to public health agencies—health care surveys'') (90 FR 60994) that supports the measure. We stated in the proposed rule that if the removal of the criterion is finalized, there would be no specific certification criteria identified for this measure. An eligible hospital or CAH would be able to use any available data exchange standard specified in 45 CFR part 170 subpart B to meet the measure. For example, the transmission could be in the form of a Consolidated Clinical Document Architecture (C-CDA) per 45 CFR 170.205(a)(4), or Quality Reporting Document Architecture (QRDA) per 45 CFR 170.205(h)(2).

Regarding the Electronic Case Reporting measure, ONC proposed to revise the criterion at 45 CFR 170.315(f)(5)—''transmission to public health agencies—electronic case reporting,'' (90 FR 60992 through 60993) identified as supporting this measure. Regarding the Antimicrobial Use Surveillance and Antimicrobial Resistance Surveillance measures, ONC proposed to revise the criterion at 45 CFR 170.315(f)(6)—''transmission to public health agencies—antimicrobial use and resistance reporting,'' (90 FR 60993) identified as supporting these measures. These ONC proposals aim to update the certification criteria to focus on functional, rather than standards-based, requirements. While ONC's proposed updates, if finalized, would revise the requirements for health IT products certified to these criteria, eligible hospitals and CAHs would continue to need to use health IT certified to these criteria to report the Electronic Case Reporting, Antimicrobial Use Surveillance, and Antimicrobial Resistance Surveillance measures.

We noted in the proposed rule that ONC proposed removing certain certification criteria such as 45 CFR 170.315(g)(3)—''safety-enhanced design'' and 45 CFR 170.315(g)(4)—''quality management system,'' (90 FR 60995 through 60997) and a series of criteria related to privacy and security functionality in 45 CFR 170.315(d)(1)–(13) (90 FR 60989 through 60990), which are included in the Health IT Module certification requirements at 45 CFR 170.550. These criteria represent capabilities found in certified health IT products used by eligible hospitals and CAHs. We noted that the proposed removal of these criteria from the ONC Health IT Certification Program would not affect an eligible hospital's or CAH's obligations to ensure the privacy and security of patients' electronic health information under the Health Insurance Portability and Accountability Act of 1996 and other applicable laws.

b. Updates to the Definition of Certified Electronic Health Record Technology in the Medicare Promoting Interoperability Program

For CY 2019 and subsequent years, the definition of CEHRT for the Medicare Promoting Interoperability Program at 42 CFR 495.4 requires the use of EHR technology certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition or subsequent Base EHR definition (as defined at 45 CFR 170.102) and has been certified to specified ONC health IT certification criteria, as adopted and updated in 45 CFR 170.315. In paragraph (2)(i), the definition further specifies that EHR technology must be certified to criteria for ''family health history'' (45 CFR 170.315(a)(12)) and ''patient health information capture'' (45 CFR 170.315(e)(3)). In paragraph (2)(ii), the definition specifies that EHR technology must be certified to ONC health IT certification criteria that are necessary to be a meaningful EHR user. Paragraph (2)(ii)(A) includes the applicable measure calculation certification criteria at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support an objective with a percentage-based measure.

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19620 through 19621), we proposed to revise the definition of CEHRT at 42 CFR 495.4 for the Medicare Promoting Interoperability Program so the definition would be consistent with certain proposed modifications to ONC health IT certification criteria in the HTI–5 proposed rule. Specifically, we proposed to remove references to the following certification criteria effective January 1, 2027:

- ''family health history''—45 CFR 170.315(a)(12)
- ''patient health information capture''—45 CFR 170.315(e)(3)
- ''automated numerator recording''—45 CFR 170.315(g)(1)
- ''automated measure calculation''—45 CFR 170.315(g)(2)

We stated that effective January 1, 2027, these criteria would no longer be included in the CEHRT definition and that the revised definition in 42 CFR 495.4 would be, in relevant part, as follows:

''*Certified electronic health record technology (CEHRT)* [.ensp;. .]

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the ONC health IT certification criteria, as adopted and updated in 45 CFR 170.315—

(i) For 2019 through 2026, at 45 CFR 170.315(a)(12) (family health history) and 45 CFR 170.315(e)(3) (patient health information capture); and

(ii) Necessary to be a Meaningful EHR User (as defined in this section), including the following:

(A) For 2019 through 2026, the applicable measure calculation certification criterion at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3)(i) and (ii) and can be electronically accepted by CMS.''

We noted that while this change is consistent with the approach in the HTI–5 proposed rule (90 FR 60970), we did not believe that ONC must finalize its proposed revisions for us to finalize the changes outlined in this section for our regulatory definition of CEHRT in the Medicare Promoting Interoperability Program.

We stated that the longstanding presence of the criteria for ''family health history'' at 45 CFR 170.315(a)(12) and ''patient health information capture'' at 45 CFR 170.315(e)(3) in the ONC Health IT Certification Program and their incorporation into Medicare Promoting Interoperability Program requirements means that the functionality reflected in these criteria is fully embedded in certified health IT and is widely available and used by eligible hospitals and CAHs. ONC anticipated that health IT developers would continue to retain these capabilities in their Health IT Modules despite the absence of certification criteria for these functionalities (90 FR 60991 and 90 FR 60982). We noted in the proposed rule that these criteria are not identified as supporting any specific measures within the Medicare Promoting Interoperability Program.

We also noted that with respect to the certification criteria needed for measure calculation (''automated numerator recording'' and ''automated measure calculation'' certification criteria in 45 CFR 170.315(g)(1) and 45 CFR 170.315(g)(2)), health IT developers seeking to support customers participating in the Medicare Promoting Interoperability Program would need to continue to support reporting of numerators and denominators for certain Medicare Promoting Interoperability Program measures, including the Electronic Prescribing measure and Providing Patients Access to Their Health Information measure. We stated that removing the requirements for certification at 45 CFR 170.315(g)(1) and 45 CFR 170.315(g)(2), and removing references to those criteria in the definition of CEHRT at 42 CFR 495.4, would reduce administrative burden for health IT developers when testing and certifying this functionality without impacting reporting requirements for the Medicare Promoting Interoperability Program.

In summary, we proposed to revise the definition of CEHRT for the Medicare Promoting Interoperability Program at 42 CFR 495.4. Specifically, we proposed to remove the certification criteria for ''family health history'' (45 CFR 170.315(a)(12)), ''patient health information capture'' (45 CFR 170.315(e)(3)), ''automated numerator recording'' (45 CFR 170.315(g)(1)), and ''automated measure calculation'' (45 CFR 170.315(g)(2)) effective January 1, 2027 in alignment with the proposed timing to remove such criteria from the Code of Federal Regulations in the HTI–5 proposed rule.

We invited public comment on these proposals.

Comment: Many commenters supported our proposal to modify the CEHRT definition. Several commenters stated that CMS should align with the proposed changes in the HTI–5 proposed rule. A few commenters noted that the health IT functionalities are already mature, broadly implemented, and embedded in certified health IT products and workflows.

Response: We thank commenters for their support. We will continue to work closely with ONC to ensure program alignment where possible. We agree with commenters that many health IT functionalities proposed for removal or revision in the HTI–5 proposed rule are already broadly implemented.

Comment: Several commenters did not support our proposal to modify the CEHRT definition. A few commenters stated that CMS should wait until ONC finalizes the HTI–5 proposed rule to support consistency and predictability in compliance across HHS programs. A commenter stated that the CY 2027 timeline for modification of the CEHRT definition is not tenable because it does not provide sufficient time for implementation.

Response: As we noted in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19621), these proposed changes are consistent with the timelines outlined in the HTI–5 proposed rule (90 FR 60970). We do not believe that ONC must finalize its proposed removals and revisions for us to finalize the changes outlined in this section to our regulatory definition of CEHRT for the Medicare Promoting Interoperability Program. Doing so also increases clarity for eligible hospitals and CAHs that may otherwise need to refer to a CEHRT definition that includes references to removed criteria, should ONC finalize its proposed removals and revisions. Regarding concerns that eligible hospitals and CAHs will not be provided a sufficient amount of time for implementation, we remind readers that our proposed revisions to the definition of CEHRT have the effect of removing, rather than adding, requirements with respect to the CEHRT definition. We therefore do not expect any new implementation requirements to arise from these proposed removals. To the extent that criteria are removed from the ONC Health IT Certification Program, ONC and CMS have stated that the underlying functionality will continue to exist unless health IT developers update their products to remove the functionality.

Comment: A few commenters stated that CMS should not remove the ''family health history'' and ''patient health information capture'' certification criteria from the CEHRT definition because there is no guarantee that these functionalities will continue to be offered within health IT products. The commenters instead recommended that CMS and ONC retain these criteria in their respective regulations.

Response: We thank commenters for their feedback. The longstanding presence of the ''family health history'' criterion at 45 CFR 170.315(a)(12) and ''patient health information capture'' criterion at 45 CFR 170.315(e)(3) in the ONC Health IT Certification Program and their incorporation into Medicare Promoting Interoperability Program requirements means that the functionality reflected in these criteria is already fully embedded in certified health IT and is widely available and used by eligible hospitals and CAHs. We firmly believe that removing the family health history certification criterion will have minimal impact on data consistency because many developers of certified health IT will continue to conform to the Systematized Nomenclature of Medicine—Clinical Terms® (SNOMED CT) US Edition standard and the functionality to code family health history with this standard will likely remain in certified health IT adopted by hospitals and physicians (90 FR 60982). Moreover, updates to the United States Core Data for Interoperability (USCDI) in USCDI v6 demonstrate ONC's commitment to the exchange of family health history information using the SNOMED CT US Edition standard.[537] We note that while USCDI v6 has not been adopted in regulation at this time, it may be considered for adoption in future rulemaking. Of note, USCDI v6 has been approved by the National Coordinator for use under the Standards Version Advancement Process (SVAP), which means health IT developers may

[537] *See https://isp.healthit.gov/united-states-core-data-interoperability-uscdi#uscdi-v6.*

voluntarily incorporate this standard into Certified Health IT Modules.[538]

Regarding the patient health information capture criterion, the capabilities described in the criterion are widely implemented and used in health IT at this time and we firmly believe these capabilities will remain in health IT products even if the corresponding criterion is removed. ONC has also noted that removing the criterion from the Certification Program could spur greater development and innovation in this area (90 FR 60991). There are other certification criteria that support patient engagement, such as the ''view, download, and transmit to 3rd party'' and ''standardized API for patient and population services'' certification criteria (90 FR 60991). ONC has seen developers integrate the functionality in the patient health information capture certification criterion as part of other patient engagement features, such as patient portals.

Accordingly, there are multiple avenues to fully implement and broadly support family health history data and the patient health information capture through standards without the need to retain references to these certification criteria in the CEHRT definition. Not only will we continue to identify opportunities to work with industry to improve data quality, but we will also continue to monitor and analyze approaches by health IT developers for real world implementation. Although these criteria are not identified as supporting any specific measures within the Medicare Promoting Interoperability Program, we will monitor these CEHRT changes and welcome comments and feedback if eligible hospitals and CAHs find their experience to be to the contrary.

Comment: A few commenters did not support the proposal to remove the references in the CEHRT definition to the certification criteria for ''automated numerator recording'' at 45 CFR 170.315(g)(1) and ''automated measure calculation'' at 45 CFR 170.315(g)(2) from the CEHRT definition. A commenter stated that removal of these criteria without a clearly defined plan for measure calculation may introduce inconsistency, data errors, and increased audit risk for eligible hospitals and CAHs. The commenter requested that CMS coordinate closely with ONC to develop standardized calculation guidance, updated specifications, and a cohesive transition strategy so that eligible hospitals and CAHs are not adversely impacted by divergent reporting methodologies once certification testing is removed. Another commenter stated that these functions remain essential for accurate Medicare Promoting Interoperability Program reporting, quality assurance, and future performance-based measures, and that the proposal is inconsistent because it acknowledges that these capabilities are still necessary for program participation. The commenter expressed concern that eliminating references to these certification criteria while retaining reporting obligations could increase calculation errors, undermine accountability, expose eligible hospitals and CAHs to inaccurate scores and, subsequently, downward payment adjustments.

Response: We thank the commenters for their feedback. Health IT developers seeking to support customers participating in the Medicare Promoting Interoperability Program will still need to support reporting of numerators and denominators for certain Medicare Promoting Interoperability Program measures, including the Electronic Prescribing measure and Providing Patients Access to Their Health Information measure. However, ONC has stated that removing the certification criteria at 45 CFR 170.315(g)(1) and 45 CFR 170.315(g)(2) would reduce administrative burden for health IT developers associated with testing and certifying this functionality without impacting reporting requirements for the Medicare Promoting Interoperability Program, and we therefore disagree with the concerns that commenters expressed. We appreciate commenters' concerns about calculation errors and accountability, but we note that our proposed revisions to the CEHRT definition do not and should not affect current functionality in this regard, and we have proposed no changes in measures with numerator and denominator calculations that would prompt configuration changes. Therefore, we recommend that eligible hospitals and CAHs work closely with their vendors to ensure that current functionality is retained. We also note that eligible hospitals and CAHs already have a responsibility to ensure the accuracy of their reported values and that merely using EHR technology that was certified to particular ONC certification criteria was never entirely sufficient because of the risk of local configuration errors.

We also note that health IT developers now have had more time and experience with CMS programs than when we first added references to § 170.315(g)(1) and § 170.315(g)(2) to the definition of CEHRT beginning with the EHR reporting period in CY 2019. We believe that health IT developers will continue to ensure that patients or actions included in a measure's numerator are recorded in a fashion that supports accurate calculation to meet CMS requirements without needing to certify their health IT products to § 170.315(g)(1) or § 170.315(g)(2). Eligible clinicians, eligible hospitals, and CAHs, may currently use a separate, non-certified system to calculate numerators and denominators and to generate reports on the measures.[539] We will continue to work closely with ONC to ensure consistency in specifications and accuracy in reporting methodologies, and we intend to include details in this respect in future measure specification documents.[540]

Comment: A few commenters recommended that CMS establish a monitoring mechanism to streamline health IT vendor software management for the changes related to numerator recording and measure calculation, stating that removing these certification requirements shifts accountability to internal data analytics and clinical informatics teams. A few commenters stated that reducing developer burden should not inadvertently penalize or burden organizations while they adjust to this technology no longer being certified by ONC. Another commenter expressed concern that excessive CEHRT deregulation could undermine standardization, interoperability, and affect other health care programs, and therefore recommended careful review of stakeholder feedback before finalizing the changes. A commenter expressed support for CMS's and ONC's efforts to align health IT regulations, reduce burden, and improve the timely, reliable exchange of data across health care programs, however they also expressed concern that reducing CEHRT requirements could create unintended consequences, including shifting validation and compliance burdens from vendors to organizations, increasing patient safety and interoperability risks, and reducing product standardization. This commenter noted that although the targeted certification criteria may not

[538] *See https://isp.healthit.gov/sites/default/files/2026-07/2026%20Standards%20for%20Approval_508.pdf.*

[539] *See https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/FAQ_CEHRT.pdf.*

[540] For the CY 2025 CMS Specifications Manual for the Medicare Promoting Interoperability Program, see: *https://www.cms.gov/files/document/cms-specifications-manual-ehr-period-cy-2025.pdf.* Specification manuals are provided yearly in advance of the relevant EHR reporting period calendar year.

directly support Medicare Promoting Interoperability Program measures, changes may still affect other programs and clinical workflows. A commenter recommended CMS provide guidance for any CEHRT definition changes, ensure that health IT vendors have sufficient time to update certified products, and protect eligible hospitals and CAHs from penalties where compliance depends on vendor readiness.

Response: We appreciate the suggestion to establish a monitoring mechanism for the changes related to numerator recording and measure calculation. We will continue to collaborate with ONC to identify opportunities for technical support that will facilitate the transition away from ONC certification of this functionality. Regarding commenters' concerns that these CEHRT definition changes may shift burden to eligible hospitals and CAHs, undermine standardization and interoperability, and impact other health care programs, we note that removal of criteria from the CEHRT definition has the effect of decreasing eligible hospitals' and CAHs' program obligations with respect to their CEHRT and that both ONC and CMS expect the underlying functionality will continue to exist within EHR systems. We therefore do not expect significant changes to eligible hospitals and CAHs from this proposal to modify the CEHRT definition. We expect that health IT developers will continue to ensure that patients or actions included in a measure calculation are recorded in a fashion that will meet CMS requirements without needing to certify their health IT products to § 170.315(g)(1) or (g)(2). We will continue to work closely with ONC to align health IT regulations where applicable, reduce administrative burden when feasible, incentivize the reliable exchange of data, and minimize any unintentional consequences of these changes. We also recognize commenters' concerns that changes to certification requirements could affect internal validation processes used by eligible hospitals, CAHs, and health systems for other CMS programs, but we still view this change as a net decrease in compliance obligations rather than an increase, and we will seek to harmonize changes across CMS programs where appropriate. We intend to monitor implementation experiences and questions related to numerator and denominator calculation, and we will provide additional sub-regulatory guidance to support consistent implementation. We will continue coordinating with ONC to help ensure that any changes to CEHRT-related requirements are clearly communicated in a manner that supports readiness among health IT developers, eligible hospitals, and CAHs.

Comment: A few commenters recommended removing the certification criteria because they do not directly support Medicare Promoting Interoperability measures, but only if CMS and ONC establish ongoing monitoring of health IT vendor retention of these functions and implement a mechanism to reinstate the requirements if necessary. A few commenters expressed concern that health IT vendors may discontinue or reduce support for clinically important capabilities or monetize necessary numerator and denominator calculation functions.

Response: We thank the commenters for their support and recommendations. We note that ONC expects that health IT developers will continue to retain these capabilities in their Health IT Modules despite the absence of certification criteria (90 FR 60991 and 90 FR 60982) as the functionality is already fully embedded in certified health IT and is widely available and used by eligible hospitals and CAHs. We understand commenters' concerns regarding the potential for health IT vendors to monetize or reduce support for these important capabilities and encourage eligible hospitals and CAHs to consider these capabilities when reviewing their EHR technology purchase options with health IT vendors and during contract negotiations. We note that if the main effect of the policy is to decrease the certification and testing burden of health IT developers, the removal of the references to these criteria in the CEHRT definition alone should not cause health IT developers to have to make changes to their products or otherwise expend development resources. Nevertheless, we agree that ongoing monitoring of the effects of removal of these criteria is necessary, and we will continue to work with ONC to do so.

Comment: A commenter recommended that CMS ensure this proposal would not shift new operational, compliance, or validation burdens onto eligible hospitals and CAHs, particularly rural hospitals and other low-resourced organizations, noting that removing certification criteria does not eliminate the need for underlying functions such as security controls, audit capabilities, reporting tools, accessibility features, and data integrity protections.

Response: We thank the commenter for their recommendation. We recognize the potential challenges that may be faced by smaller and under-resourced eligible hospitals and CAHs and are committed to continuing to receive feedback and explore ways to offer support where possible. We will continue to work closely with ONC to ensure consistency, flexibility, and stability of our policies, and to closely monitor for any unintended consequences to eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

Comment: A commenter requested clarification on our proposal, asking if CMS intends for the functional, clinically useful data elements in these criteria to be retained or removed. The commenter recommended that CMS publish a detailed list of the data elements collected for these criteria and indicate whether each is captured elsewhere in the EHR to determine if removing these certification criteria would create clinical gaps in documentation causing unforeseen operational or clinical impacts.

Response: We thank the commenter for this suggestion. We note that clinically useful data elements that support the Medicare Promoting Interoperability Program would still be retained in the CEHRT definition as many of the criteria of the Base EHR definition continue to require these data elements. We do not intend for any data elements to be removed. As for the request for a detailed list of data elements, we discussed in a prior comment how certified health IT will continue to conform to the SNOMED CT US Edition standard and the functionality to code family health history with this standard will likely remain in certified health IT adopted by hospitals and physicians (90 FR 60982). The ''patient health information capture'' criterion does not define any specific data elements. Finally, the ''automated numerator recording'' (45 CFR 170.315(g)(1)), and ''automated measure calculation'' (45 CFR 170.315(g)(2)) criteria do not have specific data element requirements but rather relate to functionality for measures derived from care delivery.

After consideration of the public comments we received, we are finalizing our proposal to revise the definition of CEHRT for the Medicare Promoting Interoperability Program at 42 CFR 495.4 to the following:

''*Certified electronic health record technology (CEHRT)* [. . .]

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR

definition, or subsequent Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the ONC health IT certification criteria, as adopted and updated in 45 CFR 170.315—

(i) For 2019 through 2026, at 45 CFR 170.315(a)(12) (family health history) and 45 CFR 170.315(e)(3) (patient health information capture); and

(ii) Necessary to be a Meaningful EHR User (as defined in this section), including the following:

(A) For 2019 through 2026, the applicable measure calculation certification criterion at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3)(i) and (ii) and can be electronically accepted by CMS.''

3. Removal of ONC Direct Review and ONC-Authorized Certification Body (ACB) Surveillance Attestations

a. Background

In the Medicare Program, Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models final rule with comment period, which appeared in the **Federal Register** on November 4, 2016 (hereafter the ''CY 2017 Quality Payment Program final rule'') (81 FR 77027), we adopted two attestations for the Medicare Promoting Interoperability Program (then called the Medicare EHR Incentive Program) related to supporting eligible hospitals and CAHs with the performance of CEHRT. The two attestations were adopted at 42 CFR 495.40(b)(2)(i)(I)(*1*) and (*2*), as follows:

- ONC Direct Review attestation: Eligible hospitals and CAHs must affirm cooperation with ONC Direct Review of their CEHRT by: (1) acknowledging the requirement to cooperate in good faith with ONC direct review of their health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received; and (2) if requested, cooperate in good faith with ONC direct review of their health information technology certified under the ONC Health IT Certification Program.[541]
- ONC–ACB Surveillance attestation: Eligible hospitals and CAHs may also attest that they engaged in supporting health care providers with the performance of CEHRT activities by attesting that they: (1) acknowledge the option to cooperate in good faith with ONC–ACB surveillance of their health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC–ACB surveillance is received; and (2) if requested, cooperated in good faith with ONC–ACB surveillance of their health information technology certified under the ONC Health IT Certification Program.[542]

The ONC Direct Review attestation has been a required element of the Medicare Promoting Interoperability Program; submitting a ''Yes'' response fulfills the requirements of the attestation. Submitting a ''No'' response would subject an eligible hospital or CAH to a downward payment adjustment for not meeting minimum program requirements. The ONC–ACB Surveillance attestation has been optional: a ''Yes'' response on the attestation, a ''No'' response on the attestation, or non-response are all acceptable answers. Both attestations have been reported through a manual attestation (''Yes'' or ''No'') process via the CMS Hospital Quality Reporting (HQR) system.

b. Removal of the ONC Direct Review and ONC–ACB Surveillance Attestations Beginning With the EHR Reporting Period in CY 2026

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19621 through 19622), we proposed to remove the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation from the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2026 and make conforming changes at 42 CFR 495.40(b)(2)(i)(I). We proposed for these changes to be effective with the data submission period beginning January 1, 2027, because neither attestation requires any specific action to occur within the 180-day EHR reporting period. We stated that the removal of these measures advances our focus on high-value, outcome-oriented measures. We stated that while we continue to support the ONC direct review process and ONC–ACB surveillance, we also recognized the need to reduce administrative burdens in our measure and attestation set when feasible.

We continue to recognize the importance of ONC direct review and ONC–ACB surveillance activities and believe these mechanisms are important for mitigating issues with health IT products that may pose serious risks to public health or safety and continue to cooperate with ONC in supporting the ONC Health IT Certification Program. As stated in the CY 2017 Quality Payment Program final rule (81 FR 77020), efforts to strengthen surveillance and direct review of certified health IT are critical to the success of HHS programs and initiatives that require the use of certified health IT to improve health care quality and the efficient delivery of care. We stated in the proposed rule we did not anticipate that the commitment from ONC and the ONC–ACBs toward such goals will change.

When we initially finalized these attestations in November 2016 in the CY 2017 Quality Payment Program final rule, we believed that the attestations would complement and strengthen ONC's ability to perform surveillance and direct review activities. In October 2015, ONC finalized the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications final rule, which added requirements that ONC–ACBs conduct more frequent and more rigorous surveillance of certified technology and capabilities ''in the field'' (80 FR 62707). In October 2016, ONC published the ONC Health IT Certification Program: Enhanced Oversight and Accountability final rule, which established regulatory processes to facilitate ONC's direct review and evaluation of the performance of certified health IT in certain circumstances (81 FR 72406). In the CY 2017 Quality Payment Program final rule, we determined that surveillance and direct review activities provided greater assurance to health care providers that their certified EHR technology would perform in a manner that meets their expectations, but that this surveillance and direct review would not be effective unless health care providers cooperated with these activities, including by granting access to and assisting ONC–ACBs and ONC to observe the performance of production systems (81 FR 77020).

While these activities remain important, we stated in the proposed rule we no longer believe that the requirement for eligible hospitals and CAHs to attest ''yes'' to the ONC Direct Review attestation is necessary to demonstrate the meaningful use of CEHRT. Since 2016, the ONC direct review process has become known to eligible hospitals and CAHs, and the value of participation has become

[541] 42 CFR 495.40(b)(2)(i)(I)(*1*).

[542] 42 CFR 495.40(b)(2)(i)(I)(*2*).

evident without dependence on an annual attestation. Likewise, we stated that the ONC–ACB Surveillance attestation, which is optional for attestation, is no longer necessary to collect because eligible hospitals and CAHs have been made aware of their ability to participate in ONB–ACB surveillance if asked. We stated that the burden of the attestations, even the minimal burden of the voluntary ONC–ACB Surveillance attestation, now outweighs their value. Removing these measures aligns with our goals of reducing administrative burden while simultaneously focusing on high-value, outcome-oriented measures. Specifically, removal of these attestations from the Medicare Promoting Interoperability Program represents an opportunity to reduce the number of discrete manual steps and reporting fields required for successful program participation without diminishing the integrity or central goals of the program. Although we proposed removing the attestations, we strongly encouraged eligible hospitals and CAHs to continue participating in these oversight processes.

We proposed the removal of the ONC Direct Review and ONC–ACB Surveillance attestations beginning with the EHR reporting period in CY 2026 to reduce burden as quickly as feasible. Since eligible hospitals and CAHs would not be reporting on these attestations until the data submission period opens on January 1, 2027, we determined that it would be feasible for eligible hospitals and CAHs to implement this change sooner. Therefore, eligible hospitals and CAHs would not have to report on these attestations by the March 1, 2027, submission deadline and there would be no effect on their FY 2028 payment determination or FY 2026 cost reimbursement, respectively.

We invited public comment on this proposal.

Comment: Several commenters supported our proposal to remove the ONC Direct Review Attestation and the ONC–ACB Surveillance Attestation from the Medicare Promoting Interoperability Program, stating that the removal of these measures would reduce unnecessary reporting and administrative burden while streamlining program requirements. A commenter stated they support this proposal because they oppose reporting that adds little value while increasing burden. A commenter noted that they intend to continue participating in these oversight processes when assistance is requested by ONC or an ONC–ACB. A commenter stated that these measures have a limited impact on daily hospital operations and do not meaningfully enhance quality or oversight. Another commenter noted that these changes show that many hospitals have achieved a baseline level of interoperability and now rely on EHR capabilities as embedded infrastructure rather than discrete compliance activities, and that reducing duplicative attestations allows organizations to focus their resources on meaningful use of interoperable data rather than procedural validation. A commenter expressed support for the proposal, specifically stating that the removal of these measures also benefits smaller developers and the hospitals they serve because it prevents the diversion of limited resources away from improving patient care.

Response: We thank commenters for their support. We agree that the removal of these attestations aligns with our goals of reducing administrative burden while simultaneously focusing on high-value, outcome-oriented measures.

Comment: A few commenters that supported our proposal offered recommendations for consideration. A few commenters recommended that CMS clarify that hospitals remain encouraged but not required to participate with ONC or an ONC–ACB if they are contacted, so not to underscore the ongoing importance of surveillance activities. A commenter noted that the ONC Direct Review and ONC–ACB Surveillance processes are robust, comprehensive, and necessary safeguards to monitor developers' adherence to requirements, mitigate issues with health IT products, and provide assurances to health care providers that their CEHRT is functioning as intended. This commenter recommended that CMS continue to support ONC in upholding and strengthening direct reviews and surveillance activities.

Response: We thank commenters for their feedback. We reiterate that although we proposed to remove these attestations, we strongly encourage eligible hospitals and CAHs to continue participating in these activities when requested. We agree with commenters that surveillance and direct review activities are an important and helpful part of an overall process to monitor whether CEHRT and certified health IT Modules perform in an expected manner. We also agree that removing these measures will reduce administrative burden. We will continue to work with ONC to support direct review and surveillance activities.

Comment: A few commenters expressed appreciation for the efforts to reduce unnecessary administrative burden, acknowledging that the ONC Direct Review and ONC–ACB Surveillance attestations are not direct measures of patient outcomes. The commenters also expressed concern that removing mechanisms that may reinforce institutional awareness of and cooperation with health IT oversight activities may contribute to delayed diagnosis, interoperability failures, missed abnormal results, medication errors, communication breakdowns, and other patient safety risks. The commenters recommended CMS and ONC continue to maintain strong oversight, transparency, and organizational accountability regarding certified health IT performance and safety.

Response: We thank the commenters for their feedback. We strongly encourage eligible hospitals and CAHs to continue participating in oversight processes when assistance is requested by ONC or an ONC–ACB. We will continue to work with ONC to strengthen direct review and surveillance activities.

After consideration of the public comments we received, we are finalizing our proposal to remove the ONC Direct Review attestation and the ONC–ACB Surveillance attestation from the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2026 and make conforming changes at 42 CFR 495.40(b)(2)(i)(I). Although we are finalizing the removal of these attestations, we strongly encourage eligible hospitals and CAHs to continue participating in these oversight processes when assistance is requested by ONC or an ONC–ACB.

4. Removal of the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information Measures

a. Background on the Health Information Exchange Objective

The Health Information Exchange objective and its associated measures encourage and leverage the interoperability of electronic health information on a broader scale and promote health IT-based care coordination. The Health Information Exchange objective includes five measures: Support Electronic Referral Loops by Sending Health Information, Support Electronic Referral Loops by Receiving and Reconciling Health Information, Health Information Exchange (HIE) Bi-Directional Exchange, Enabling Exchange Under the

Trusted Exchange Framework and Common Agreement (TEFCA), and Electronic Prior Authorization. For background on this objective and its associated measures, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41656 through 41661), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42596 through 42597), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58969), the FY 2022 IPPS/LTCH PPS final rule (86 FR 45465 through 45470), the FY 2023 IPPS/LTCH PPS final rule (87 FR 49327 through 49334), and the 2024 Interoperability and Prior Authorization final rule (89 FR 8926).

The Support Electronic Referral Loops by Sending Health Information measure requires that, for at least one transition of care or referral, the eligible hospital or CAH that transitions or refers its patient to another setting of care or health care provider: (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

- *Numerator:* Number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.
- *Denominator:* Number of transitions of care and referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (Place of Service [POS] 21 or 23) was the transitioning or referring health care provider.

The Support Electronic Referral Loops by Receiving and Reconciling Health Information measure requires, for at least one electronic summary of care record received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, medication allergy, and current problem list using CEHRT.

- *Numerator:* The number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication—Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy—Review of the patient's known medication allergies; and (3) Current Problem List—Review of the patient's current and active diagnoses.
- *Denominator:* Number of electronic summary of care records received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the reconciling party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has not previously encountered the patient.

An eligible hospital or CAH has been required to satisfy the Health Information Exchange objective by using one of three reporting options: Option 1 (report on the Support Electronic Referral Loops by Sending Health Information measure AND the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure), Option 2 (report on the HIE Bi-Directional Exchange measure), or Option 3 (report on the Enabling Exchange Under TEFCA measure) (87 FR 49334). The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure are each worth 15 points within the Health Information Exchange objective, and an eligible hospital or CAH may receive a maximum of 30 points by reporting on both measures. Eligible hospitals and CAHs must also attest ''Yes'' on the Electronic Prior Authorization measure beginning with the EHR reporting period in CY 2027 to meet all requirements for the Health Information Exchange objective (89 FR 8926 through 8927).[543]

Two ONC health IT certification criteria in 45 CFR 170.315 have supported the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure. In the ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017'' final rule, we finalized that eligible hospitals and CAHs must use the ''transitions of care'' certification criterion at 45 CFR 170.315(b)(1) for the measure (80 FR 62882) that we subsequently renamed as the Support Electronic Referral Loops by Sending Health Information measure (83 FR 41658). In the FY 2019 IPPS/LTCH PPS final rule, for the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure, we finalized that eligible hospitals and CAHs must utilize both the ''transitions of care'' certification criterion at 45 CFR 170.315(b)(1) and the ''clinical information reconciliation and incorporation'' certification criterion at 45 CFR 170.315(b)(2) (83 FR 41661). These certification criteria, based upon the C–CDA standard, enable eligible hospitals and CAHs to complete the actions described in the measures around sending, receiving, and reconciling summary of care records.

In the HTI–5 proposed rule (90 FR 60984 through 60985), ONC proposed multiple updates to the ONC health IT certification criteria that facilitate reporting the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures. Notably, ONC proposed to reduce the scope of the ''transitions of care'' certification criterion at 45 CFR 170.315(b)(1) to focus its requirements on enabling the receipt of a C–CDA document to position the criterion for a future evolution to receipt of Fast Healthcare Interoperability Resources® (FHIR)-formatted data. ONC also proposed to remove the ''clinical information reconciliation and incorporation'' certification criterion at 45 CFR 170.315(b)(2) based on its review of industry adoption of the criterion. ONC's review found that the capabilities of the criterion are widely implemented and used in health IT and thus are not likely to go away as a supported capability by developers of certified health IT based solely on removal of the criterion from the ONC Health IT Certification Program. For more details regarding these ONC proposals, please see the HTI–5 proposed rule at 90 FR 60984.

b. Removal of the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information Measures

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19622 through 19625), we proposed to remove the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures beginning with the EHR reporting period in CY 2028. We stated that removing these measures would streamline reporting and reduce the complexity of multiple measure reporting options for the Health Information Exchange objective, while focusing program performance on measures that assess the adoption of

[543] In section IX.F.5 of this final rule, we are finalizing several updates to the Electronic Prior Authorization measure and associated reporting requirements.

newer health information technologies and more comprehensive methods of information-sharing. We proposed that beginning with the EHR reporting period in CY 2028, eligible hospitals and CAHs would fulfill requirements in the Health Information Exchange objective by attesting ''Yes'' to either the HIE Bi-Directional Exchange measure or the Enabling Exchange Under TEFCA measure, as well as attesting ''Yes'' or claiming an Exclusion on the Electronic Prior Authorization measure.[544]

The Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures have been measures of meaningful use since Stage 2 of the EHR Incentive Program, the precursor to the Medicare Promoting Interoperability Program (77 FR 54044). Since their initial adoption, these measures have supported widespread adoption of functionality in EHRs for supporting the exchange of summary care records using the C–CDA standard. Use of this functionality as advanced by the current measures and their predecessors has served as a key driver for the adoption and use of exchange capabilities across the health care landscape for over a decade.

With this baseline of functionality broadly available to eligible hospitals and CAHs, we began to explore additional measures that foster the availability of longitudinal care records for patients and facilitate enhanced care coordination across settings by adding the Health Information Exchange (HIE) Bi-Directional Exchange measure and, later, the Enabling Exchange Under TEFCA measure (86 FR 45470 and 87 FR 49334, respectively). We stated we are further advancing this work by proposing to remove the prior measures and transitioning eligible hospitals and CAHs to focus on broader-scale interoperability approaches by prioritizing pathways that leverage Health Information Exchanges and Qualified Health Information Networks (QHINs) under TEFCA.

We described this transition as consistent with trends already underway in the program. Since the HIE Bi-Directional Exchange and Enabling Exchange Under TEFCA measures were adopted in the program, we have seen increased reporting of these measures to meet the Health Information Exchange objective. For the EHR reporting period in CY 2024, which was the most recent program data available, 68.8 percent of reporting eligible hospitals and CAHs reported on the HIE Bi-Directional Exchange measure and 4.6 percent of reporting facilities reported on the Enabling Exchange Under TEFCA measure, while only 26.6 percent of reporting eligible hospitals and CAHs reported on the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures. CAHs were disproportionately represented among the facilities that reported the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures, with 33.1 percent of CAHs compared to 23.9 percent of eligible hospitals reporting the measures.

However, we stated this statistic also showed that a majority of eligible hospitals and CAHs have been able to successfully report either the HIE Bi-Directional Exchange measure or the Enabling Exchange Under TEFCA measure. We stated that these measures of participation in network-based exchange are more comprehensive indicators of meaningful health information exchange than the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures. For example, exchanging information through an HIE or entity participating in TEFCA supports on-demand patient health information exchange to any location in an entire network of participants rather than the submission of a summary of care document to a single specified recipient. We stated that removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures, although impacting the eligible hospitals and CAHs that report on those measures, would benefit patients by assessing regional and national network-based longitudinal health information exchange among these eligible hospitals and CAHs rather than assessing the transmission of patient information to a single location at a single point in time. We also stated that all eligible hospitals, including small, rural hospitals, and CAHs benefit from increased access to patient health information for the patients they treat through increased participation in health information exchanges or TEFCA. Removal of these measures would also streamline reporting and reduce program complexity by decreasing the overall number of measures in the program. We welcomed comments with respect to whether there are additional barriers beyond what we have mentioned that small hospitals, rural hospitals, or CAHs may encounter to successfully report either the HIE Bi-Directional Exchange measure or Enabling Exchange Under TEFCA measure.

Finally, we also stated in the proposed rule that the removal of the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures, which are C–CDA-based measures, would encourage eligible hospitals and CAHs to further explore new exchange modalities that move away from document-centric standards and point-to-point exchange. We stated the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures focus on the exchange of summary of care records using the C–CDA standard, but industry trends toward increased FHIR adoption have enabled easier scalability to support real-time data exchange and access to more discrete data elements when compared to the document-centric CDA standard.[545] We have sought to improve the use of electronic health records over time, and one such aspect of doing so is fostering eligible hospitals' and CAHs' use of emerging data exchange standards that may improve upon those that were adopted in prior years.

We noted that the proposed removal of these measures does not imply that the underlying exchange activities targeted by the Health Information Exchange objective are fully and effectively implemented at this time, including among eligible hospitals and CAHs. We stated that we are considering evaluating performance-based measures under the Health Information Exchange objective for future rulemaking. Specifically, we plan to continue to evaluate future potential changes to the current HIE Bi-Directional Exchange and Enabling Exchange Under TEFCA measures to transition from attestation-based to performance-based measures to drive further improvement around ongoing gaps in health information exchange among eligible hospitals and CAHs. We

[544] In section IX.F.5 of this final rule, we are finalizing several updates to the Electronic Prior Authorization measure and associated reporting requirements.

[545] *https://healthit.gov/data/data-briefs/hospital-use-of-apis-to-enable-data-sharing-between-ehrs-and-third-party-technology/.*

also noted that we expect the use of C–CDA-based exchange to continue to serve as an ongoing capability for health information exchange even though we have determined that the Medicare Promoting Interoperability Program would no longer need a measure of its adoption and use. While the removal of these measures from the Medicare Promoting Interoperability Program seeks to encourage the use of new technology approaches that improve the function of electronic health records over time, we acknowledged the impact and value of these exchange methods.

We proposed removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures beginning with the EHR reporting period in CY 2028, rather than in an earlier reporting period, to provide the 26.6 percent of eligible hospitals and CAHs currently reporting on these measures sufficient time to prepare for reporting on the HIE Bi-Directional Exchange measure or the Enabling Exchange Under TEFCA measure. We reasoned that making these measure removals effective in the EHR reporting period in CY 2028 would allow those eligible hospitals and CAHs time to plan, procure, configure, and validate new workflows for participation with an entity facilitating health information exchange, whether through the HIE Bi-Directional Exchange or the Enabling Exchange Under TEFCA measures. This additional lead time would support a safe and reliable transition, while eligible hospitals and CAHs that wish to transition earlier and report on HIE Bi-Directional Exchange or Enabling Exchange Under TEFCA measures, if they are not already doing so, would be able to do so for the EHR reporting period in CY 2026 or CY 2027 if they so choose. Although eligible hospitals and CAHs may incur additional costs as a result of joining a Health Information Exchange or a QHIN under TEFCA to report either of the measures, we stated that these benefits outweigh the costs considering the value of broad health information exchange networks to patient care [546] and the fact that such networks are more valuable to each participant as more and more participants are present in the network.[547]

We proposed that following the removal of these measures, eligible hospitals and CAHs would be required to satisfy the Health Information Exchange objective by reporting the HIE Bi-Directional Exchange measure or reporting the Enabling Exchange Under TEFCA measure. We proposed to maintain the same scoring policy for these two measure options; attesting ''Yes'' to either the HIE Bi-Directional Exchange or Enabling Exchange Under TEFCA measure would result in a maximum score of 30 points. Additionally, eligible hospitals would be required to meet the Electronic Prior Authorization measure requirement in the Health Information Exchange objective, which we discuss in section IX.F.5 of this final rule.

We invited public comment on these proposals.

Comment: Many commenters supported CMS's proposal to remove the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures beginning with the EHR reporting period in CY 2028 because they believe the measures are outdated, duplicative of or less useful than newer network-based exchange options, and no longer meaningfully differentiate performance among eligible hospitals and CAHs with established interoperability capabilities. Commenters stated that removing these measures would streamline reporting, reduce burden and program complexity, align the Medicare Promoting Interoperability Program with more modern health information exchange approaches, and allow eligible hospitals and CAHs to focus on broader-scale interoperability through the HIE Bi-Directional Exchange and Enabling Exchange Under TEFCA measures.

Response: We appreciate the commenters' support. We agree that removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures will streamline reporting under the Health Information Exchange objective and better align the Medicare Promoting Interoperability Program with broader, network-based exchange approaches. We also agree that the HIE Bi-Directional Exchange and Enabling Exchange Under TEFCA measures provide a broader and more robust assessment of health information exchange than measures focused on sending and receiving summary of care documents for individual referrals.

Comment: A few commenters supported the proposal but recommended that CMS provide additional implementation support during the transition, flexibility, hardship exceptions, or transitional policies for eligible hospitals and CAHs that do not currently have established HIE or TEFCA relationships, particularly small, rural, critical access, low-resourced, underserved, and inner-city hospitals. Commenters recommended clear reporting guidance, sufficient transition time, targeted financial or technical assistance, and outreach to small and rural hospital leaders and health IT developers, and sub-regulatory guidance so that affected hospitals can move to the HIE Bi-Directional Exchange or Enabling Exchange Under TEFCA measures without compliance gaps or disruption to information exchange during care transitions.

Response: We thank the commenters for their support and recommendations that we offer technical assistance, implementation support, flexibility, hardship exceptions, and transitional policies. We recognize that some eligible hospitals and CAHs, including small, rural, or otherwise under-resourced hospitals may need additional time and support to plan, procure, configure, and validate workflows for participation in the HIE Bi-Directional Exchange or Enabling Exchange Under TEFCA measures. We note that the current C–CDA exchange functionality underlying the removed measures would not disappear with the measure removal and should not disrupt information exchange. We agree that transition considerations should be balanced with the program goal of moving toward broader-scale exchange, and we are finalizing this proposal to allow ample transition time for affected eligible hospitals and CAHs. We note that significant hardship exceptions up to a statutory limit of five years (section 1886(b)(3)(B)(ix)(II) of the Act) are available and can be requested in the case of extreme and uncontrollable circumstances (codified at 42 CFR 412.64(d)(4)(ii)(B)), but not solely due to inability to successfully attest to a measure due to circumstances within one's control. We decline to provide additional incentives beyond the payment adjustment already present within the program because the program's statutory period of incentive payments is completed and no such mechanism now exists.

Comment: Several commenters recommended that CMS provide

[546] Menachemi N, Rahurkar S, Harle CA, Vest JR. The benefits of health information exchange: an updated systematic review. Journal of the American Medical Informatics Association. 2018 Sep;25(9):1259–65.

[547] Yaraghi N, Du AY, Sharman R, Gopal RD, Ramesh R. Network effects in health information exchange growth. ACM Transactions on Management Information Systems (TMIS). 2013 Apr 1;4(1):1–26.

additional time before removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures, stating that the proposed timeline of removal for the EHR reporting period in CY 2028 may not provide sufficient time for eligible hospitals and CAHs to transition successfully. Commenters expressed concern that some eligible hospitals and CAHs may face barriers related to readiness, vendor implementation timelines, costs, staffing constraints, and technical onboarding.

Response: We thank commenters for their feedback regarding the proposed timeline. We recognize commenters' concerns that some eligible hospitals and CAHs may need additional time to transition to other available Health Information Exchange reporting options. Therefore, after considering commenter feedback and the possibility that some eligible hospitals and CAHs may need additional time, we are finalizing the removal of the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures beginning with the EHR reporting period in CY 2029, rather than beginning with the EHR reporting period in CY 2028, as proposed.

Comment: A few commenters supported CMS's continued emphasis on the HIE Bi-Directional Exchange and Enabling Exchange Under TEFCA measures but recommended continued investment in TEFCA infrastructure and governance. A few commenters recommended that CMS and ONC ensure TEFCA supports practical use cases such as admission, discharge, and transfer (ADT) notifications, transitions of care for long-term and post-acute care, and pharmacy interoperability. Commenters also recommended that CMS consider stronger data protection and monitoring of QHINs so vendors cannot obtain patient data under the banner of care coordination without an appropriate clinical relationship.

Response: We thank the commenters for their support and recommendations regarding continued development of TEFCA infrastructure and governance. We agree that trust, privacy, security, and practical use cases are important components of the continued development of a nationwide health information exchange. We thank commenters for their suggestions regarding the continued development of use cases within TEFCA and will share those with ONC. We will also continue coordinating with ONC as TEFCA implementation advances. We also acknowledge the commenters' recommendations regarding stronger data protection and monitoring of QHINs and participants and note that additional information on applicable TEFCA requirements, including the Common Agreement and Standard Operating Procedures, is available in the TEFCA Resource Library at *https://rce.sequoiaproject.org/tefca-and-rce-resources/*. We will continue to work with ONC and monitor TEFCA implementation to support appropriate health information exchange consistent with applicable privacy and security requirements and any other legal requirements.

Comment: A commenter supported reducing unnecessary administrative burden where appropriate but emphasized that continuity of information exchange during care transitions remains foundational to patient safety.

Response: We thank the commenter for their support and agree that continuity of health information exchange during care transitions remains foundational to patient safety. Removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures does not diminish the importance of health information exchange during care transitions. Rather, the two remaining measures under the Health Information Exchange objective will continue to support timely and broad access to patient information across networks, including during care transitions. We also expect that the health IT functionality to directly exchange health information via C–CDA will continue to be available for use by hospitals as needed.

Comment: A few commenters did not support CMS's proposal to remove the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures beginning with the EHR reporting period in CY 2028, or did not support the removal timeline as proposed, because they stated eligible hospitals, CAHs, and health IT vendors would need additional time to develop, deploy, procure, configure, validate, and operationalize capabilities needed to successfully attest to the HIE Bi-Directional Exchange or Enabling Exchange Under TEFCA measures. Commenters expressed concern that removal would disproportionately affect rural hospitals, CAHs, and other low-resourced health care providers that may still depend on C–CDA-based workflows and may face barriers such as direct HIE or QHIN participation costs, uneven regional HIE availability, EHR vendor limitations or integration costs, limited health IT staff and workforce capacity, lack of technical assistance, and operational disruption. Commenters recommended that CMS delay removal, retain the measures as a reporting option during transition, assess and document readiness for the remaining HIE reporting pathways, clarify requirements and transaction volume expectations, and publish targeted technical assistance and measure specification guidance before finalizing or implementing removal.

Response: We appreciate the commenters' concerns regarding operational readiness, health IT vendor configuration, workflow transition, rural hospital and CAH barriers, and the timing of removal. We continue to believe that removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures is appropriate because these measures are less comprehensive indicators of meaningful health information exchange than participation in broader network-based exchange as reflected in the HIE Bi-Directional Exchange or Enabling Exchange Under TEFCA measures, and because removal would reduce the complexity of multiple Health Information Exchange objective reporting options. We clarify that, even with the removal of these measures, we anticipate hospitals and CAHs will continue exchanging health information using C–CDA as appropriate, including for exchange with HIEs and entities participating in TEFCA under the HIE Bi-Directional Exchange or Enabling Exchange Under TEFCA measures. We recognize that some eligible hospitals and CAHs may face resource, health IT vendor, workforce, cost, and regional infrastructure constraints when transitioning to the remaining reporting options, and that these barriers may be particularly acute for eligible hospitals and CAHs with limited health IT staffing resources or exchange options. However, these associated costs also come with the significant benefit of wider network-based availability of patient electronic health information. We also recognize that uneven regional availability of HIE infrastructure may affect eligible hospitals' and CAHs' ability to participate in health information exchange. We continue to support flexible pathways for health

information exchange, including participation through state-designated HIEs, other bi-directional exchange networks, and TEFCA-enabled approaches, as available and appropriate. Therefore, after considering commenter feedback, we are finalizing our proposal with modification to delay the removal of these measures, effective beginning with the EHR reporting period in CY 2029. We agree that eligible hospitals and CAHs need to understand the requirements for the remaining Health Information Exchange objective reporting options, including what is needed for successful reporting. We will continue to coordinate with ONC and consider commenters' recommendations regarding readiness, regional availability, transition costs, measure specification guidance, clarification of reporting expectations and transaction volume, and targeted technical assistance materials, as appropriate.

Comment: A few commenters did not support removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures because they stated C–CDA-based exchange remains widely used and continues to provide an important interoperability floor for eligible hospitals and CAHs that have not fully adopted alternative exchange pathways, such as FHIR-based exchange or TEFCA. Commenters stated that C–CDA-supported functionality is still prevalent, is often used by under-resourced eligible hospitals, CAHs, and health information professionals, and helps ensure that patient information can travel where needed. Commenters expressed concern that removing these measures, especially alongside related proposed ONC certification changes, could signal movement away from existing technologies, jeopardize nationwide interoperability, and create additional vendor or implementation burden before alternative HIE pathways are sufficiently established and broadly available.

Response: We appreciate the commenters' concerns regarding the continued use of C–CDA-based exchange and the importance of maintaining an interoperability baseline. We acknowledge the value of C–CDA-based exchange and expect that it may continue to serve as an ongoing capability for health information exchange, including for eligible hospitals and CAHs that have not fully adopted network-based exchange pathways. Removing the Support Electronic Referral Loops measures does not prohibit eligible hospitals and CAHs from continuing to use C–CDA-based exchange where it remains clinically or operationally appropriate, nor does it reflect a view that existing exchange technologies no longer have value. For example, C–CDA-based exchange remains identified as a capability to support the other HIE measures through the criterion at 45 CFR 170.315(b)(1), which ONC proposed to revise, not remove. Therefore, we do not anticipate negative impacts to nationwide interoperability by the removal of these two measures. At the same time, we continue to believe that the Medicare Promoting Interoperability Program should focus the Health Information Exchange objective on broader, network-based exchange approaches, which better demonstrate more comprehensive health information exchange capabilities. In response to concerns about burden on eligible hospitals and CAHs and readiness of the alternative HIE pathways, we note that we are delaying by one year the requirement to select either the HIE Bi-Directional Exchange or Enabling Exchange Under TEFCA measures (beginning with the EHR reporting period in CY 2029). This delay provides an additional year beyond our proposal to choose the best option and further develop the HIE pathways reflected in the two measures.

Comment: A few commenters expressed concern that removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures could weaken the Medicare Promoting Interoperability Program's emphasis on referral reconciliation, incorporation of clinically relevant information into care workflows, and closed-loop interdisciplinary care coordination during transitions of care. Commenters stated that continuity of care is foundational to patient safety, improved outcomes, and lower costs, and that interoperability failures and communication gaps can contribute to preventable harm across transitions of care. Commenters encouraged CMS to continue to focus on continuity of care and care coordination, and to remain focused on outcome measures and process measures that identify opportunities for improvement in patient safety and care transitions. A commenter stated that participation in a broader exchange network does not necessarily ensure that information is effectively exchanged, reconciled, or incorporated, and recommended that CMS continue prioritizing interoperability approaches that support meaningful referral communication, reconciliation of clinical information, and longitudinal care coordination across settings.

Response: We agree that the exchange and use of clinically relevant information during transitions of care remains important. Removing these measures from the Medicare Promoting Interoperability Program does not diminish the importance of these activities. Rather, the HIE Bi-Directional Exchange and Enabling Exchange Under TEFCA measures support broader access to longitudinal patient information across exchange networks and care settings, and that information can support referral communication, reconciliation of clinical information, incorporation of relevant information into care workflows, and care coordination across health care providers. Although removal of the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure does represent a decreased emphasis on this particular aspect of health information exchange, we believe that the HIE Bi-Directional Exchange and Enabling Exchange Under TEFCA measures are more comprehensive measures of health information exchange and that the program's goals are advanced more fully by requiring one of those measures rather than retaining the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure as an option. We may consider future refinements to the Health Information Exchange objective, as necessary, if we find additional opportunities to promote the meaningful use of health information technology to support patient safety and care transitions.

Comment: A few commenters recommended that CMS establish exclusions or hardship pathways before removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures for eligible hospitals and CAHs that cannot successfully participate in the activities necessary to report the HIE Bi-Directional Exchange or Enabling Exchange Under TEFCA measures due to circumstances outside the eligible hospital's or CAH's control. Commenters requested accommodations for situations in which network capability is unavailable, a hospital is migrating to a new exchange environment, newly acquired facilities are integrating into a different exchange environment, HIE or QHIN coverage is

insufficient, or documented barriers that prevent successful participation despite reasonable efforts. Commenters also recommended that CMS clarify the documentation hospitals should retain to support an exclusion or hardship request.

Response: We appreciate the commenters' recommendations regarding exclusions, hardship pathways, and suggested documentation to keep on site. We did not propose exclusions for the HIE Bi-Directional Exchange or Enabling Exchange Under TEFCA measures, but we recognize that some eligible hospitals and CAHs may encounter circumstances outside their control, including network availability, regional exchange coverage, or third-party readiness issues. The hardship exception process remains available for eligible hospitals and CAHs up to a statutory limit of five years of granted hardships. We note that failing to successfully attest to a measure may not qualify for a hardship exception. We agree that transition concerns should be addressed while maintaining the policy goal of moving the Health Information Exchange objective toward broader network-based exchange. We will continue to consider these operational issues and provide additional guidance and educational tools as feasible. If needed and appropriate, we may also revisit issues through future rulemaking if necessary.

Comment: A few commenters recommended that CMS preserve flexibility in how eligible hospitals and CAHs satisfy the Health Information Exchange objective as CMS removes the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures. Commenters recommended that CMS continue recognizing state-designated HIE networks that support bi-directional exchange, avoid requiring hospitals to use a single exchange framework before the full care continuum is ready, and proceed cautiously before making TEFCA the sole pathway for meeting the Health Information Exchange objective. Commenters also recommended that CMS ensure concerns related to TEFCA participant vetting, data privacy, and security are addressed before further movement toward TEFCA-based reporting.

Response: We appreciate the commenters' recommendations regarding flexibility in satisfying the Health Information Exchange objective. We agree that eligible hospitals and CAHs operate in varied exchange environments and that it is appropriate for the Medicare Promoting Interoperability Program to recognize more than one network exchange-based pathway for satisfying the Health Information Exchange objective at this time. TEFCA is one of two pathways (one of two separate measures) for meeting this program objective; eligible hospitals and CAHs may satisfy the objective by reporting either the HIE Bi-Directional Exchange measure or the Enabling Exchange Under TEFCA measure. We confirm that state-designated HIEs that meet the attributes described in the measure are acceptable for meeting the HIE measure, and hospitals may also meet the measure through participation in other bi-directional exchange networks that meet these attributes. We agree that trust, privacy, and security are important considerations for nationwide exchange, and we note that TEFCA QHINs have security frameworks associated with their use.

Comment: A few commenters recommended that CMS continue to monitor the effect of removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures on continuity of information exchange during care transitions and on care coordination among hospitals, specialists, primary care physicians, post-acute health care providers, and other clinical settings.

Response: We appreciate the commenters' recommendations and agree that continuity of health information exchange during care transitions is foundational to patient safety, care coordination, and improved outcomes. We stated that removing the Support Electronic Referral Loops measures will not diminish the importance of these activities. Instead, we believe that HIE Bi-Directional Exchange and Enabling Exchange Under TEFCA support broader access to longitudinal patient information and more comprehensive exchange across care settings. We will continue to monitor the effects of these reporting changes on information exchange during care transitions and care coordination across eligible hospitals, CAHs, and health care providers and may consider future refinements to the Health Information Exchange objective, as necessary and appropriate.

Comment: A commenter recommended that, when CMS removes measures, CMS provide stakeholder messaging to reinforce that underlying operational expectations for health information exchange remain unchanged, including the need to update, send, and reconcile clinical information. The commenter also stated that CMS should not transition prematurely to receipt of FHIR-formatted data until FHIR is standard across health care, because some health care providers that receive discharge data from hospitals, such as nursing facilities and physical therapy groups, may not have electronic medical records with FHIR-formatted data capabilities.

Response: We appreciate the commenter's recommendations regarding stakeholder messaging and readiness for FHIR-formatted data. We agree that removal of duplicative or less comprehensive measures should not be understood to mean that the underlying operational need for health information exchange during care transitions has changed, including the need to update, send, receive, and reconcile clinical information, as appropriate. Removal of the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures should not impact the ability of eligible hospitals, CAHs, and their exchange partners to continue to engage in C–CDA-based exchange where it remains clinically or operationally appropriate. Most HIEs and TEFCA QHINs themselves continue to support C–CDA exchange as a primary form of data exchange, and although some now also support FHIR-based exchange, there is no defined timeline for a complete transition away from C–CDA. We are actively evaluating readiness for a future FHIR transition for particular use cases, as we discussed most recently in a Request for Information on a FHIR transition timeline for the reporting of CQMs in the Medicare and Medicaid Programs; CY 2027 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program proposed rule (CY 2027 PFS proposed rule) (91 FR 44152 through 44154).

After consideration of the public comments we received, we are finalizing our proposal with the following modification: we are removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures beginning with the EHR reporting period in CY 2029, rather than beginning with the EHR reporting period in CY 2028 as proposed. After considering commenters' feedback, we

have determined that an additional year of planning is appropriate before these measures are removed.

5. Updates to the Electronic Prior Authorization Measure

a. Background

In the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), we adopted the Electronic Prior Authorization measure under the Health Information Exchange objective in the Medicare Promoting Interoperability Program. We finalized that eligible hospitals and CAHs would be required to attest to the Electronic Prior Authorization measure beginning with the EHR reporting period in CY 2027 (89 FR 8910). We explained that for purposes of the Electronic Prior Authorization measure, a prior authorization request must be made using a Prior Authorization Application Programming Interface (API) using data from CEHRT to attest ''Yes'' to the measure, unless the eligible hospital or CAH claims an applicable exclusion. We finalized the following text for the measure description (89 FR 8916):

For at least one hospital discharge and medical item or service (excluding drugs) ordered during the EHR reporting period, the prior authorization is requested electronically via a Prior Authorization API using data from CEHRT.

• *Exclusions: Any eligible hospital or CAH that—*

++ *Does not order any medical items or services (excluding drugs) requiring prior authorization during the EHR reporting period.*

++ *Only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets CMS's specified Prior Authorization API requirements during the applicable EHR reporting period.*

We finalized that only a ''Yes'' attestation, or claiming an applicable exclusion, fulfills the requirements of the measure. Additionally, we finalized that the measure will not be scored (that is, not assigned points for a ''Yes'' attestation) for the EHR reporting period in CY 2027 and a ''No'' attestation will result in the eligible hospital or CAH not meeting the measure. If an eligible hospital or CAH does not meet the measure, they would not meet minimum program requirements and be subject to a downward payment adjustment (89 FR 8911).

The 2024 CMS Interoperability and Prior Authorization final rule also finalized that Medicare Advantage plans, state Medicaid Fee-for-service (FFS) programs, state Children's Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plans (QHP) issuers on the federally facilitated exchanges (collectively referred to as ''impacted payers'') must implement and maintain a Prior Authorization API beginning in CY 2027 (by January 1, 2027 for MA organizations and state Medicaid and CHIP FFS programs; by the first rating period beginning on or after January 1, 2027 for Medicaid managed care plans and CHIP managed care entities; and for plan years beginning on or after January 1, 2027 for individual market QHP issuers on the FFEs) (89 FR 8759 through 8760). In that rule we also recommended, rather than required, specific FHIR Implementation Guides (IGs) to support the APIs (89 FR 8937).

In the Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization final rule (HTI–4 final rule), which was published as part of the FY 2026 IPPS/LTCH PPS final rule (90 FR 37164 through 37182), ONC finalized three ONC health IT certification criteria for electronic prior authorization:

• ''Provider prior authorization API—coverage requirements discovery'' in 45 CFR 170.315(g)(31);

• ''Provider prior authorization API—documentation templates and rules'' in 45 CFR 170.315(g)(32); and

• ''Provider prior authorization API—prior authorization support'' in 45 CFR 170.315(g)(33).

These certification criteria are based on three IGs developed by the Health Level Seven® (HL7) Da Vinci project, which ONC adopted in the HTI–4 final rule [548] at 45 CFR 170.215(j)(1), (2), and (3):

• HL7 FHIR Da Vinci—Coverage Requirements Discovery (CRD) IG;

• HL7 FHIR Da Vinci—Documentation Templates and Rules (DTR) IG; and

• HL7 FHIR Da Vinci—Prior Authorization Support (PAS) IG.

Together, these certification criteria can enable electronic prior authorizations for health care providers. We refer readers to the HTI–4 final rule (90 FR 37162 through 37175) for a more detailed discussion of ONC's finalized certification criteria at 45 CFR 170.315(g)(31) through (33) and section XI.B.4.b (90 FR 36541 through 36542) of the same rule for a summary of all the finalized ONC policies.

We also recently released the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges'' proposed rule (2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule). Among other policies, in the 2026 CMS Interoperability and Prior Authorization for Drugs proposed rule, we proposed to require impacted payers to implement and maintain Prior Authorization APIs that conform to the CRD, DTR, and PAS IGs adopted by ONC on behalf of the Secretary at 45 CFR 170.215(j)(1), (2), and (3) (91 FR 19908). We proposed an October 1, 2027 compliance date for impacted payers to conform to the proposed standards and IGs (impacted payers must still implement Prior Authorization APIs beginning in CY 2027) (91 FR 19908). Finally, in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, ONC proposed to adopt updated versions of the CRD, DTR, and PAS IGs (91 FR 20002). In section X.E. of this final rule, ONC is finalizing the proposals to adopt updated versions of the health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) so health IT developers implementing the functionality can utilize the latest versions of these specifications.

The proposals in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule for impacted payers to implement and maintain the Prior Authorization APIs using the CRD, DTR, and PAS IGs, along with the provisions ONC finalized in the HTI–4 final rule to adopt the CRD, DTR, and PAS IGs and establish electronic prior authorization certification criteria for health IT developers, collectively support the Electronic Prior Authorization measure for eligible hospitals and CAHs and advance interoperability by applying consistent standards across HHS programs. For more information, please see the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule and the HTI–4 final rule for the three health IT certification criteria to support electronic prior authorization at 45 CFR 170.315(g)(31), (32), and (33) (90 FR 37169 and 91 FR 20002).

[548] In the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, ONC proposed updated versions of these implementation guides. Section X.E. of this final rule includes finalization of these proposals.

b. Modification of the Electronic Prior Authorization Measure Beginning With the EHR Reporting Period in CY 2027

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19625 through 19629), we proposed several changes to the Electronic Prior Authorization measure, reflected in the following modified text for the measure description:

For at least one medical item or service (excluding drugs) ordered during a hospital encounter that occurs within the EHR reporting period, the prior authorization is requested electronically through a Prior Authorization API using CEHRT.

As reflected in the text, we proposed to modify the measure description by revising the phrase ''using data from CEHRT'' to ''using CEHRT.'' In section IX.F.5.c of this final rule, we clarify the requirement to use health IT certified to specific certification criteria included in the definition of CEHRT for this measure. When we adopted the Electronic Prior Authorization measure, we did not identify specific ONC health IT certification criteria required to complete the actions specified in the measure (89 FR 8910 through 8915). We stated that gathering structured data from CEHRT would be achievable without additional certification criteria specific to the measure (89 FR 8925), which had not been proposed or finalized at the time we issued the 2024 CMS Interoperability and Prior Authorization final rule. The proposed update to the measure language to state that a prior authorization must be requested electronically ''using CEHRT'' is consistent with the availability of certified Health IT Modules that must be used to complete the action specified in the Electronic Prior Authorization measure.

We also proposed to change the word ''discharge'' to ''encounter'' to more clearly delineate that a prior authorization request may occur at any time during the hospital encounter, rather than be associated temporally with the discharge, about which some stakeholders had expressed confusion regarding the measure. We did not propose any modifications to the exclusion criteria previously finalized for the Electronic Prior Authorization measure (89 FR 8916). Nor did we propose any exclusions for the Electronic Prior Authorization measure for the EHR reporting period in CY 2027, as exclusions are unnecessary for optional measures, consistent with our proposal to make the Electronic Prior Authorization measure a bonus measure for the EHR reporting period in CY 2027.

We invited public comment on this proposal.

Comment: Several commenters supported CMS's proposed updates to the Electronic Prior Authorization measure text. Commenters specifically supported revising the measure language from ''hospital discharge'' to ''hospital encounter,'' stating that the change better reflects the intent of the measure and likely prior authorization workflows within eligible hospitals and CAHs. A few commenters also supported requiring the use of CEHRT for the measure, rather than ''data from CEHRT,'' and aligning the measure's technical requirements with ONC's electronic prior authorization certification criteria. These commenters stated that using consistent certification standards would support broader adoption, improve interoperability, and help streamline prior authorization workflows.

Response: We thank commenters for their support. We agree that revising the measure language from ''hospital discharge'' to ''hospital encounter'' better reflects the expectation that prior authorization activities may occur at any time during a patient's hospitalization. We also agree that the use of CEHRT and alignment with ONC health IT certification criteria will help establish a consistent technical foundation for the measure, support broader adoption of standards-based electronic prior authorization, and improve interoperability across eligible hospitals, CAHs, and payers.

Comment: Regarding the proposal to modify the measure to require the use of CEHRT, a few commenters appreciated the flexibility regarding the ability to utilize different combinations of certified Health IT Modules to meet the measure because they viewed it as a practical way to encourage real adoption of electronic prior authorization without making eligible hospitals or CAHs responsible for workflows or technical dependencies that may not yet be fully mature.

Response: We appreciate commenters' support for allowing eligible hospitals and CAHs to use a combination of functionality found in one or more of the ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) to meet measure requirements and agree this provides practical flexibility at this time while these functionalities continue to be integrated into EHRs. For instance, we expect that many health IT developers may choose to initially focus on development and deployment of health IT certified to the ''provider prior authorization API—coverage requirements discovery'' criterion in 45 CFR 170.315(g)(31). Under the measure we are finalizing through this final rule, eligible hospitals and CAHs could use health IT certified to this criterion to complete a prior authorization request and satisfy the measure.

Although we are finalizing the proposals for the EHR reporting periods in CY 2027 and 2028 in this final rule, we are very strongly considering advancing the use of available certified health IT in rulemaking in the FY 2028 IPPS/LTCH PPS proposed rule by proposing to require the use of functionality found in each of the three ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) beginning with the CY 2028 EHR reporting period. This would be in alignment with the proposed CY 2028 performance period/2030 MIPS payment year requirements for the Electronic Prior Authorization measure for MIPS eligible clinicians in the CY 2027 PFS proposed rule (91 FR 44176 through 44182).

Comment: Several commenters opposed changing the measure language from ''using data from CEHRT'' to ''using CEHRT.'' Commenters stated that hospitals often rely on multiple systems, including EHRs, revenue cycle systems, payer portals, clearinghouses, HIEs, intermediaries, and other tools to facilitate a prior authorization request, and that a narrow ''using CEHRT'' requirement could limit practical software implementation options, increase burden, and force duplicative connections across systems. Commenters recommended that CMS retain the current ''using data from CEHRT'' language and clarify that hospitals may use standards-based intermediaries or other interoperable solutions to support electronic prior authorization workflows, provided that relevant data from CEHRT are used and privacy, security, and auditability requirements are met. Commenters also noted that adopting new FHIR IGs, conforming to ONC certification criteria, building and testing interfaces, and aligning with payer implementation timelines may require substantial lead time and would impact eligible hospitals' and CAHs' ability to fulfill the measure.

Response: We appreciate commenters' concerns regarding the proposed change from ''using data from CEHRT'' to ''using CEHRT.'' We recognize that electronic prior authorization workflows may involve multiple systems and entities, including EHRs, revenue cycle systems, payer systems, clearinghouses, intermediaries, HIEs, and other technology solutions. Our intent is not to prohibit the use of standards-based

intermediaries or other interoperable tools that support the electronic prior authorization workflow. Rather, the measure is intended to ensure that eligible hospitals and CAHs conduct the measure action using standards-based health IT functionality certified to ONC's electronic prior authorization certification criteria. We note that eligible hospitals and CAHs may use any combination of Health IT Modules to fulfill the measure action. Moreover, nothing in our proposal prohibits intermediaries from supporting electronic prior authorization exchange in other ways separate from the capabilities reflected in the electronic prior authorization certification criteria. As discussed in section IX.F.5.d, we are finalizing our proposal to make the measure a bonus measure for the EHR reporting period in CY 2027, which will help to address commenters' concerns regarding additional flexibility for initial implementation lead time, interface testing, and payer readiness.

Comment: A commenter did not support the proposed updates to the Electronic Prior Authorization measure description because they wanted several clarifications regarding its requirements. The commenter noted that electronic prior authorizations are often initiated during inpatient stays for post-discharge services, creating ambiguity about which services would be captured and how orders and authorizations would be attributed across eligible hospitals, CAHs, clinics, and health systems. The commenter requested clear numerator and denominator definitions and stated that it would be difficult for eligible hospitals and CAHs to operationalize and demonstrate compliance with the measure without them. The commenter also urged CMS to ensure that payers share responsibility for meeting technology standards, warning that hospitals could otherwise face increased vendor and payer-specific costs without improved efficiency. The commenter recommended that CMS clarify its intent, provide detailed use cases, and consider retaining the ''discharge'' measure text rather than changing to ''encounter.''

Response: We agree that electronic prior authorization workflows may vary depending on the service and care setting. We proposed the change from ''hospital discharge'' to ''hospital encounter'' because electronic prior authorization activities may occur at any time during an encounter and are not always tied solely to the discharge event. Discharge is still an eligible moment within the hospital encounter to request a prior authorization. We will provide educational and guidance resources, as appropriate and feasible, to clarify implementation details. We disagree with the commenter that the measure is not feasible absent a numerator/denominator format because attestation-based measures are typically less complicated to implement and report as an initial measure. However, we agree that clarity is important regarding which actions constitute a successful prior authorization request for purposes of attestation, as discussed in the following comment response. We agree that a numerator/denominator measure could be a meaningful next step in the program to monitor the progress of electronic prior authorization. In response to the commenter urging CMS to ensure that payers share responsibility for meeting technology standards, as proposed in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (91 FR 19908), payers impacted by that regulation would need to use the same standards required for health IT certification criteria beginning on October 1, 2027.

Comment: A few commenters requested clarification on what constitutes a successful prior authorization request for purposes of attestation, including whether a request should count as successful when a payer responds that no prior authorization is required and whether the same treatment should apply for drug prior authorization requests. A commenter asked CMS to clarify whether a request is satisfied when a request is made and a response is received, or only when additional information is subsequently submitted to the payer. Another commenter recommended that CMS should permit fulfillment of the measure by using CEHRT to conduct a check for whether an item or service requires prior authorization for only CY 2027, after which time only a full prior authorization request should count to satisfy the measure.

Response: We appreciate commenters' requests for clarification regarding what constitutes a successful electronic prior authorization action for purposes of the measure. At this time, prior authorization for drugs covered under a medical benefit is not within the scope of this measure, nor prior authorization for drugs covered under a prescription benefit. In addition, any medical item or service that does not require prior authorization by the payer is not within the scope of the measure. In other words, it is necessary for the measure that the need for prior authorization for the medical item or service has been established. For example, if an eligible hospital or CAH submits a query through the Prior Authorization API as to whether prior authorization is needed for a particular medical item or service, and the payer response is that prior authorization is not needed, then this scenario is not within the scope of the measure. While an important step, we disagree that the measure in CY 2027 should be limited to the action of querying whether a prior authorization is needed or not for a medical item or service.

Further, to successfully meet measure requirements, where the measure description requires that ''a prior authorization is requested electronically through a Prior Authorization API,'' an eligible hospital or CAH must first query a Prior Authorization API to request the prior authorization. According to the Da Vinci IGs, the eligible hospital or CAH that queries a payer's Prior Authorization API will receive a response to the prior authorization request such as: *covered = not-covered* (*i.e.,* no coverage or possibility of coverage); *pa-needed = no-auth* (*i.e.,* service is covered and does not require prior authorization); *pa-needed = satisfied* (*i.e.,* prior authorization required, conditions evaluated, and authorization can be bypassed); *conditional* (*i.e.,* the payer cannot yet determine coverage, prior authorization, or documentation requirements); and *pa-needed = auth-needed* (*i.e.,* a prior authorization request is required, so the workflow can proceed through DTR and PAS until it is ultimately complete, having been approved or denied). To attest ''Yes'' for the measure in CY 2027, a request made using CEHRT by an eligible hospital or CAH must result in a satisfied, approved, or denied request.

For CY 2027, based on the complexity of the medical item or service and the payer's particular documentation requirements for the prior authorization request, the prior authorization request may be fulfilled using one or more of the certification criteria at 45 CFR 170.315(g)(31)–(33). For CY 2028 and beyond, as we noted above, we are very strongly considering returning to rulemaking in the FY 2028 IPPS/LTCH PPS proposed rule in order to align our requirements with the CY 2028 requirements proposed for MIPS eligible clinicians in the CY 2027 PFS proposed rule. Specifically, in the CY 2027 PFS proposed rule (91 FR 44178), there is a proposal to require the use of functionality when submitting a prior authorization request that is based on a complete prior authorization workflow, as reflected in the combined use of all three ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33)

for the CY 2028 performance period/2030 MIPS payment year.

Comment: A commenter did not support this proposal and instead recommended that CMS should preserve flexibility for hospitals to receive credit when electronic prior authorization transactions use data from CEHRT, rather than conditioning successful participation on certification or API-version requirements that may not yet be fully testable or broadly available. A commenter expressed concern with the timeline of the requirement, noting that eligible hospitals, CAHs, and payers are currently investing in version 2.1 implementation and that CRD 2.2 test tools were released in early June 2026, and stated that 12 to 18 months are needed for development, certification, and deployment. The commenter stated that most eligible hospitals and CAHs would not be using version 2.2 until late 2027 or 2028, so the use of certified Health IT Modules within CEHRT would not be achievable for many eligible hospitals and CAHs. The commenter recommended CMS revert to the previous language for 2027, requiring that electronic prior authorization transactions use data from a certified EHR, rather than requiring use of a certified API specifically, noting that this approach would maintain momentum on electronic prior authorization implementation by allowing hospitals actively conducting electronic prior authorization transactions on version 2.1 to earn bonus points while the industry works toward adopting version 2.2.

Response: We recognize that some eligible hospitals and CAHs may face barriers to deploying technology certified to certification criteria at 45 CFR 170.315(g)(31)–(33), which will require use of version 2.2 of the Da Vinci IGs. We took this into consideration when developing our proposal to modify the Electronic Prior Authorization measure as an optional bonus measure for the EHR reporting period in CY 2027. Finalizing the measure as an optional measure for the EHR reporting period in CY 2027 allows eligible hospitals and CAHs to explore electronic prior authorization transactions using version 2.2 of the Da Vinci IGs in 2027 without imposing immediate requirements that could create challenges for entities that have not yet deployed CEHRT, which will be required to use version 2.2 of the Da Vinci IGs as part of ONC Health IT Certification Program requirements.

For more information about the standards required for health IT developers certifying Health IT Modules to the electronic prior authorization criteria in 45 CFR 170.315(g)(31)–(33), see section X.E. of this final rule, in which ONC has adopted version 2.2.1 of the CRD and PAS IGs, and version 2.2.0 of the DTR IG and finalized to replace previously adopted versions upon the effective date of the final rule. The effect of the policies ONC has finalized in section X.E. is that these versions of the IGs will be the only versions health IT developers may use to meet the electronic prior authorization certification criteria as of the effective date of this final rule.

Comment: A few commenters recommended that CMS include drugs as counting toward the Electronic Prior Authorization measure and align any such changes with CMS's payer Prior Authorization API requirements for drugs, stating that drugs administered during hospital stays, including certain cancer therapies typically administered in outpatient settings, could benefit from improved electronic prior authorization timeliness.

Response: We appreciate commenters' recommendations regarding drugs. We recognize that prior authorization for drugs, including drugs administered during hospital stays or in connection with cancer care, may affect timely access to care. At this time, prior authorization for drugs covered under a medical benefit are not within the scope of this measure, nor prior authorization for drugs covered under a prescription benefit. We will take these recommendations into consideration for future rulemaking. We also note that for the MIPS Promoting Interoperability performance category in the CY 2027 PFS proposed rule, we are proposing to adopt a new measure, Electronic Prior Authorization for Prescription Drugs, beginning with the CY 2028 performance period/2030 MIPS payment year (91 FR 44174).

Comment: A commenter requested that CMS allow EHR products used for the Electronic Prior Authorization measure to achieve certification by the last day of the applicable EHR reporting period, consistent with CMS's prior practice. The commenter stated that this flexibility is important for newly proposed measures because technology may be deployed during the performance period while certification remains pending.

Response: We appreciate the commenter's request regarding certification timing. We recognize that new measures may require development, testing, deployment, and certification activities during the EHR reporting period. We confirm that we continue to allow health IT vendors to certify their products by the last day of the relevant EHR reporting period and this practice would still fulfill CMS's expectations with respect to use of CEHRT.

Comment: A commenter recommended that CMS provide additional incentives for eligible hospitals and CAHs and clear interoperability requirements for EHR vendors to ensure that eligible hospitals and CAHs can consistently use and benefit from future electronic prior authorization infrastructure.

Response: We agree that successful implementation depends on alignment among eligible hospitals, CAHs, health IT developers, and payers. However, we did not propose, and therefore are not establishing, additional incentives for this measure beyond the Medicare Promoting Interoperability Program policies finalized in this rule. Interoperability requirements for health IT developers are directly addressed through the voluntary ONC Health IT Certification Program.

Comment: A commenter stated that CMS had not specified how hospitals and CAHs would document, for audit purposes, which certified Health IT Modules were used to satisfy the Electronic Prior Authorization measure, creating implementation uncertainty for hospitals, health IT developers, physicians, and hospital staff. The commenter warned that new or unclear documentation requirements could shift additional administrative burden onto the same personnel expected to use the certified technology, undermining the measure's burden reduction goals. The commenter recommended that CMS and ONC rely on existing Certified Health IT Product List information and standard CEHRT documentation rather than creating new electronic prior authorization record keeping requirements, and that CMS issue sub-regulatory guidance before the effective date. The commenter also recommended that ONC regularly publish information on certified Health IT Module availability and deployment so stakeholders can determine whether the technology environment is ready for the measure's implementation timeline.

Response: We agree that documentation requirements should support program integrity without creating unnecessary recordkeeping burden. As with other measures under the program, eligible hospitals and CAHs should indicate the certified health IT that they used to complete the measures and objectives of the Medicare Promoting Interoperability Program as part of the CMS EHR Certification ID submitted to meet program

requirements. Eligible hospitals and CAHs that report on the Electronic Prior Authorization measure for the EHR reporting period in CY 2027 should include Health IT Modules certified to one or more of the electronic prior authorization criteria in 45 CFR 170.315(g)(31)–(33) that they used to complete the measure as part of their CMS EHR Certification ID. We also intend to continue coordinating with ONC regarding transparency into certified Health IT Module availability so that CMS can monitor progress around deployment of these capabilities.

Comment: A commenter recommended that CMS consider the operational impact of future electronic prior authorization requirements on rural eligible hospitals and CAHs. The commenter stated that many rural hospitals face interoperability and infrastructure barriers outside their control and that imposing additional requirements around interoperability, reporting, or electronic performance before ensuring consistent payer standardization and functionality could disproportionately burden rural hospitals with limited staffing, financial resources, and health IT infrastructure.

Response: We appreciate the concerns regarding rural eligible hospitals and CAHs and recognize that rural hospitals may face resource, staffing, infrastructure, connectivity, and interoperability challenges that affect the implementation of electronic prior authorization. We believe the phased approach for the Electronic Prior Authorization measure, including making the measure optional for the initial year as discussed in section IX.F.5.d of this final rule, helps mitigate burden while allowing eligible hospitals, CAHs, and health IT vendors additional time to prepare. We will continue to monitor implementation experience and consider whether additional guidance, flexibility, or future policy refinements are needed for eligible hospitals and CAHs. We also note our previously stated belief (89 FR 8862) that making the prior authorization process electronic will reduce the time and burden associated with manual prior authorization processes, allowing providers to devote more time to direct patient care, and that this adoption of electronic prior authorization ultimately will reduce provider burnout.

Comment: A commenter recommended that CMS require the ''using CEHRT'' standard as the sole compliance path, with the standard anchored to the finalized versions of the Coverage Requirements Discovery, Documentation Templates and Rules, and Prior Authorization Support IGs.

Response: We thank the commenter for the recommendation, which is in line with the policy being finalized. Our proposal was designed to allow eligible hospitals and CAHs to leverage various certified health IT capabilities, ensuring they can choose the solutions that best fit their operational needs. We remain committed to supporting adaptable approaches that promote participation while minimizing burden for the EHR reporting period in CY 2027, and we will continue to adapt our policies as necessary as hospitals' electronic prior authorization capabilities mature. We note that we are very strongly considering returning to rulemaking in the FY 2028 IPPS/LTCH PPS proposed rule in order to align our requirements to match the proposed requirements for MIPS eligible clinicians in the CY 2027 PFS proposed rule, which proposes to require the use of functionality found in each of the three ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) for CY 2028.

After consideration of the public comments we received, we are finalizing our proposal to modify the text in the measure description to the following:

For at least one medical item or service (excluding drugs) ordered during a hospital encounter that occurs within the EHR reporting period, the prior authorization is requested electronically through a Prior Authorization API using CEHRT.

We also note that in addition to our finalization of the proposals in this final rule, we are very strongly considering further modifying the Electronic Prior Authorization measure in the FY 2028 IPPS/LTCH PPS proposed rule to propose aligning our requirements with the proposed modifications for MIPS eligible clinicians in the CY 2027 PFS proposed rule, if finalized. This would include a proposal to revise the measure to focus on submitting a prior authorization request based on a complete prior authorization workflow as reflected in the combined use of the functionality found in each of the three ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) for CY 2028 (91 FR 44178).

c. Health IT Certification Criteria To Support the Electronic Prior Authorization Measure

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19626), we discussed specifying the use of health IT certified to these certification criteria as required for the Electronic Prior Authorization measure in light of our proposal that an electronic prior authorization must be requested using CEHRT to satisfy the Electronic Prior Authorization measure as well as the finalization of health IT certification criteria in 45 CFR 170.315(g)(31), (32), and (33) in the HTI–4 final rule. We affirm the same approach in this final rule now that we are finalizing those proposals. Use of certified health IT to support electronic prior authorization transactions included in the measure would ensure that eligible hospitals and CAHs have standards-based capabilities within their health IT systems to interact with Prior Authorization APIs established by impacted payers and successfully complete the measure.

As discussed above, the three certification criteria are based on the HL7 Da Vinci CRD, DTR, and PAS IGs, and address different parts of the electronic prior authorization workflow. The ''provider prior authorization API—coverage requirements discovery'' in 45 CFR 170.315(g)(31) enables a health care provider to request information from payers about coverage requirements. Where further information is needed to support a prior authorization request, the ''provider prior authorization API—documentation templates and rules'' criterion in 45 CFR 170.315(g)(32) provides a mechanism for clinicians and other EHR users to navigate and quickly assemble the information needed to support a prior authorization request according to a payer's requirements. Finally, the ''provider prior authorization API—prior authorization support'' in 45 CFR 170.315(g)(33) enables submission of prior authorization requests from health IT systems as well as checking the status of a previously submitted request. By finalizing each component of the workflow as a separate certification criterion, ONC sought to support a more dynamic health IT marketplace in which a health IT developer could develop Health IT Modules demonstrating conformance to all three IGs or focus on a specific element or elements (90 FR 37169).

Different prior authorization scenarios that allow an eligible hospital or CAH to successfully attest to the Electronic Prior Authorization measure may require the functionality of one, or more than one, Health IT Modules certified to the criteria in 45 CFR 170.315(g)(31), (32), and (33). For instance, an eligible hospital or CAH could successfully report on the measure using CEHRT that only includes a Health IT Module certified to the ''provider prior authorization API—coverage requirements discovery'' criterion in 45 CFR 170.315(g)(31). Consider a

hypothetical scenario in which a Medicare Advantage (MA) enrollee has stable coronary artery disease and new exertional dyspnea (feeling shortness of breath during physical exertion). The beneficiary's cardiologist, working in an eligible hospital or CAH, wants to order an outpatient transthoracic echocardiogram (TTE) to assess left ventricular function and valvular disease. When the cardiologist places an order for a TTE in the EHR, a Health IT Module certified to the ''provider prior authorization API—coverage requirements discovery'' criterion (45 CFR 170.315(g)(31)) automatically sends a real-time query to the beneficiary's MA plan endpoint to determine whether prior authorization is required for the requested service (the TTE) and, if so, what documentation is needed. The MA plan returns a CRD response (via CDS Hooks ''card'' [549]) indicating that prior authorization is necessary and has been approved under the beneficiary's plan benefits and network status, including information such as the prior authorization number and assumed billing codes.

In this hypothetical scenario, the prior authorization request is satisfied using only the capabilities represented with the ''provider prior authorization API—coverage requirements discovery'' certification criterion (45 CFR 170.315(g)(31)). The health care provider submitted a query for prior authorization, the payer responded that prior authorization was required, the prior authorization was approved, and the health care provider received a response indicating this approval from the payer using the payer's API. In this case, the receipt of an approval indicates that the health care provider effectively submitted a request for prior authorization, consistent with the requirements of the Electronic Prior Authorization measure.

However, in other scenarios, the initial prior authorization query from a health care provider to a payer could result in a response indicating the need for additional information before a determination as to whether prior authorization is approved or denied can be provided, based on the coverage requirements identified. Additional certified Health IT Modules supporting additional elements of the electronic prior authorization workflow would then need to be used to submit the prior authorization request after collecting the necessary documentation.

[549] A CDS Hooks card is a user-facing, real-time alert or suggestion returned by a Clinical Decision Support (CDS) service to an EHR in response to a specific clinical event. See *https://cds-hooks.org/* for additional information.

Consider another hypothetical scenario where an MA enrollee has been diagnosed with metastatic colorectal cancer. The beneficiary's oncologist, working in an eligible hospital or CAH, has ordered a PET–CT scan and immunotherapy infusion. In this scenario, the oncologist places the order for a PET–CT scan and immunotherapy infusion in the EHR, which is certified to the ''provider prior authorization API—coverage requirements discovery'' criterion (45 CFR 170.315(g)(31)) and automatically queries the beneficiary's MA plan's FHIR API. The EHR receives a response via CDS Hooks card indicating that prior authorization is required for both services and describes coverage criteria and documentation needs. Because the EHR is also certified to 45 CFR 170.315(g)(32), the certified health IT enables the oncologist to complete prior authorization following the DTR IG. An embedded SMART on FHIR app fetches the payer's specific documentation template and rules for oncology prior authorizations. For the PET–CT, the payer's documentation rules ask for the cancer staging information and previous imaging results; for immunotherapy, the payer's documentation rules require the patient's biomarker (for example, PD–L1 expression) status, prior treatment history, and recent lab results. Much of this information can be auto populated because the embedded DTR app uses Clinical Quality Language (CQL) logic and FHIR queries to pull the beneficiary's latest CT scan report and lab results from their medical record, and it confirms her cancer diagnosis and stage from the problem list. The oncologist answers a few additional questions (such as confirming the beneficiary has no contraindications and that a required biomarker test was positive) within the embedded DTR app. By the end of this step, the EHR has compiled all necessary supporting documentation for the prior authorization, ensuring the request will be complete.

Next, the oncologist's office submits the prior authorization request electronically using the capabilities under the ''provider prior authorization API-prior authorization support'' criterion (45 CFR 170.315(g)(33)) to bundle the request and documentation and send it to the MA plan's prior authorization endpoint. This bundle is transmitted via a FHIR RESTful interaction to the payer, as defined by the PAS IG. The EHR's certified Health IT Module ensures the request conforms to the required FHIR structure and sends it securely. Because all required information was provided up front and matched the plan's coverage criteria, the MA plan's system could potentially automatically adjudicate and approve the requests in near real-time. If that happened, the oncologist could now schedule the beneficiary's therapy without delay, confident that the services are covered.

Both scenarios described result in a prior authorization request that successfully satisfies the action required by the proposed Electronic Prior Authorization measure and therefore would allow the eligible hospital or CAH to successfully report the measure. However, each example utilized different combinations of Health IT Modules certified to electronic prior authorization certification criteria in 45 CFR 170.315(g)(31), (32), and (33). In the first scenario, the health care provider used a Health IT Module certified to the ''provider prior authorization API—coverage requirements discovery'' criterion (45 CFR 170.315(g)(31)) to complete actions necessary for the eligible hospital or CAH to successfully attest ''Yes'' to the measure. In the second scenario, the health care provider used Health IT Modules certified to all three of the electronic prior authorization certification criteria to complete all actions for the eligible hospital or CAH to successfully attest ''Yes'' to the measure.

Consistent with these hypothetical examples, we note that an eligible hospital or CAH would be able to successfully attest to the measure using only those certified Health IT Modules necessary for the eligible hospital or CAH to complete the measure. Eligible hospitals and CAHs would not be required to adopt additional electronic prior authorization certified Health IT Modules if they are not needed for the purposes of successfully reporting the measure. We expect that the ability to utilize different combinations of certified Health IT Modules to meet the measure will afford eligible hospitals, CAHs, and health IT developers flexibility in how they deploy, adopt, and use different aspects of certified health IT functionality for electronic prior authorization. We note that we are very strongly considering returning to rulemaking in the FY 2028 IPPS/LTCH PPS proposed rule in order to align our requirements to match the proposed requirements for MIPS eligible clinicians in the CY 2027 PFS proposed rule, which proposes to revise the measure to focus on submitting a prior authorization request based on a complete prior authorization workflow as reflected in the combined use of all three ONC health IT certification criteria

at 45 CFR 170.315(g)(31), (32), and (33) for CY 2028 (91 FR 44178).

d. Finalization of the Electronic Prior Authorization Measure as a Bonus Measure for the EHR Reporting Period in CY 2027

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19627 through 19628), we proposed to modify our previously finalized requirement that an eligible hospital or CAH must report the Electronic Prior Authorization measure to be considered a meaningful EHR user for the EHR reporting period in CY 2027 (89 FR 8911). We stated that, for multiple reasons, eligible hospitals and CAHs may need additional time and flexibility before requiring the Electronic Prior Authorization measure. First, we stated that we recognized that eligible hospitals, CAHs, and health IT developers will need additional time for procurement, integration, and testing to operationalize standards-based electronic prior authorization capabilities that support the Electronic Prior Authorization measure. Second, we stated that stakeholders have indicated that achieving widespread implementation and routine use of these capabilities in CY 2027 may be challenging, particularly for small, rural, and otherwise under-resourced eligible hospitals and CAHs. Third, we stated that we expected additional implementation complexity for eligible hospitals, CAHs, and their vendors due to proposed changes in Prior Authorization API standards requirements that would occur in CY 2027. For these reasons, we stated that we believed that a year of optional reporting will both incentivize adoption of CEHRT through bonus points and offer flexibility to those hospitals and CAHs that could benefit from additional time to test, implement, and deploy CEHRT functionality necessary to support electronic prior authorization.

Therefore, we proposed to make the Electronic Prior Authorization measure, with the proposed measure updates, optional and eligible for 10 bonus points for eligible hospitals and CAHs that attest ''Yes'' to the measure for the EHR reporting period in CY 2027. We stated that allocating 10 bonus points is an appropriate and effective incentive to promote the adoption and use of certified technology for requesting electronic prior authorizations among eligible hospitals and CAHs. An eligible hospital or CAH attesting ''No'' will not earn any bonus points, but attesting ''No'' will also not result in the eligible hospital or CAH failing to meet the measure, and, therefore, failing to meet minimum program requirements and not being considered a meaningful EHR user for the EHR reporting period in CY 2027. This proposal was a modification to the policy we adopted for this measure in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8911). We stated that optional reporting for the first year is particularly important for small, rural, or otherwise under-resourced eligible hospitals and CAHs navigating new measure requirements while minimizing and balancing burden.

Exclusions would not be available for the Electronic Prior Authorization measure for the EHR reporting period in CY 2027, as exclusions are unnecessary for optional measures. Only those eligible hospitals and CAHs that attest ''Yes'' to the measure would receive the 10 bonus points. Given the time eligible hospitals and CAHs have had to become familiar with the Electronic Prior Authorization measure since the 2024 Interoperability and Prior Authorization final rule, we believe making this an optional bonus measure solely for the EHR reporting period in CY 2027 would provide eligible hospitals and CAHs enough time to adopt and begin utilizing the certified health IT necessary to successfully report the Electronic Prior Authorization measure.

We invited public comment on these proposals.

Comment: Many commenters supported the proposal stating that, given the limitations of EHR vendors' current software functionality and the complexity of implementation, additional time is needed to implement the required APIs and IGs to enable prior authorization workflows. Several commenters described it as an appropriate phased approach for eligible hospitals, CAHs, and vendors to implement and test the prior authorization APIs, modify workflows, update policies, train staff, and troubleshoot technical and operational challenges to ensure successful functionality prior to required reporting of the measure. A few commenters agreed that one year of reporting as a bonus measure is sufficient time to test the Prior Authorization APIs, modify workflows as needed, update policies, train staff, and address technical and operational challenges to ensure successful functionality of systems prior to required reporting of the Electronic Prior Authorization measure. A commenter also noted that electronic prior authorization will result in more efficient care while maintaining appropriate controls to prevent fraud. Another commenter supported the proposal stating that current health IT certification criteria support different parts of the electronic prior authorization process separately, including discovery of coverage requirements, and that depending on the service, payer, and clinical scenario, hospitals may need different combinations of certified Health IT Modules to complete a full electronic prior authorization workflow.

Response: We thank commenters for their support. We agree that the additional time prior to this measure becoming required provides eligible hospitals and CAHs the flexibility and stability they may need to develop and update their systems and coordinate with their EHR vendors as necessary. We agree that one year of reporting as a bonus measure is sufficient time to test the Prior Authorization APIs, modify workflows as needed, update policies, train staff, and address technical and operational challenges to ensure successful functionality of systems prior to required reporting of the Electronic Prior Authorization measure.

Comment: A few commenters supported the proposal due to concerns about the disproportionate burden the measure may impose on small, rural, or under-resourced hospitals, and stated these entities would benefit from the additional time to manage the complexities of implementation. A commenter stated that small hospitals have unique challenges to electronic prior authorization implementation such as managing staffing shortages, new transitions from manual to electronic workflows, limited payer coordination, and inadequate technical resources to drive these changes. The commenter expressed appreciation for the proposal, noting that it will support meaningful adoption of the measure while reducing the burden on small facilities. Another commenter expressed concern with the impact on smaller facilities, citing that smaller hospitals, rural hospitals, CAHs, and independent organizations may not have the same health IT vendor relationships, payer connectivity, or technical infrastructure that is available to larger health systems.

Response: We thank commenters for their support. One reason we proposed the Electronic Prior Authorization measure as a bonus measure for the EHR reporting period in CY 2027 rather than a required measure is because requiring the measure may have otherwise caused undue hardship for small, rural, or under-resourced eligible hospitals and CAHs. We agree that the additional time provides eligible small, rural and under-resourced hospitals and CAHs the additional flexibility they may need to develop and update their systems and

coordinate with their EHR vendors given the unique challenges they may face in implementing electronic prior authorization workflows.

Comment: Several commenters who supported the proposal offered recommendations for consideration. A commenter recommended CMS continue evaluating implementation timelines, specifically payer readiness and alignment with ONC-certified Health IT Module availability. The commenter noted, for example, that current payer implementation timelines for the Da Vinci version 2.2 standards may result in eligible hospitals and CAHs having limited reporting periods in the initial implementation year and create operational challenges during the transition. A few commenters recommended that CMS continue to keep the Electronic Prior Authorization measure as a bonus measure through the EHR reporting period in CY 2028. A commenter recommended CMS delay mandatory reporting until CY 2029 or later to allow hospitals adequate time for configuration, testing, and training, and recommended CMS focus on medical services initially and not expand the measure to include other categories, such as drugs. Another commenter recommended that CMS explicitly limit the Electronic Prior Authorization measure bonus reporting period to only the EHR reporting period in CY 2027 and clearly state that this is an optional, incentive-based approach that will not be extended beyond that year. The commenter noted that explicitly stating that the bonus period is time-limited reinforces CMS's expectation that electronic prior authorization will become a standard, required capability rather than a permanently optional measure, and that this would further support operational planning, promote timely adoption of certified technology, and maintain the credibility of the electronic prior authorization measure. A commenter recommended CMS keep its requirements consistent across CMS programs and ONC certification criteria so that developers can build once and deploy across settings rather than maintain duplicative implementations. Another commenter expressed concern that engagement with electronic modalities is heavily reliant on the payers and health IT vendors' capacities to implement these provisions, and they recommended CMS avoid adopting mandatory measures where the activity being evaluated is novel. The commenter also recommended that CMS continue to provide flexibility during implementation and closely monitor payer readiness and technology adoption across the industry before finalizing mandatory reporting requirements, noting that successful electronic prior authorization depends not only on eligible hospital and CAH capabilities, but also on the readiness of health plans, technology vendors, and other industry partners to support these transactions in a consistent and reliable manner.

Response: We thank commenters for their support and recommendations. We note we proposed that the Electronic Prior Authorization measure would be a bonus measure for only the CY 2027 EHR reporting period. Continuing to improve the interoperability of health information exchange by enabling eligible hospitals and CAHs to have more reliable data and provide timely, efficient care are key goals of the Medicare Promoting Interoperability Program. We will continue to monitor technological advancements and strive to maintain the consistency, flexibility, and stability of our policies, and note that one year of reporting as an optional bonus measure provides sufficient time for eligible hospitals and CAHs to successfully deploy and test EHR upgrades by working with vendors, and to address any current challenges to electronic prior authorization implementation. Regarding commenters' feedback about keeping requirements consistent across CMS programs and ONC certification criteria, we reiterate that we will continue to work closely with ONC to evaluate implementation timelines, payer readiness, and alignment with ONC certification criteria availability.

Comment: A commenter recommended that CMS adopt the same optional bonus measure timeline for MIPS-eligible clinicians in CY 2027, citing that alignment across programs would reduce implementation burden for vendors supporting both hospital and ambulatory settings and minimize confusion for clinicians who practice across care settings.

Response: We thank the commenter for their feedback. We plan to continue to work within CMS to evaluate measure implementation timelines and cross-program alignment to streamline requirements where possible. We note in the CY 2027 PFS proposed rule (91 FR 44177), we made a similar proposal that the Electronic Prior Authorization measure would be a bonus measure for only the CY 2027 performance period/2029 MIPS payment year for the MIPS Promoting Interoperability performance category. We note that we are very strongly considering returning to rulemaking in the FY 2028 IPPS/LTCH PPS proposed rule in order to align our requirements to match the proposed requirements for MIPS eligible clinicians in the CY 2027 PFS proposed rule, which proposes to revise the measure to focus on submitting a prior authorization request based on a complete prior authorization workflow as reflected in the combined use of all three ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) for CY 2028 (91 FR 44178).

Comment: A commenter stated that the 2024 CMS Interoperability and Prior Authorization final rule allows up to seven calendar days for standard requests, which in the commenter's experience, is too slow for inpatient and other time-sensitive care. The commenter recommended CMS require payer responses within 72 hours for standard requests and within 24 hours for emergent or expedited requests, noting that FHIR-based APIs and automated adjudication make these timelines feasible. The commenter expressed that if payers can use automation to deny requests quickly, they can also use it to approve them quickly, and that patients should not bear the consequences of payer inefficiency.

Response: We thank the commenter for the recommendation. We did not propose to modify the decision timeframes for impacted payers, as this rulemaking concerns eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program and does not include proposals for impacted payers.

Comment: A few commenters supported the proposal and stated that it would help ease administrative burden. A commenter supported the proposal, noting that it would reduce implementation burden and improve the likelihood of the long-term success of electronic prior authorization as eligible hospitals, CAHs, payers, and health IT vendors move toward standardized electronic prior authorization workflows.

Response: We thank commenters for their support. We agree that the additional time to ensure proper implementation of electronic prior authorization workflows will reduce burden by providing flexibility to those eligible hospitals and CAHs that could benefit from additional time to test, implement, and deploy CEHRT functionality necessary to support electronic prior authorization.

Comment: A few commenters did not support this proposal. A commenter recommended keeping mandatory reporting of the measure for the EHR reporting period in CY 2027 and

including it as a scored measure in the Medicare Promoting Interoperability Program, noting the importance of advancing the adoption of electronic prior authorization because it would drive improvements in reducing cost through more efficient and timely health care, lower administrative burden, and help prevent unsafe, low-value care. The commenter stated that the measure should be mandatory because a voluntary measure will not be a meaningful incentive to eligible hospitals and CAHs.

Response: While we understand the importance of providing timely incentives to drive the adoption of electronic prior authorization, one year of optional reporting of the measure would not delay or impede the progress eligible hospitals and CAHs have made in implementation of electronic prior authorization workflows. We proposed the Electronic Prior Authorization measure would be a bonus measure for only the EHR reporting period in CY 2027 to both incentivize adoption of CEHRT through bonus points and offer flexibility to those hospitals and CAHs that could benefit from additional time to test, implement, and deploy CEHRT functionality necessary to support electronic prior authorization. Finalizing the measure as an optional measure for the EHR reporting period in CY 2027 allows eligible hospitals and CAHs to explore electronic prior authorization transactions using version 2.2 of the Da Vinci IGs underlying the certification criteria in 2027 without imposing immediate requirements that could create challenges for entities that have not yet deployed CEHRT, which will be required to use version 2.2 of the Da Vinci IGs as part of ONC Health IT Certification Program requirements.

For more information about the standards required for health IT developers certifying Health IT Modules to the electronic prior authorization criteria in 45 CFR 170.315(g)(31)–(33), see section X.E. of this final rule, in which ONC has adopted version 2.2.1 of the CRD and PAS IGs, and version 2.2.0 of the DTR IG. The effect of the policies ONC has finalized in section X.E. is that these versions of the IGs will be the only versions health IT developers may use to meet the electronic prior authorization certification criteria as of the effective date of this final rule.

Comment: A few commenters did not support the proposal for other reasons. A commenter opposed required reporting in CY 2028 because they stated it would impose a new certification-based compliance requirement too quickly despite limited certified module deployment and evolving IGs. The commenter recommended a more gradual transition with alternative compliance pathways. A commenter opposed the proposal, stating they do not support adding new required measures under the Medicare Promoting Interoperability Program. The commenter suggested electronic prior authorization tools should reduce burden and gain adoption voluntarily if they are functional, reliable, and well-integrated into clinical workflows, rather than through additional reporting requirements.

Response: We appreciate commenters' concerns. We recognize that electronic prior authorization implementation depends on certified technology availability, standards implementation, and workflow integration, and that some eligible hospitals and CAHs may need time to adopt the applicable functionality. We continue to believe, however, that use of CEHRT is appropriate for this measure because it aligns with ONC's electronic prior authorization certification criteria and promotes consistent, standards-based implementation across health care providers, health IT developers, and payers. We also believe that including the measure in the Medicare Promoting Interoperability Program will advance broader adoption of electronic prior authorization in a manner consistent with the program's goals of improving interoperability and assessing meaningful use of CEHRT.

Comment: A few commenters provided recommendations regarding the proposal. A commenter stated that adoption challenges vary significantly across clinical settings and service lines, and that certain specialties such as oncology and other complex care environments may encounter unique operational and workflow challenges as electronic prior authorization processes are integrated into existing clinical and revenue cycle systems. The commenter also expressed concern that implementation of electronic prior authorization remains dependent on a complex ecosystem of payers, intermediaries, health IT developers, and third-party platforms, and that eligible hospitals and CAHs often navigate varying payer requirements, health IT vendor relationships, and transaction pathways, which can create additional administrative complexity and costs. Another commenter expressed concern that while standards-based APIs represent an important step toward greater consistency, eligible hospitals and CAHs continue to encounter fragmented implementation approaches that may require separate technical integrations or operational processes depending on the payer and technology platform involved and may also require additional investments.

Response: We acknowledge the commenters' concerns and recognize that eligible hospitals, CAHs, and health IT developers need additional time for procurement, integration, and testing to operationalize standards-based electronic prior authorization capabilities that support the Electronic Prior Authorization measure, and that implementation in certain care settings is more complex. Achieving widespread implementation and routine use of these capabilities during the EHR reporting period in CY 2027 may be challenging, and that is why we proposed one year of optional reporting for this measure. There may be additional implementation complexity for eligible hospitals, CAHs, and their health IT vendors due to the proposed changes in Prior Authorization API standards requirements in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule that would occur in CY 2027 (91 FR 19908), and this is another reason we proposed one year of optional reporting. This one year of optional reporting will both incentivize adoption of CEHRT through bonus points and offer flexibility to those eligible hospitals and CAHs that could benefit from additional time to test, implement, and deploy CEHRT functionality necessary to support electronic prior authorization.

Comment: A commenter expressed concern that successfully reporting the bonus measure for the EHR reporting period in CY 2027 would be limited by the ability of health IT vendors to certify their Health IT Modules on time. The commenter recommended that, if CMS finalizes its proposal to make the measure a bonus measure for the EHR reporting period in CY 2027, CMS should consider permitting Health IT Module certification to be in place by the end of the reporting period instead of the beginning of the reporting period, given implementation challenges.

Response: We acknowledge that some eligible hospitals and CAHs may face barriers to advancing their electronic prior authorization workflows based on limitations in health IT vendor readiness. We took this into consideration in developing the proposed timeline of the measure, and this is one reason we proposed that the Electronic Prior Authorization measure would be an optional bonus measure and would not negatively impact scoring for eligible hospitals and CAHs that do not participate for the EHR reporting period in CY 2027. We confirm that we intend to continue to

allow certification of the relevant Health IT Modules and functionality to occur by the end of the applicable EHR reporting period rather than requiring that certification be in place beforehand.

After consideration of the public comments we received, we are finalizing our proposal to make the Electronic Prior Authorization measure, with the proposed measure updates, optional and eligible for 10 bonus points for eligible hospitals and CAHs that attest ''Yes'' to the measure for the EHR reporting period in CY 2027.

e. Required Reporting of the Electronic Prior Authorization Measure Beginning With the EHR Reporting Period in CY 2028

When we adopted the Electronic Prior Authorization measure in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), we finalized that eligible hospitals and CAHs would be required to attest to the Electronic Prior Authorization measure beginning with the EHR reporting period in CY 2027 (89 FR 8910) and that only a ''Yes'' attestation, or claiming an applicable exclusion, would fulfill the requirements of the measure. Additionally, we finalized that although the measure would not be scored (that is, not assigned points for a ''Yes'' attestation) for the EHR reporting period in CY 2027, a ''No'' attestation would result in the eligible hospital or CAH not meeting the measure. The eligible hospital or CAH would therefore not meet minimum program requirements and not be considered a meaningful EHR user for the relevant EHR reporting period and be subject to a downward payment adjustment (89 FR 8911).

As discussed in section IX.F.5.d, we are finalizing our proposal to make the Electronic Prior Authorization measure optional for the EHR reporting period in CY 2027. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19628), we also proposed that, should we finalize that proposal, eligible hospitals and CAHs would be required to attest ''Yes'' to the updated Electronic Prior Authorization measure beginning with the EHR reporting period in CY 2028. Consistent with the revised text we proposed for the measure, we also proposed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19628 through 19629) that an eligible hospital or CAH must request a prior authorization electronically using CEHRT to send a request through a payer's Prior Authorization API for at least one medical item or service (excluding drugs) ordered during a hospital encounter that occurs within the EHR reporting period to attest ''Yes'' to the measure, or else the eligible hospital or CAH must claim an applicable exclusion. Only a ''Yes'' attestation or claiming an applicable exclusion would fulfill the requirements of the measure. A ''No'' response would result in the eligible hospital or CAH not meeting measure requirements. We proposed that if an eligible hospital or CAH does not meet the measure requirements, it would not meet minimum program requirements nor be considered a meaningful EHR user for an EHR reporting period, and, therefore, the hospital would be subject to a downward payment adjustment. This proposed change mirrors the response requirements we adopted when we first adopted the measure but applies them to the EHR reporting period in CY 2028. We proposed this modification to provide eligible hospitals and CAHs additional time to prepare to successfully report the measure, consistent with making the measure an optional bonus measure for the EHR reporting period in CY 2027.

We proposed that the measure exclusions originally adopted in the 2024 Interoperability and Prior Authorization final rule (89 FR 8916 through 8923) would be available to eligible hospitals and CAHs for the EHR reporting period in CY 2028 and subsequent years. The available exclusions would be: (1) an eligible hospital or CAH did not order any medical item or service (excluding drugs) requiring prior authorization during the EHR reporting period; or (2) the eligible hospital or CAH only ordered medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets CMS's specified Prior Authorization API requirements during the applicable EHR reporting period.

When we adopted the Electronic Prior Authorization measure in the 2024 Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), we finalized that eligible hospitals and CAHs would report the measure as an unscored attestation for only the EHR reporting period in CY 2027 (89 FR 8910), but we did not specify its scoring methodology for subsequent years because we determined that it would be more appropriate to determine the measure's scoring structure closer in time to its effective date. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19629), we proposed that the Electronic Prior Authorization measure would remain unscored for the EHR reporting period in CY 2028 and subsequent years, which would allow time for eligible hospitals and CAHs to adjust to the new electronic prior authorization workflow using Prior Authorization APIs without undue focus on scoring implications in the Medicare Promoting Interoperability Program. We stated that we believe that the Electronic Prior Authorization measure will retain its importance as an aspect of health information exchange.

We invited public comment on this proposal.

Comment: Several commenters supported the proposal because it would allow additional time to properly implement the new measure. Across these comments, there was broad support for making the Electronic Prior Authorization measure a bonus measure in CY 2027 and requiring it beginning in CY 2028, with commenters describing that timeline as a pragmatic, phased approach that better matches the operational and technical realities of implementation. Several commenters expressed that the added time is needed for implementation, testing, validation, integration, and workflow redesign before the measure becomes mandatory. A few commenters pointed to the clinical and technical complexity of electronic prior authorization workflows, including dependencies on EHR vendors, certified technology, and payer readiness. A few commenters stated current EHR functionality and broader market readiness are not yet sufficient to support the measure as intended, making a delayed or phased rollout more workable. A few commenters supported the phased approach because it would allow eligible hospitals, CAHs, and developers to adopt the electronic prior authorization workflow more gradually and meaningfully. A few commenters also supported the proposal because of the longer-term benefits of standardized electronic prior authorization, including reduced administrative burden, faster approvals, and improved patient access to care.

A few commenters expressed general support for the proposal to phase in the Electronic Prior Authorization measure and delay making the measure a required measure, including making reporting initially optional before transitioning to a required measure. One such commenter commended CMS' continued efforts to advance interoperability and promote more standardized electronic prior authorization processes across the health care system. Another commenter stated continued progress on data interoperability would benefit patients, eligible hospitals, CAHs, and care outcomes. A commenter stated that movement to facilitate electronic prior

authorization could reduce turnaround times for approvals, improve timely access to care, and maintain appropriate safeguards against fraud.

Response: We thank commenters for their support. We agree that making the Electronic Prior Authorization measure a bonus measure for the EHR reporting period in CY 2027 and a required measure beginning with the EHR reporting period in CY 2028 provides an appropriate phased approach for implementation. We recognize that successful electronic prior authorization workflows require coordination among eligible hospitals, CAHs, health IT developers, and payers, as well as time for development, certification, testing, integration, validation, and workflow redesign. We also agree that continued progress toward standardized electronic prior authorization can reduce administrative burden, provide more timely prior authorization decisions, improve patient access to care, and foster greater interoperability across the health care system.

Comment: Several commenters did not support the proposal as written. Several commenters said the measure should remain optional for longer, with some recommending optional reporting through the EHR reporting period in CY 2028 and delaying mandatory reporting until the EHR reporting period in CY 2029 or later. A few commenters generally cited the need for additional time to test, implement, configure, train, and operationalize electronic prior authorization workflows; significant technical build requirements, workflow redesign, and staff training needs; continued dependence on vendor readiness, payer participation, and external partner alignment. A few commenters stated concerns that FHIR standards, APIs, and IGs are still maturing and may not yet be sufficiently tested across real-world settings. A few commenters cited competing IT priorities across multiple regulatory programs and their view that eligible hospital and CAH compliance should not depend on payer API readiness or uneven standards-based functionality across markets.

Several commenters also recommended CMS avoid making the measure a required measure until the broader ecosystem (including payers, vendors, and standards) is ready and workflows can be implemented reliably. A few commenters recommended conditioning making the measure a required measure on demonstrated payer and health IT vendor readiness, avoiding penalties for failed transactions or incomplete payer participation, and providing clearer guidance on measure specifications, exclusions, and acceptable workflows, including how the measure would apply in different hospital electronic prior authorization scenarios.

Response: We appreciate commenters' concerns regarding the timing and readiness of the health IT functionality to support the Electronic Prior Authorization measure. We recognize that implementation will require technical build, testing, configuration, staff training, workflow redesign, and coordination with health IT developers, payers, and other external partners. We also acknowledge commenters' concerns regarding standards maturity, payer API readiness, and variation in implementation across markets. However, we believe that finalizing the measure as an optional bonus measure for the EHR reporting period in CY 2027 before making the measure a required measure beginning with the EHR reporting period in CY 2028 provides a reasonable and balanced transition period. This approach gives eligible hospitals, CAHs, developers, payers, and other partners time to gain implementation experience while continuing to advance standardized electronic prior authorization. We note that we have proposed in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (91 FR 19908) that payers impacted by that regulation would need to use the same standards required for health IT certification criteria beginning on October 1, 2027. We also note the importance of wide, cross-sector efforts to improve prior authorization that depend on participation from eligible hospitals and CAHs in addition to payers and health IT developers.[550]

Comment: A commenter recommended that CMS ensure that electronic prior authorization requirements are supported by mature, fully tested IGs before requirements for eligible hospitals and CAHs become mandatory. The commenter suggested IGs should be validated through real-world testing across multiple payer and EHR environments, health care provider types, and shared service settings before eligible hospitals and CAHS are held accountable. The commenter also cautioned that, without that testing, rural and low-resourced hospitals, including CAHs, could face inconsistent workflows, manual workarounds, operational disruption, duplicative effort, and compliance risk due to infrastructure gaps outside their control.

Response: We appreciate the commenter's recommendation and recognize the importance of mature, tested IGs and standards-based workflows for successful electronic prior authorization implementation. We refer readers to section X.E. of this final rule for additional discussion about the IG versions included in certification. We also agree that implementation depends on appropriate testing among health IT developers, payers, health care providers, and other partners, and that rural and low-resourced hospitals, including CAHs, may face additional challenges related to infrastructure, staffing, shared services, and payer connectivity. We believe the phased implementation approach, under which the measure would be an optional measure for the EHR reporting period in CY 2027 before becoming a required measure for the EHR reporting period in 2028, will provide adequate additional time for testing, standards adoption, and operational readiness. We will continue to monitor eligible hospitals' and CAHs' implementation experience and coordinate with ONC and other CMS components as standards, IGs, and payer-facing requirements continue to mature.

Comment: Many commenters supported CMS' goal of advancing electronic prior authorization, but recommended pairing implementation with clearer operational guidance, stronger payer accountability, and timelines that reflect the current readiness of payers, health IT vendors, and health IT infrastructure. Several commenters expressed that expectations for eligible hospitals and CAHs should be aligned with the readiness of payer APIs, health IT vendors, certification tools, staffing, and technical infrastructure. These commenters emphasized that inconsistent or immature payer and health IT vendor capabilities could force eligible hospitals and CAHs into duplicative manual workflows and undermine the intended burden reduction of electronic prior authorization.

A few commenters requested clearer operational guidance on how the measure would work in practice. Suggestions included allowing prior authorization at any point during an encounter rather than only at discharge, clarifying qualifying workflows and eligible services, defining exclusions with numeric thresholds, and explaining whether all three certified electronic prior authorization functions must be available throughout the reporting period. A few commenters

[550] For more information, see: *https://www.cms.gov/newsroom/press-releases/cms-announces-early-adopters-advance-solutions-electronic-prior-authorization-accelerating-momentum.*

recommended CMS preserve flexibility and avoid moving faster than standards, testing tools, certification, and implementation support allow. These commenters supported phased adoption, continued stakeholder engagement, technical assistance, and timelines that reflect the reality of evolving IGs and vendor readiness.

Response: We agree that electronic prior authorization is most effective when health care providers, payers, health IT vendors, eligible hospitals, CAHs, and standards-based capabilities are aligned. The Electronic Prior Authorization measure is intended to encourage eligible hospitals and CAHs to adopt standards-based workflows using CEHRT. Under the measure finalized in this rule, eligible hospitals and CAHs are not required to have all three certified electronic prior authorization functions available during the EHR reporting period. However, we are very strongly considering proposing in next year's rulemaking to align this aspect of the measure with similar proposals under the MIPS Promoting Interoperability performance category for CY 2028. We will consider commenters' requests for additional guidance on qualifying workflows, eligible services, exclusions, timing during the encounter, and certified functionality as we develop additional resources and sub-regulatory guidance. We also recognize concerns regarding rural and under-resourced health care providers, health IT vendor readiness, payer API implementation, and evolving IGs. We believe the phased approach, including making the Electronic Prior Authorization measure an optional measure for the EHR reporting period in CY 2027 before the measure becomes a required measure beginning in the EHR reporting period in CY 2028, provides additional time for implementation, testing, and workflow redesign.

Comment: Several commenters suggested the measure would only reduce burden if payers are also held accountable for timely, meaningful decisions. These commenters recommended CMS require faster payer turnaround times, address large gaps between initial denials and appeal overturns, curb ''deny first, appeal later'' practices, and consider the patient care consequences of delayed prior authorizations. A few commenters suggested that electronic prior authorization should be paired with broader efforts to reduce the overall volume of prior authorization requirements. These commenters called for more deliberate and limited use of electronic prior authorization, consideration of exemptions or gold-carding, and reassessment of which services truly warrant prior authorization.

Response: Broader payer obligations, prior authorization timeframes, considerations regarding more limited use of electronic prior authorization, exemptions, gold-carding, and assessment of which services warrant prior authorization, and related process requirements are being addressed through multi-pronged HHS efforts, including CMS and ONC policies and rulemaking, as applicable. However, comments regarding these topics are outside the scope of this proposal. In addition to our rulemaking efforts in this respect, we note additional CMS efforts to advance solutions for electronic prior authorization. These efforts include promoting API-enabled data exchange for prior authorization using FHIR-based standards as well as defined timeframes for prior authorization decisions.[551]

Comment: A commenter suggested that making the measure mandatory but unscored would create a mismatch between implementation cost, financial risk, and program incentives. This commenter recommended awarding eligible hospitals and CAHs points once the measure becomes mandatory, so hospitals are not asked to invest heavily while facing downside payment risks. A commenter recommended that CMS expand the measure to include drugs, consistent with the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule.

Response: We do not believe that there is a mismatch between implementation cost, financial risk, and program incentives and having the measure be unscored. Whether we assign points or not to the measure, all eligible hospitals and CAHs are required to attest ''Yes'' to the updated Electronic Prior Authorization measure or claim an exclusion to avoid a downward payment adjustment. Therefore, the unscored measure retains sufficient incentive to reflect the implementation cost and financial risk.

After consideration of the public comments we received, we are finalizing our proposal that eligible hospitals and CAHs would be required to attest ''Yes'' to the updated Electronic Prior Authorization measure or claim an exclusion beginning with the EHR reporting period in CY 2028 in order to be a meaningful EHR user and that the measure will be unscored. We note that we are very strongly considering returning to rulemaking in the FY 2028 IPPS/LTCH PPS proposed rule in order to align our requirements to match the proposed requirements for MIPS eligible clinicians in the CY 2027 PFS proposed rule, which proposes to revise the measure to focus on submitting a prior authorization request based on a complete prior authorization workflow as reflected in the combined use of all three ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) for CY 2028 (91 FR 44178).

[551] For more information, see: *https://www.cms.gov/newsroom/press-releases/cms-announces-early-adopters-advance-solutions-electronic-prior-authorization-accelerating-momentum.*

f. Request for Information on Future Potential Performance-Based Measure of Electronic Prior Authorization

While we believe the current measure requirement of achieving ''at least one'' electronic prior authorization is appropriate for the initial inclusion of the measure in the Medicare Promoting Interoperability Program, we do not expect this minimal requirement to fully increase electronic prior authorization usage over time. Therefore, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19629), we sought comments on potential future updates we could make to this measure to incentivize eligible hospitals and CAHs to use electronic prior authorization for a more substantial set of the electronic prior authorization requests that they submit over the course of an EHR reporting period. Consistent with statutory requirements in section 1886(n)(3)(A)(ii) of the Act, we envision that expanding the scope of the measure in future rulemaking would lead to increased interoperable exchange of data that would not only decrease administrative burden but could improve the quality of health by reducing the time needed for a patient to get access to necessary medical services and items. Reducing delays in the exchange of data and as a result providing patients care more efficiently, drives better care coordination, which is a key objective of meaningful use. Additionally, because electronic prior authorization requires data sharing, this advances interoperability, which is a primary focus of meaningful use.

We also intend to drive consistent adoption of certified health IT capabilities supporting the complete electronic prior authorization workflow over time, by requiring eligible hospitals and CAHs to address a wider array of prior authorization requests that require more complex interactions with payers. The public input we received will contribute to future considerations for potentially updating the Electronic Prior Authorization measure in a manner that helps achieve HHS's goals of promoting

meaningful use of certified EHR technology, electronic exchange of health information, and submission of clinical quality measures.

We invited comments on how we can further strengthen the Electronic Prior Authorization measure in a manner that incentivizes progress while minimizing burden on eligible hospitals and CAHs. We also sought comment on barriers and challenges small, rural, or otherwise under-resourced eligible hospitals and CAHs might face reporting a performance-based electronic prior authorization measure.

Commenters generally supported CMS' goal of advancing electronic prior authorization and recognized its potential to reduce administrative burden, improve transparency, speed access to care, and support interoperability, but many urged CMS to proceed cautiously before adopting any future performance-based measure. Commenters recommended that CMS use a phased approach, including sequential implementation of coverage requirements discovery, documentation templates and rules, and prior authorization support, and avoid performance thresholds until payer APIs, EHR functionality, IGs, certification tools, and health care provider workflows are mature and tested. Many commenters emphasized that performance measurement would depend heavily on factors outside hospital control, including payer readiness, vendor capabilities, API reliability, service-line coverage, and inconsistent payer requirements, and recommended payer accountability, shared or bi-directional performance measures, public reporting of payer responsiveness, and protections against penalizing health care providers for payer-side failures.

Commenters also requested clearer measure specifications regarding attribution, numerator and denominator construction, qualifying workflows, payer errors, exclusions, and whether checking if prior authorization is required should count as a meaningful electronic action. Several commenters cautioned that rural, small, CAH, and under-resourced hospitals could face disproportionate costs and workflow disruption, and recommended flexibility, hardship exemptions, technical assistance, and phased timelines.

We appreciate all the comments and interest in this topic. While we are not responding to specific comments in response to the RFI in this final rule, we believe that this input is very valuable and will continue to take all concerns, comments, and suggestions into account for future development and consideration of this measure for the Medicare Promoting Interoperability Program. We thank commenters for their responses and will take them into consideration for future rulemaking.

6. Adoption of the Unique Device Identifiers for Implantable Medical Devices Measure in the Public Health and Clinical Data Exchange Objective

a. Background

Under section 519(f) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(f)), the Food and Drug Administration (FDA) issued regulations establishing a unique device identification system [552] for medical devices (78 FR 58786).[553] The Unique Device Identifier (UDI) is a standard identifier that adequately identifies a medical device from manufacturing through distribution to patient use. The UDI is composed of the Device Identifier (UDI–DI), which identifies the specific version or model of a device and the labeler of that device, and the Production Identifier(s) (UDI–PI), which contain production information about a device such as lot or batch number, serial number, expiration and manufacturing dates, and distinct identification code for human cellular or tissue-based products regulated as devices.[554] The FDA UDI system requires device labelers to include UDIs on device labels and packages in both human readable form and machine-readable form such that it can be read by a bar code scanner or other similar technology,[555] and submit device identification information to FDA's Global Unique Device Identification Database (GUDID), which is accessible from two public portals, AccessGUDID[556] and OpenFDA.[557]

FDA designed the UDI system to serve multiple public health objectives by enabling rapid and accurate device identification throughout distribution and use (78 FR 58786). UDIs can reduce medical errors by allowing health care providers to positively identify devices and access key attributes through GUDID rather than consulting multiple and potentially inconsistent sources, thus eliminating confusion that can lead to inappropriate device use. The UDI system also allows for accurate identification of devices associated with adverse events, enabling manufacturers and FDA to more rapidly aggregate and analyze related reports, isolate underlying problems, and develop appropriate solutions for safety issues. Routine inclusion of UDIs as discrete data elements in EHRs and registries would enable accurate identification of devices used during patient care delivery, facilitate rapid notification and follow-up care during recalls, and improve care coordination across health care providers. Additionally, discrete documentation of UDI strengthens real-world data sources for use across the device lifecycle, which will improve the FDA's ability to conduct post-market surveillance and outcomes-based research.[558] UDIs also enable more efficient and effective inventory and supply chain management, providing the foundation for a global, secure distribution chain, helping to address counterfeiting and diversion while supporting preparedness for medical emergencies.

While the foundation for the UDI system is established with UDI being present on device labels and data available in GUDID, the health care system has yet to achieve broad adoption of UDI documentation. Fully realizing the benefits of the UDI system depends on UDIs being integrated into data sources throughout the health care system, including the supply chain, EHRs, medical device registries, and claims.[559] [560] Multiple barriers and challenges to UDI adoption have been noted,[561] including lack of knowledge across the health care system about the benefits and return on investment for UDI implementation, and lack of regulatory and policy mandates.

However, capabilities to capture UDI in the EHR have been widely adopted by eligible hospitals and CAHs. In the ONC Health IT Certification Program, the ''implantable device list'' certification criterion at 45 CFR 170.315(a)(14) requires Health IT Modules certified to the criterion to record and allow a user to access a list of UDIs associated with a patient's implantable devices. This certification

[552] For more information, see: *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.*

[553] *https://www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system.*

[554] 21 CFR 801.3. See also, *https://accessgudid.nlm.nih.gov/about-gudid#what-is-udi.*

[555] *https://www.fda.gov/media/99084/download.*

[556] *https://accessgudid.nlm.nih.gov/.*

[557] *https://open.fda.gov/apis/device/udi/.*

[558] *https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence.*

[559] Wang X, Ayakulangara Panickan V, Cai T, Xiong X, Cho K, Cai T, Bourgeois FT. Endovascular aneurysm repair devices as a use case for postmarketing surveillance of medical devices. JAMA Internal Medicine. 2023 Oct;183(10):1090–7.

[560] Rathi VK, Ross JS, Redberg RF. Unique device identifiers—missing in action. JAMA internal medicine. 2023 Oct;183(10):1049–50.

[561] *https://nestcc.org/wp-content/uploads/NESTcc-UDI-Playbook_11-15-2022.pdf.*

criterion is currently included in the Base EHR definition and has been widely implemented in health IT products, with 341 Health IT Modules identified as certified to the criterion. Other certification criteria also support the use of UDI. Under the ''standardized API for patient and population services'' criterion in 45 CFR 170.315(g)(10), which is also included in the Base EHR definition, a certified Health IT Module must be able to make UDI information for a patient's implantable device(s) available using a standards-based API according to the HL7 FHIR US Core IG, the STU 6.1.0 FHIR IG. Additionally, the criteria at 45 CFR 170.315(b)(1)—''transitions of care'' and 45 CFR 170.315(b)(2)—''clinical information reconciliation and incorporation,'' which have long been required for measures in the Health Information Exchange Objective, support the ability for health care providers to receive, send, and reconcile documents that contain UDI information.

The wide use of products certified to these criteria indicates that eligible hospitals and CAHs have the ability to store and exchange UDIs if UDIs have been recorded through documentation.[562] Published evidence via health system case studies show that capturing UDI using barcode scanning at the point of care is operationally feasible.[563] [564] In cardiac catheterization lab implementation studies, barcode scanning was successfully integrated into routine workflows to link UDIs with clinical records.[565] Frontline nursing evaluations in surgical services report that implant barcode scanning is workable in practice.[566] Together, these studies demonstrate that structured UDIs captured in EHRs using barcode technology can be implemented without substantial workflow disruption.

b. Adoption of the Unique Device Identifiers for Implantable Devices Measure Beginning With the EHR Reporting Period in CY 2027

As we stated in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19630), the routine, electronic capture and discrete storage of UDIs for implantable medical devices directly advances the Secretary's core responsibility, articulated in the statutory authority for the Medicare Promoting Interoperability Program, to improve the use of electronic health records and health care quality over time. Such electronic capture and discrete storage of UDIs would advance the safety of health care, an essential element of health care quality. Broader use of UDIs is similarly aligned with the meaningful use of CEHRT through the Medicare Promoting Interoperability Program. A primary aspect of the meaningful use of CEHRT is whether valuable data are captured at the point of care and available for subsequent exchange and use by health care providers. For example, in the ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program'' final rule (75 FR 44328), the precursor program to the Medicare Promoting Interoperability Program, we implemented multiple data capture-related measures such as ''Record Smoking Status'' and ''Maintain Active Medication List'' because, as we noted, the availability of pertinent clinical data is important to the meaningful use of CEHRT. We stated that integrating a UDI-focused measure into the Medicare Promoting Interoperability Program would foster consistent workflows for capturing device data as discrete EHR elements and strengthen the ability of eligible hospitals, CAHs, beneficiaries, and public health agencies to use interoperable health information to improve outcomes, manage risk, and respond rapidly to device-related safety concerns. We also noted that multiple studies and pilots have discussed the ease of UDI capture at the point of care through bar code scanning, storage in the EHR, and transmission to the health plan through claims.[567] [568]

Therefore, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19630 through 19632) we proposed to adopt the Unique Device Identifiers for Implantable Medical Devices measure under the Public Health and Clinical Data Exchange objective. We stated that this measure would further public health surveillance benefits that would arise from capturing the UDI for implanted medical devices.

Measure Description: The eligible hospital or CAH uses CEHRT during the EHR reporting period to electronically capture and store, as one or more discrete data elements within the patient's electronic health record, the complete Unique Device Identifier (UDI), which includes the device identifier and, when present on the device label, the production identifier, for each implantable medical device subject to UDI requirements used for patient care delivery.

Reporting Requirements: ''Yes'' or ''No'' attestation.

Exclusion: The eligible hospital or CAH implanted five or fewer medical devices subject to UDI requirements during the calendar year of the applicable EHR reporting period.

We proposed to require eligible hospitals and CAHs to attest to this measure beginning with the EHR reporting period in CY 2027. We proposed that eligible hospitals and CAHs would be required to attest ''Yes'' or ''No'' to meet measure requirements or claim an applicable exclusion. Failure to attest ''Yes'' or ''No'' or claim an applicable exclusion would result in the eligible hospital or CAH being subject to a downward payment adjustment for not meeting minimum program requirements. We proposed that no points will be assigned to this measure; rather, it would be one of seven measures required to satisfy the Public Health and Clinical Data Exchange objective. We proposed to allow both ''Yes'' and ''No'' responses, which would allow eligible hospitals and CAHs to become familiar with UDI and highlight its importance while avoiding undue burden. We also noted that the measure only applies to implantable medical devices subject to UDI requirements under 21 CFR 801.20(a) and 21 CFR part 830, subpart E, which represents most implantable medical devices. We noted that under certain circumstances,[569] some devices, such as investigational devices, devices for research use only, and custom devices, are excepted from UDI requirements and are therefore not included in this measure. In the proposed rule, we also stated that we intend to propose modifications to this measure in future rulemaking to further promote the appropriate capture of UDIs within the EHR. We proposed one exclusion for the UDIs for Implantable Medical Devices measure and invited comments on any additional exclusions that should be considered in the future.

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19631), there are numerous ONC health IT certification criteria that reference UDI,

[562] *https://chpl.healthit.gov/#/search.*

[563] *https://www.ahrmm.org/resource-repository-ahrmm/stanford-health-care-udi-capture-work-group-case-study-2017-1.*

[564] *https://www.ahrmm.org/resource-repository-ahrmm/baptist-health-udi-capture-work-group-case-study-2017-1.*

[565] *https://pubmed.ncbi.nlm.nih.gov/27343161/.*

[566] Wilson N, Jehn M, Kisana H, Reimer D, Meister D, Valentine K, Reiser M, Clarke H. Nurses' perceptions of implant barcode scanning in surgical services. CIN: Computers, Informatics, Nursing. 2020 Mar 1;38(3):131–8.

[567] Krupka, Dan C. Ph.D., et.al. Transmitting Device Identifiers of Implants From the Point of Care to Insurers: A Demonstration Project. Journal of Patient Safety 17(3):p 223–230, April 2021. | DOI: 10.1097/PTS.0000000000000828 Journal of Patient Safety.

[568] N Wilson, et.al., Advancing Patient Safety Surrounding Medical Devices: Barriers, Strategies, and Next Steps in Health System Implementation of Unique Device Identifiers—PubMed.

[569] 21 CFR 801.30.

including the ''implantable device list'' certification criterion in 45 CFR 170.315(a)(14), which would be required to support the measure. However, we noted that ONC proposed to remove this criterion in the HTI–5 proposed rule (90 FR 60983), and that if ONC finalizes removal of this criterion, it would no longer be required to support the measure. Separate from this dedicated certification criterion, UDI is a named data element within USCDI Version 3 as the ''Unique Device Identifier(s) for a patient's implantable device(s)'' and therefore is a supported element within the HL7 FHIR US Core IG STU 6.1.0 IG, which Health IT Modules certified to the certification criterion at 45 CFR 170.315(g)(10) must be capable of using to respond to requests for patient data. We identified the criterion at 45 CFR 170.315(g)(10) as required to support fulfillment of the measure, which is also part of the Base EHR definition in 45 CFR 170.102 and already incorporated into the definition of CEHRT at 42 CFR 495.4. We welcomed comments as to whether other certification criteria should be considered to support this measure.

We invited public comment on these proposals, to include the feasibility of the timeline, additional exclusions, and any additional certification criteria that we should consider for this measure in future rulemaking.

Comment: Many commenters supported our proposal to adopt the Unique Device Identifiers for Implantable Medical Devices measure, noting that recording UDI in EHRs would improve post-market surveillance and care coordination, reduce patient safety risks, and enable faster, more accurate public health responses. Several commenters noted that allowing for ''Yes'' and ''No'' attestation is reasonable for preparing eligible hospitals and CAHs for future modifications to the UDI measure.

Response: We thank the commenters for their support, and we agree that standardized UDI capture in EHRs would improve post-market surveillance, reduce patient safety risks, and enable faster, more accurate public health responses.

Comment: A few commenters generally supported the proposed UDI measure but requested clarification regarding the scope of the implantable device requirements, including what devices qualify and whether they apply only to the health care provider inserting the device or also to devices implanted by another health care provider.

Response: We intend this measure to apply to medical devices implanted by the eligible hospital or CAH during the EHR reporting period that are subject to FDA's UDI requirements under 21 CFR 801.20(a) and 21 CFR part 830, subpart E. We note that devices excepted under the general exceptions from UDI requirements at 21 CFR 801.30 would also be excepted from this measure.

Comment: Several commenters asked that CMS clarify whether eligible hospitals and CAHs may use CEHRT alone or in combination with integrated non-CEHRT systems to capture, validate, reconcile, exchange, and transmit complete, structured UDI data into the EHR. Commenters stated that this approach that allows use of integrated non-CEHRT systems would better align with clinical and operational workflows, reduce burden, and improve data quality. A commenter also recommended that CMS require electronic capture rather than manual entry of UDIs within the measure.

Response: We note that activities other than ''capture'' and ''store'' are outside the scope of this measure and therefore approaches to these and other activities related to integrating UDI data into the EHR and exchange of that information are not subject to the requirements of this measure. We also wish to clarify that the measure's requirement that an eligible hospital or CAH must use CEHRT to electronically capture complete UDI information is intended to refer to the ultimate capture and storage of this information, and that intermediate steps or systems used outside of CEHRT to capture this information are permissible as long as the complete UDI is ultimately captured and stored in CEHRT.

Comment: Several commenters supported the proposal but made recommendations regarding its details. A few commenters recommended CMS allow sufficient implementation time before CMS considers shifting to a required ''Yes'' attestation or a performance-based metric. A few commenters recommended that CMS define the scope of ''implantable medical devices'' and provide documented exception categories for circumstances such as UDI-exempt devices, emergencies, damaged or unavailable labels/barcodes, items pending manual validation, and implants outside the hospital's operational control. Another commenter recommended that CMS treat eligible hospitals and CAHs as compliant if they can collect and share either the UDI–DI or UDI–PI as discrete data, rather than requiring a complete UDI–DI plus UDI–PI string. Another commenter recommended that CMS encourage eligible hospitals and CAHs to include UDI data in discharge summaries and patient portals to empower patients with information about their implanted devices. A commenter asked for guidance regarding surgical implants that are too small to be directly marked with a UDI and whose linkage to a full UDI may have been lost at a manufacturer's distribution center before its use at the point of care.

Response: CMS intends to allow sufficient implementation time should we add additional requirements to the measure in future rulemaking. As discussed earlier, documented exception categories include UDI-exempt devices and implants not performed at the eligible hospital or CAH. We clarify that ''each implantable device'' and ''implantable medical devices'' refer to medical devices that were implanted in a procedure performed during the EHR reporting period at that eligible hospital or CAH and that are subject to UDI requirements. The measure assesses compliance at the facility level, and the facility's responsibility to store UDIs within CEHRT extends to all eligible implantable devices implanted during the EHR reporting period in order for the eligible hospital or CAH to attest ''Yes'' to the measure. An eligible hospital or CAH could claim an exclusion if it implanted five or fewer medical devices subject to UDI requirements during the calendar year of the applicable EHR reporting period. For the purposes of the measure, CMS would interpret an eligible hospital's or CAH's responsibility as extending to all implantable devices with a valid UDI at the time the eligible hospital or CAH receives that device. That is, if a UDI is not available to the eligible hospital or CAH at the time of receipt of the implantable device, then the implantable device would not count for measure assessment purposes. The full value of the UDI system depends on recording and storage of both the UDI–DI and the UDI–PI, so we decline to allow only one of these data elements to meet the measure requirement for UDI at this time. Similarly, although we agree that inclusion of UDI data in discharge summaries and patient portals is in keeping with the goals of the UDI system, we decline to require such actions in the current version of the measure. We encourage eligible hospitals, CAHs, and health IT developers to adopt functionality that benefits Medicare beneficiaries and health care providers. We emphasize that we intend the measure to foster the comprehensive availability of implantable device UDIs within CEHRT.

Comment: A few commenters supported CMS' proposed adoption of the UDIs for Implantable Medical Devices measure but opposed any future requirement to report UDIs on claims, asserting that claims are designed for billing rather than granular device traceability and such a requirement would impose administrative and operational burden.

Response: We will take the commenters' suggestions into consideration for future rulemaking. The current measure does not require incorporation of UDI information into claims.

Comment: A commenter supported finalizing the proposed UDI measure but recommended that CMS reiterate that the primary purpose of the measure and capture of this information is to support the clinical and public health purposes of UDI data rather than encouraging device-specific pricing decisions without appropriate clinical context.

Response: We agree with the commenter that the purpose of this measure is to support the clinical and public health purposes of UDI data.

Comment: Several commenters did not support our proposal to adopt the measure and recommended that CMS delay implementation of required reporting and provide a multi-year transition period before requiring full participation or moving toward performance-based measurement. Commenters stated that eligible hospitals, CAHs, and health systems would need additional time to configure EHRs and related systems, revise workflows, train staff, test processes, validate data, resolve supply chain and inventory-system gaps. Commenters also stated that CMS would need to establish clear definitions and implementation guidance. Commenters noted that current capture of UDI often relies on manual documentation rather than barcode scanning, and that many device barcodes may not be represented in internal systems or may not populate into CEHRT without substantial operational and technical work. Commenters urged CMS to make the measure optional or voluntary for CY 2027, with some recommending a delay of at least three years or until 2028, to avoid penalizing hospitals for implementation barriers outside their control and to allow more consistent, accurate, and interoperable UDI capture.

Response: We proposed that the UDIs for Implantable Medical Devices measure would be an attestation-based measure where either a ''Yes'' or ''No'' response would count as fulfillment of the requirements of the measure. Therefore, we disagree that eligible hospitals and CAHs need more time to implement the measure. The number of eligible hospitals and CAHs that report ''No'' for the measure also gives us valuable information on the overall adoption of UDI storage within CEHRT and the readiness of eligible hospitals and CAHs in this respect. Because the number of eligible hospitals and CAHs attesting ''No'' to the measure gives CMS valuable information, we also decline to make the measure an optional measure for the EHR reporting period in CY 2027. We also note that recording and display of UDI data is already supported within certified health IT as a part of the ''implantable device list'' ONC health IT certification criterion at 45 CFR 170.315(a)(14), and that this criterion has been included in CEHRT as part of the Base EHR definition for a significant period of time. However, we agree that eligible hospitals and CAHs should be given implementation time before we consider any changes to make it a performance-based measure, which this period as an attestation measure would provide.

Comment: A few commenters did not support the proposal and stated that the proposed UDI capture measure would create implementation expectations without sufficient financial or operational support for hospitals and health systems. Many commenters noted that effective UDI adoption may require significant investments in system integration, workflow redesign, governance, and coordination across EHRs, supply chain systems, administrative transactions, and other operational platforms. These commenters recommended that CMS consider additional support, such as financial incentives or other implementation assistance, to promote adoption.

Response: We appreciate commenters' concerns regarding implementation burden and timing. We note that eligible hospitals and CAHs already have obligations to capture UDI information for implantable devices at 21 CFR 821.30 and that the proposed measure only assesses whether that information is stored in CEHRT as structured data. We also note that we proposed that eligible hospitals and CAHs could attest either ''Yes'' or ''No'' to meet the measure requirement; we did not propose to require a ''Yes'' response. An eligible hospital or CAH that attests ''No'' would still be considered to have successfully reported the measure for program purposes. We do not intend for the measure to penalize hospitals that are not yet routinely capturing UDI in CEHRT, but rather we intend to establish a baseline for future policy development and continued progress toward improved device traceability, patient safety, and interoperability. Accordingly, a separate incentive is not necessary for this initial measure, which is designed to establish baseline information and support continued progress toward improved device traceability, patient safety, and interoperability without penalizing eligible hospitals and CAHs that have not yet implemented this capability.

Comment: A few commenters did not support our proposal to adopt the measure because they wanted CMS to clarify the measure description requiring eligible hospitals and CAHs to use CEHRT to electronically capture UDI information, stating that the phrase could be interpreted as requiring barcode scanning and direct capture within CEHRT even though many hospitals currently use inventory management, procedural documentation, or other non-CEHRT systems that transmit UDI data to their EHRs. Commenters recommended that CMS revise the measure description language to allow hospitals and CAHs to use CEHRT alone or in combination with interoperable non-CEHRT systems, including inventory management, procedural documentation, and point-of-use systems, to capture and transmit complete UDI data to CEHRT.

Response: We appreciate commenters' request for clarification regarding permissible methods for electronically capturing UDI information. We clarify that the measure does not preclude the use of non-CEHRT systems that transmit UDI data to the EHR. Eligible hospitals and CAHs may use barcode scanning, other automated identification and data capture technologies, or separate systems to transmit UDI information provided that the UDI is captured and stored as structured, discrete data in the eligible hospital or CAH's EHR consistent with the measure requirements.

Comment: A commenter did not support the proposal and recommended that CMS broaden compliance for the UDI measure to include non-CEHRT data platforms in addition to CEHRT. The commenter stated that UDI data often originates in supply chain, inventory, logistics, and other operational systems before being linked to clinical information, and that limiting compliance to CEHRT could create data silos and reduce the value of UDI-enabled interoperability.

Response: While we acknowledge that eligible hospitals and CAHs may use a variety of operational, supply chain, inventory, procedural, or other systems to support UDI capture, validation, and

internal workflows, we decline to broaden the measure as suggested. The Medicare Promoting Interoperability Program is focused on the use of CEHRT to support interoperable health information exchange; therefore we intend the measure to assess whether UDI information is stored in CEHRT as structured, discrete data. Accordingly, for purposes of this measure, we are maintaining the focus on CEHRT rather than expanding compliance to include non-CEHRT systems.

Comment: A commenter opposed adoption of the proposed measure because the commenter viewed the attestation measure as a first step toward future requirements to include device identifiers on claims. The commenter stated that requiring UDI information on claims would be duplicative of clinical data capture, impose unnecessary administrative burden on health care providers, create technical challenges because multiple UDIs may be associated with a single product model or implantable device system, and risk payment delays or inefficient claims processing. The commenter further stated that claims systems are not designed for this level of device detail and that claims-derived DI data may be incomplete, difficult to query, and unreliable for post-market surveillance or research.

Response: We appreciate the commenter's concerns regarding possible future uses of UDI data. We clarify that this measure does not establish any requirements regarding the inclusion of UDIs on claims. The measure is limited to whether an eligible hospital or CAH uses CEHRT to electronically capture and store UDI information for implantable medical devices as structured data. The purpose of this measure is to support improved device documentation, interoperability, patient safety, recall management, and related clinical and public health uses.

Comment: A commenter did not support our proposal to adopt the measure within the Public Health and Clinical Data Exchange objective, stating that UDI capture is primarily a patient safety and device traceability function and does not align with the objective's focus on exchange with public health agencies and registries. The commenter stated that adding a required UDI measure would increase burden within an already complex objective. The commenter recommended that CMS clarify permissible capture methods, required UDI data elements, the level at which compliance would be assessed, audit documentation requirements, and whether workflow constraints or external system limitations could support an exclusion or hardship request.

Response: We appreciate the commenter's concerns. Although we agree that patient safety is an important aspect of UDI use, we believe this measure is appropriately situated within the Public Health and Clinical Data Exchange objective because structured UDI capture in CEHRT supports interoperable exchange of device information for patient safety, recall management, care coordination, post-market surveillance, and other public health and clinical data uses. Because we did not propose to assign points to the measure, require eligible hospitals and CAHs to attest ''Yes'' to the measure, or impose a performance threshold, we stated and continue to believe that the measure provides an appropriate initial step while giving eligible hospitals and CAHs additional time to continue building UDI capture capabilities. As for permissible data capture methods, we noted earlier in this section that we are not precluding the use of non-CEHRT systems that transmit UDI data to the EHR. Eligible hospitals and CAHs may use barcode scanning, other automated identification and data capture technologies, or separate systems to transmit UDI information provided that the UDI is captured and stored as structured, discrete data in the patient's EHR consistent with the measure requirements. We will provide additional guidance, including additional information on permissible electronic capture methods, data elements, documentation, and applicable exclusions in program measure specification manuals that we provide on a yearly basis on the CMS QualityNet website.

Comment: Several commenters recommended that CMS delay mandatory implementation or phase in additional requirements in the measure over multiple years. Commenters stated that eligible hospitals and CAHs would need substantial time to assess system capabilities, redesign workflows, configure EHR and related systems, integrate supply chain and procedural platforms, train staff, test processes, and validate data. Commenters recommended that CMS begin with voluntary or attestation-based reporting, avoid immediate performance-based scoring or penalties, and provide sufficient transition time before requiring full participation. Some commenters also urged CMS to avoid penalizing hospitals for missing or incomplete data resulting from vendor limitations, manufacturer data gaps, or infrastructure constraints outside the hospital's control.

Response: We appreciate commenters' recommendations regarding future expansion of the measure. We will take commenters' recommendations regarding broader device scope, additional care settings, expanded data elements, and future uses of UDI data into consideration for future rulemaking.

Comment: Several commenters requested that CMS clarify that the proposed UDI measure is limited to clinical documentation and interoperability purposes and does not establish or signal a requirement to report UDI or device identifier information on Medicare claims or cost reports. Commenters stated that hospital claims, HIPAA transaction sets, NUBC revenue codes, and Medicare cost reporting rules serve billing and payment functions and should remain distinct from FDA's UDI framework. Commenters expressed concern that claims-based UDI reporting would duplicate EHR or registry documentation, increase administrative burden, create technical and payment-processing challenges, and produce data that may be incomplete or unreliable for surveillance. Commenters also requested that CMS confirm that FDA's definition of ''implantable device'' for UDI purposes does not alter or supersede the HIPAA transaction set definitions, NUBC revenue code assignments, or CMS cost reporting instructions that govern hospital billing and cost reporting.

Response: We confirm that the proposed UDI measure does not establish a requirement to report UDI or device identifier information on Medicare claims or cost reports. The measure does not modify HIPAA transaction set requirements, NUBC revenue code assignments, Medicare claims reporting requirements, or Medicare cost reporting instructions.

Comment: A few commenters recommended that CMS treat the proposed implantable-device UDI measure as an initial step toward a broader UDI framework that would extend beyond implantable devices and apply across medical devices subject to the UDI rule in additional care settings. Commenters stated that complete UDI data should be captured, interpreted, validated, stored, and used in structured and discrete form to support patient care and safety, recall management, patient access, analytics, exchange, longitudinal surveillance, facility operations, and supply chain security. Commenters recommended that CMS signal this broader future direction

while phasing in detailed data elements over time, including raw UDI, capture method, device identifier, production identifiers when present, GUDID-derived attributes, patient and encounter context, capture source, and validation status.

Response: We appreciate commenters' recommendations regarding the potential future development of a broader UDI framework. We will take commenters' recommendations into consideration for future rulemaking.

Comment: A commenter stated concern with ONC's proposal to remove the implantable device list ONC health IT certification criterion at 45 CFR 170.315(a)(14) and how it would impact performance on the measure. The commenter stated that the criterion enables UDI to link to core device attributes in AccessGUDID, including brand name, model or version, company name, and MRI safety information, thereby supporting patient access to meaningful device information and improving patient safety. The commenter asserted that maintaining the implantable device list criterion would help ensure referential integrity and improve GUDID data quality over time.

Response: We appreciate the commenter's concern regarding ONC's proposal to remove the implantable device list certification criterion at 45 CFR 170.315(a)(14) and the potential effect on UDI-related functionality. We agree that linking UDI information to device attributes, including information available through AccessGUDID, can support patient access to meaningful device information, patient safety, and data quality. However, if ONC finalizes this proposal, we believe that health IT functionality related to UDI access, storage, and exchange would continue to be maintained because other ONC certification criteria continue to reference or support exchange of UDI for implantable devices, including the standardized API for patient and population services criterion at 45 CFR 170.315(g)(10).

We also note that removal of the specific implantable device list criterion would not preclude health IT developers from continuing to support AccessGUDID lookup, device attribute display, validation, or related functionality. We will continue to coordinate with ONC and monitor implementation to ensure that eligible hospitals and CAHs have appropriate certified health IT capabilities to support UDI capture and exchange.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Unique Device Identifiers for Implantable Medical Devices measure beginning with the EHR reporting period in CY 2027. Eligible hospitals and CAHs will be required to attest ''Yes'', ''No'', or claim an applicable exclusion to fulfill the measure requirements. If an eligible hospital or CAH does not meet the minimum requirements, it will be subject to a downward payment adjustment.

c. Future Direction of the Unique Device Identifiers for Implantable Devices Measure and Additional Options for Utilizing UDI

As we finalize adoption of the measure, we also intend to consider future modifications to this measure and invited public comment on a series of questions about the future direction of the measure (91 FR 19631).

Commenters generally supported the long-term goal of expanded UDI capture and use, but recommended that CMS proceed gradually before adopting performance-based requirements. Commenters suggested possible future measures based on the percentage of implant procedures, encounters, selected procedure codes, or covered devices for which complete UDI data are captured and stored as structured data, but many stated that performance-based measurement would be premature until hospitals have reliable workflows, clear numerator and denominator definitions, and better integration among EHR, supply chain, procedural, and inventory systems. Commenters identified non-sterile, tray-based, small, consigned, multi-component, and unpackaged devices as especially difficult to capture, and recommended phased implementation, exceptions, and collaboration with manufacturers and vendors to improve labeling, validation, and data quality. Commenters also supported future UDI exchange through certified health IT, FHIR APIs, registries, discharge summaries, after-visit summaries, and patient portals, and encouraged CMS to consider future uses for recall management, patient follow-up, real-world evidence, quality measurement, and expansion to additional procedural settings when infrastructure is ready.

We appreciate all the comments and interest in this topic. While we are not responding to specific comments in response to the RFI in this final rule, we believe that this input is very valuable and will continue to take all concerns, comments, and suggestions into account for future development and consideration of this measure for the Medicare Promoting Interoperability Program. We thank commenters for their responses and will take them into consideration for future rulemaking.

7. Overview of Scoring Methodology

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636), we adopted a performance-based scoring methodology for eligible hospitals and CAHs reporting to the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019. This methodology included a minimum scoring threshold that eligible hospitals and CAHs must meet in addition to the requirement to report on the objectives and measures of meaningful use under 42 CFR 495.24. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), we finalized a proposal to increase the performance-based scoring threshold to 70 points for the EHR reporting period in CY 2025 and to 80 points beginning with the EHR reporting period in CY 2026.

As shown in Table IX.F.–02., for the EHR reporting period in CY 2027, the points associated with the required measures sum to 100 points, and reporting on one or more of the optional bonus measures (including 10 bonus points for reporting on the Electronic Prior Authorization measure for the EHR reporting period in CY 2027), offers up to an additional 15 bonus points. The scores for each of the required measures and bonus measures are added together to calculate a total score of up to 115 possible points for each eligible hospital or CAH. We refer readers to Table IX.F.–02. in this final rule, which reflects the objectives, measures, maximum points available, and whether a measure is required or optional for the EHR reporting period in CY 2027 based on our previously adopted policies and the proposals finalized in this final rule.

As shown in Table IX.F.–03., for the EHR reporting period in CY 2028, the points associated with the required measures sum to 100 points. For the EHR reporting period in CY 2028, the Electronic Prior Authorization measure is being finalized as a required measure thereby eliminating the 10 bonus points offered for the EHR reporting period in CY 2027, and 5 bonus points remain available under the Public Health and Clinical Data Exchange objective. The scores for each of the required measures and bonus measures are added together to calculate a total score of up to 105 possible points for each eligible hospital or CAH.

BILLING CODE 4169–69–P

TABLE IX.F.-02.: PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIOD IN CY 2027

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing (e-Prescribing)	e-Prescribing	10 points	Required
	Query of Prescription Drug Monitoring Program (PDMP)	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (eligible hospitals and CAHs must choose one of the three reporting options)
	-AND-		
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	HIE Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange Under TEFCA	30 points	
	Electronic Prior Authorization*	10 points (*bonus*)	Optional
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following seven measures: • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Laboratory Reporting • Antimicrobial Use Surveillance • Antimicrobial Resistance Surveillance • Unique Device Identifier**	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Public Health Reporting using TEFCA	5 points (*bonus*)	Optional

Notes: The Security Risk Analysis measure, SAFER Guides measure, and Information Blocking attestation required by section 106(b)(2)(B) of the Medicare Access and CHIP Reauthorization Act of 2015 are required but will not be scored. Reporting electronic clinical quality measures (eCQMs) is required but will not be scored. Eligible hospitals and CAHs must also submit their level of active engagement for measures under the Public Health and Clinical Data Exchange objective. Participants may spend only one EHR reporting period at Option 1: Pre-production and Validation level per measure and must progress to Option 2: Validated Data Production level for the following EHR reporting period. See the FY 2023 IPPS/LTCH PPS final rule (87 FR 49337) for more details about active engagement. In section IX.F.3 of this final rule, we are finalizing removal of the ONC Direct Review and ONC-ACB Surveillance attestations for the EHR reporting period in CY 2026 and subsequent years.

* In section IX.F.5.d of this final rule, we are finalizing that the Electronic Prior Authorization measure be an optional bonus measure for CY 2027 EHR reporting period.

** In section IX.F.6 of this final rule, we are finalizing our proposal to adopt the Unique Device Identifier measure beginning with the EHR reporting period in CY 2027.

TABLE IX.F.-03. : PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIOD IN CY 2028

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing (e-Prescribing)	e-Prescribing	10 points	Required
	Query of Prescription Drug Monitoring Program (PDMP)	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information*	15 points	Required (eligible hospitals and CAHs must choose one of the three reporting options)*
	-AND-		
	Support Electronic Referral Loops by Receiving and Reconciling Health Information*	15 points	
	-OR-		
	HIE Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange Under TEFCA	30 points	
	Electronic Prior Authorization**	Unscored	Required
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following seven measures: • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Laboratory Reporting • Antimicrobial Use Surveillance • Antimicrobial Resistance Surveillance • Unique Device Identifier***	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Public Health Reporting using TEFCA	5 points (*bonus*)	Optional

Notes: The Security Risk Analysis measure, SAFER Guides measure, and Information Blocking attestation required by section 106(b)(2)(B) of the Medicare Access and CHIP Reauthorization Act of 2015 are required but will not be scored. Reporting electronic clinical quality measures (eCQMs) is required but will not be scored. Eligible hospitals and CAHs must also submit their level of active engagement for measures under the Public Health and Clinical Data Exchange objective. Participants may spend only one EHR reporting period at Option 1: Pre-production and Validation level per measure and must progress to Option 2: Validated Data Production level for the following EHR reporting period. See the FY 2023 IPPS/LTCH PPS final rule (87 FR 49337) for more details about active engagement. In section IX.F.3 of this final rule, we are finalizing removal of the ONC Direct Review and ONC-ACB Surveillance attestations for the EHR reporting period in CY 2026 and subsequent years.

*In section IX.F.4 of this final rule, the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures will be removed for the EHR reporting period in CY 2029 and subsequent years. Eligible hospitals and CAHs must choose one of the two reporting options beginning with the EHR reporting period in CY 2029.

** In section IX.F.5 of this final rule, we are finalizing our proposal to make the Electronic Prior Authorization optional in the CY 2027 EHR reporting period and required, but unscored, starting with the EHR reporting period in CY 2028.

*** In section IX.F.6 of this final rule, we are finalizing our proposal to adopt the Unique Device Identifier measure beginning with the EHR reporting period in CY 2027.

BILLING CODE 4169–69–C

The maximum number of points available for each measure described in Tables IX.F.–02. and IX.F.–03. does not include the points that would be redistributed in the event an exclusion is claimed for a given measure. We are not making any changes to our policy for point redistribution in the event an exclusion is claimed. We refer readers to Table IX.F.–04. in this final rule, which shows point redistribution among the objectives and measures for the EHR reporting period in CY 2027 in the event an eligible hospital or CAH claims an exclusion. Similarly, Table IX.F.–05. shows the redistribution for the EHR reporting periods in CY 2028 and subsequent years.

We note that we adopted and codified a measure suppression policy for the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2026 at § 495.24(f)(3) in the Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program final rule (CY 2026 PFS final rule) (90 FR 49881). Specifically, we codified that if certain circumstances occur that impact our assessment of the performance of eligible hospitals and CAHs on a measure selected for the Medicare Promoting Interoperability Program, we have the sole discretion to suppress the affected measure by excluding it from our assessment of performance. In this case, we would allocate the maximum points available or provide full credit for the affected measure if the eligible hospital or CAH reports the affected measure, or we would exclude the affected measure from the determination of a meaningful EHR user if the affected measure is not scored. For more information, see the CY 2026 PFS final rule at 90 FR 49881.

BILLING CODE 4169–69–P

TABLE IX.F.-04. : EXCLUSION REDISTRIBUTION FOR THE EHR REPORTING PERIOD IN CY 2027

Objective	Measure	Redistribution if Exclusion is Claimed
e-Prescribing	e-Prescribing	10 points to Health Information Exchange objective
	Query of PDMP	10 points to e-Prescribing measure
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information*	No exclusion
	-AND-	
	Support Electronic Referral Loops by Receiving and Reconciling Health Information*	No exclusion
	-OR-	
	HIE Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange Under TEFCA	No exclusion
	Electronic Prior Authorization (Optional)	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following seven measures: ● Syndromic Surveillance Reporting ● Immunization Registry Reporting ● Electronic Case Reporting ● Electronic Laboratory Reporting ● AU Surveillance ● AR Surveillance ● Unique Device Identifier***	If an exclusion is claimed for each of the seven measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure

* In section IX.F.4 of this final rule, we are finalizing our proposal to remove the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures beginning with the EHR reporting period in CY 2029 and for subsequent years.
** In section IX.F.5 of this final rule, we are finalizing our proposal to make the Electronic Prior Authorization optional in the CY 2027 EHR reporting period.
*** In section IX.F.6 of this final rule, we are finalizing our proposal to adopt the Unique Device Identifier measure beginning with the EHR reporting period in CY 2027.

TABLE IX.F.-05. : EXCLUSION REDISTRIBUTION FOR THE EHR REPORTING PERIOD IN CY 2028

Objective	Measure	Redistribution if Exclusion is Claimed
e-Prescribing	e-Prescribing	10 points to Health Information Exchange objective
	Query of PDMP	10 points to e-Prescribing measure
Health Information Exchange*	Support Electronic Referral Loops by Sending Health Information*	No exclusion
	-AND-	
	Support Electronic Referral Loops by Receiving and Reconciling Health Information*	No exclusion
	-OR-	
	HIE Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange Under TEFCA	No exclusion
	Electronic Prior Authorization**	No redistribution for exclusion**
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following seven measures: ● Syndromic Surveillance Reporting ● Immunization Registry Reporting ● Electronic Case Reporting ● Electronic Laboratory Reporting ● AU Surveillance ● AR Surveillance ● Unique Device Identifier***	If an exclusion is claimed for each of the seven measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure

* In section IX.F.4 of this final rule, the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures will be removed for the EHR reporting period in CY 2029 and subsequent years.

** In section IX.F.5 of this final rule, we are finalizing our proposal to make the Electronic Prior Authorization required but unscored starting with the EHR reporting period in CY 2028.

*** In section IX.F.6 of this final rule, we are finalizing our proposal to adopt the Unique Device Identifier measure beginning with the EHR reporting period in CY 2027.

BILLING CODE 4169–69–C

8. Overview of Objectives and Measures

Table IX.F.–06. lists objectives and measures for the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2027 and reflects the policies finalized in this final rule as well as finalized changes that would go into effect for the EHR reporting period beginning with CY 2028. For measures that have differing information between the EHR reporting period in CY 2027 and the EHR reporting period in CY 2028 and subsequent years, the applicable year will be noted in the measure column. Table IX.F.–07. lists the ONC health IT certification criteria required to meet specific objectives and measures.

TABLE IX.F.-06.: OBJECTIVES AND MEASURES FOR THE MEDICARE PROMOTING INTEROPERABILITY PROGRAM FOR THE EHR REPORTING PERIODS IN CY 2027, CY 2028 AND SUBSEQUENT YEARS

Objective	Measure	Numerator	Denominator	Exclusion	Calculation considerations related to counting unique patients or actions
e-Prescribing	e-Prescribing: For at least one hospital discharge, medication orders for permissible prescriptions (for new and changed prescriptions) are transmitted electronically using CEHRT.	The number of prescriptions in the denominator generated and transmitted electronically.	The number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed, other than controlled substances for patients discharged during the EHR reporting period.	Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions, and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period.	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
e-Prescribing	Query of PDMP: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Y/N)	N/A (measure is Y/N)	(1) Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances that include Schedule II, III and IV drugs and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period. (2) Any eligible hospital or CAH that could not report on this measure in accordance with applicable law.	N/A (measure is Y/N)
Health Information Exchange	Electronic Prior Authorization (EHR Reporting Period in CY 2027 *only*):* For at least one medical item or service (excluding drugs) ordered during a hospital encounter that occurs within the EHR reporting period, the prior authorization is requested electronically through a Prior Authorization API using CEHRT.	N/A (measure is Y/N)	N/A (measure is Y/N)	None*	N/A (measure is Y/N)

Health Information Exchange	Electronic Prior Authorization (EHR Reporting Period in CY 2028 and Subsequent Years):** For at least one medical item or service (excluding drugs) ordered during a hospital encounter that occurs within the EHR reporting period, the prior authorization is requested electronically through a Prior Authorization API using CEHRT.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH that: (1) Does not order any medical items or services (excluding drugs) requiring prior authorization during the EHR reporting period; or (2) Only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets the Prior Authorization API requirements during the applicable EHR reporting period.*	N/A (measure is Y/N)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information:** For at least one transition of care or referral, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) Electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.**	Number of transitions of care and referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (Place of Service [POS] 21 or 23) was the transitioning or referring provider.**	None**	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.**

Health Information Exchange	Support Electronic Referral Loops by Receiving and Reconciling Health Information:** For at least one electronic summary of care record received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, medication allergy, and current problem list using CEHRT.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication Allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.**	Number of electronic summary of care records received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the reconciling party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient.**	None**	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.**

Health Information Exchange	HIE Bi-Directional Exchange The eligible hospital or CAH must attest to the following: (1) Participating in a Health Information Exchange system (HIE) in order to enable secure, bi-directional exchange of information to occur for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy. (2) Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners. (3) Using the functions of CEHRT to support bi-directional exchange with an HIE.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)

Health Information Exchange	Enabling Exchange Under TEFCA The eligible hospital or CAH must attest to the following: (1) Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) in good standing (that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy. (2) Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)

Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information: For at least one unique patient discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23): (1) the patient (or patient-authorized representative) is provided timely access to view online, download, and transmit their health information; and (2) the eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application programming interface (API) in the eligible hospital's or CAH's CEHRT.	The number of patients in the denominator (or patient authorized representatives) who are provided timely access to health information to view online, download and transmit to a third party and to access using an application of their choice that is configured to meet the technical specifications of the API in the eligible hospital's or CAH's CEHRT.	The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.	None	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

Public Health and Clinical Data Exchange	Immunization Registry Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit immunization data and receive immunization forecasts and histories from the public health immunization registry or immunization information system (IIS).	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the eligible hospital or CAH: (1) Does not administer any immunizations to any of the populations for which data are collected by its jurisdiction's immunization registry or IIS during the EHR reporting period; (2) Operates in a jurisdiction for which no immunization registry or IIS is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no immunization registry or IIS has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N)

Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit syndromic surveillance data from an emergency department (POS 23).	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH: (1) Does not have an emergency department; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N)
Public Health and Clinical Data Exchange	Electronic Case Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit case reporting of reportable conditions.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the eligible hospital or CAH: (1) Does not treat or diagnose any reportable diseases for which data are collected by its jurisdiction's reportable disease system during the EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N)

Public Health and Clinical Data Exchange	Electronic Laboratory Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit Electronic Laboratory Reporting results.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the Electronic Laboratory Reporting measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of accepting the specific Electronic Laboratory Reporting standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive Electronic Laboratory Reporting results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N)
Public Health and Clinical Data Exchange	Antimicrobial Use Surveillance: The eligible hospital or CAH is in active engagement with CDC's National Health Safety Network (NHSN) to submit Antimicrobial Use data for the EHR reporting period and receives a report from NHSN indicating its successful submission of Antimicrobial Use data for the EHR reporting period.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH may be excluded from the measure if the eligible hospital or CAH: (1) Does not have any patients in any patient care location for which data are collected by NHSN during the EHR reporting period; (2) Does not have electronic medication administration record (eMAR)/barcode medication administration (BCMA) electronic records or an admission, discharge, transfer (ADT) system during the EHR reporting period; or (3) Does not have a data source containing the minimal discrete data elements that are required for reporting.	N/A (measure is Y/N)
Public Health and Clinical Data Exchange	Antimicrobial Resistance Surveillance: The eligible hospital or CAH is in active engagement with	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH may be excluded from the measure if the eligible hospital or CAH: (1) Does not have any patients in any patient care location for	N/A (measure is Y/N)

	CDC's NHSN to submit Antimicrobial Resistance data for the EHR reporting period and receives a report from NHSN indicating its successful submission of Antimicrobial Resistance data for the EHR reporting period.			which data are collected by NHSN during the EHR reporting period; (2) Does not have a laboratory information system (LIS) or ADT system during the EHR reporting period; or (3) Does not have a data source containing the minimal discrete data elements that are required for reporting.	
Public Health and Clinical Data Exchange	Public Health Registry Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit data to public health registries.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)
Public Health and Clinical Data Exchange	Public Health Reporting Using TEFCA: The eligible hospital or CAH (1) Participates as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website); (2) is not suspended; (3) submits health information using TEFCA to a PHA consistent with one or more of the measures under the Public Health and Clinical Data Exchange objective; (4) is in active engagement Option 2 (validated data production) with a PHA to transfer	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)

	health information for one or more of the measures under the Public Health and Clinical Data Exchange objective; and (5) uses the functions of CEHRT to exchange data with the PHA.				
Public Health and Clinical Data Exchange	Unique Device Identifier:* The eligible hospital or CAH uses CEHRT during the EHR reporting period to electronically capture and store, as one or more discrete data elements within the patient's electronic health record, the complete Unique Device Identifier (UDI), which includes the device identifier and, when present on the device label, the production identifier, for each implantable medical device subject to UDI requirements used for patient care delivery.	N/A (measure is Y/N)	N/A (measure is Y/N)	The eligible hospital or CAH implanted five or fewer medical devices subject to UDI requirements during the calendar year of the applicable EHR reporting period.	N/A (measure is Y/N)
Protect Patient Health Information	Security Risk Analysis: First, conduct or review a security risk analysis and second, conduct security risk management activities, in accordance with the requirements under 45 CFR 164.308(a)(1)(ii)(A) and (B). Security risk analysis and management activities include addressing the security of data created or maintained by CEHRT (to include encryption), in accordance with 45 CFR 164.312(a)(2)(iv) and 45 CFR	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)

	164.306(d)(3). The encryption implementation specified at 45 CFR 164.312(a)(2)(iv) must be implemented if it is reasonable and appropriate; if encryption is not reasonable and appropriate, then the eligible hospital or CAH would adopt an equivalent alternative measure if it is reasonable and appropriate to do so. Actions included in the security risk analysis measure may occur any time during the calendar year in which the EHR reporting period occurs.				
Protect Patient Health Inormation	Safety Assurance Factors for EHR Resilience (SAFER) Guides Conduct an annual self-assessment using all eight of the 2025 SAFER Guides at any point during the calendar year in which the EHR reporting period occurs, beginning with the EHR reporting period in CY 2026 and subsequent years.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)

* Signifies a policy finalized in this FY 2027 IPPS/LTCH PPS final rule that applies to the EHR reporting period in CY 2027.

** We have finalized a policy in this FY 2027 IPPS/LTCH PPS final rule to remove this measure in the EHR reporting period in CY 2029 and subsequent years.

TABLE IX.F.-07. : MEDICARE PROMOTING INTEROPERABILITY PROGRAM OBJECTIVES AND MEASURES AND ONC HEALTH IT CERTIFICATION CRITERIA

Objective	Measure	ONC Health IT Certification Criteria as defined in the following sections of Title 45 CFR	ONC Health IT Certification Criteria Changes If HTI-5 Proposals Are Finalized as Proposed
e-Prescribing	e-Prescribing	170.315(b)(3) e-Prescribing	No change
	Query of PDMP	170.315(b)(3) e-Prescribing	No change
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information*	170.315(b)(1) Transitions of care	Revised
	Support Electronic Referral Loops by Receiving and Reconciling Health Information*	170.315(b)(1) Transitions of care	Revised
		170.315(b)(2) Clinical information reconciliation and incorporation	Removed
Health Information Exchange (alternative)	HIE Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:	

		170.315(b)(1) Transitions of care	Revised
		170.315(b)(2) Clinical information reconciliation and incorporation	Removed
		170.315(g)(7) Application access — patient selection	Removed
		170.315(g)(9) Application access — all data request	Removed
		170.315(g)(10) Application access — standardized API for patient and population services	No change
Health Information Exchange (alternative)	Enabling Exchange Under TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:	
		170.315(b)(1) Transitions of care	Revised
		170.315(g)(7) Application access — patient selection	Removed
		170.315(g)(9) Application access — all data request	Removed
		170.315(g)(10) Application access — standardized API for patient and population services	No change
Health Information Exchange	Electronic Prior Authorization*	Certified health IT capabilities that may support the actions of this measure	
		170.315(g)(31) Provider prior authorization API — coverage requirements discovery*	No change
		170.315(g)(32) Provider prior authorization API — documentation templates and rules*	No change
		170.315(g)(33) Provider prior authorization API — prior authorization support*	No change
Provider to Patient Exchange	Provide patients electronic access to their health information	170.315(e)(1) View, download, and transmit to 3rd party	Revised
		170.315(g)(7) Application access — patient selection	Removed
		170.315(g)(9) Application access — all data request	Removed
		170.315(g)(10) Application access — standardized API for patient and population services	No change
Public Health and Clinical Data Exchange	Immunization registry reporting	170.315(f)(1) Transmission to immunization registries	No change
	Syndromic surveillance reporting	170.315(f)(2) Transmission to public health agencies — syndromic surveillance	No change

	Electronic case reporting	170.315(f)(5) Transmission to public health agencies — electronic case reporting	Revised
	Public health registry reporting	170.315(f)(7) Transmission to public health agencies — health care surveys.	Removed
	Clinical data registry reporting	No ONC health IT certification criteria at this time.	No change
	Public health reporting using TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:	
		170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results	No change
		170.315(f)(5) Transmission to public health agencies — electronic case reporting	Revised
	Electronic laboratory reporting	170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results	No change
	Antimicrobial Use Surveillance	170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting	Revised
	Antimicrobial Resistance Surveillance	170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting	Revised
	Unique Device Identifier*	170.315(a)(14) Implantable device list	Removed
		170.315(g)(10) Application access — standardized API for patient and population services	No change
Electronic Clinical Quality measures (eCQMs)	eCQMs for eligible hospitals and CAHs	170.315(c)(1)	No change
		170.315(c)(2)	No change
		170.315(c)(3)(i) and (ii)	No change
Protect Patient Health Information	Security Risk Analysis	No ONC health IT certification criteria at this time.	No change
	SAFER Guides	No ONC health IT certification criteria at this time.	No change

*Signifies a measure with a policy finalized in this FY 2027 IPPS/LTCH PPS final rule.

BILLING CODE 4169–69–C

9. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

a. Background on Clinical Quality Measurement for Eligible Hospitals and CAHs

Under sections 1814(l)(3)(A) and 1886(n)(3)(A) of the Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on clinical quality measures (also referred to as electronic clinical quality measures, or eCQMs) selected by CMS using CEHRT as part of the Medicare Promoting Interoperability Program.

As we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38479), we intend to continue to align the eCQM reporting requirements and eCQM measure set for the Medicare Promoting Interoperability Program with similar requirements under the Hospital Inpatient Quality Reporting Program, to the extent feasible. Section 1886(n)(3)(B)(i)(I) of the Act requires the Secretary to provide preference for the selection of clinical quality measures that are also used in the Hospital Inpatient Quality Reporting Program or endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act (referred to in this rule as the consensus-based entity (CBE)). Furthermore, aligning eCQM reporting requirements between the Medicare Promoting Interoperability Program and the Hospital Inpatient Quality Reporting Program allows for improved coordination, burden reduction, and the promotion of quality care.

b. Adoption and Removal of eCQMs

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19652), as discussed in section IX.B.1., section IX.C.3., section IX.C.4., and section IX.C.8.c. of the preamble of the proposed rule, and in alignment with the Hospital Inpatient Quality Reporting Program, we proposed to adopt and remove the same eCQMs for the Medicare Promoting Interoperability Program beginning with the CY 2028 reporting period. Specifically, we proposed to adopt the following two eCQMs in the Medicare Promoting Interoperability Program eCQM measure set from which eligible hospitals and CAHs could self-select to report, beginning with the CY 2028 reporting period: (1) Hospital Harm—Postoperative Venous Thromboembolism (VTE); and (2) Advance Care Planning. Additionally, we proposed to remove the following three eCQMs from the Medicare Promoting Interoperability Program eCQM measure set, beginning with the CY 2028 reporting period: (1) Discharged on Antithrombotic Therapy eCQM; (2) VTE Prophylaxis eCQM; and (3) Intensive Care Unit VTE Prophylaxis eCQM.

We invited public comment on these proposals.

The comment summaries and responses in this section are specific to the Medicare Promoting Interoperability Program. For more complete summaries of the comments we received on these measure proposals, we refer readers to the Hospital Inpatient Quality Reporting Program discussion in section IX.C.8.c. of this final rule where we discuss the comments we received regarding both programs and our responses.

Comment: A few commenters supported CMS's proposals to align eCQM adoption and removal across the Medicare Promoting Interoperability Program and the Hospital Inpatient Quality Reporting Program, including removing eCQMs that they believed had become clinically dated, because they believed the proposals would promote consistency across hospital quality reporting programs, reduce duplicative reporting, simplify hospital workflows, maintain consistent measure specifications and submission requirements, and support meaningful quality improvement.

Response: We appreciate the commenters' support. We agree that aligning the eCQM reporting requirements and eCQM measure set for the Medicare Promoting Interoperability Program with similar requirements under the Hospital Inpatient Quality Reporting Program, to the extent feasible, allows for improved coordination, burden reduction, and the promotion of quality care. We also agree that maintaining a consistent measure set across programs supports clearer expectations for eligible hospitals and CAHs.

After consideration of the public comments we received, we are finalizing our proposals to adopt the Hospital Harm—Postoperative VTE and Advance Care Planning eCQMs and to remove the three VTE-related eCQMs beginning with the CY 2028 reporting period.

c. Modification of the eCQM Reporting and Submission Requirements

As we stated in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19652), consistent with our goal to align the eCQM reporting periods and criteria in the Medicare Promoting Interoperability Program with the Hospital Inpatient Quality Reporting Program, eligible hospitals and CAHs are currently required to annually report data for each required eCQM and three self-selected eCQMs for the CY 2026 reporting period and subsequent years (85 FR 58975 through 58976, 86 FR 45496, 87 FR 49365 through 49367, and 89 FR 69623 through 69624). We did not propose changes to our previously finalized policy that progressively increases the number of mandatory eCQMs a hospital must report for the CY 2026 reporting period or the CY 2027 reporting period (89 FR 69623 through 69624). In alignment with the Hospital Inpatient Quality Reporting Program, we did propose changes to the reporting and submission requirements for eCQMs for the Medicare Promoting Interoperability Program beginning with the CY 2028 reporting period. Specifically, in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19652 through 19654), we proposed to modify the eCQM reporting and submission requirements for the Hospital Harm eCQMs such that beginning with the CY 2028 reporting period these eCQMs would become mandatory for reporting after 2 years of self-selected reporting. Under the proposed changes, for example, the Hospital Harm—Falls with Injury eCQM and the Hospital Harm—Postoperative Respiratory Failure eCQM would become mandatory for reporting beginning with the CY 2028 reporting period. Consistent with the proposed approach for the Hospital Harm eCQMs (that is, two years of self-selected reporting followed by mandatory reporting in the third year), the proposed Hospital Harm—Postoperative VTE eCQM would be available for self-selected reporting for the CY 2028 and CY 2029 reporting periods and would become mandatory for reporting beginning with the CY 2030 reporting period. We refer readers to section IX.C.8.c. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and section IX.C.8.c. of this final rule for more detailed discussion in the Hospital Inpatient Quality Reporting Program.

Further, we proposed to require mandatory reporting of the Malnutrition Care Score eCQM beginning with the CY 2028 reporting period. The Hospital Harm—Falls with Injury eCQM, the Hospital Harm—Postoperative Respiratory Failure eCQM, and the Malnutrition Care Score eCQM would continue to be available as self-selected measures for the CY 2027 reporting period. These proposed changes are intended to further incentivize improvements in patient safety and nutrition care. We refer readers to

section IX.C.8.c. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule and section IX.C.8.c. of this final rule for more detailed discussion in the Hospital Inpatient Quality Reporting Program about our rationale.

We invited public comment on the proposals to modify reporting and submission requirements for eCQMs beginning with the CY 2028 reporting period.

We did not receive any comments specific to the Medicare Promoting Interoperability Program and refer readers to the Hospital Inpatient Quality Reporting Program discussion in section IX.C.8.c. of this final rule where we discuss the comments we received regarding both programs and our responses. We are finalizing our proposal to modify eCQM reporting, submission, and public reporting requirements with modification, beginning with the CY 2028 reporting period. Specifically, we are finalizing the proposed timeline under which Hospital Harm eCQMs will become mandatory after 2 years of self-selected reporting, with a modification to publicly report data on the more research-focused Provider Data Catalog for the first year of mandatory reporting before moving it to the consumer-focused Care Compare site, including Star Ratings, beginning with the second year of mandatory reporting. These measures will not be publicly reported during the 2-year self-selection period. This policy will apply to all Hospital Harm eCQMs adopted under the program, including any such measures adopted in future rulemaking. We are also finalizing mandatory reporting for the Hospital Harm—Falls with Injury eCQM, the Hospital Harm—Postoperative Respiratory Failure eCQM, and the Malnutrition Care Score eCQM.

We also refer readers to the Request for Information on FHIR-based digital quality measurement in the CY 2027 PFS proposed rule (91 FR 44152 through 44154), in which we are seeking comment on a phased timeline, key milestones, and implementation considerations for transitioning to FHIR-based digital quality reporting in the Quality Payment Program and other CMS clinician and hospital quality programs, including the Medicare Promoting Interoperability Program.

d. Summary of Previously Finalized and Newly Finalized eCQMs Available for Eligible Hospitals and CAHs to Report Under the Medicare Promoting Interoperability Program

Table IX.F.–8 summarizes our finalized policies to modify reporting and submission requirements for eCQMs beginning with the CY 2028 reporting period.

BILLING CODE 4169–69–P

TABLE IX.F.-08. SUMMARY OF ECQM REPORTING AND SUBMISSION REQUIREMENTS

Reporting Period	Total Number of eCQMs Reported	eCQMs Required to be Reported	eCQMs for Self-selection (must report 3)
CY 2028	Fourteen	• Safe Use of Opioids—Concurrent Prescribing • Cesarean Birth • Severe Obstetric Complications • Malnutrition Care Score* • Hospital Harm—Severe Hyperglycemia • Hospital Harm—Severe Hypoglycemia • Hospital Harm—Opioid-Related Adverse Events • Hospital Harm—Pressure Injury • Hospital Harm—Acute Kidney Injury • Hospital Harm—Falls with Injury* • Hospital Harm—Postoperative Respiratory Failure*	• Anticoagulation Therapy for Atrial Fibrillation/Flutter • Antithrombotic Therapy by the End of Hospital Day Two • Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults • Advance Care Planning** • Hospital Harm—Postoperative Venous Thromboembolism***
CY 2029	Fourteen	• Safe Use of Opioids—Concurrent Prescribing • Cesarean Birth • Severe Obstetric Complications • Malnutrition Care Score* • Hospital Harm—Severe Hyperglycemia • Hospital Harm—Severe Hypoglycemia • Hospital Harm—Opioid-Related Adverse Events • Hospital Harm—Pressure Injury • Hospital Harm—Acute Kidney Injury • Hospital Harm—Falls with Injury* • Hospital Harm—Postoperative Respiratory Failure*	• Anticoagulation Therapy for Atrial Fibrillation/Flutter • Antithrombotic Therapy by the End of Hospital Day Two • Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults • Advance Care Planning** • Hospital Harm—Postoperative Venous Thromboembolism***
CY 2030 and subsequent years	Fifteen	• Safe Use of Opioids—Concurrent Prescribing • Cesarean Birth • Severe Obstetric Complications • Malnutrition Care Score* • Hospital Harm—Severe Hyperglycemia • Hospital Harm—Severe Hypoglycemia • Hospital Harm—Opioid-Related Adverse Events • Hospital Harm—Pressure Injury • Hospital Harm—Acute Kidney Injury • Hospital Harm—Falls with Injury* • Hospital Harm—Postoperative Respiratory Failure* • Hospital Harm—Postoperative Venous Thromboembolism***	• Anticoagulation Therapy for Atrial Fibrillation/Flutter • Antithrombotic Therapy by the End of Hospital Day Two • Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults • Advance Care Planning**

* Finalized from self-selected to mandatory reporting beginning with the CY 2028 reporting period.
** Finalized for adoption as a self-selected eCQM beginning with the CY 2028 reporting period.
*** Finalized for adoption as a self-selected eCQM for two years beginning with the CY 2028 reporting period. The measure will become mandatory beginning with the CY 2030 reporting period after two years of self-selected reporting.

BILLING CODE 4169–69–C

Table IX.F.–9 summarizes the previously finalized and newly finalized eCQMs available for eligible hospitals and CAHs to report under the Medicare Promoting Interoperability Program for the specified reporting periods, including whether the measure is mandatory or self-selected as further discussed in section IX.C.8.c. regarding finalized changes to this latter policy.

BILLING CODE 4169–69–P

TABLE IX.F.-09: PREVIOUSLY FINALIZED AND NEWLY FINALIZED PROMOTING INTEROPERABILITY PROGRAM MEASURE SET BY DATA COLLECTION METHOD AND REPORTING PERIOD

Measure Name	CBE Number	CY 2026	CY 2027	CY 2028	CY 2029	CY 2030
Discharged on Antithrombotic Therapy**	0435e	*	*	Removal	Removal	Removal
Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e	*	*	*	*	*
Antithrombotic Therapy by the End of Hospital Day Two	0438e	*	*	*	*	*
Venous Thromboembolism Prophylaxis**	0371e	*	*	Removal	Removal	Removal
Intensive Care Unit Venous Thromboembolism Prophylaxis**	0372e	*	*	Removal	Removal	Removal
Safe Use of Opioids - Concurrent Prescribing	3316e	✓	✓	✓	✓	✓
Hospital Harm—Opioid-Related Adverse Events	3501e	*	✓	✓	✓	✓
Hospital Harm—Severe Hypoglycemia	3503e	✓	✓	✓	✓	✓
Hospital Harm—Severe Hyperglycemia	3533e	✓	✓	✓	✓	✓
Hospital Harm—Pressure Injury	3498e	*	*	✓	✓	✓
Hospital Harm—Acute Kidney Injury	3713e	*	*	✓	✓	✓
Hospital Harm—Falls with Injury***	4120e	*	*	Mandatory Reporting	Mandatory Reporting	Mandatory Reporting
Hospital Harm—Postoperative Respiratory Failure***	4130e	*	*	Mandatory Reporting	Mandatory Reporting	Mandatory Reporting
Hospital Harm—Postoperative Venous Thromboembolism****	5325e			Self-selected Reporting	Self-selected Reporting	Mandatory Reporting
Cesarean Birth	0471e	✓	✓	✓	✓	✓
Severe Obstetric Complications	3687e	✓	✓	✓	✓	✓
Malnutrition Care Score***	3592e	*	*	Mandatory Reporting	Mandatory Reporting	Mandatory Reporting
Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient)	3663e	*	*	*	*	*
Advance Care Planning****	N/A			Self-Selected Reporting	Self-Selected Reporting	Self-Selected Reporting

✓Measure is mandatory for the specified reporting period.

* Measure is a self-selected eCQM for the specified reporting period. Hospitals are required to self-select three eCQMs, in addition to all mandatory eCQMs, to submit for the specified reporting period.

** Removal finalized in this final rule beginning with the CY 2028 reporting period.

*** Finalized in this final rule from self-selected to mandatory reporting beginning with the CY 2028 reporting period and subsequent years.

**** Adopted in this final rule beginning with the CY 2028 reporting period. We refer readers to section IX.C.8.c. for our finalized policy to modify reporting and submission requirements for the Hospital Harm eCQMs; under this finalized policy the Hospital Harm—Postoperative VTE eCQM would become mandatory after two years of self-selected reporting beginning with the CY 2030 reporting period.

BILLING CODE 4169–69–C

X. Other Provisions Included in This Final Rule

A. Changes to the Transforming Episode Accountability Model (TEAM)

1. Background

a. Purpose

TEAM is a 5-year mandatory alternative payment model tested by the CMS Innovation Center that began on January 1, 2026, and will end on December 31, 2030. TEAM tests whether an episode-based pricing methodology linked with quality measure performance for select acute care hospitals reduces Medicare program expenditures while preserving or improving the quality of care for Medicare beneficiaries who initiate certain episode categories. Specifically, TEAM tests five surgical episode categories: Coronary Artery Bypass Graft Surgery (CABG), Lower Extremity Joint Replacement (LEJR), Major Bowel Procedure, Surgical Hip/Femur Fracture Treatment (SHFFT), and Spinal Fusion.

As discussed in greater detail in section X.A.1.b. of the preamble of this final rule, TEAM was established through notice and comment rulemaking. As a mandatory model, new

policies or policy modifications require notice and comment rulemaking. In the proposed rule, we sought to make updates to TEAM that include the following modifications:

- Adding new Medicare Severity Diagnosis Related Groups (MS–DRGs) to the spinal fusion episode category.
- Adjusting episode attribution.
- Adjusting the measurement performance periods for certain quality measures.
- Adjusting the construction of the CQS baseline period.
- Capturing Ambulatory Payment Classification (APC) and MS–DRG changes in preliminary target prices.
- Adjusting the construction of the prospective normalization factor.

We also solicited public comment on two Requests for Information (RFI) in the following policy areas:

- Ambulatory Surgical Center (ASC) Episodes.
- Hospital with Physician Ownership (POH).

The policies in this final rule reflect our commitment to ensuring TEAM's incentives help to drive beneficiary quality of care improvements and reductions in Medicare spending.

b. Statutory Authority and Background

Under the authority of section 1115A of the Act, through notice-and-comment rulemaking, the CMS Innovation Center established TEAM in the FY 2025 IPPS/LTCH PPS final rule that appeared in the August 28, 2024, **Federal Register** (89 FR 69626 through 69879). The intent of TEAM is to improve beneficiary care through financial accountability for episode categories that begin with one of the following procedures: CABG, LEJR, major bowel procedure, SHFFT, and spinal fusion. TEAM tests whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries.

Under Original Medicare, Medicare makes separate payments to providers and suppliers for the items and services furnished to a beneficiary over the course of an episode of care. Because providers and suppliers are paid for each individual item or service delivered, providers may not be incentivized to invest in quality improvement and care coordination activities. As a result, care may be fragmented, unnecessary, or duplicative. By holding hospitals accountable for all items and services provided during an episode, providers would be better incentivized to coordinate patient care, avoid duplicative or unnecessary services, and improve the beneficiary care experience during care transitions.

Under TEAM, all acute care hospitals, with limited exceptions, located within the Core Based Statistical Areas (CBSAs) that CMS selected for model implementation are required to participate in TEAM. CMS allowed a one-time opportunity for hospitals that participated until the last day of the last performance period in the Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model or the last day of the last performance year of the Comprehensive Care for Joint Replacement (CJR) Model, that are not located in a mandatory CBSA selected for TEAM participation, to voluntarily opt into TEAM. TEAM includes a 1-year glide path opportunity that allows TEAM participants to ease into full financial risk as well as three different participation tracks to accommodate different levels of financial risk and reward. Track 1 is an upside only risk track available for all TEAM participants in the first performance year and available to safety net hospitals for the first 3 performance years. Track 2 is a two-sided risk track that has lower financial risk and reward, relative to Track 3, and will be available to select TEAM participants in performance years 2 through 5.[570] Track 3 is a two-sided risk track that has higher financial risk and reward, relative to Track 2, and is available to all TEAM participants in performance years 1 through 5.

Episodes include non-excluded Medicare Parts A and B items and services and begin with an anchor hospitalization or anchor procedure and will end 30 days after hospital discharge. TEAM participants continue to bill Medicare FFS as usual for items and services delivered to beneficiaries in an episode but will receive preliminary target prices for episodes prior to each performance year. Target prices are based on 3 years of baseline data, prospectively trended forward to the relevant performance year, and calculated at the level of Medicare Severity Diagnosis Related Group/Healthcare Common Procedure Coding System (MS–DRG/HCPCS) episode type and region. Target prices also include a discount factor and risk-adjustment. Participants will receive reconciliation (final) target prices that will incorporate a capped retrospective trend factor adjustment and a capped normalization factor.

Performance in the model will be assessed by comparing TEAM participants' actual Medicare FFS spending during a performance year to their reconciliation target price as well as by assessing performance on selected quality measures. TEAM participants may earn a payment from CMS, subject to a quality performance adjustment, if their spending is below the reconciliation target price. TEAM participants may owe CMS a repayment amount, subject to a quality performance adjustment, if their spending was above the reconciliation target price.

2. TEAM Provisions of This Final Rule

a. Episodes

(1) Background

As indicated in the FY 2025 IPPS/LTCH PPS final rule, an episode has two significant dimensions: (1) a clinical dimension that describes which clinical conditions and associated services are included in the episode; and (2) a time dimension that describes the beginning and end of the episode, its length, and when the episode may be cancelled prior to the end of the episode (89 FR 69710). Under TEAM, episodes begin when a beneficiary is admitted for an anchor hospitalization or an anchor procedure identified by specific Medicare Severity Diagnosis Related Groups (MS–DRGs) or Healthcare Common Procedure Coding System (HCPCS) codes, identified in 42 CFR 512.525(d). TEAM episodes include all spending for Medicare Parts A and B items and services during the anchor hospitalization or anchor procedure and a 30-day post-discharge period, as described in 42 CFR 512.525(e), with limited exclusions as outlined in 42 CFR 512.525(f). An episode may be cancelled if the beneficiary (1) does not meet the beneficiary inclusion criteria, as outlined in 42 CFR 512.535; (2) dies during the anchor hospitalization or anchor procedure; or (3) the episode qualifies for the extreme and uncontrollable circumstances policy, as described in 42 CFR 512.537(b)(3).

TEAM tests five episode categories, identified in Table X.A.–01, that represent high-expenditure, high-volume care delivered to Medicare beneficiaries. These episode categories also generally have a greater proportion of spending in the post-acute period relative to the anchor hospitalization or procedure, that present a greater opportunity to improve care transitions for beneficiaries and reduce

[570] TEAM participants eligible for Track 2 include safety net hospitals, rural hospitals, Medicare dependent hospitals, Sole Community Hospitals, and Essential Access Community Hospitals, all defined at § 512.505.

unnecessary hospitalizations and emergency care.

TABLE X.A.-01: EPISODE CATEGORIES AND CORRESPONDING CODES THAT INITIATE AN ANCHOR HOSPITALIZATION OR ANCHOR PROCEDURE

Episode Category	Anchor Hospitalization Trigger Code (MS-DRG)	Anchor Procedure Trigger (HCPCS)
Coronary Artery Bypass Graft	231, 232, 233, 234, 235, or 236	Not Applicable
Lower Extremity Joint Replacement	469, 470, 521, or 522	27447, 27130, or 27702
Major Bowel Procedure	329, 330, or 331	Not Applicable
Surgical Hip Femur Fracture Treatment	480, 481, or 482	Not Applicable
Spinal Fusion	402, 426, 427, 428, 429, 430, 447, 448, 450, 451, 471, 472, or 473	22551, 22554, 22612, 22630, or 22633

(2) Changes to Spinal Fusion Episode Category

Generally, CMS assesses MS–DRG classification changes on an annual basis with the fiscal year IPPS rulemaking cycle. These changes may result in the addition, modification, or deletion of MS–DRGs. Since inpatient episodes in TEAM rely on MS–DRG codes to identify when an anchor hospitalization is initiated, any changes to the MS–DRGs included in TEAM may affect episode volume and ultimately the number of beneficiaries included in the model. As described in section II.C of the preamble of this final rule, there are final policies to change certain MS–DRGs that affect the spinal fusion episode category in TEAM. Specifically, three new MS–DRGs are being finalized to better classify beneficiary acuity and resource utilization for a subset of spinal fusion procedures. As indicated in the proposed rule, if these new MS–DRGs were finalized, we would make conforming changes in TEAM, therefore we proposed at § 512.525(d)(4)(i) that starting on October 1, 2026, MS–DRGs 523, 524, and 525 would be added to the spinal fusion episode category that would initiate a spinal fusion anchor hospitalization. We also proposed at § 512.505 to update the spinal fusion definition to include these three new MS–DRGs. This means the other spinal fusion MS–DRGs remain unchanged and would initiate a spinal fusion anchor hospitalization starting on January 1, 2026. We believed it was important to include these new MS–DRGs in TEAM so that hospitals can continue to have sufficient spinal fusion episode volume to pursue efficiencies in care delivery, spread financial risk, and increase the potential to maximize beneficiaries access to value-based care. Further, we indicated in the proposed rule that not including these new MS–DRGs may reduce the scale and create evaluation challenges for the spinal fusion episode category. Lastly, we also believed it was important to capture proposed MS–DRG updates in TEAM to reflect current coding standards, ensuring consistency with IPPS policies.

We considered in the proposed rule, but did not propose, not to update the MS–DRGs in TEAM for the spinal fusion episode category. This would mean that only the spinal fusion MS–DRGs that remain unchanged would initiate a spinal fusion anchor hospitalization in TEAM. While this approach would minimize change during the model test, episode volume would remain a concern. Additionally, we noted in the proposed rule that we believed not updating the spinal fusion MS–DRGs was not a feasible long-term approach because not updating the spinal fusion MS–DRGs is not responsive to Medicare policy changes and prohibits beneficiaries from accessing the benefits of the model.

We sought comment on our proposals at § 512.505 to update the spinal fusion definition and at § 512.525(d)(4)(i) to add MS–DRGs 523, 524, and 525 to the spinal fusion episode category.

The following is a summary of the public comments received on the proposed policy for updating the spinal fusion definition to add MS–DRGs 523, 524, and 525 to the spinal fusion episode category, and our responses to these comments:

Comment: A few commenters supported the inclusion of MS–DRGs 523, 524, and 525 in the TEAM spinal fusion episode category starting October 1, 2026, noting that this would ensure alignment with underlying coding structure changes, preserve adequate volume for the spinal fusion episode category, and capture more complex cases in the model. A commenter also highlighted that excluding these MS–DRGs from TEAM would create a financial disincentive for participants to utilize innovative spine technology and subsequently limit access for Medicare beneficiaries.

Response: We thank the commenters for their support of including MS–DRGs 523, 524, and 525 in the TEAM spinal fusion episode category. We agree that the inclusion of these MS–DRGs aligns with current coding standards and ensures participants have sufficient episode volume for the spinal fusion category.

Comment: A few commenters supported the inclusion of MS–DRGs 523, 524, and 525 in the TEAM spinal fusion episode category, but expressed their concerns and suggestions regarding the implementation of this change. A commenter recommended the inclusion of additional risk adjusters for the spinal fusion episode category, such as functional and disability status, to ensure that participants that perform these complex procedures are not disadvantaged. A couple commenters also suggested that CMS delay the implementation of the new MS–DRGs to the start of PY2, to avoid adding codes during the performance year, or to PY3, to allow participants time to adapt to the revised episode definitions and associated methodologies. A commenter also requested additional technical assistance materials to help participants prepare for this update, such as scaling factor implications and mappings for impacted codes. Lastly, a commenter recommended that CMS monitor whether the inclusion of MS–DRGs 523, 524, and 525 results in any unintended consequences, such as variation in target prices or benchmark prices.

Response: We appreciate the concerns that commenters shared regarding CMS's proposal to include MS–DRGs 523, 524, and 525 in TEAM starting October 1, 2026. We believe the risk adjustment model for the spinal fusion episode category finalized in the FY2026 IPPS/LTCH PPS final rule sufficiently captures hospital- and beneficiary-level risk. We will continue to analyze and monitor our risk adjustment model and consider changes through future notice and comment rulemaking. We understand stakeholder concerns about incorporating new trigger MS–DRGs during the performance year and requests to postpone the implementation of this change. However, we believe that implementing all MS–DRG-related changes in accordance with the standard fiscal year update cadence

ensures alignment with the most current IPPS policies. We also acknowledge the request for technical assistance materials to support participants. CMS intends to continue providing learning resources to educate participants on key changes to the model, minimize burden and optimize participants' opportunities for success in the model. Finally, we will continue to monitor for any unintended consequences of this change on participants and beneficiaries.

Comment: Some commenters opposed the inclusion of MS–DRGs 523, 524, and 525 in the TEAM spinal fusion episode category. A few commenters noted that many of the procedures that are included in MS–DRGs 523, 524, and 525 are not currently TEAM-eligible procedures, and the inclusion of these procedures would represent an expansion of the spinal fusion episode category with no clear evidence that these changes are necessary. A commenter urged CMS to provide data regarding the spending patterns and expected financial impacts of these newly included MS–DRGs. In addition, a commenter cited that this would create significant administrative burden for participants, including modifications to EHR workflows, episode identification logic, and operational processes. A commenter urged CMS to refrain from mid-model expansions to TEAM's MS–DRG scope, stating that any such change should be made to future model iterations instead. Another commenter encouraged CMS to allow sufficient time for evaluation of the initial MS–DRGs before considering additional episode expansions. A commenter raised concerns that the new MS–DRGs do not have sufficient historic data for reliable target price calibration, meaningful risk adjustment, or accurate benchmarking of episode expenditure, and could expose participants to inappropriate risk and limit beneficiary access to these procedures. They recommended CMS delay implementation until there is sufficient historical claim data under the new MS–DRG structure.

Response: We thank commenters for sharing their concerns. We disagree that there is no clear rationale behind the inclusion of MS–DRGs 523, 524, and 525 in TEAM since many of the underlying procedure codes that were reassigned to these MS–DRGs are currently included in the spinal fusion episode category. Moreover, implementing updates to TEAM-eligible MS–DRGs in tandem with the standard fiscal year MS–DRG update cadence ensures alignment with the most current IPPS policies and ensures TEAM participants continue to have sufficient spinal fusion episode volume.

We acknowledge concerns about the administrative burden the additional MS–DRGs may put on TEAM participants. CMS intends to provide technical assistance materials to TEAM participants to inform them about the new MS–DRGs and relevant procedures to help mitigate this burden. CMS intends to continue to provide learning resources to educate participants on key changes to the model, minimize burden and optimize participants' opportunities for success in the model. Additionally, we believe the advantages of including these MS–DRGs, such as spreading financial risk and increasing the potential to maximize beneficiary access to value-based care, outweigh the administrative challenges.

We thank the commenters for their suggestions to delay the addition of new MS–DRGs. However, we believe that it is important to make conforming and timely changes in TEAM so as not to reduce the scale of the model or create evaluation challenges for the spinal fusion category, and to ensure alignment with annual MS–DRG updates in IPPS. That being said, CMS intends to continue monitoring the impact of these additional MS–DRGs over the course of the model.

Regarding concerns on insufficient historical data, we believe the TEAM target price construction methodology sufficiently addresses changes and updates to MS–DRG classifications. As finalized in the FY2026 IPPS/LTCH PPS Final Rule, CMS already accounts for changes in MS–DRG definitions through the three-step mapping approach. We believe this will mitigate risks related to insufficient historical claims data for MS–DRG 523, 524, and 525.

Comment: A couple commenters also stated that MS–DRGs 523, 524, and 525 encapsulate highly complex procedures that are not appropriate for TEAM. A commenter noted that these MS–DRGs group together spinal fusions of more than two levels and eight or more levels fused and argued that a single target price for the MS–DRG is not appropriate, given the potential variation in procedure complexity. Furthermore, the commenter highlighted that spending variation for these procedures cannot always be explained by differences in patient case-mix, and as such, excluding these procedures from TEAM is favorable. Another commenter noted that these procedures often have unexpected complications that make these MS–DRGs difficult for participants to proactively identify for TEAM inclusion. The commenter further noted these MS–DRGs included procedures that are often staged, and such cases would be captured as a readmission in TEAM, posing financial risk for participants. In addition, the commenter noted that these procedures are often disproportionately completed at tertiary referral centers and neuroscience programs, and these high acuity centers could be financially penalized for treating these patients. Finally, the commenter recommended that all staged procedures are excluded from TEAM.

Response: We acknowledge that MS–DRGs 523, 524, and 525 include complex procedures which require accurate target pricing but disagree that these are not appropriate for TEAM. Excluding specific MS–DRGs that are associated with existing TEAM episode categories can reduce the number of patients covered by value-based care arrangements and may even create new opportunities for gaming by providers. We believe that the inclusion of these MS–DRGs increases the potential to maximize beneficiaries' access to value-based care and encourages improvements in quality and cost-efficiency without creating distorted financial incentives. As previously stated, we believe our risk adjustment and target price methodology sufficiently account for hospital and beneficiary characteristics as well as variation in spending across MS–DRGs and procedure types. We will continue to monitor how the introduction of these new MS–DRGs impact participants and if updates to the risk-adjustment model for spinal fusion episodes are necessary to propose in future rule making.

We also understand that hospitals may not know the assigned MS–DRG of a beneficiary at the time of discharge. We urge TEAM participants to proactively track underlying diagnosis and procedure codes to identify potential TEAM triggers and undertake care coordination for all potential TEAM beneficiaries. We acknowledge the comment related to staged procedures and the need to account for planned subsequent admissions during the 30-day discharge period. We believe that undertaking a second spinal fusion procedure within a 30-day episode period will be infrequent within TEAM, assuming the need for pre-operative medical optimization, including recovery from prior procedures and management of underlying conditions. We will continue to monitor the frequency and circumstances of such occurrences for future consideration.

Additionally, we want to clarify that TEAM participant clinical episodes are identified based on the CMS

Certification Number (CCN) on the triggering inpatient or outpatient claim with a TEAM qualifying MS–DRG or HCPCS code. If a TEAM participant hospital has tertiary referral centers or other specialty centers that bill under the same CCN as the participant hospital, all procedures triggered at these other facilities can be included in TEAM.

After consideration of the public comments, we are finalizing without modification the proposal at § 512.525(d)(4)(i) to add MS–DRGs 523, 524, and 525 to the spinal fusion episode category.

(3) Changes to Episode Attribution

In section X.C. of the preamble of this final rule, the Comprehensive Care for Joint Replacement Expanded (CJR–X) Model is being finalized as an expanded phase II model test under Section 1115A(c) of the Act. Similar to TEAM, CJR–X will be a mandatory episode-based payment model for acute care hospitals with a focus on Lower Extremity Joint Replacement (LEJR) episodes. Both TEAM and CJR–X test LEJR episodes, however TEAM tests a 30-day post-discharge period episode length while CJR–X will test a 90-day post-discharge period episode length. We stated in the proposed rule that given the model similarities and our desire to assess differences in outcomes between these two episode durations, the CJR–X model proposed to exclude TEAM participants from participating in CJR–X, as described in section X.C.2.b.(2)(i) of the preamble of this final rule. We also stated in the proposed rule that while this exclusion would prevent a TEAM participant from being a CJR–X participant, it does not address instances where a beneficiary is in a CJR–X episode and receives care at a TEAM participant during the CJR–X 90-day post-discharge period. Therefore, we proposed at § 512.537(b)(4) that if a beneficiary in a CJR–X episode has a procedure performed at a TEAM hospital that would initiate a TEAM episode during the CJR–X 90-day post-discharge period, then that procedure would not initiate a TEAM episode or be attributed to the TEAM participant and the spending from that procedure would be included in the CJR–X episode. We noted in the proposed rule that while this instance would result in the TEAM participant not being attributed the episode, the procedure and its associated spending would be included in TEAM target price construction, which relies on average episode spending and average trends across all MS–DRG/HCPCS region combinations. As noted in section X.C.2.(h)(2) of the preamble of this final rule, we considered TEAM precedence in this situation and dropping the CJR–X episode to initiate a TEAM episode to support episode volume in TEAM, but we believed it was important to hold the hospital where the anchor hospitalization or anchor procedure took place accountable for spending and care coordination throughout the episode, especially given the investments that hospitals employ to manage a beneficiary's care. We also believed this policy would avoid duplicative calculations for the same procedure in a model that is similar in overall design.

We sought comment on our proposals at § 512.537(b)(4) to not attribute an episode to a TEAM participant if the beneficiary is in a CJR–X episode and has a procedure performed at a TEAM participant that would initiate an episode during the CJR–X 90-day post-discharge period.

The following is a summary of the public comments received on the proposed policy to not attribute an episode to a TEAM participant if the beneficiary is in a CJR–X episode and has a procedure performed at a TEAM participant that would initiate an episode during the CJR–X 90-day post-discharge period, and our responses to these comments:

Comment: Many commenters supported the proposed episode attribution policy. Some commenters appreciated the clear episode attribution rules, noting that they are essential for avoiding duplicative accountability, confusion among participants and beneficiaries, and reconciliation complexity. A commenter also supported excluding CJR–X episodes from TEAM performance reconciliation while including the associated spending in TEAM target prices to ensure accurate benchmarking.

Response: We thank commenters for their support. We agree that clear attribution rules for CJR–X and TEAM are crucial for participants.

Comment: Some commenters requested CMS continue to provide data and guidance on how TEAM participants can identify beneficiaries impacted by this overlap policy. A commenter suggested that CMS monitor this policy to ensure it adequately prevents episode overlap.

Response: We appreciate the commenters' suggestions. CMS will explore potential resources, including technical assistance materials, to aid participants in identifying beneficiaries that are impacted by the episode attribution policy. CMS intends to also monitor the frequency and impact of the TEAM and CJR–X episode attribution policy.

Comment: A commenter requested that CMMI specify which episode applies when a second procedure occurs at a TEAM hospital or when CJR–X and TEAM episode windows overlap.

Response: We thank the commenter for their request. If a beneficiary has an initial procedure at a CJR–X participant hospital and a subsequent TEAM-eligible procedure within the CJR–X 90-day post-discharge window at a TEAM-participant hospital, the subsequent procedure would be attributed to the CJR–X participant episode and would not initiate a TEAM episode. In this scenario, the subsequent procedure and its associated spending would still be captured in TEAM target price construction to ensure average episode spending, benchmarking, and trends are accurately captured, but it would not be attributed to a TEAM participant.

Comment: A commenter raised concerns that the concurrent implementation of CJR–X and TEAM requires health systems to manage similar patients under different financial and episode structures (including the distinct post-discharge period windows) and recommended aligning key design elements, such as attribution, to reduce complexity and burden.

Response: We appreciate the concerns raised by this commenter. Although the models are similar, CJR–X's 90-day post-discharge window and TEAM's 30-day post-discharge window are intentionally distinct to identify differences in outcomes between these two episode durations. We also believe the proposed episode attribution policy will avoid duplicative, complex calculations.

After consideration of the public comments, we are finalizing without modification the proposal at § 512.537(b)(4) to not attribute an episode to a TEAM participant if the beneficiary is in a CJR–X episode and has a procedure performed at a TEAM participant that would initiate an episode during the CJR–X 90-day post-discharge period.

b. Quality Measures

(1) Background

As discussed in the FY25 and FY26 IPPS/LTCH PPS final rule (89 FR 68986 and 90 FR 36536), Medicare payment policy continues to move away from fee-for-service (FFS) payments that are not linked to quality of care. As previously noted in the prior rules, through the Medicare Modernization Act and the Affordable Care Act, we have implemented specific IPPS programs

like the Hospital Inpatient Quality Reporting (IQR) Program (section 1886(b)(3)(B)(viii) of the Act), the Hospital Outpatient Quality Reporting (OQR) Program (section 1833(t)(17)(C) of the Act), the Hospital Value-Based Purchasing (VBP) Program (subsection (o) of section 1886), the Hospital-Acquired Condition (HAC) Reduction Program (subsection (q) of section 1886), and the Hospital Readmissions Reduction Program (subsection (p) of section 1886), where payment may reflect the quality of care delivered to Medicare beneficiaries or be impacted by the reporting of quality measures.

TEAM quality measures focus on care coordination, patient safety, and patient-reported outcomes (PROs), which are areas critical to patients undergoing acute procedures. To streamline reporting in this mandatory model, we align quality measures in TEAM with those used in existing CMS models and reporting programs wherever feasible. TEAM participants will not submit separate quality data to CMS for TEAM. Instead, CMS will utilize data already reported through established CMS quality reporting programs, eliminating duplicate reporting requirements. TEAM's finalized set of quality measures are used to calculate the Composite Quality Score (CQS). The CQS will be combined with the TEAM participants' reconciliation amount during the reconciliation process to tie quality performance to payment. We proposed and finalized seven quality measures due to their: (1) alignment with the goals of TEAM; (2) hospitals' familiarity with the measures due to their use in other CMS hospital quality programs, including the Hospital IQR, OQR and HAC Reduction Programs; and (3) alignment to CMS priorities, including the CMS National Quality Strategy, which has goals that support safety, outcomes, and engagement. We believe these quality measures reflect these goals and accurately measure hospitals' level of achievement on such goals.

The measures are—

- For all TEAM inpatient episodes in PY1—PY5: Hybrid Hospital-Wide All-Cause Readmission (Hybrid HWR) Measure with Claims and Electronic Health Record Data (CMIT ID #356), claims-only for PY1 and full hybrid for PY2—PY5;
- For all TEAM inpatient episodes in PY1: CMS Patient Safety and Adverse Events Composite (CMS PSI–90) (CMIT ID #135);
- For all TEAM inpatient LEJR episodes in PY1—PY5: Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO–PM) (CMIT ID #1618);
- For all TEAM inpatient episodes in PY2—PY5: Hospital Harm—Falls with Injury (CMIT ID #1518);
- For all TEAM inpatient episodes in PY2—PY5: Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788);
- For all TEAM inpatient episodes in PY2—PY5: Thirty-day Risk—Standardized Death Rate among Surgical Inpatients with Complications (ISCMR) (CMIT ID #134); and
- For all TEAM outpatient LEJR and Spinal Fusion episodes in PY3—PY5: Information Transfer Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM) (CMIT ID #1797).

We believe the TEAM quality measure set provides CMS with sufficient measures to monitor quality and to calculate scoring on quality performance. As stated in the FY25 and FY26 IPPS/LTCH PPS final rules (89 FR 68986 and 90 FR 36536), we may adjust the measure set in future performance years via rulemaking if we determine those adjustments to be appropriate at the time.

(2) Measurement Performance Periods for Certain Quality Measures

As stated previously, TEAM aims to, whenever possible, align with existing reporting requirements so as not to introduce additional burden to participants. In the FY25 IPPS/LTCH PPS final rule (89 FR 68986), we finalized the Hospital Harm—Falls with Injury, Hospital Harm—Postoperative Respiratory Failure, and Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (ISCMR) and stated these measures would align with the hospital reporting programs. At that time, we stated our intent to align these measures with the performance periods used in the Hospital IQR Program. However, we did not propose or finalize the specific measurement performance periods for these measures within TEAM.

In this final rule, we are establishing measurement performance periods for these three quality measures. In the proposed rule for Hospital Harm—Falls with Injury and Hospital Harm—Postoperative Respiratory Failure, we proposed alignment with the Hospital IQR Program's calendar year reporting requirements, utilizing a one-year measurement performance period. For ISCMR, we proposed alignment with the Hospital IQR Program's 2-year rolling measurement performance period. Table X.A–02 displays the proposed measurement performance periods for these specific quality measures in TEAM. We believed these measurement performance periods were consistent with other CMS quality reporting programs and therefore would help minimize TEAM participant confusion.

TABLE X.A.-02: FINALIZED QUALITY MEASUREMENT PERFORMANCE PERIODS

	TEAM PERFORMANCE YEAR (PY) QUALITY MEASUREMENT PERFORMANCE PERIOD			
Quality Measure	**PY2 Performance Period**	**PY3 Performance Period**	**PY4 Performance Period**	**PY5 Performance Period**
Hospital Harm—Falls with Injury (CMIT ID #1518)	January 1, 2027 – December 31, 2027	January 1, 2028 – December 31, 2028	January 1, 2029 – December 31, 2029	January 1, 2030 – December 31, 2030
Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788)	January 1, 2027 – December 31, 2027	January 1, 2028 – December 31, 2028	January 1, 2029 – December 31, 2029	January 1, 2030 – December 31, 2030
Thirty-day Risk—Standardized Death Rate among Surgical Inpatients with Complications (ISCMR) (CMIT ID #134)	July 1, 2024 – June 30, 2026	July 1, 2025 – June 30, 2027	July 1, 2026 – June 30, 2028	July 1, 2027 – June 30, 2029

We sought comment on the proposed measurement performance period timeframes for TEAM performance years 2 through 5 for the Hospital Harm—Falls with Injury and Hospital Harm—Postoperative Respiratory Failure, and ISCMR quality measures.

The following is a summary of the public comments received on the proposed measure performance period timeframes for these three measures, and our responses to these comments:

Comment: A commenter expressed concerns that changing measurement performance periods in the middle of a TEAM performance year would make it difficult for participants to identify stable targets and plan quality improvement efforts. The commenter recommended that CMS release an annual calendar specifying which measures applied to each performance year and detailing any updates to performance periods.

Response: We appreciate the commenter's concern regarding participants' ability to identify stable targets and plan quality improvement efforts under TEAM. While we finalized these measures in the FY 2025 IPPS/LTCH PPS final rule and stated that we intended to align these measures with the measurement performance periods used in the Hospital IQR Program, we did not propose or finalize specific measurement performance periods for these measures within TEAM in that rule. This is the first instance we have proposed measurement performance periods for these measures. Given that the proposed measurement performance periods for the Hospital Harm measures do not begin until January 1, 2027, and these measures are not applicable until Performance Year 2, we believe that participants will have adequate time to identify targets and plan quality improvement efforts for these measures. While the proposed ISCMR measurement performance period begins on July 1, 2024, proposing a measurement performance period that begins after the release of this final rule, the earliest of which would be July 1, 2027–June 30, 2029, would not be feasible given the timelines of the TEAM reconciliation process. We thank the commenter for their suggestion to release an annual calendar providing more details on the quality measures used in TEAM and will take this suggestion into consideration.

Comment: A commenter requested that CMS push back the measurement performance periods for the Hospital Harm—Falls with Injury and Hospital Harm—Postoperative Respiratory Failure eCQMs, as these measures are not currently mandatory to report under the Hospital IQR Program and will not be available to report under the Hospital IQR Program until FY 2028 payment determination, noting that hospitals need more time to prepare their systems for new measures. Another commenter expressed concern that having measurement performance periods for these measures prior to mandatory reporting, when the measures are ''untested'' will place additional burden on TEAM participants and contradict CMS' proposal to allow 2 years of self-selected reporting for new Hospital Harm eCQMs before making them mandatory.

Response: We thank the commenters for sharing their concerns. However, we disagree that hospitals have not had adequate time to prepare for the inclusion of the Hospital Harm measures in TEAM, or that this proposal would add administrative burden for TEAM participants. Hospitals have had the ability to choose the Hospital Harm—Falls with Injury and Hospital Harm—Postoperative Respiratory Failure measures as one of their three self-selected eCQMs beginning with the CY 2026 reporting period, which corresponds to FY 2028 payment determination. In the FY 2026 IPPS/LTCH PPS final rule, we finalized that TEAM participants that have no or an incomplete raw quality measure score for a given quality measure would receive a scaled quality score of 50 for that measure. Accordingly, any hospitals that choose not to report the Hospital Harm measures as one of their self-selected eCQMs in CY 2027 will receive a scaled score of 50 for those measures in performance year 2. While these measures will begin mandatory reporting under the Hospital IQR Program in CY 2028 as finalized in section IX.C.8.c.(3), there is no TEAM-specific mandate that hospitals report these measures, and any hospitals that have no or an incomplete raw quality measure score for these measures will receive a scaled score of 50. Because there is no TEAM specific mandate to report these measures in any years of the model, and because hospitals had 2 years of voluntary reporting for the Hospital Harm measures under the Hospital IQR Program, we do not believe that this proposal contradicts our policy of allowing 2 years of self-selected reporting for new Hospital Harm eCQMs before making them mandatory.

After consideration of the public comments, we are finalizing without modification the proposal to apply measurement performance period timeframes, as specified in Table X.A.-02, to TEAM performance years 2 through 5 for the Hospital Harm—Falls with Injury and Hospital Harm—Postoperative Respiratory Failure, and ISCMR quality measures.

(3) Changes to TEAM CQS Baseline Period Methodology

In the FY25 IPPS/LTCH PPS final rule (89 FR 68986), we established fixed CQS baselines for calculating CQS performance that would remain constant throughout the model's duration, using calendar year (January–December) CQS baseline periods for all quality measures. The CQS baselines are national distributions of quality measure scores against which TEAM participants are ranked. After evaluating this approach and considering alignment with existing CMS hospital quality reporting programs, we proposed two changes to the CQS baseline methodology: (1) establishing a sliding historical CQS baseline methodology and (2) aligning CQS baseline periods with the CMS hospital reporting program timeframes for specific measures that are currently not aligned. We proposed at § 512.547(a)(1) through (3) replacing the current fixed CQS baseline approach with a sliding historical CQS baseline methodology for all quality measures except the CMS PSI–90 measure which applies only in TEAM PY1 and therefore does not require advancement of baseline periods beyond that performance year. We stated that the proposal to change to a sliding historical CQS baseline would be effective beginning with TEAM PY1. Under this proposed approach, CQS baselines would be calculated using a rolling window of historical performance data that updates annually, rather than remaining fixed throughout the model's tenure. We noted in the proposed rule that this approach would allow CQS baselines to evolve with improvements in care delivery, providing a responsive quality assessment framework.

Considering the proposed shift from fixed to sliding historical CQS baselines, we also proposed at § 512.547(a)(1)–(3) to update the baseline periods from a calendar year to a July to June period for the Hybrid HWR, CMS PSI–90, THA/TKA PRO–PM, and the ISCMR measures, Specifically, we proposed to align the CQS baseline periods with the hospital program required measurement periods of July–June timeframe rather than the previously finalized calendar year (January–December) periods. This proposed alignment is consistent with the Hospital IQR and HAC programs requirement of July–June measurement periods. Aligning TEAM CQS baseline periods with these established timeframes ensures consistency and reduces confusion. We noted in the proposed rule that this proposal would not affect the Hospital Harm—Falls with

Injury and Hospital Harm—Postoperative Respiratory Failure or the Information Transfer PRO–PM, which will continue to use calendar year CQS baseline periods as originally finalized, consistent with their respective hospital reporting program requirements. These measures maintain calendar year CQS baseline periods because their respective hospital reporting program requirements utilize calendar year measurement periods, ensuring consistency between TEAM CQS baselines and the established reporting infrastructure for these specific measures. Additionally, we also stated in the proposed rule that aligning the CQS baseline periods with existing hospital measure timeframes ensures that the necessary data are available and validated according to established timelines. Using the same measurement periods for the existing hospital reporting and TEAM CQS baselines periods leverages this existing data infrastructure and ensures timely availability of baseline data for CQS calculations.

We believed it was important to implement this alignment beginning in TEAM PY1 and to apply it consistently throughout the duration of the model. Beginning this alignment in TEAM PY1 avoids introducing a mid-model change in CQS baseline period timeframes that could create confusion and complicate longitudinal performance assessment. We stated it also ensures that TEAM participants' quality performance is evaluated under a single, transparent methodological framework for the entire duration of the model. In addition, because certain TEAM PY1 measures are not calculated on a calendar-year basis within their respective hospital reporting programs, it would be operationally challenging to re-specify and recalculate these measures solely for TEAM. Aligning TEAM CQS baseline periods with the Hospital IQR and HAC Reduction Program timeframes from the start of the model leverages validated data already calculated for existing programs and minimizes TEAM participant confusion.

We also considered in the proposed rule an alternative approach under which the transition from fixed CQS baselines to the sliding historical CQS baseline methodology would begin in TEAM PY2 rather than TEAM PY1. Under this alternative, TEAM PY1 would continue to use the fixed CQS baseline methodology finalized in the FY25 IPPS/LTCH PPS final rule, and the sliding historical CQS baseline methodology (including the July through June baseline period alignment described previously) would begin with TEAM PY2 and apply for the remainder of the model. Under this alternative, all CQS baseline periods and methodologies finalized in the FY25 IPPS/LTCH PPS final rule would apply unchanged for TEAM PY1, and the July through June baseline alignment and sliding historical methodology would first apply to TEAM PY2 measurement and CQS calculations. We considered this alternative because beginning the transition in TEAM PY2 could reduce operational and participant risk associated with implementing a baseline methodology change at model launch. Specifically, this risk refers to the potential for operational disruptions, such as insufficient time for participants to adapt systems and processes to the new methodology, as well as the possibility that participants may not have adequate time to understand, prepare for, and respond to changes in how their quality performance is assessed beginning in TEAM PY1. However, beginning in TEAM PY2 would introduce a mid-model change in baseline methodology, which could create participant confusion and complicate longitudinal performance assessment across performance years. We sought comment on whether beginning the transition to the sliding historical CQS baseline methodology in TEAM PY2, rather than TEAM PY1, would be preferable.

We also recognized in the proposed rule that updating to the proposed CQS baseline periods beginning in TEAM PY1 meant that different months of performance may be reflected in the CQS baseline compared to a calendar-year approach. For example, if a hospital's performance improved during the latter half of calendar year (CY) 2025, those improvements would be included under the proposed July through June CQS baseline period rather than excluded based solely on a calendar-year cutoff. While this proposed change in baseline timeframe could result in differences in PY1 CQS scoring compared to a CY CQS baseline, improved performance captured within the aligned reporting timeframe would be incorporated as the proposed sliding historical CQS baseline updates in subsequent performance years. We stated in the proposed rule that under the proposed approach, the Hybrid HWR measure would use the same CQS baseline period (July 1, 2025, through June 30, 2026) for TEAM PY2 and PY3. This was necessary under the proposed sliding historical approach due to the measure transitioning from claims-only methodology in TEAM PY1 to hybrid methodology beginning in TEAM PY2 and TEAM PY3, intending to serve as the initial reference point for the sliding historical CQS baseline methodology before advancing annually in PY4 and PY5. However, we are not finalizing the proposed sliding historical CQS baseline methodology. Under the concurrent rolling CQS baseline methodology finalized in this rule, the Hybrid HWR CQS baseline period advances each performance year in alignment with the applicable measurement period, as reflected in Table X.A.-03. TEAM PY1 will use a claims-only CQS baseline (July 1, 2024, through June 30, 2025), and beginning in TEAM PY2, the hybrid CQS baseline advances annually in alignment with the applicable measurement period for each performance year, as reflected in Table X.A.-03.

We believed that adopting sliding historical baselines for CQS measurement offered several advantages over the current fixed baseline approach. Specifically, a sliding historical CQS baseline methodology would enable TEAM to capture and reflect evolving trends in quality performance over time. As quality improvement initiatives advance, this baseline approach would ensure that performance benchmarks remain relevant and responsive to these changes. This approach also acknowledged that quality performance is dynamic, requiring evolving baselines to reflect current care standards. Additionally, for the Hospital Harm—Falls with Injury and Hospital Harm—Postoperative Respiratory Failure, which are self-selected voluntary reporting measures in the Hospital IQR Program, the proposed sliding historical CQS baseline approach ensures that baselines remain representative of the current reporting population over time. Further, it would ensure performance expectations continue to challenge TEAM participants to improve, rather than meet static targets. We acknowledged in the proposed rule that, similar to the concurrent CQS baseline approach discussed later in this section, the sliding historical CQS baseline methodology also presented challenges in tracking long-term progress from the start of the model because the baseline updates annually. However, we believed the proposed sliding historical CQS baseline approach mitigates this concern by using historical data rather than contemporaneous data, in most instances, providing greater stability and predictability while still maintaining relevant performance benchmarks. The proposed sliding historical CQS baseline methodology

would align with the target price baseline approach used in TEAM, which rolls forward annually, creating a more coherent performance assessment framework for participating hospitals. We indicated this alignment would eliminate the disconnect where cost performance is evaluated against recent benchmarks while quality performance is measured against a static historical reference point, making it easier for TEAM participants to understand the relationship between quality and cost metrics. The parallel baseline structures would enable hospitals to develop improvement strategies that address both quality and cost objectives simultaneously.

We proposed implementing the sliding historical CQS baseline methodology beginning with TEAM PY1. We believe beginning implementation of this methodology change in TEAM PY1 is appropriate for several reasons. We stated in the proposed rule that TEAM PY1 CQS calculations and reconciliation would not occur until Fall 2027. This would allow the implementation of this methodology before the calculations occur. Also, all TEAM participants were able to select Track 1 for TEAM PY1 and participants who did not actively select a track were assigned to Track 1 by default. Track 1 does not involve downside financial risk during TEAM PY1. Additionally, the proposed changes aligned CQS baseline timeframes with existing hospital reporting program requirement timeframes, meaning hospitals are already collecting and validating data during these timeframes for reporting purposes. Additionally, implementing the proposed sliding historical CQS baseline approach beginning in TEAM PY1 ensured consistent CQS baseline methodology throughout the model's duration and avoids mid-model transitions that could create confusion or complicate performance tracking. This proposed approach, starting in TEAM PY 1, would provide participants with clarity and predictability regarding how their quality performance will be assessed throughout all performance years. We stated in the proposed rule that this consistency supports participants' ability to develop and implement long-term quality improvement strategies that align with both TEAM goals and existing hospital quality reporting requirements.

We also considered in the proposed rule, but did not propose, the implementation of a rolling concurrent CQS baselines for quality measures throughout all TEAM performance years. Under a rolling concurrent CQS baseline methodology, the CQS baseline for a given TEAM performance year would be identical to the applicable TEAM measurement period for that year. In other words, the national distribution of measure performance scores against which TEAM participants are ranked would be derived from contemporaneous performance-year data.

This concurrent baseline methodology would require quality performance benchmarks to be recalculated annually using contemporaneous data. For each performance year, the national distribution of measure performance, including risk-adjusted scores, expected-value parameters, and national averages specified in the measure methodology, would be recalibrated based on that same performance year's data before CQS scoring is finalized.

We stated in the proposed rule that while the proposed sliding historical CQS baseline approach also recalculates benchmarks annually, it uses historical data, in most instances, rather than contemporaneous data. In this context, the reference to ''in most instances'' reflects that, under the proposed sliding historical approach, the CQS baseline for a given TEAM performance year would generally be based on a completed historical measurement period that precedes the applicable performance year. For certain measures and performance years, however, the same CQS baseline period may apply to more than one performance year or may rely on the first available validated measure reporting period to ensure methodological consistency and the use of complete, validated data.

We indicated in the proposed rule that a concurrent CQS baseline approach offers several advantages, such as capturing real-time performance, encouraging continuous quality improvement, and addressing concerns about outdated benchmarks. In addition, since concurrent CQS baselines compare quality measure scores to baseline scores from the same year, the measure scores and baseline scores are calculated using the same methodology. This methodological alignment is particularly relevant for TEAM quality measures that incorporate expected values with formulas that are recalibrated annually and rely on national averages of hospitals' performance in that year.

However, under a concurrent CQS baseline, improvement would always be assessed relative to a moving CQS baseline. We stated in the proposed rule that a concurrent CQS baseline, like a sliding historical CQS baseline, would introduce uncertainty for participants because final CQS baseline calculations, including risk adjustment coefficients and national averages used in mapping raw measure scores, would not be available in advance of the applicable performance year. Because the national distribution would be constructed from the same performance-year data, participants would not know the final percentile thresholds or scaling parameters until after the measurement period concludes and national data are finalized.

We recognized in the proposed rule that similar timing limitations apply under the sliding historical CQS baseline approach, given the lag between baseline construction and finalization of national performance data. We recognized that several limitations apply to both the concurrent and proposed sliding historical CQS baseline approaches. However, because the proposed sliding historical CQS baseline relies on completed historical data, in most instances, rather than contemporaneous data, it may provide comparatively greater stability relative to a fully concurrent CQS baseline approach. Although we did not propose a concurrent CQS baseline methodology, we considered this approach and we sought comment on its potential implementation. Additionally, we considered whether such an approach, if adopted, should begin in TEAM PY1 or TEAM PY2, and we sought comment on those timing options. We noted in the proposed rule that beginning in TEAM PY1 would avoid a mid-model change in CQS baseline methodology and would allow quality performance to be assessed under a single methodological framework for the duration of the model. Beginning in TEAM PY2 could reduce implementation risk at model launch by providing additional time for participants to operationalize the methodology and prepare for changes in quality performance assessment. We sought comment on whether a concurrent CQS baseline methodology would be preferable to the proposed sliding historical CQS baseline methodology and, if so, whether implementation should begin in TEAM PY1 or TEAM PY2.

We also considered in the proposed rule, but did not propose, an alternative approach that would maintain a fixed historical CQS baseline methodology while changing the CQS baseline periods from calendar year to July through June timeframes for the Hybrid HWR, CMS PSI–90, THA/TKA PRO–PM, and the ISCMR measures. Under this alternative fixed CQS baseline approach with updated timeframes, the

Hybrid HWR CQS baseline would be established concurrently with the measurement performance period for TEAM PY1 and would be July 1, 2024, through June 30, 2025, using claims only data and would be updated once more for TEAM PY2 and would be July 1, 2025, through June 30, 2026, using hybrid data to account for the measure's transition from claims-only to hybrid methodology, after which it would remain fixed for TEAM PY3 through PY5. The CMS PSI–90 measure, which is only used in TEAM PY1, would have a CQS baseline period of July 1, 2023, through June 30, 2025, concurrent with its TEAM PY1 measurement period. The THA/TKA PRO–PM would have a concurrent CQS baseline and measurement period for TEAM PY1 of July 1, 2024, through June 30, 2025, which would then remain fixed throughout TEAM PY2 through PY5. Similarly, the ISCMR measure CQS baseline would be July 1, 2023, through June 30, 2025, and remain fixed for TEAM PY2 through PY5. The Hospital Harm—Falls with Injury and Hospital Harm—Postoperative Respiratory Failure CQS baselines would remain calendar year 2026 (January 1, 2026–December 31, 2026) for TEAM PY2 through PY5 and the Information Transfer PRO–PM CQS baseline would remain calendar year 2027 (January 1, 2027–December 31, 2027) for TEAM PY3 through PY5.

We stated in the proposed rule that the fixed historical CQS baseline approach has several benefits. It offers stable targets that provide greater certainty for participants, as performance benchmarks are known in advance whenever possible. This approach facilitates tracking of long-term quality improvement goals from the start of the model and eliminates the need for annual CQS baseline recalculations, reducing administrative complexity compared to sliding historical CQS baselines. However, we determined that the fixed historical CQS baseline approach presents significant disadvantages. The fixed CQS baselines can become outdated and less reflective of current performance conditions over time. Fixed CQS baselines may also reduce incentives for continuous improvement once participants meet initial targets. Additionally, data anomalies, such as missing or incomplete data from the CQS baseline period, cannot be adjusted under a fixed CQS baseline approach, which could result in inequitable performance assessments throughout the model's duration. We noted in the proposed rule that these limitations led us to propose the sliding historical CQS baseline methodology instead, which we believed better supports ongoing quality improvement and maintains relevant performance benchmarks throughout the model.

We sought comment on our proposal at § 512.547(a)(1) through (5) for the proposed changes to the CQS baseline methodology in TEAM to include the transition from fixed CQS baseline periods to sliding historical CQS baseline periods and the change from calendar year to July to June timeframe for the Hybrid HWR, CMS PSI–90, THA/TKA PRO–PM, and ISCMR measures. We also sought comment on whether beginning the transition to the sliding historical CQS baseline methodology in TEAM PY2, rather than TEAM PY1, would be preferable. We also sought comment on whether either a fixed historical CQS baseline methodology or a concurrent CQS baseline methodology, each incorporating the updated July through June timeframes for applicable measures as described previously, would be preferable to the proposed sliding historical CQS baseline methodology. With respect to the concurrent CQS baseline methodology specifically, we sought comment on whether, if adopted, implementation should begin in TEAM PY1 or TEAM PY2.

The following is a summary of the public comments received on the proposed changes to the TEAM CQS baseline period, and our responses to these comments:

Comment: Many commenters supported the proposal to update the CQS baseline periods from a calendar year to a July to June period for the Hybrid HWR, CMS PSI–90, THA/TKA PRO–PM, and the ISCMR measures. Some of these commenters noted that doing so would reduce administrative burden on participants and reduce confusion.

Response: We thank the commenters for their support. We agree that this proposal will reduce administrative burden and confusion for TEAM participants.

Comment: Some commenters supported the proposal to adopt sliding historical CQS baseline periods. One of the commenters stated that an advantage of the sliding historical CQS baseline period methodology was that it would hold hospitals accountable to more up-to-date standards of quality, as opposed to a static baseline, which could become outdated. They expressed support for rewarding continuous improvement as the benchmark moves forward with new evidence-based practices in perioperative care. Another commenter stated that the proposal would better synchronize quality measurement with TEAM's target price methodology where the baseline period is updated on a rolling basis for each PY.

Response: We thank the commenters for their support. We agree that measuring hospitals against a more up-to-date standard of quality and alignment with TEAM's target price methodology are both advantages of utilizing a sliding historic CQS baseline period as compared to a fixed CQS baseline period. These advantages are also present in a concurrent CQS baseline period. While the concurrent CQS baseline period methodology aligns slightly less with the target price framework than the sliding historic CQS baseline methodology, the concurrent CQS baseline period methodology holds participants accountable to the most up-to-date standard of quality and current practices of any of the methodologies.

Comment: A few commenters opposed the proposal to transition to sliding historic CQS baseline periods, preferring a fixed CQS baseline period. A commenter stated that a sliding baseline period would punish hospitals who achieved high quality scores in the early years of the model. It would incentivize hospitals to manage their quality improvement efforts in a way that avoids raising future benchmarks. A few commenters stated that a fixed CQS baseline period would provide a stronger incentive to improve quality, making it easier for hospitals to set actionable targets. A commenter requested that CMS use a fixed CQS baseline period that ends before the start of the first performance period for each measure.

Response: We thank the commenters for sharing their concerns. We disagree that a sliding CQS baseline period would incentivize hospitals to manage their quality improvements to avoid raising benchmarks. The CQS baseline period is constructed using a large cohort of hospitals including both TEAM participants and IPPS/OPPS-eligible hospitals not participating in TEAM. TEAM hospitals are not measured exclusively against their own past performance, but rather against this large cohort, of which their own performance comprises only one data point. Therefore, any efforts by a hospital to manage quality improvement to avoid increasing their benchmark would have a negligible effect on the CQS baseline period benchmarks the hospital was measured against and could negatively impact their performance compared to this benchmark. Under a concurrent CQS baseline period methodology, a

hospital's quality score in previous performance periods will have no impact on the CQS baseline period benchmarks they are measured against.

While we acknowledge that a fixed CQS baseline period may make it easier for hospitals to set actionable targets for quality improvement under TEAM within the context of the CQS, we disagree that the incentive to improve quality is stronger under a fixed CQS baseline period. We believe that the incentive to improve quality is strongest under a concurrent CQS baseline period, as this methodology holds participants accountable to the most up-to-date standard of quality. We are concerned that, under a fixed CQS baseline period methodology, participants who achieve a scaled score that they deem acceptable on a measure will have no incentive to improve on this score in future performance years.

Comment: A couple of commenters expressed concerns that a sliding CQS baseline period would be subject to year-to-year data variability. One of the commenters added that this risk was exacerbated by the fact that many TEAM quality measures are low-volume and episodic, making them more susceptible to year-to-year variations driven by small sample size, and added that the sliding CQS baseline period could penalize regression to the mean. One of the commenters also expressed concerns that under a sliding CQS baseline period, changing benchmarks could reflect measure maturity.

Response: We thank the commenters for sharing their concerns. Regarding the point that a sliding baseline period would be subject to year-to-year data variability, we anticipate that the cohort of hospitals used to construct the CQS baseline will be large enough to generate reasonably stable percentiles once participants have established data reporting processes. Concerns about low-volume and episodic measures impacting individual hospital's raw measure scores, or about hospital performance on a given measure regressing to the mean, would remain the same regardless of the CQS baseline period methodology.

One of the benefits of a sliding or concurrent CQS baseline period is that, unlike a fixed CQS baseline period, any anomalies in the baseline data, for example missing data caused by immature reporting infrastructure, would not carry through for the duration of the model.

Another benefit of utilizing a concurrent baseline methodology is that it ensures apples-to-apples comparisons for measures that are recalibrated or have methodological changes between years. For example, many of the TEAM quality measures are formulated as observed (or predicted) outcome divided by expected outcome multiplied by a national average of that outcome, with the coefficients and national average being recalibrated annually, which confounds comparisons of raw measure scores across time.

Regarding the concern that a sliding baseline period would reflect measure maturation, while we agree with the commenter that changes in the CQS baseline period scores under a sliding or concurrent CQS baseline period will reflect improvements in measure performance as the model progresses, we believe that this is a benefit of the proposal. We do not believe that measuring participants against static targets that reflect outdated quality standards sufficiently incentivizes quality improvement.

Comment: A few commenters expressed concerns that the use of a sliding CQS baseline period would reduce the transparency and predictability of the targets that participants are measured against. A few commenters stated that a sliding CQS baseline would negatively impact hospital's ability to manage quality improvement, such as setting internal quality improvement targets, tracking improvement over time, or engaging clinicians.

Response: We appreciate the commenters' concerns about maintaining transparent and predictable benchmarks in the model. We agree that the stability of targets provided under a fixed CQS baseline period is an advantage over the sliding historic and concurrent CQS baseline periods and considered this carefully when weighing the merits of these methodologies. Ultimately, we decided that the advantages of a concurrent baseline, which we believe provides the strongest incentive for continuing quality improvement, outweighed this disadvantage. Regarding hospital's ability to manage quality improvement, while we recognize that both a concurrent CQS baseline period and a sliding historic CQS baseline period will prevent hospitals from receiving the percentiles that map raw measure scores to scaled scores prior to each performance year, hospitals can still track improvements in their raw measures scores over time. While it may be more difficult to set target scaled scores for quality improvement efforts under a concurrent CQS baseline methodology, we believe that these efforts, which will reflect the most up-to-date standards of care, will be more impactful than those based on historic targets. We believe that the potential lack of incentive to improve quality later in the model under a fixed CQS baseline methodology represents a larger risk to quality of care under the model.

Comment: A commenter expressed concerns that the proposed sliding baseline period, in conjunction with the use of new quality measures that hospitals have had little time to understand, operationalize, or benchmark against, would introduce risk that was disconnected from quality performance. The Information Transfer PRO–PM measure, which begins voluntarily reporting under the Hospital OQR Program in CY 2026, was cited as an example.

Response: We thank the commenter for their feedback. While we understand the commenter's concerns about participants' ability to properly prepare for quality measures, we disagree that participants will have insufficient time to familiarize themselves with the quality measures utilized in the CQS before they are included in TEAM. Specifically, TEAM participants' scores on the Information Transfer PRO–PM measure will not contribute to their CQS until the CY 2028 reporting period, meaning that they will have one year of mandatory reporting under the Hospital OQR Program to prepare for the measure's inclusion. We also disagree that the risk associated with utilizing new measures in conjunction with a sliding or concurrent CQS baseline period would be disconnected from quality performance. We acknowledge that concurrent CQS baseline periods likely assess TEAM participants against more challenging benchmarks but believe that this is directly tied to evaluating quality performance against the current standard of care, as opposed to outdated static targets. Similarly, all of the measures added to the model, such as the Information Transfer PRO–PM, were added to better capture quality of care.

Comment: A commenter supported the use of a concurrent CQS baseline period as opposed to a sliding historic CQS baseline period, noting that doing so would provide hospitals with more consistent targets. The commenter added that a sliding historic CQS baseline period would introduce compounding variables that would make financial forecasting more difficult.

Response: We thank the commenter for their feedback. We believe that, under a historic sliding CQS baseline period, the potential for differences in measure methodologies between the

CQS baseline period and the corresponding measurement performance period could complicate financial forecasting, and agree that this issue would not be present under a concurrent CQS baseline period.

Comment: A commenter opposed a concurrent CQS baseline period. The commenter stated that, while they favored a fixed CQS baseline period, a historic sliding CQS baseline period was preferrable to a concurrent CQS baseline period, as the former better mitigated the issue of not accounting for improvement in measure scores as the model progressed.

Response: We thank the commenter for their feedback. We agree with the commenter that benchmarks under the concurrent CQS baseline period methodology would best reflect up-to-date standards of quality performance, but disagree that this is a disadvantage of the methodology. As discussed previously, we see this ability to reflect the most current standards of quality as a significant advantage of the concurrent CQS baseline period methodology. After consideration of comments received, and weighing the advantages and disadvantages of the fixed CQS baseline period, sliding historical baseline period, and concurrent CQS baseline period methodologies, we believe that the concurrent CQS baseline period methodology provides the strongest incentive for participants to continue to improve their quality of care throughout the duration of the model. Therefore, we are finalizing a concurrent CQS baseline period methodology

Comment: A few commenters recommended that, if CMS were to implement a sliding CQS baseline period, its implementation should be delayed, with a couple of commenters supporting delaying implementation until PY 2 or PY 3. A few of these commenters added that changing the methodology mid performance year would not give participants enough time to respond to the change and flagged that hospitals needed more time to become familiar with TEAM measures and establish stable performance.

Response: We thank the commenters for their recommendation and understand the desire to have more time to prepare for changes to the model. Regarding the recommendation to delay implementing changes to the CQS baseline periods until PY 2, while the proposal to update the CQS baseline periods from a calendar year to a July to June period for the Hybrid HWR, CMS PSI–90, THA/TKA PRO–PM, and the ISCMR measures would impact the PY 1 CQS baseline periods, implementing concurrent CQS baseline periods would not impact PY 1 outside of this alignment because PY 1 already leverages concurrent baselines. Accordingly, there would be no difference between implementing a concurrent CQS baseline period beginning in PY 1 or beginning in PY 2. Therefore, we do not view this policy, which affects PY 2 and beyond, as a mid-performance year change. Regarding the recommendation to delay implementation until PY 3, we believe that implementing the change in PY 1 would allow for consistency throughout the duration of the model. If we were to implement a concurrent CQS baseline period beginning in PY 3, hospitals would be measured against a concurrent baseline period for PY 1, then a historic baseline for PY 2, before going back to a concurrent baseline from PY 3 onwards. We believe that this would cause more confusion for participants than simply utilizing concurrent CQS baselines for the duration of the model.

Comment: A commenter suggested that CMS implement changes to the CQS baseline periods more gradually and consider a hybrid approach, with fixed CQS baselines at the start of the model and protections to limit year-to-year changes in the CQS baseline benchmarks. The commenter also suggested CMS could evaluate the statistical merit of sliding baselines individually for each measure.

Response: We thank the commenter for their feedback. While we appreciate the desire to provide further stability in benchmarks and time for participants to prepare for model changes, we feel that a hybrid approach with protections to limit year-to-year changes in the CQS baseline benchmarks would overly complicate the model. We believe that it would be preferable to assess quality framework under a single methodological framework for the duration of the model.

Comment: A commenter expressed concerns that CMS was changing parameters of TEAM after hospitals had made operational commitments. They recommended that CMS only modify model parameters under extraordinary circumstances. The commenter added that, should CMS proceed with modifying the CQS baseline period methodology, they should provide more transparency into CQS baseline calculations prior to each performance year.

Response: We acknowledge the commenter's concern. We understand participant desire to limit modifications to the model. While we recognize that the proposal to update the CQS baseline periods from a calendar year to a July to June period for the Hybrid HWR, CMS PSI–90, THA/TKA PRO–PM, and the ISCMR measures will impact PY 1, we believe that this change will ultimately reduce burden for participants. Given that the concurrent baseline methodology, as discussed previously, would not impact PY 1, we do not believe that this policy will have a significant impact on hospital's prior operational commitments. We appreciate the suggestion to provide more transparency into baseline calculations prior to each performance year and will take it into consideration as we design future resources.

TABLE X.A.-03: FINALIZED CONCURRENT MEASUREMENT PERIODS & CQS BASELINE PERIODS

Quality Measure	PY1 Measurement Period & CQS Baseline Period	PY2 Measurement Period & CQS Baseline Period	PY3 Measurement Period & CQS Baseline Period	PY4 Measurement Period & CQS Baseline Period	PY5 Measurement Period & CQS Baseline Period
Hybrid Hospital-Wide All-Cause Readmission (Hybrid HWR) Measure with Claims and Electronic Health Record Data (CMIT ID #356)	July 1, 2024, through June 30, 2025 (claims-only)	July 1, 2025, through June 30, 2026 (hybrid)	July 1, 2026, through June 30, 2027 (hybrid)	July 1, 2027, through June 30, 2028 (hybrid)	July 1, 2028, through June 30, 2029 (hybrid)
CMS Patient Safety and Adverse Events Composite (CMS PSI-90) (CMIT ID #135)	July 1, 2023, through June 30, 2025	N/A	N/A	N/A	N/A
Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618)	July 1, 2024, through June 30, 2025	July 1, 2025, through June 30, 2026	July 1, 2026, through June 30, 2027	July 1, 2027, through June 30, 2028	July 1, 2028, through June 30, 2029
Hospital Harm—Falls with Injury (CMIT ID #1518)	N/A	January 1, 2027, through December 31, 2027	January 1, 2028, through December 31, 2028	January 1, 2029, through December 31, 2029	January 1, 2030, through December 31, 2030
Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788)	N/A	January 1, 2027, through December 31, 2027	January 1, 2028, through December 31, 2028	January 1, 2029, through December 31, 2029	January 1, 2030, through December 31, 2030
Thirty-day Risk—Standardized Death Rate among Surgical Inpatients with Complications (ISCMR) (CMIT ID #134)	N/A	July 1, 2024, through June 30, 2026	July 1, 2025, through June 30, 2027	July 1, 2026, through June 30, 2028	July 1, 2027, through June 30, 2029
Information Transfer Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM) (CMIT ID #1797)	N/A	N/A	January 1, 2028, through December 31, 2028	January 1, 2029, through December 31, 2029	January 1, 2030, through December 31, 2030

After consideration of the public comments, we are finalizing with modification the proposal at § 512.547(a)(1) through (5) to change the CQS baseline methodology in TEAM to using a concurrent CQS baseline period starting in PY 1. Specifically, we are finalizing a concurrent CQS baseline period methodology rather than the proposed sliding historical CQS baseline methodology, effective beginning with TEAM PY1. Under this approach, the CQS baseline for a given TEAM performance year is identical to the applicable measurement period for that year. We are also finalizing without modification to change from calendar year to July to June timeframe for the Hybrid HWR, CMS PSI–90, THA/TKA PRO–PM, and ISCMR measures.

c. Pricing Methodology

(1) Background

As finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), TEAM participants will be provided with target prices for each MS–DRG/HCPCS episode type. These target prices will be calculated using 3 years of rolling baseline episode spending, trended forward with 2 additional historical years to the performance year, at the level of MS–DRG/HCPCS episode type and region, with updates to be made using the performance year data during the reconciliation process. The regions are defined as the nine U.S. census divisions and the MS–DRG/HCPCS episode type is based on the episode categories that will be tested in the model: Coronary Artery Bypass Graft (CABG), Lower Extremity Joint Replacement (LEJR), Major Bowel Procedure, Surgical Hip Femur Fracture Treatment (SHFFT), and Spinal Fusion.

Episode spending will be capped at the 99th percentile for each of the 29 MSDRG/HCPCS episode types and 9 regions, and the benchmark price will be calculated as the average capped and standardized spending in the most recent baseline year dollars for each MS–DRG/HCPCS episode type in each region, resulting in 261 benchmark prices. Benchmark prices will be calculated using all hospitals in a region, regardless of TEAM participation status. CMS will apply a prospective trend factor and a discount factor to benchmark prices. During reconciliation, these preliminary target prices will be modified by updating the trend (subject to a cap) and normalization factor (subject to a cap) and by adjusting for each participant's realized performance year case mix.

Risk adjustment factors will be calculated and made available to TEAM participants prior to the start of each performance year, so TEAM participants will be able to use them to estimate their episode-level target prices. Risk adjusters finalized in the FY 2025 IPPS/LTCH PPS final rule and FY 2026 IPPS/LTCH PPS final rule include age group, Hierarchical Condition Category (HCC) count, and beneficiary economic risk, as well as episode category-specific HCC adjusters and hospital-level adjusters including a hospital bed size factor and a safety net hospital factor. The risk adjustment factors will be calculated at the MS–DRG/HCPCS level using a weighted linear regression where episodes are weighted differentially based on whether they belong to year 1, 2, or 3 of the baseline periods. As finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), episodes from baseline year 1 will be weighted at 17 percent, baseline year 2 at 33 percent, and baseline year 3 at 50 percent. The risk adjustment factors will be fixed and applied to performance year episodes at reconciliation based on the realized case mix of the TEAM Participant in the performance year.

After risk adjusting for the performance year case-mix, CMS will normalize the target prices to ensure that the average of the total risk-adjusted preliminary target price does not exceed the average of the total non-risk adjusted preliminary target price. The final normalization factor will be calculated as the mean of the benchmark price for each MS–DRG/HCPCS episode type and region divided by the mean of the risk-adjusted benchmark price for the same MS–DRG/HCPCS episode type and region. As finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) it will be capped should this ratio exceed ±5 percent of the prospective normalization factor. The final target prices will include a retrospective trend factor, which will be capped at being within 3 percent of the prospective trend, as finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986). The retrospective trend factor will be calculated as the average capped performance year episode spending at the MS–DRG/HCPCS episode type and region level divided by the capped average baseline episode spending in the most recent baseline year dollars at the MS–DRG/HCPCS episode type and region level (that is, national mean benchmark price).

The reconciliation (final) target price will be calculated as the product of the capped mean baseline episode spending in the most recent baseline year dollars, the discount factor, the risk adjustment multiplier using the performance year case-mix, the capped final normalization factor, and the capped retrospective trend factor.

TEAM participants will have the opportunity to achieve a reconciliation payment amount, after accounting for quality performance, if their performance year spending is below the reconciliation target price, or they may owe a repayment amount if their spending is above the reconciliation target price.

(2) Ambulatory Payment Classification (APC) and Medicare Severity Diagnosis Related Groups (MS–DRG) Update Factors

(a) Background

TEAM relies on the Medicare Severity Diagnosis Related Group (MS–DRG) and Healthcare Common Procedure Coding System (HCPCS) codes to identify procedures to initiate an anchor hospitalization or anchor procedure. MS–DRG and HCPCS codes, and more specifically the assignment of HCPCS codes to Ambulatory Payment Classifications (APCs), may be modified because of changes in treatment patterns, technology, and any other factors that may change the relative use of hospital and provider resources. Typically, CMS proposes and finalizes coding changes, as applicable, through established annual payment rules. MS–DRG changes are generally aligned with the fiscal year (FY) in the IPPS/LTCH proposed and final rules, while HCPCS and APC changes generally align with the calendar year (CY) in the Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) proposed and final rules.

Because TEAM uses 3 years of rolling baseline episode spending, with 2 additional historical trend years, to construct target prices for a given performance year, changes in the MS–DRG or HCPCS–APC mappings and weights after the baseline period and either prior to or during the performance year may result in target prices that do not appropriately reflect episode spending in the performance year. Additionally, any new code established prior to or during the performance year that did not exist in the baseline period would not have a target price. In the FY 2026 IPPS/LTCH PPS final rule (90 FR 36536), we finalized the definition of a scaling factor at § 512.505 and methodology at § 512.540(a)(2)(i) through (iii) to account for changes to MS–DRGs and HCPCS between the baseline period and the performance year using a three-step mapping and scaling approach. The scaling factor, calculated as the ratio of MS–DRG or APC weight in the performance year to that in the baseline year, accounts for relative weight changes for MS–DRGs in the inpatient setting and APCs for HCPCS in the outpatient setting. However, this approach does not address changes that may arise after preliminary target prices are released to TEAM participants.

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), we established that preliminary target prices would be constructed only once per performance year and shared with TEAM participants prior to each performance year, which covers a calendar year timeframe. Therefore, due to the availability of data and timing of when target prices are released to TEAM participants, target prices are constructed using the previous calendar year HCPCS–APC mappings and weights (that is, the year prior to the performance year) and only the first three quarters of the current fiscal year's MS–DRG definitions and weights. TEAM target prices do not account for any MS–DRG definition or weight changes that are implemented in the last quarter of the performance year because fiscal years span October 1 to September 30. For example, performance year 1 (January 1, 2026–December 31, 2026) preliminary target prices are constructed using calendar year 2025 (January 1, 2025–December 31, 2025) HCPCS–APC mappings and weights and fiscal year 2026 (October 1, 2025–September 30, 2026) MS–DRG definitions and weights. HCPCS–APC mappings and weight changes in the CY OPPS/ASC and MS–DRG definition or weight changes in the FY IPPS/LTCH final rules would alter observed and scaled spending in the baseline period. Further, MS–DRG definition or weight changes may shift which code would initiate an anchor hospitalization and subsequently change the composition of inpatient episodes. As a result, benchmark and target prices would not reflect changes between calendar years (for instance, if HCPCS codes are reassigned to different APC weights during a performance year) or between fiscal years (for instance, MS–DRG definition changes between the first and second fiscal years of a performance year). At reconciliation, these changes may not be sufficiently accounted for by the retrospective trend factor which is capped at ±3 percent. Additionally, there may not be benchmark prices or other target price components available for episodes with anchor hospitalization end dates in the second fiscal year. To avoid these inconsistencies we proposed, as

discussed in section X.A.2.c.(2).(b). and (c). of this final rule, the application of APC and MS–DRG update factors in final target price calculations beginning in performance year 1, to ensure the final target price and reconciliation amounts align with payment rates and weights that are applied during each performance year.

(b) APC Update Factor

We proposed to update the Definitions at § 512.505 and the pricing methodology at § 512.540(b)(7) to add an APC update factor to the calculation of the prospective trend factor and at § 512.545(f)(1) to the retrospective trend factor. We proposed to define the APC update factor at § 512.505 as the component applied to the prospective trend factor to ensure that the APC weights corresponding to the performance year are incorporated into the final target price calculations. The APC update factor, as set forth in 512.540(b)(7), would be calculated at the MS–DRG/HCPCS episode type and region level as the ratio of the benchmark prices calculated with APC weights corresponding to the calendar year of the performance year (CY 2026 for performance year 1) to the preliminary benchmark prices calculated with the APC weights corresponding to the calendar year prior to the performance year (CY 2025 for performance year 1). The APC update factor would be calculated after the CY OPPS/ASC final rule is published each year and would be shared with TEAM participants to ensure that all information that is used to calculate final target prices is available. The APC update factor would be applied as a multiplier to the prospective trend factor, creating an updated prospective trend factor, which will be applied during final target price calculations. Specifically, we proposed to update § 512.545(f)(1) such that the retrospective trend factor is capped relative to the updated prospective trend factor to ensure that final target prices are aligned with performance year payment rates and weights.

We stated in the proposed rule that we believed this would be a straightforward approach to account for calendar year changes in APC weights by directly applying the corresponding changes to the prospective trend factor, without creating and distributing multiple preliminary target prices. For example, TEAM participants would only need to multiply the APC update factor to the prospective trend factor as compared to receiving a new preliminary target price with other updated pricing components. We noted in the proposed rule that if the APC relative weights decrease between calendar years, the application of the APC update factor may result in a decrease in benchmark prices. Additionally, risk adjustment coefficients are not updated and may not reflect changes between calendar years. Internal analysis assessed the impact of using outdated APC weights on TEAM benchmark prices, comparing the average scaled and winsorized spending in the most recent baseline year at the MS–DRG/HCPCS episode type and region level using CY 2025 and CY 2026 APC weights. Findings from this internal analysis indicated that episodes with APC assignment changes between calendar years 2025 and 2026 had significant percent differences in APC weights between years (49 percent). Additionally, the percent differences in average scaled and winsorized spending for TEAM initiating episodes with changed APC assignments between calendar years 2025 and 2026 were large, ranging from 33 percent to 40 percent, and the percent difference between baseline benchmark prices ranged from 2 percent to 8 percent.

We stated in the proposed rule that though we anticipated only minor adjustments to APC weights during the calendar year, internal analyses indicated that benchmark prices and therefore the final target price calculations at reconciliation would not account for code reassignments that significantly change relative APC weights. We considered but did not propose applying the APC update factor beginning in performance year 2. As detailed later in this section, APC update factors would be shared in advance of final target price calculations and would improve target price accuracy, aligning reconciliation amounts with payment rates and weights applied during the performance year. Given this, we proposed adjusting the prospective trend factor methodology at § 512.540(b)(7) and the retrospective trend factor methodology at § 512.545(f)(1) to account for changes in relative APC weights between calendar years in the TEAM performance year.

The following is a summary of the public comments received on the proposed policy to include an APC update factor to the prospective trend factor, and our responses to these comments:

Comment: Many commenters expressed support for the APC update factor proposal. Some of these commenters stated the application of the APC update factor should help ensure target prices more accurately reflect APC weight changes between calendar years. A few of these commenters expressing support also noted that ensuring target prices reflect performance year APC weights is essential to reduce the risk of under- or over-estimating target prices and support consistency and predictability for TEAM participants. A couple commenters expressed appreciation for CMS' consideration of complex timelines across annual payment rules and efforts to address timing inconsistencies between preliminary target price construction and annual CY OPPS/ASC payment system updates.

Response: We thank the commenters for sharing their support for the APC update factor proposal. We agree that the APC update factor should help ensure target price accuracy and predictability. We also believe the APC update factor will help address timing inconsistencies between calculation of preliminary target prices and the CY OPPS/ASC payment system updates.

Comment: A commenter expressed support for providing the APC update factor to participants during the performance year after the CY OPPS/ASC final rule is published, noting it should improve participants' ability to manage a known target.

Response: We thank the commenter for their support.

Comment: A couple commenters encouraged CMS to provide clear and timely visibility and communication into any updates associated with OPPS/ASC changes prior to the start of the applicable performance year, noting that this will help participants better anticipate how payment system updates are reflected in target prices and support more effective care and budget planning. A commenter suggested CMS maintain transparency regarding the APC update factor methodology by addressing any changes through IPPS/LTCH rulemaking prior to the start of the performance year in which the methodology change would be applied.

Response: We thank the commenters for their suggestions. We appreciate commenters' suggestions and recognize that providing participants with timely visibility into payment system updates is critical for effective care delivery and budget planning. CMS is committed to maintaining transparency in our payment methodologies and communications. To support planning and operational readiness, CMS believes it is important to provide participants with preliminary target prices ahead of each performance year as it allows participants to make informed operational decisions, allocate

resources, and plan for the upcoming year with greater certainty.

However, due to the timing of the rulemaking cycle, the OPPS/ASC final rules are typically released just before the start of the applicable TEAM performance year. Since preliminary target prices are also shared with TEAM participants prior to the start of the performance year, it is not feasible to incorporate the relevant OPPS/ASC changes applicable to the target prices during the preliminary target price release itself. As stated in the proposed rule, CMS will calculate the APC update factor after the CY OPPS/ASC final rule is published and share the APC update factor with TEAM participants in advance of final target price calculations. We believe that this will ensure that TEAM participants receive the most accurate and up-to-date information before the final target prices are set. Additionally, CMS intends to release updated methodology specifications that include the APC update factor methodology and application.

Comment: A couple commenters recommended assessing the impact of the APC update factor over time, ensuring the multiplier appropriately reflects evolving clinical and payment environments without introducing unintended variability in target prices. These commenters noted stable and transparent methodologies are critical in maintaining provider engagement and allowing hospitals to effectively plan and manage episode-based care.

Response: We thank the commenters for their recommendation. We agree that maintaining stable and transparent pricing methodology is critical for TEAM participants' engagement and planning. CMS intends to monitor the impacts of the APC update factor, as well as other methodological refinements, to ensure the factor enhances target price accuracy.

Comment: A couple commenters suggested that if the APC update factor is applied starting in PY1, it should only be applied in cases where it results in favorable adjustments for TEAM participants. These commenters noted that since PY1 has already started, and hospitals have already made operational and financial decisions based on the original PY1 methodology, participants should not be held accountable for any retroactive changes that increase repayment obligations to CMS or otherwise worsen their financial position.

Response: We thank the commenters for their suggestions. We acknowledge that PY1 has already started, and the proposed policy would result in a methodology change mid-performance year. However, as noted previously, APC update factors will be shared in advance of final target price calculations and would improve target price accuracy and align reconciliation amounts with APC payment weights applied during the performance year. While we acknowledge that the APC update factor may result in downward adjustments in target prices if the APC relative weights decrease between calendar years, and that not having the APC update factor information released until late in PY1 makes it difficult for participants to make timely operational or performance-based adjustments, CMS believes there are important mitigating factors. Specifically, the IP–OP blended price methodology helps absorb smaller downward adjustments in APC weight changes, reducing the effect on target prices. Moreover, most participants have selected Track 1 for PY1, where there is no downside risk. As a result, the potential negative impacts of downward adjustments due to APC update factors are further mitigated for participants in PY1.

Comment: A commenter requested CMS to consider publishing the updated target price methodology with examples at a minimum of 90 days prior to the beginning of each performance year.

Response: We thank the commenter for their request. Due to the timing of the rulemaking cycle, the OPPS/ASC final rules are typically released just before the start of the applicable TEAM performance year. Since preliminary target prices are also shared with TEAM participants prior to the start of the performance year, it is not feasible to incorporate the relevant OPPS/ASC changes applicable to the target prices during the preliminary target price release itself. CMS intends to publish updated methodology specifications prior to each performance year so participants are well-informed about the methodology and any changes before the performance year begins. As stated in the proposed rule, CMS will calculate the APC update factor after the CY OPPS/ASC final rule is published and share the APC update factor with TEAM participants in advance of final target price calculations. We believe that this will ensure that TEAM participants receive the most accurate and up-to-date information before the final target prices are set.

After consideration of the public comments, we are finalizing without modification the proposal at § 512.505 to add an APC update factor definition and without modification the proposal at § 512.540(b)(7) and § 512.545(f)(1) to add an APC update factor to the calculation of the prospective trend factor.

(c) MS–DRG Update Factor

To account for changes in MS–DRG mapping and weights between the first and second fiscal years in a TEAM performance year, we proposed updates to the Definitions at § 512.505 and the pricing methodology at § 512.540, § 512.545, and § 512.550 to adjust the target price and reconciliation amount accordingly. Specifically, we proposed updating methodology at § 512.540(b)(7) to add a MS–DRG update factor to the calculation of the prospective trend factor for episodes with anchor end dates in the fourth quarter of the performance year. We proposed to define the MS–DRG update factor at § 512.505 as the component applied to the prospective trend factor for episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of the performance year to account for changes in MS–DRG definitions and weights between the first and second fiscal years in the performance year. We stated in the proposed rule that the MS–DRG update factor would be calculated at the MS–DRG/HCPCS episode type and region level as the ratio of benchmark prices calculated with the second fiscal year inputs (FY 27 MS–DRG definitions and weights for performance year 1) to preliminary benchmark prices calculated with the first fiscal year inputs (FY 26 MS–DRG definitions and weights for performance year 1). The MS–DRG update factor would be calculated after the FY IPPS/LTCH final rule is published each year and would be shared with TEAM participants as a multiplier to the prospective trend factor to ensure that all information that is used to calculate final target prices is available.

We stated in the proposed rule that when TEAM initiating MS–DRGs change between the first and second fiscal years in a performance year, the reconciliation target price for episodes with anchor end dates in the fourth quarter of the performance year would be calculated using MS–DRG mappings and weights from both fiscal years. We proposed at § 512.550(c), that initiating MS–DRGs with anchor end dates in the second fiscal year of a performance year would be mapped and assigned a first fiscal year MS–DRG. We proposed to update the methodology at § 512.545 to specify the fiscal year MS–DRG(s) of each reconciliation target price component for episodes with anchor end dates in the fourth quarter of the performance year. Components derived from baseline data, such as the

benchmark price and the risk adjustment coefficients, would be calculated using MS–DRG mappings and weights from the assigned first fiscal year in a performance year (as described in § 512.545(a) through (d)). The final normalization factor, described at § 512.545(e) would be calculated specific to the assigned first and second fiscal year MS–DRG and region combination, and cannot exceed ±5 percent of the prospective normalization factor, as specified at 512.540(b)(6), for the assigned first FY MS–DRG. For instance, if two TEAM initiating MS–DRGs are mapped to one MS–DRG in the second fiscal year, the normalization factor would be calculated using the benchmark price and risk adjustment coefficients of the assigned first fiscal year MS–DRG applied to the realized case mix of the second fiscal year MS–DRG. The retrospective trend factor described at § 512.545(f) would be calculated with performance year spending specific to the second fiscal year MS–DRG mapping combination, and cannot exceed ±3 percent of the updated prospective trend factor. The updated prospective trend factor would be the product of the prospective trend factor and the corresponding APC update factor and MS–DRG update factor. We proposed at § 512.505 to define the updated prospective trend factor as the multiplier incorporated into the preliminary target price to estimate changes in spending patterns between the baseline period and the corresponding calendar year and fiscal year in the performance year. See Table X.A–05 for summary of target price components and applicable fiscal year MS–DRGs.

TABLE X.A.-05: SUMMARY OF APPLICABLE FISCAL YEAR MS-DRG FOR EACH TARGET PRICE COMPONENT IN A PERFORMANCE YEAR

Episodes with Anchor End Dates in:	Benchmark Price	Risk Adjuster Coefficients	Risk Adjuster Multiplier	Prospective Normalization Factor	Final Normalization Factor	Prospective Trend Factor	Retrospective Trend Factor
Quarters 1-3	FY 1	FY1	FY1	FY1	FY1	FY1 *	FY1
Quarter 4	FY1	FY1	PY (FY1; FY2)***	FY1	PY (FY1; FY2)***	FY1 **	PY (FY1; FY2)***

* APC-UF as described previously would be applied to the prospective trend factor to generate the updated prospective trend factor in the calculation of target prices.

** APC-UF and DRG-UF as described previously would be applied to the prospective trend factor to generate the updated prospective trend factor in the calculation of target prices.

*** Refers to the assigned first and second fiscal year MS-DRG mapping combinations as proposed at § 512.550(c).

Further, for performance years in which diagnosis or procedure codes are mapped to different TEAM initiating MS–DRGs between the first and second fiscal years, we proposed updating methodology at § 512.550(c) to add a step to assign a first fiscal year MS–DRG to episodes with anchor end dates in the fourth quarter. We noted in the proposed rule that based on logic described in the IPPS/LTCH final rules, CMS would identify and map diagnosis and procedure codes from TEAM initiating MS–DRGs in the second fiscal year MS–DRGs to the first fiscal year MS–DRGs. Episodes with anchor end dates in the fourth quarter of the performance year based on the second fiscal year MS–DRG would continue to initiate, and the reconciliation target price assigned to the episode would be specific to the assigned first and second fiscal year MS–DRG mapping combination for each hospital. CMS would sum the values for each second FY MS–DRG/HCPCS episode type and, ultimately, across all MS–DRG/HCPCS episode types to determine the reconciliation amount.

As previously noted, some MS–DRG definition changes may result in preliminary benchmark prices and target price components not being available. See Table X.A–06 for a summary of the possible MS–DRG mapping scenarios between the first and second fiscal year of a TEAM performance year. For example, a non-TEAM MS–DRG, meaning a MS–DRG that does not initiate a TEAM anchor hospitalization, in the first fiscal year is mapped to a TEAM MS–DRG, meaning a MS–DRG that initiates a TEAM anchor hospitalization, in the second fiscal year of a performance year (scenario 4). We stated in the proposed rule that in this situation, we would not be able to produce a final target price for the episode, as preliminary benchmark prices and target price components would not be available for the non-TEAM MS–DRG based on the first fiscal year inputs. Therefore, we proposed that TEAM participants would not be accountable for episodes with anchor end dates in the fourth quarter of the performance year that are initiated by anchor hospitalizations that would have been assigned a non-TEAM MS–DRGs in the first three quarters of the performance year.

TABLE X.A.-06: SUMMARY OF MS-DRG MAPPING SCENARIOS BETWEEN FISCAL YEARS OF A PERFORMANCE YEAR

Scenario	Fiscal Year 1 MS-DRG	Fiscal Year 2 MS-DRG	TEAM Participant Episode Accountability under the Proposed Approach
1. No MS-DRG mapping changes	TEAM MS-DRG AAA	TEAM MS-DRG AAA	Accountable for episodes in both fiscal years.
2. Mapping changes result in a TEAM MS-DRG mapped to a different TEAM MS-DRG	TEAM MS-DRG AAA	TEAM MS-DRG BBB	Accountable for episodes in both fiscal years
3. Mapping changes result in a TEAM MS-DRG mapped to a Non-TEAM MS-DRG	TEAM MS-DRG AAA	Non-TEAM MS-DRG CCC	Accountable for episodes in fiscal year 1 but not fiscal year 2
4. Mapping changes result in a Non-TEAM MS-DRG mapped to a TEAM MS-DRG	Non-TEAM MS-DRG CCC	TEAM MS-DRG BBB	Not accountable for episodes in either fiscal year.

We believed adding the MS–DRG update factor to the calculation of prospective trend factors for episodes with anchor end dates in the fourth quarter of the performance year is an effective way to account for fiscal year changes in MS–DRG definitions and weights without reissuing preliminary target prices and reduces TEAM

participant burden by not having to manage multiple preliminary target prices within a given performance year. We acknowledged that, depending on the magnitude of changes between the fiscal years in the performance year, some target prices may lack precision or may not be available. Specifically, the risk adjustment coefficients are not updated and will be more reflective of the first fiscal year case mix. We noted in the proposed rule that internal analysis used fiscal years 2024 and 2025 inputs to assess the impact of MS–DRG mapping and weight changes between fiscal years on TEAM benchmark prices. This assessment demonstrated that conducting reconciliation calculations using target prices solely based on FY 2024 inputs, without accounting for FY 2025 MS–DRG mappings and weight changes, may penalize participants. Specifically, five spinal fusion MS–DRGs were deleted in FY 2024 and mapped to 10 new spinal fusion MS–DRGs in FY 2025. As a result, 72 percent of final TEAM spinal fusion episodes were without available FY 2024 benchmark prices, and differences in scaled inpatient stay costs ranged from -56 percent to 71 percent.

As previously noted, the APC and MS–DRG update factors would be calculated after the CY OPPS/ASC and the FY IPPS/LTCH final rules are published and would be shared with TEAM participants to ensure that all information that is used to calculate final target prices is available. Table X.A–07 provides an example operational timeline of APC and MS–DRG update factor availability. We noted in the proposed rule that the operational timeline is subject to change contingent on finalization and publication of the CY OPPS/ASC and FY IPPS/LTCH rules.

TABLE X.A.-07: EXAMPLE OPERATIONAL TIMELINE OF APC UPDATE FACTOR AND MS-DRG UPDATE FACTOR AVAILABILITY

Performance Year	Preliminary Target Prices	APC Update Factor	MS-DRG Update Factor
1	4th quarter of 2025	4th quarter of 2026	4th quarter of 2026
2	4th quarter of 2026	1st quarter of 2027	4th quarter of 2027
3	4th quarter of 2027	1st quarter of 2028	4th quarter of 2028
4	4th quarter of 2028	1st quarter of 2029	4th quarter of 2029
5	4th quarter of 2029	1st quarter of 2030	4th quarter of 2030

We considered in the proposed rule but did not propose to update and deliver preliminary target prices to TEAM participants for each calendar and fiscal year final rule. We believed managing three different preliminary target prices in a given performance year will increase participant burden and pricing methodology complexity. We also considered, but did not propose, to backwards map and descale spending for episodes with anchor end dates in the fourth quarter of the performance year. A descaling factor, the ratio of MS–DRG relative weight in the first fiscal year to the MS–DRG relative weight in the second fiscal year, would be applied to episode spending. The descaled episode costs would be applied to the numerator of the retrospective trend factor as well as directly to the final target price through a factor, which would be calculated as the difference between the average episode cost and the average descaled episode cost, divided by the preliminary target price plus one. Episodes with anchor end dates in the fourth quarter of the performance year would be triggered based on the mapped first fiscal year MS–DRG and reconciled using original episode costs before descaling. We indicated in the proposed rule that although this approach could improve target price accuracy, we believed it would introduce additional complexity, increasing the risk of confusion and challenges in implementation. We considered but did not propose applying the update factors beginning in performance year 2. We believed this would negatively impact participants in performance year 1, resulting in misalignment between target prices, reconciliation amounts, and payment rates and weights applied during the performance year. However, we sought comment on this alternative considered. Lastly, we also considered but did not propose removing the ±3 percent capping of the retrospective trend factor adjustment. Applying a full retrospective trend factor to reconciliation target prices, rather than capping at ±3 percent would account for actual performance year spending and would incorporate APC or MS–DRG mapping and weight changes not captured in preliminary target prices. However, we recognized that removing the ±3 percent cap may introduce target price instability making it more difficult for TEAM participants to predict reconciliation target prices and assess spending performance in the model.

We sought comment on our proposal at § 512.505 to add definitions of the APC update factor, MS–DRG update factor, and updated prospective trend factor. We also sought comment on our proposal at § 512.540(b)(7) to add APC and MS–DRG update factors in the calculation of the prospective trend factor to account for changes in HCPCS–APC and MS–DRG mappings and weights during a TEAM performance year. We also sought comment on our proposals for performance years in which diagnosis or procedure codes are mapped to different TEAM triggering MS–DRGs between the first and second fiscal years. At § 512.545 to specify the FY MS–DRG(s) that each reconciliation target price component reflects for episodes with anchor end dates in the fourth quarter of the performance year. At § 512.550(c) to add a step to assign a first FY MS–DRG to performance year episodes with anchor end dates in the fourth quarter and modify the calculations to the assigned first and second fiscal year MS–DRG/HCPCS episode type.

The following is a summary of the public comments received on the proposed policy to include an MS–DRG update factor to the prospective trend factor, and our responses to these comments:

Comment: Many commenters expressed support for the MS–DRG update factor proposal. Some of these commenters stated the application of the MS–DRG update factor should help ensure target prices more accurately reflect MS–DRG mapping and weight changes between fiscal years. A few of these commenters expressing support also noted that ensuring target prices reflect performance year MS–DRG definitions and weights is essential to maintain alignment between clinical practice, reimbursement, and episode accountability, reduce the risk of under- or over-estimating target prices, and support consistency and predictability

for TEAM participants. A couple commenters expressed appreciation for CMS' consideration of complex timelines across annual payment rules and efforts to address timing inconsistencies between preliminary target price construction and annual FY IPPS/LTCH payment system updates.

Response: We thank the commenters for sharing their support for the MS–DRG update factor proposal. We agree that the MS–DRG update factor should help ensure target price accuracy, predictability, and alignment between clinical practice, reimbursement, and episode accountability. We also believe the MS–DRG update factor will help address timing inconsistencies between preliminary target price construction and the FY IPPS/LTCH payment system updates for the second fiscal year in a performance year.

Comment: A commenter expressed support for providing the MS–DRG update factor to participants during the performance year after the FY IPPS/LTCH final rule is published, noting it should improve participants' ability to manage a known target.

Response: We thank the commenter for their support.

Comment: A couple commenters encouraged CMS to provide clear and timely visibility and communication into any updates associated with IPPS/LTCH changes prior to the start of the applicable performance year, noting that this will help participants better anticipate how payment system updates are reflected in target prices and support more effective care and budget planning. A commenter suggested CMS maintain transparency regarding the MS–DRG update factor methodology by addressing any changes through IPPS/LTCH rulemaking prior to the start of the performance year in which the methodology change would be applied.

Response: We thank the commenters for their suggestions. We agree that timely visibility and communication on relevant IPPS/LTCH changes will help TEAM participants better anticipate how these changes will be reflected in final target prices. Any finalized MS–DRG definition or weight changes will be available in the FY IPPS/LTCH final rules, regardless of whether they are mentioned specifically in the TEAM Provisions section. In order to calculate the MS–DRG update factor, CMS must wait until the FY IPPS/LTCH final rule for the second fiscal year in a performance year is published. As such, we note that it will not be feasible to share the MS–DRG update factor, or relevant IPPS/LTCH changes, prior to the start of the applicable performance year. As stated in the proposed rule, CMS will calculate the MS–DRG update factor after the FY IPPS/LTCH final rule for the second fiscal year is published and share the MS–DRG update factor with TEAM participants in advance of final target price calculations. We believe that this will ensure all information that is used to calculate final target prices is available to TEAM participants. Additionally, CMS intends to release materials on relevant changes for the MS–DRG update factor as soon as feasible, such as MS–DRG mapping specifications, so participants are well-informed about the applicable changes to TEAM.

Comment: A couple commenters recommended assessing the impact of the MS–DRG update factor over time, ensuring the multiplier appropriately reflects evolving clinical and payment environments without introducing unintended variability in target prices. These commenters noted stable and transparent methodologies are critical in maintaining provider engagement and allowing hospitals to effectively plan and manage episode-based care.

Response: We thank the commenters for their recommendation. We agree that maintaining stable and transparent pricing methodology is critical for TEAM participants' engagement and planning. CMS intends to monitor the impacts of the MS–DRG update factor, as well as other methodological refinements, to ensure the factor enhances target price accuracy.

Comment: A couple of commenters suggested that if the MS–DRG update factor is applied starting in PY1, it should only be applied in cases where it results in favorable adjustments for TEAM participants. These commenters noted that since PY1 has already started, and hospitals have already made operational and financial decisions based on the original PY1 methodology, participants should not be held accountable for any retroactive changes that increase repayment obligations to CMS or otherwise worsen their financial position.

Response: We thank the commenters for their suggestions. We acknowledge that PY1 has already started, and the proposed policy would result in a methodology change mid-performance year. We note that the proposed changes related to the MS–DRG update factor only apply to and affect the final quarter of PY1 and the availability of the PY1 MS–DRG update factor is contingent upon the finalization of proposed MS–DRG changes for FY2027 and the publication of the FY2027 IPPS/LTCH final rule. Additionally, we acknowledge that the MS–DRG update factor may result in downward adjustments to target prices. However, given that these changes impact only the last quarter of the performance year and most participants are in Track 1, where there is no downside risk during PY1 reconciliation. As such, we believe the potential negative impacts of any downward adjustments in target prices due to the MS–DRG update factor in PY1 will be mitigated.

Comment: A commenter requested CMS to consider publishing the updated target price methodology with examples at a minimum of 90 days prior to the beginning of each performance year.

Response: We thank the commenter for their request. As previously noted, CMS must wait until the FY IPPS/LTCH final rule for the second fiscal year in a performance year is published to calculate the MS–DRG update factor. As such, it will not be feasible to share the MS–DRG update factor, or relevant IPPS/LTCH changes, prior to the start of the applicable performance year. CMS will calculate the MS–DRG update factor after the FY IPPS/LTCH final rule for the second fiscal year is published and share the MS–DRG update factor with TEAM participants in advance of final target price calculations. CMS intends to publish updated methodology specifications prior to each performance year so participants are well-informed about the methodology and any changes before the performance year begins.

After consideration of the public comments, we are finalizing without modification the proposals at § 512.505 to add definitions for MS–DRG update factor and updated prospective and at § 512.540(b)(7) to add MS–DRG update factors in the calculation of the prospective trend factor. We are also finalizing without modification the proposals at § 512.545 to specify the FY MS–DRG(s) that each reconciliation target price component reflects for episodes with anchor end dates in the fourth quarter of the performance year. Lastly, we're finalizing without modification the proposals at § 512.550(c) to add a step to assign a first fiscal year MS–DRG to performance year episodes with anchor end dates in the fourth quarter and modify the calculations to the assigned first and second fiscal year MS–DRG/HCPCS episode type.

(3) Prospective Normalization Factor Construction

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) that established TEAM, a normalization factor was included in the calculation of preliminary and reconciliation target prices to ensure that the average

benchmark price after risk adjustment does not exceed the average benchmark price prior to risk adjustment. The FY26 IPPS/LTCH PPS final rule (90 FR 36536) revised the language at § 512.505 to clarify that the prospective normalization factor will be calculated using the benchmark prices rather than using preliminary target prices. Additionally, the FY26 IPPS/LTCH PPS final rule modified §§ 512.540(b)(6) and 512.545(e)(1)(i) to calculate the prospective and final normalization factors at the MS–DRG/HCPCS episode type and region level rather than at national level.

For each MS–DRG/HCPCS episode type and region combination, the normalization factor is calculated as the average benchmark price divided by the average risk-adjusted benchmark price. The risk-adjusted benchmark price is the product of the benchmark price and a risk adjustment multiplier, which accounts for variation in spending due to hospital and beneficiary characteristics. The risk adjustment multiplier, as defined in current policy at § 512.540(b)(6)(i), is calculated by applying risk adjustment coefficients to the most recent baseline year episodes. Since the baseline period, as defined in § 512.505 and further addressed in § 512.540(b)(2), is a rolling three-year period, the most recent baseline year for a given performance year would always be baseline year 3. The construction of the normalization factor relying on the most recent baseline year was designed to maintain simplicity while using the most recent data available. However, we stated in the proposed rule that we have concerns that only using the most recent baseline year may not accurately reflect all the episodes used to calculate the benchmark price. Nor does using only the most recent baseline year consistently recenter the risk adjusted benchmark prices back to the average of the total non-risk adjusted benchmark price.

To improve predictive accuracy, better represent all episodes used in benchmark price construction, and recenter the risk adjusted benchmark price to the average of the total non-risk adjusted benchmark price, we proposed that starting with performance year 2 to update the definition at § 512.540(b)(6) to calculate the prospective normalization factor at the MS–DRG/HCPCS episode type and region level based on the applicable episodes in the baseline period. We proposed to update § 512.540(b)(6)(i) to apply the risk adjustment coefficients to all applicable baseline year episodes, rather than restricting application to the most recent baseline year episodes, in the calculation of the risk adjustment multiplier. We indicated in the proposed rule that this should improve the accuracy of the multiplier and help to smooth short-term fluctuations, if any, in the most recent baseline year. An internal analysis compared the observed and expected average hospital-level spending for each MS–DRG/HCPCS episode type and region using clinical episodes with start dates on or after January 1, 2022, and anchor end dates on or before December 31, 2024. Findings demonstrated that the multipliers and normalization factors constructed with all the baseline episodes improved predictive accuracy compared to those constructed using only the most recent baseline year episodes. We noted the difference between the MS–DRG/HCPCS episode type and region-level normalization factors calculated using only the most recent baseline year episodes and the normalization factors calculated using all baseline year episodes ranged from −0.03 to 0.02 (−3.46 percent to 2.56 percent). While this difference was small, we believed using all baseline episodes to construct the normalization factor is a more sound mathematical approach and will recenter average expected spending around average observed spending.

We considered in the proposed rule, but did not propose to calculate the normalization factor using an additional 2 years of data prior to the baseline period, similar to the trend factor construction. However, this would not recenter the risk adjusted benchmark prices and would not improve predictive accuracy.

We sought comment on our proposal at § 512.540(b)(6) and (b)(6)(i) to calculate the risk adjustment multiplier and normalization factor using the baseline period clinical episodes starting with performance year 2.

The following is a summary of the public comments received on the proposed policy to update the calculation of the risk adjustment multiplier and normalization factor starting with performance year 2, and our responses to these comments:

Comment: Some commenters supported, and a commenter did not oppose, the proposed update to the prospective normalization factor construction. A few of the commenters agreed that the proposed methodology update would improve the predictive accuracy of the prospective normalization factor. A couple commenters appreciated that the proposed update would improve target price accuracy without adding undue volatility. A couple other commenters further expressed that the proposed methodology would more effectively capture a hospital's episode and patient case mix variations.

Response: We thank the commenters for their support for the proposal to calculate the risk adjustment multiplier and normalization factor using all baseline period clinical episodes starting with performance year 2. We agree with the commenters that using all three baseline years' data in calculating the risk adjustment multiplier and prospective normalization factor would improve accuracy without adding undue volatility and more effectively capture a hospital's episode and patient case mix variation.

Comment: A commenter recommended that any revisions to target price methodologies applied to performance year 1 should be implemented prior to the start of the performance year or should otherwise only result in favorable adjustments for participants. The commenter further suggested that participants should not be held accountable for any retroactive changes that increase their repayment amount to CMS or otherwise result in negative financial impacts.

Response: We appreciate the recommendation and acknowledge that performance year 1 commenced before the methodology update to the construction of the prospective normalization factor was proposed. However, the methodology update will be applied beginning in performance year 2. CMS intends to publish updated target price specifications ahead of the start of that performance year, to ensure that participants are well-informed of the applicable performance year's methodology and any changes that apply.

After consideration of the public comments, we are finalizing without modification the proposals at § 512.540(b)(6) and (b)(6)(i) to calculate the risk adjustment multiplier and normalization factor using the baseline period clinical episodes starting with performance year 2.

d. Ambulatory Surgical Center (ASC) Episodes Request for Information

We received many thoughtful and wide-ranging comments in response to the Ambulatory Surgical Center (ASC) Episodes RFI and we thank the commenters for responding. Due to the breadth of topics covered in the ASC Episodes RFI and public comments, as well as the variety of viewpoints expressed in response to this RFI, we are not responding to specific comments submitted. However, we appreciate the valuable input on the parameters under

which ASCs could be incorporated into TEAM, including the degree to which the addition of ASCs would necessitate a separate model test. We are conducting an in-depth review of the comments received, and this may help to inform potential future rulemaking proposals.

e. Hospital with Physician Ownership Request for Information

We stated in the proposed rule that the CMS Innovation Center is considering initiating a voluntary opt-in period to allow hospitals with physician ownership (POHs) located in core-based statistical areas (CBSAs) not selected for Transforming Episode Accountability Model (TEAM) inclusion to participate in TEAM. A POH is any hospital in which a physician, or an immediate family member of a physician, has an ownership or investment interest in the hospital. An ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in the hospital.[571] It is estimated that more than 240 hospitals are owned and operated by physicians.[572]

Section 1877 of the the Act (42 U.S.C. 1395nn), also known as the physician self-referral law (and commonly referred to as the ''Stark'' law):

- Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless the requirements of an applicable exception are satisfied; and
- Prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payor) for any improperly referred designated health services.

A financial relationship may be an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

Section 1877(d) of the Act sets forth exceptions related to ownership or investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes designated health services. Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in rural providers (the ''rural provider exception''). To use the rural provider exception, an entity must furnish substantially all of the designated health services that it furnishes to residents of a rural area (as defined in section 1886(d)(2) of the Act). To satisfy the requirements of the rural provider exception, the designated health services must be furnished in a rural area and, in the case where the entity is a hospital, the hospital must meet the requirements of section 1877(i)(1) of the Act no later than September 23, 2011. Section 1877(d)(3) of the Act provides an exception for ownership or investment interests in a hospital located outside of Puerto Rico (the ''whole hospital exception''). To satisfy the requirements of the whole hospital exception, the referring physician must be authorized to perform services at the hospital, the ownership or investment interest must be in the hospital itself (and not merely in a subdivision of the hospital), and the hospital must meet the requirements of section 1877(i)(1) of the Act no later than September 23, 2011. These exceptions are codified in our regulations at § 411.356(c)(1) and (3), respectively.

Section 6001(a) of the Affordable Care Act effectively eliminated the exceptions for physician ownership or investment in hospitals, although hospitals with physician ownership or investment and a Medicare provider agreement on December 31, 2010, are grandfathered and able to continue using the rural provider exception, if applicable, and the whole hospital exception.

Section 6001(a)(3) of the Affordable Care Act amended the rural provider exception and the whole hospital exception to provide that a hospital with physician ownership or investment may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a Medicare provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the effective date of such provider agreement). However, the Secretary may grant an exception from the prohibition on facility expansion.

In the proposed rule, we referenced section 1877 of the Act (the Act) (42 U.S.C. 1395nn) and section 6001(a)(3) of the Affordable Care Act that limit the expansion of POHs to avoid the underlying concerns of the physician self-referral law, including but not limited to overutilization, patient steering, cherry-picking, and lemon-dropping. We also noted that there is some evidence that suggests that POHs may help control costs, maintain or improve patient outcomes, and prevent hospital consolidation.[573] [574] [575]

We sought public comment in the Request for Information on voluntary opt-in of POHs to participate in TEAM. The following is a summary of public comments received:

Comment: The vast majority of commenters supported allowing hospitals with physician ownership to voluntarily opt in to participate in TEAM. These commenters urged CMS to create a broad opt-in opportunity, and not limit eligibility based on geography, grandfathered status, rural or urban location, or whether the POH is outside a selected mandatory TEAM CBSA.

Some commenters suggested generally that POH participation would be consistent with patient-centered care, physician independence, and value-based care. They stated that physicians who directly care for patients should be able to own, lead, or control care-delivery settings, rather than being required to work as employees of large hospital systems, insurers, private equity entities, or administrator-led organizations. Some commenters asserted that physician-led governance would better align hospital operations with clinical judgment, patient welfare, care coordination, staffing, transitions, and episode-based care redesign. Many commenters stated that POHs could improve quality, patient experience, and continuity of care while reducing costs, waste, and administrative burden. They described POHs as efficient, transparent, less bureaucratic, and more accountable to physicians and patients. Some commenters also asserted that POH participation could increase competition, reduce consolidation pressures, expand patient choice, and provide an alternative to large vertically integrated health systems.

Some commenters also supported POH participation as a way to expand access and respond to community needs, including in rural, underserved, or consolidated markets where patients may face long wait times, service shortages, hospital closures, or limited access to specialty procedures, cancer care, GI services, obstetric care, or emergency surgical care. Some commenters requested that CMS evaluate POHs as a distinct category and separately assess their performance on cost, quality, utilization, patient experience, episode outcomes, and care coordination so TEAM could generate clearer evidence about physician-led delivery models.

[571] 42 CFR 411.351 and 411.254(b).

[572] Physician-Led Healthcare for America. (2026). *Physician-Led Hospitals. https://physiciansled.com/physician-led-hospitals-2/*

Response: We thank the commenters for their support of a voluntary opt-in opportunity for POHs to participate in TEAM. We agree with commenters that allowing additional POHs to participate in TEAM can support the goals of the model by expanding the number of hospitals participating in episode-based accountability, increasing the number of Medicare beneficiaries who may receive care under value-based care arrangements, and supporting continued investment in care redesign, care coordination, and improved transitions of care. We also agree that POHs may have staff, clinical focus, and the physician-led governance structures that could contribute to TEAM's test of whether episode-based payment can reduce Medicare expenditures while preserving or improving quality of care.

We recognize commenters' views that POHs may be well positioned to align operational decisions with clinical judgment and patient needs. TEAM is intended to test accountability for selected surgical episodes, and POHs that furnish services included in TEAM episodes may be able to implement care redesign strategies, engage treating physicians, coordinate post-discharge care, and manage avoidable spending in ways that are consistent with the model's goals. We believe that allowing additional POHs to participate could provide an opportunity for these hospitals to demonstrate whether and how physician-led care delivery structures perform under the same episode-based payment, quality, and reconciliation framework that applies to other TEAM participants.

We also agree with commenters that POH participation through a voluntary opt-in may increase beneficiary access to providers participating in value-based care. We believe that permitting additional eligible POHs to participate in TEAM may allow additional beneficiaries to receive care in settings that are accountable for episode cost and quality. This is consistent with CMS's interest in expanding value-based care opportunities while maintaining model integrity and beneficiary protections.

We also agree with commenters that POH participation may generate useful evidence about physician-led delivery models. This may include reviewing POH performance on cost, quality, patient experience, care coordination, episode outcomes, readmissions, post-acute care use, beneficiary mix, and other measures relevant to model performance and program integrity.

We also agree that competition and patient choice are important considerations. TEAM does not require a beneficiary to receive care from a particular hospital, and participating hospitals must continue to comply with applicable beneficiary protections and Medicare requirements. Allowing additional POHs outside of mandatory TEAM CBSAs to participate may give beneficiaries and referring providers additional options among hospitals that are accountable for episode quality and cost. We believe this may be especially relevant in markets where commenters stated that consolidation, service gaps, or limited access may reduce patient options.

While we appreciate commenters' assertions that POHs may be efficient, transparent, less bureaucratic, and accountable to physicians and patients, we are not relying on these assertions for the final policy. If POHs participating in TEAM can improve care coordination, reduce avoidable spending, maintain or improve quality, and support positive beneficiary outcomes, those results may be observable through model monitoring and evaluation.

After consideration of the public comments we received, we intend to propose in future rulemaking a policy to allow POHs not located in mandatory CBSAs to participate in TEAM. With POH concentration in the clinical areas that TEAM is designed to improve, we believe participation of additional POH will further test whether financial accountability for all costs of care for an episode will incentivize care coordination, improve patient care transition, and reduce unnecessary readmissions.

Comment: Many commenters emphasized that many POHs are specialty-focused facilities, including orthopedic, spine, surgical, cardiac, oncology, gastroenterology, or other physician-led settings relevant to TEAM episodes. Commenters indicated that they believe physician-led specialty hospitals can coordinate perioperative care, manage episodes across the full course of treatment, reduce variation, and deliver high-volume surgical expertise. Several commenters connected POHs to TEAM's surgical episode categories and stated that excluding specialty-focused POHs would leave out facilities that may be well positioned to succeed under bundled or episode-based accountability.

Response: We appreciate commenters highlighting the role of specialty-focused POHs in surgical care and how they may be relevant to the episode categories tested in TEAM. We agree that physician-led specialty hospitals may have experience in orthopedic, spine, cardiac, and other surgical service lines that are relevant to TEAM's episode-based design. We also agree that having specialty-focused experience may help some hospitals standardize care pathways, engage clinicians, manage post-acute transitions, and identify opportunities to reduce unnecessary spending while preserving or improving quality. These considerations support allowing eligible POHs a pathway into TEAM and specifically testing whether POHs are able to reduce Medicare spending while improving or maintaining quality of care in TEAM episodes. However, we must also ensure that specialty-focused POHs do not inappropriately steer beneficiaries, avoid higher-risk patients, or limit access in a way that would undermine the model or beneficiary protections. For these reasons, we agree that specialty-focused POHs can bring relevant expertise to TEAM, but we intend to consider accountability, quality, and compliance requirements in conjunction with POH participation in future rulemaking.

Comment: Some commenters supported or did not oppose consideration of POH participation but stressed that CMS should proceed with caution. Commenters discussed concerns related to appropriate utilization, patient selection, program integrity safeguards, and beneficiary choice. Some commenters supported a broad opt-in as allowed by statute, while others cautioned that POH participation through a voluntary opt-in could raise equity, evaluation, or compliance issues if POHs were treated more favorably than mandatory acute care hospital participants.

Response: We agree that any POH participation through a voluntary opt-in policy should include appropriate guardrails. In future rulemaking, we intend to address beneficiary protections, monitoring requirements, and the potential for remedial action in the event of noncompliance. We also agree that preserving beneficiary protections and maintaining model integrity are important considerations in determining whether and how additional POHs should be allowed to participate in TEAM.

We also agree that beneficiary choice must be protected. TEAM does not permit participating hospitals to restrict where beneficiaries receive care, require beneficiaries to use particular providers or suppliers, or deny medically necessary covered services. CMS will consider whether to require that newly participating POHs include the same beneficiary protections as other TEAM participants, including requirements

related to beneficiary notification, access to medically necessary care, and continued Medicare coverage and choice protections.

We also agree that appropriate utilization and patient selection would be important issues to monitor. TEAM episodes are initiated based on model episode criteria, not based on a hospital's ability to select individual beneficiaries for inclusion or exclusion after the fact. However, we recognize that commenters raised concerns about whether POHs could alter referral patterns, service mix, or case mix in ways that may affect model performance. Along with the POH participation policy, we intend to propose policies requiring POHs to participate in monitoring activities as specified by CMS. Monitoring POH performance may include the use of available claims, utilization, quality, episode, and reconciliation data to identify patterns that may indicate inappropriate behavior, including unusual changes in case mix, episode volume, beneficiary characteristics, referral patterns, admission source, emergency department use, transfer patterns, readmissions, post-acute care utilization, outlier spending, or quality outcomes. We note that TEAM policies allow for remedial action, as permitted under § 512.592, or TEAM participant termination, as permitted under § 512.596, to mitigate concerns identified through monitoring.

We agree with commenters that POH participation through a voluntary opt-in should not undermine model evaluation. We recognize that a voluntary opt-in opportunity can introduce self-selection concerns, including the possibility that hospitals that opt in voluntarily may differ from mandatory participants. Additionally, we appreciate concerns that participation of POHs that opt in could be more favorable than mandatory participation. We will consider these concerns in future rulemaking and may align the terms of POH participation with existing TEAM participation where possible and appropriate.

Comment: Some commenters opposed POH participation through a voluntary opt-in or urged CMS to limit it because of concerns about selective patient mix, negotiating leverage, profits for physician owners, and program integrity. Commenters stated that POHs can be selective in the patients they treat and the case mix they maintain and raised concerns about cherry-picking, lemon-dropping, steering, and differences between POHs and other acute care hospitals. These commenters generally believed that allowing POH participation through a voluntary opt-in could create inequities for mandatory participants and could distort TEAM's cost, quality, and evaluation results. A commenter strongly objected to allowing any new subset of hospitals, including POHs, to voluntarily opt in to participate in TEAM if CMS finalized CJR–X. This commenter believed that creating a POH-only opt-in would produce an uneven playing field, compromise TEAM and CJR–X evaluation integrity, and effectively give only POHs a path to opt out of CJR–X. Another commenter strongly opposed a voluntary opt-in period for POHs, stating that longstanding concerns about self-referral, overutilization, patient steering, cherry-picking healthier and better-insured patients, and limited emergency-service capacity still apply. The commenter stated that POHs tend to treat younger, less complex, and wealthier patients; provide fewer emergency services; report on fewer Medicare quality measures; and could destabilize full-service community and rural hospitals by siphoning profitable patients while leaving more complex and vulnerable patients to other hospitals. The commenter also stated that allowing only POHs to voluntarily opt into TEAM would create self-selection bias, destabilize target prices, threaten access for dual-eligible, low-income subsidy, rural, and underserved beneficiaries, and unfairly favor POHs over full-service hospitals. The commenter cited a study that found that POHs treat younger, less complex, and wealthier patients; are five times more likely to receive CMS' maximum readmission penalty; provide fewer emergency services and rely on community hospitals for critical care. The study also found that POHs report on fewer Medicare quality measures, raising concerns about transparency and accountability. They also cited another study that found that if a new POH opens in the same market as a full-service rural hospital, the full-service hospital's margins decrease significantly as the POH siphons off healthier and commercially insured patients, risking access to 24/7 care and community jobs.

Response: We thank the commenters for raising concerns about program integrity, beneficiary access, patient selection, model evaluation, and the interaction between POH that voluntarily opt in to TEAM and other CMS models. We take these concerns seriously. However, we believe that the design of the model and program integrity safeguards could mitigate the potential harms identified by the commenters.

As previously noted, we intend to propose a policy for additional POH participation in TEAM in future rulemaking. We believe that POHs may be able to contribute to TEAM's goals of improving care coordination and supporting care redesign. TEAM is designed to test whether financial accountability for selected surgical episodes can reduce Medicare expenditures while preserving or improving quality. TEAM participation provides an opportunity for POHs to operate under a value-based model, implement care redesign activities, coordinate care across an episode, and be accountable for cost and quality performance. Allowing additional POHs to participate will allow CMS to monitor whether POHs can succeed under the model without creating a distinct set of operational advantages over other TEAM participants.

We recognize the concerns that limited-service hospitals could raise issues related to overutilization, patient steering, cherry-picking, lemon-dropping, conflicts of interest, and impacts on full-service hospitals. We take these concerns seriously and intend to consider these issues when proposing POH participation and monitoring policies in future rulemaking.

We acknowledge commenters' concerns that voluntary opt-in may introduce self-selection into the model. We noted this concern in the proposed rule, including the potential cost and evaluation implications of voluntary opt-in and the risk that voluntary opt-in may affect model evaluation if not appropriately bounded. However, we do not agree that these concerns require rejecting POH participation through a voluntary opt-in altogether.

We also disagree that POH voluntary opt-in will, by itself, compromise beneficiary protections or permit inappropriate cherry-picking, lemon-dropping, or steering. TEAM does not give participants authority to deny medically necessary care, restrict beneficiary choice, alter Medicare coverage rules, or select beneficiaries for episode inclusion based on expected profitability. TEAM episodes are initiated based on specified clinical episode triggers, as identified by a MS–DRG or HCPCS code, along with beneficiary inclusion criteria, and not initiated based on a hospital's discretionary selection of individual beneficiaries.

We recognize that commenters are concerned that POHs may have different patient mix, service-line focus, emergency-care capacity, or referral patterns than other acute care hospitals. We intend to take these concerns into

account when considering and proposing monitoring policies in conjunction with POH participation in future rulemaking.

We also acknowledge participants' concerns that POH participation through a voluntary opt-in could destabilize target prices or distort TEAM's cost and quality results. We intend to propose a POH policy that considers these concerns in future rulemaking.

We recognize commenters' concerns that a targeted opt-in opportunity would be inequitable, and we intend to consider equity concerns when proposing POH participation policies in future rulemaking. We also do not agree that allowing POHs to opt in to TEAM voluntarily would give them a special exemption from CJR–X because at the end of TEAM, all TEAM participants, inclusive of POHs, would participate in CJR–X.

We acknowledge commenters' concerns about physician financial incentives and conflicts of interest and intend to consider these concerns in future rulemaking.

We also recognize concerns that POHs may focus on profitable service lines and may not furnish the same range of emergency or complex services as full-service community hospitals. We do not agree that these concerns justify excluding otherwise eligible POHs from participation in TEAM. TEAM is itself an episode-based model focused on specified surgical episodes, and all TEAM participants are accountable within the scope of the model's episode categories and payment rules. However, we intend to take service delivery concerns into consideration when proposing POH participation policies in future rulemaking.

We also recognize commenters' concerns that POH participation through a voluntary opt-in may harm rural or underserved communities. We intend to consider these concerns when proposing policies for POH participation and associated monitoring in future rulemaking.

Comment: Some commenters generally supported POH participation in TEAM but stated that a voluntary opt-in opportunity for POHs would not be meaningful without fraud and abuse waivers issued under the Innovation Center's authority. Many commenters urged CMS to revisit and substantially modernize broader federal restrictions on POHs, including the physician self-referral law, Affordable Care Act, and section 6001 limits on POH ownership, expansion, operating rooms, procedure rooms, beds, and facility capacity. Commenters believed that existing restrictions limit physician-led competition, protect incumbent hospital systems, create a double standard compared with large health systems, insurers, and other vertically integrated entities, and prevent POHs from responding to population growth, surgical demand, specialty-service shortages, and beneficiary access needs. Other commenters opposed issuing any fraud and abuse waivers for POHs voluntarily opting in to the model. They believed waivers of section 1877(d) and (i) of the Act would exceed CMS's testing and waiver authority under section 1115A(b) and (d)(1) of the Act. The same commenters also believed the resulting limited-service hospitals would compound the very problems that Congress sought to directly address when enacting the express limitations on new and expanded POHs in section 1877 of the Act.

Response: We appreciate the perspectives shared regarding federal regulations governing hospitals with physician ownership. We note that CMS does not have authority to amend, modify or repeal any statutory provisions. For this model and consistent with the authority under section 1115A(d)(1) of the Act, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act as may be necessary solely for purposes of testing models described in section 1115A(b) of the Act. No fraud or abuse waivers are being issued in this final rule. Any potential exercise of this statutory waiver authority will be addressed in separately issued documentation. Any such waiver would apply solely to TEAM and could differ in scope or design from waivers granted for other programs or models. Thus, notwithstanding any provision of this final rule, TEAM participants must comply with all applicable laws and regulations, except as explicitly provided in any such separately documented waiver that may be issued pursuant to section 1115A(d)(1) of the Act specifically for TEAM.

After consideration of the public comments we received, we intend to propose in future rulemaking a policy for POH participation in TEAM. We believe additional participation of POHs in TEAM will promote greater choice and competition.

B. Revision to Provider-Based Location Criteria Regulations Applicable to Off-Campus Facilities or Organizations (§ 413.65)

1. Background

Section 1861(u) of the Act lists the types of facilities that are regarded as providers of services but does not use or define the term ''provider-based''. Since the beginning of the Medicare program, however, some providers, referred to as *main providers,* have functioned as a single entity while owning and operating multiple subordinate facilities that were treated as part of the main provider for Medicare purposes (as related to, for instance, payment; certification; coverage; and/or billing). With this treatment, compared to being treated as a freestanding facility, provider-based facilities might experience a number of advantages, including most notably, increased payments from Medicare. Therefore, we have maintained that having clear criteria for treating a facility as provider-based, as opposed to operating as a freestanding facility, is important because failure to properly distinguish between the two risks inaccurate program payments, which can result in provider overpayments and increased beneficiary coinsurance liability, with no commensurate benefit to the Medicare program or its beneficiaries.

Program Memorandum A–967, published on August 27, 1996, provided instructions for specific entity types from previously published documents consolidated into a general instruction for the designation of provider-based status for all facilities or organizations. That Program Memorandum was subsequently reissued, without substantive change, as Program Memoranda A–98–15 and A99–24 and, in October 1999, was manualized by the Provider Reimbursement Manual, Part I, Transmittal 411 (adding new section 2446), and the State Operations Manual, Transmittal 11 (replacing previous section 2003 and adding new section 2004). The Medicare rules regarding provider-based status of facilities and organizations are set forth at 42 CFR 413.65 and have been revised and updated on numerous occasions since initial issuance on April 7, 2000 (65 FR 18504). We note that implementation of the April 7, 2000 regulations was delayed for many providers by Public Law 106–554 in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), which further amended the criteria for determining provider-based status, as implemented in a final rule

published in the **Federal Register** on November 30, 2001 (66 FR 59909).

Since the initial creation and implementation of the provider-based rules, CMS included requirements that the facility or organization seeking provider-based status and the main provider either be located on the same ''campus,'' as defined in regulations,[577] or, amongst other criteria, demonstrate they serve the same patient population. In the initial versions of the provider-based rules, the requirements regarding servicing the same patient population included a requirement that the facility or organization seeking provider-based status be in the ''immediate vicinity'' of the main provider's campus. The precise distance for an ''immediate vicinity'' determination was not defined in rulemaking, though the limit was generally understood to not exceed 35 road miles from the main facility, consistent with prior guidance. In response to a commenter in the final rule with comment period published in the **Federal Register** on April 7, 2000 (65 FR 18516), CMS concurred that establishing more precise criteria was required and finalized alternative methods to determine whether a provider-based facility or organization could demonstrate that it serves the same patient population as the main provider, even if it did not meet the ''immediate vicinity'' criterion. As revised, this ''same patient population'' test required hospitals to annually demonstrate a geographic overlap in service area through comparisons of patients' home zip code data from the main provider and the facility or organization seeking provider-based status.

Section 404(b) of BIPA further amended the immediate vicinity criterion by stating that the facility or organization must be located within a 35-mile radius of the potential main provider. The legislation also required the facility or organization to satisfy the regulatory criteria previously finalized by CMS at § 413.65(d)(7), and redesignated in 2003 as § 413.65(e)(3)(iii), which required a facility or organization to demonstrate it serves the same patient population as the potential main provider (the ''75 percent'' tests). And to encourage delivery of care to uninsured, low-income individuals, BIPA added alternative qualification criteria for certain hospitals with a disproportionate share adjustment greater than 11.75 percent.

In the FY 2001 IPPS/LTCH PPS final rule (65 FR 18517 through 18518), commenters requested that the requirement to serve the same patient population be modified to exclude off-campus inpatient facilities of hospitals because these facilities provide similar types of service as the main provider but serve patient populations from different geographic areas. We responded by stating that CMS recognizes there may be some cases in which a main hospital and another facility or organization seeking provider-based status may meet most or all other determining criteria in the regulations yet not qualify under the same patient population tests. We disagreed that this result should lead us to abandon the same patient population test, however, and pushed back on the commenter's assumption that because the program memorandum and proposed rule were issued in response to situations primarily involving outpatient facilities, they can apply only to such facilities. In that rule, we expressed specific concerns regarding payment implications for certain potential arrangements that we believed warranted application of the provider-based rules to both outpatient and inpatient locations. Specifically, we stated that the establishment of off-campus facilities excluded from the inpatient PPS could lead to payment abuses, such as circumvention of certain payment caps. We further addressed more general requests to exempt off-campus inpatient facilities from provider-based rules in the FY 2003 IPPS/LTCH PPS final rule (67 FR 50081 through 500082), reaffirming our position that provider-based rules should apply to both inpatient and outpatient facilities and organizations.

2. Proposed Revision to the ''Same Patient Population'' Location Criteria

To satisfy the location criterion set forth at § 413.65(e)(3)(iii), the regulation requires the facility or organization demonstrate that it serves the ''same patient population'' as the main provider by submitting records showing that, during the immediately preceding 12-month period, and for each subsequent 12-month period, that either: at least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider (§ 413.65(e)(3)(iii)(A)); or at least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (§ 413.65(e)(3)(iii)(B)). The provision at § 413.65(e)(3)(iv) provides a temporary test for newly established facilities that would not yet have 12 months of data to evaluate. We continue to believe that hospitals operating off-campus inpatient sites, such as a remote location or satellite facility, must meet one of the location requirements set forth in § 413.65(e)(3). However, upon further evaluation, we have concerns that aspects of the 75 percent tests do indeed pose an issue regarding facilities that furnish inpatient services.

Within the text of § 413.65(e)(3)(iii)(B), an example is provided to illustrate that to meet the requirement a hospital must demonstrate that at least 75 percent of the patients of a rural health clinic (RHC) seeking provider-based status received inpatient hospital services from the main provider hospital. This example describes a *referral* relationship between the main provider and the off-campus facility. That is, in certain geographic areas, where obtaining more acute follow-up care may require longer travel times, this provision provides an exception to a distance-based criterion for establishing the boundaries for a ''same patient population'' service area. We believe this example was meant to reinforce CMS' intention that this provision could be applied to exceptionally isolated outpatient facilities where additional services are routinely received by patients at more distant acute care facilities. Distinguishably, if a hospital chooses to operate two distinct inpatient locations more than 35 miles apart, we do not believe the hospital should be able to document that they serve the same patient population via the referral-based 75 percent test. Further, for PPS hospitals, inpatient services are generally paid based on the geographic location of the inpatient facility. Therefore, we do not believe that obtaining provider-based status for a remote location facility would have significant financial implications. By contrast, however, we are concerned that allowing this referral-based exception for inpatient facilities, certain specialty and PPS-excluded hospitals could obtain significant payment advantages for inpatient services provided at considerable distances from the main provider. We are aware that hospitals may, on occasion, transfer, or schedule additional follow-up for patients between related inpatient facilities. Even so, we believe these cases are likely limited to exceptional circumstances and not adequately demonstrative of whether one facility provides services to the same patient population as another.

For these reasons, we proposed to limit the application of § 413.65(e)(3)(iii)(B) to outpatient

[577] *See* 42 CFR 413.65(a)(2).

departments only. When a patient that ''required the type of care furnished by the main provider'' is referenced, it was contemplated that the encounter(s) at the proposed provider-based location would deliver outpatient services rather than inpatient services. We believe that this proposed revision maintains the original intent of the policy by permitting a proposed provider-based outpatient practice location to exceed the 35-mile radius in circumstances where inpatient services are not readily available in the area. And it eliminates the aforementioned potential for arguably unwarranted payment advantages by certain hospitals. Accordingly, we proposed to revise § 413.65(e)(3)(iii)(B) to specify that at least 75 percent of the patients served by an outpatient facility or organization who required the type of care furnished by the main provider received that care from that provider. An inpatient facility or organization, by contrast, would be excluded from utilizing this test to meet the location requirement altogether. Further, we proposed the addition of clarifying language at § 413.65(e)(3)(iii)(A) to make explicit that provision may still be utilized by either an inpatient or outpatient facility or organization.

We sought comment on this proposal.

Comment: Commenters argued that CMS's proposal contradicts the agency's own longstanding policy and would risk significant potential harm to patient access—particularly in rural and underserved communities.

Commenters stated that provider-based status allows off-campus locations to operate as integral parts of the hospital, expanding access to rural and underserved patients and improving access for the most medically complex patients. Commenters cited general trends in the industry to operate more remote specialty inpatient locations that would routinely refer patients to a large, better equipped tertiary hospital for additional treatment. Multiple commenters stated CMS's own prior policy that explicitly applied the referral-based test to both inpatient and outpatient provider-based facilities and requested CMS withdraw the proposal entirely or, at minimum, provide an exception provision for existing provider-based facilities. A commenter also questioned whether the proposal is necessary, given that CMS stated it would have a negligible financial impact on hospitals.

Response: We appreciate the input provided by the commenters. We note that while multiple commenters expressed concerns regarding potential negative impacts to hospitals, no commenter provided a specific example of an existing facility that would be negatively affected by this proposal. We acknowledge that this proposal is making a limited modification to longstanding CMS policy that applied provider-based regulations to both inpatient and outpatient facilities. While this policy has been in place for over 20 years, CMS has reviewed few provider-based attestations that utilized either of the 75 percent tests and, based on a search of records, could locate no case that relied on this specific referral test. We believe a hospital would likely seek CMS guidance or approval before presuming to qualify for the 75 percent test exceptions to the 35-mile proximity requirement, particularly before acquiring or constructing an inpatient facility. We do not believe it is appropriate to provide an exception, as requested by commenters, for existing off-campus remote locations because we do not believe that to the extent these facilities are receiving higher payments than would otherwise be justified by the geographic area where those facilities are located, or higher payments than other facilities, if any, that are located in that geographic area are receiving, that those higher payments are justified or equitable.

Additionally, as described above, we typically would not expect provider-based status to produce higher payment for inpatient facilities, as most payment systems base payment on the geographic location of the inpatient facility, whether it is enrolled separately or operated as a provider-based remote location. For example, remote locations of IPPS hospitals that are located in a different payment area than its main provider hospital are indicated with a ''B'' or ''C'' in the third position of the hospital's CCN in Table 2 in the addendum to this final rule, and have a wage index applied based on the remote location's geographic location. As stated in the proposed rule, however, we have become aware of potential scenarios where payments to IPPS-excluded hospitals could be increased by obtaining provider-based status for remote locations. Therefore, while we believe the impact on current hospital facilities is negligible, we find it is necessary to modify the provider-based rules to refine which facilities would be eligible for the referral-based 75 percent test.

Regarding commenters' concerns regarding potential negative impacts on providing integrated care in rural and underserved communities, we note that the referral arrangements they cited are currently allowable under Medicare policy, and provider-based status is not a requirement. Hospital systems routinely operate a variety of hospital and non-hospital facilities and can coordinate care and make necessary referrals between separately enrolled hospitals under current payment systems, facilitating the provision of more advanced or specialty services when medically necessary. The provider-based regulations define what may be considered an integrated part of an individual hospital, and do not restrict new service locations from enrolling with the program and receiving payments in accordance with the applicable payment system. While certain potential administrative efficiencies may be gained by obtaining provider-based status, we do not believe this alone is sufficient justification to provide broad exceptions to the provider-based location requirements.

Comment: One commenter argued that CMS's proposal lacks statutory authority, stating that, in BIPA Section 404(b), Congress ''adopted the 75 percent referral test as written'' and that, based on the commenter's read of § 413.65, Congress ''codified the application to both inpatient and outpatient locations'' such that any change would be contrary to Congressional intent.

Response: We disagree with commenters that BIPA precludes CMS from making any refinements to the 75 percent tests. Furthermore, CMS is maintaining the 75 percent tests and only updating our regulations to address scenarios that likely were not contemplated at the time of BIPA's passage, namely attempts by IPPS-excluded hospitals to increase Medicare payments by obtaining provider-based status for remote locations even if those remote locations are hospitals in other geographically urban areas in proximity to IPPS hospitals. We also note that off-campus inpatient locations will remain eligible to meet the requirements at 413.65(e)(3)(iii)(A).

After consideration of the public comments we received, we are finalizing the policy to exclude inpatient locations from 413.65(e)(3)(iii)(B), as proposed.

C. Expansion of the Comprehensive Joint Replacement (CJR) Model

1. Overview of Expansion of the Comprehensive Care for Joint Replacement (CJR) Model

a. Introduction

CJR was a Phase I mandatory alternative payment model tested by the Center for Medicare and Medicaid Innovation (Innovation Center) between April 1, 2016, and December 31, 2024,

in all eligible acute care hospitals within selected Metropolitan Statistical Areas (MSAs). Based on evaluation results indicating the model successfully reduced spending without reducing quality of care and the Secretary determining that the model has met the requirements for expansion, as described in section X.C.1.c. of this final rule, we proposed to expand CJR to all eligible acute care hospitals nationwide. The CJR model expansion, referred to as the Comprehensive Care for Joint Replacement Expanded (CJR–X) Model, presents an opportunity to further improve the quality of care for lower extremity joint replacements (LEJRs) furnished to Medicare beneficiaries nationwide by incentivizing hospitals, physicians, and post-acute care providers to work together to improve the quality and coordination of care from the initial hospitalization or procedure through recovery. As stated in the proposed rule, and finalized in this final rule, all eligible acute care hospitals would be required to participate in the CJR–X Model. We note that we proposed that CJR–X would start on October 1, 2027, but in response to comments, we are finalizing a model start date of January 1, 2028, as discussed in section X.C.2.a. of this final rule.

In order to distinguish our discussion of policies for CJR–X from our discussion of the initial CJR Model test, we will refer to the latter as ''the CJR Model''. Additionally, we noted that the CJR Model was initially designed to end on December 31, 2020, but was extended with modifications to the methodology, as described in section X.C.1.b. of this final rule. As a result, some of the policies we discuss in this final rule will have been applicable only prior to the extension while others will have been applicable only during the extension period (for example, the extension period broadened the definition of episodes to include outpatient episodes and modified the target price methodology). To distinguish the timeframe in which these particular policies applied, we will henceforth use the term ''original CJR Model'' for the former and ''CJR Extension'' for the latter. For specific policies that were consistent across both the original and extension periods, or discussion of the CJR Model test as a whole, we will continue to use the term ''the CJR Model.'' To distinguish the performance years in the CJR Model as defined at § 510.2 from our definition of performance years (PYs) in CJR–X at § 512.605, we will refer to the former as ''CJR Model PYs.''

b. Background

The Innovation Center implemented the CJR Model under the authority of section 1115A of the Act, through notice-and-comment rulemaking. The Innovation Center issued a final rule titled ''Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services'' (referred to as the ''2015 CJR final rule''), which appeared in the November 24, 2015, **Federal Register** (80 FR 73274). The first CJR Model performance period began April 1, 2016. The goal of the CJR Model was to support better and more efficient care for beneficiaries undergoing the most common inpatient surgeries for beneficiaries: hip and knee replacements (also called lower extremity joint replacements or LEJR). Using the randomized selection methodology finalized in the 2015 CJR final rule, we selected 67 MSAs and initially required the approximately 800 acute care hospitals located in those MSAs to participate in the model through December 31, 2020. The selection of mandatory MSAs was reduced to 34 of the original 67 in later performance years of the model to focus on highest average spending MSAs to allow us to evaluate the effects of the CJR Model across a wide range of providers, including some that might not otherwise participate in the model (82 FR 57073).

The CJR Model tested quality and spending accountability for an episode of care associated with hip and knee replacements to encourage hospitals, physicians, and post-acute care providers to work together to improve the quality and coordination of care from the initial hospitalization through recovery. Specifically, the CJR Model was a retrospective bundled payment model where CMS provided participant hospitals with a target price for each CJR episode type (based on the MS–DRG assigned to the hospitalization and the presence or absence of a hip fracture in the original CJR Model and the MS–DRG or HCPCS code assigned to the hospitalization or procedure in the CJR Extension), prior to the start of each CJR Model PY. All providers and suppliers furnishing LEJR episodes of care to patients throughout the year were paid under existing Medicare payment systems. The target price included a discount that served as Medicare's portion of reduced expenditures from the LEJR episode, and initially incorporated a blend of historical, hospital-specific spending and regional spending for LEJR episodes, with the regional component of the blend increasing over time and eventually being 100 percent regional for PYs 4 through 8. Following the end of a CJR Model PY, actual total spending for a hospital's episodes was compared to the target price for those episodes. Depending on the participant hospital's quality and episode spending performance, the hospital could receive an additional payment from Medicare if spending was less than the target price or be required to repay Medicare for a portion of the episode spending that exceeded the target price.

In the January 2017 final rule (82 FR 180) and the December 2017 final rule (82 FR 57066), CMS implemented revisions to the CJR Model, including creating an Advanced APM track within the model and finalizing technical refinements and clarifications for certain payments, reconciliation and quality provisions. Additionally, in the December 2017 final rule, CMS offered rural and low-volume hospitals selected for participation in the CJR Model, as well as those hospitals located in 33 of the 67 MSAs, a one-time option to choose whether to continue their participation in the model until the initial CJR Model end date of December 31, 2020. All other participating hospitals in the remaining 34 MSAs continued to be mandatory participants (henceforth referred to as ''mandatory hospitals'').

While initial evaluation results for the first and second year of the CJR Model indicated that the model was having a positive impact on lowering episode costs when CJR participant hospitals were compared to non-CJR hospitals (with no negative impacts on quality of care), changes in program payment policy and national care delivery patterns had occurred since the CJR Model began.[578] [579] Specifically, knee replacements (total knee arthroplasty, or TKA) had been removed from the Inpatient Only (IPO) List as of January 1, 2018. Hip replacements (total hip arthroplasty, or THA) were subsequently removed from the IPO List as of January 1, 2020. These policy changes meant that TKA and THA procedures would be paid by Medicare when performed in the outpatient setting (meaning in a hospital outpatient department, or HOPD). However, the definition of an episode in the original

[578] Comprehensive Care for Joint Replacement Model—First Annual Report (*https://www.cms.gov/files/document/cjr-firstannrptpdf.pdf*).

[579] Comprehensive Care for Joint Replacement Model—Second Annual Report (*https://www.cms.gov/files/document/cjr-secondannrptpdf.pdf*).

CJR Model included only those TKA and THA procedures performed in the inpatient setting. Additionally, changes in national care delivery patterns meant that hospitals nationwide (including those not participating in the CJR Model) were reducing spending on LEJR episodes, but the model's original prospective target price methodology did not sufficiently account for these nationwide trends. As a result, target prices were artificially inflated, leading to concerns about the ability of the model to demonstrate savings over time.

In order to update the original CJR Model to address those changes to policy and care delivery patterns and improve the model's ability to demonstrate savings, CMS issued a proposed rule titled ''Medicare Program: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing'' (referred to as the ''2020 CJR 3-Year Extension proposed rule''), which appeared in the February 24, 2020 **Federal Register** (85 FR 10516). This rule proposed to extend the CJR Model for an additional three CJR Model PYs with modifications that included adding outpatient TKAs and THAs to the episode definition, adjusting the target price methodology and risk adjustment, and simplifying the reconciliation process.

Shortly before the 2020 CJR 3-Year Extension proposed rule was published, on January 31, 2020, Secretary of Health and Human Services Alex M. Azar II determined that a public health emergency (PHE) existed and had existed nationwide since January 27, 2020 due to confirmed cases of the 2019 Novel Coronavirus (2019-nCoV, hereafter referred to as ''COVID–19'').[580] In April 2020, in response to the COVID–19 PHE, CMS issued the April 2020 Interim Final Rule with Comment Period (IFC) (85 FR 19230), which addressed the impact of the COVID–19 PHE on participant hospitals. CMS delayed the proposed extension and modification of the original CJR Model and instead extended CJR Model PY5 through March 31, 2021, to minimize disruption to CJR Model participants as they dealt with the challenges of the COVID–19 PHE. CMS also adjusted the CJR Model's extreme and uncontrollable circumstances policy (originally designed to provide a time-limited period of financial protection to hospitals in the case of natural disasters such as hurricanes, floods, and wildfires) to apply to all CJR episodes during the COVID–19 PHE. This updated policy effectively waived downside risk for all CJR episodes during the COVID–19 PHE.

Subsequently, CMS issued the November 2020 interim final rule with comment period (IFC) (85 FR 71142), which implemented several changes to the CJR Model. Among them, CMS made a technical change to include MS–DRGs 521 and 522 in the CJR episode definition to ensure that the model continued to include the same inpatient LEJR procedures, despite the introduction in FY 2020 of new MS–DRGs to describe those procedures. CMS also finalized a more targeted application of the extreme and uncontrollable circumstances policy to episodes with a COVID–19 diagnosis. This change increased the likelihood of model savings while providing participants with financial protection against COVID–19 episodes after the COVID–19 PHE ended.

Evaluation results from the first four years of the CJR Model indicated that mandatory hospitals generated $72 million in savings to Medicare while maintaining quality, although the savings were not statistically significant. But in PY 5, reconciliation payments substantially increased, generating $95.4M in statistically significant Medicare losses, due to adjustments made to the model during the COVID–19 PHE. CMS implemented these temporary adjustments, which effectively waived downside risk for all CJR episodes, in order to minimize any financial burden associated with model participation given the financial challenges and uncertainties hospitals faced early in the COVID–19 PHE. These adjustments resulted in reconciliation payments being triple what they were in previous years, which reversed the savings trajectory and resulted in statistically significant losses to Medicare for mandatory hospitals. The losses in CJR Model PY 5 were large enough to offset total estimated savings prior to the PHE.[581]

In order to return the model to a savings trajectory, CMS published the final rule titled ''Medicare Program: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing; Medicare and Medicaid Programs; Policies and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' in the May 3, 2021 **Federal Register** (86 FR 23496) (referred to in this final rule as the ''2021 CJR 3-Year Extension final rule''). The 2021 CJR 3-Year Extension final rule finalized the extension and modification of the original CJR Model that CMS had proposed in the 2020 CJR 3-Year Extension proposed rule. This rule extended the length of the model through December 31, 2024, by adding an additional 3 CJR Model PYs. Also, CMS finalized revisions to certain aspects of the CJR Model including the episode definition (which was modified to include outpatient episodes), the target price calculation, the reconciliation process, the beneficiary notice requirements, and the appeals process. In addition, for PYs 6 through 8, the 50 percent cap on gainsharing payments, distribution payments, and downstream distribution payments for certain recipients was eliminated.

By 2024, CMS continued to believe the CJR Model could demonstrate savings after extending the model with modifications to account for policy and practice pattern changes. However, assessing the impact of these modifications on the potential for certification and expansion of the CJR Model would require additional time to collect and analyze evaluation data. Although preliminary evaluation results for CJR Model PY6 suggested that the modifications would result in Medicare savings, preliminary evaluation results for the full 3-year CJR Extension would not be available until late 2025. In the meantime, CMS sought to continue the care transformation efforts that we had promoted through both the CJR and Bundled Payments for Care Improvement Advanced (BPCI Advanced) Models. To achieve this goal, CMS finalized the Transforming Episode Accountability Model (TEAM) in the FY 2025 IPPS/LTCH PPS final rule, which appeared in the August 28, 2024, **Federal Register** (89 FR 68986). TEAM is a mandatory episode-based payment model for selected acute care hospitals that includes five surgical episodes, including LEJR. As we noted in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69631), TEAM is based on: (1) lessons learned from testing the Bundled Payments for Care Improvement (BPCI) initiative, the BPCI Advanced Model, and the CJR Model; and (2) comments received from the ''Request for Information; Episode-Based Payment Model'' (88 FR 45872) published in the **Federal Register** on July 18, 2023. The first TEAM performance year began on January 1, 2026.

The LEJR episode and payment methodology currently being tested in

[580] Administration for Strategic Preparedness & Response: Determination That A Public Health Emergency Exists (*https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx*).

[581] Comprehensive Care for Joint Replacement Model—Fifth Annual Report (*https://www.cms.gov/priorities/innovation/data-and-reports/2023/cjr-py5-annual-report*).

TEAM are similar to the CJR Model in many ways, but there are a few key differences between the models. For example, TEAM episodes include the 30-day period after the discharge date (for inpatient procedures) or procedure date (for outpatient procedures), rather than the 90-day post-acute period included in the CJR Model. TEAM incorporates a more comprehensive set of risk adjustment factors into episode target prices as compared to the CJR Extension. TEAM also includes provisions for safety net hospitals (as defined at § 512.505) and hospitals with a low volume of episodes during the applicable baseline period to protect those hospitals from disproportionate financial risk. As stated previously, each element of TEAM that differs from either original CJR Model or the CJR Extension was included based on evaluation findings from the CJR and BPCI Advanced Models or stakeholder feedback, including responses to the July 2023 ''Request for Information; Episode-Based Payment Model''.

The final CJR Model PY ended on December 31, 2024, and the first TEAM performance year began on January 1, 2026. In the interim period between the end of the CJR Model and the beginning of TEAM, final evaluation results for the CJR Model PYs 6 and 7 and preliminary evaluation results for CJR Model PY 8 became available, due to the time required after a given CJR Model PY to allow for claims run out, the reconciliation process, and data analysis. Evaluation results for CJR Model PYs 6 through 8 indicated that the modifications in the CJR Extension, along with the more targeted application of the extreme and uncontrollable circumstances policy to COVID–19 episodes, had succeeded in returning the CJR Model to a positive savings trajectory. The seventh annual evaluation report found that the CJR Model had produced $112.7 million in net savings to Medicare across CJR Model PYs 6 and 7 while maintaining quality of care.[582]

Given the success of the CJR Model in achieving savings for Medicare across CJR Model PYs 6 through 8 while maintaining quality of care resulting from the CJR Extension policy modifications, CMS proposed to expand the CJR Model to all eligible acute care hospitals nationwide. For hospitals currently participating in TEAM, which includes an LEJR episode, CMS proposed that those TEAM participant hospitals would be exempt from CJR–X until the end of the TEAM model test. We proposed minor modifications in CJR–X that will align with some of the policies we implemented in TEAM because we believe these changes represent improvements to the CJR Model methodology, as we discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69631) and will discuss in further detail in the following sections of this final rule. We proposed to codify CJR–X policies at §§ 512.600 through 512.695, as discussed in more detail in the sections that follow.

c. Requirements for Expansion of the CJR Model

Section 1115A(c) of the Act provides the Secretary with the authority to expand (including implementation on a nationwide basis), through rulemaking, the duration and the scope of a model that is being tested under section 1115A(b) of the Act if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) the Secretary determines that such expansion is expected to reduce spending without reducing quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that such expansion would reduce (or would not result in any increase in) net program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of benefits.

- *Reduced Spending while Maintaining Quality of Care:* As observed in the Seventh Annual Evaluation Report, the CJR Model achieved savings to Medicare of $112.7 million across PY 6 and 7 while maintaining quality of care as measured by emergency department (ED) visits, unplanned readmission rates, mortality rates, and LEJR complication rates.[583] Based on these findings, the Secretary determined that expansion of the CJR Model would reduce spending while maintaining quality of care.
- *Impact on Medicare Spending:* The CMS Chief Actuary has certified that expansion of the CJR Model would produce Medicare savings if expanded to all eligible acute care hospitals nationwide.
- *No Alteration in Coverage or Provision of Benefits:* The CJR Model did not make any changes to coverage or provision of benefits for beneficiaries. Therefore, the Secretary has determined that expansion of the CJR Model would not deny or limit the coverage or provision of Medicare benefits for beneficiaries.

Consistent with our statutory authority, we proposed to continue to test and evaluate the CJR Model as CJR–X. We note that CJR–X would not be considered a Phase I model, as described under section 1115A(b) of the Act, but rather it would be a Phase II model under section 1115A(c) of the Act. As a nationally expanded Phase II model, we would continue to assess whether the expanded implementation of CJR–X is either continuing to reduce Medicare spending without reducing quality of care or improving the quality of patient care without increasing spending. We note that we may modify CJR–X as appropriate through future notice and comment rulemaking.

The following is a summary of general comments about CJR–X, and our responses to these comments:

Comment: A few commenters supported CJR–X implementation. Many commenters specifically supported the refinements made to CJR–X, including the low volume hospital policy, more robust risk adjustment methodology, and increased financial protections for safety net hospitals.

Response: We thank the commenters for their support.

Comment: Some commenters asserted that CJR–X would exceed the Innovation Center's statutory authority, and it would not be a lawful expansion of the CJR Model. A commenter stated that CMS' CJR–X proposal would be unlawful for at least three reasons: (1) it exceeds the Innovation Center authority; (2) it raises serious constitutional concerns, including separation of powers; and (3) it includes unauthorized waivers. Another commenter believed CJR–X is ineligible for expansion under section 1115A(c) because CJR is not a model that is being tested and CJR–X includes untested elements and changes beyond a mere expansion in duration and scope. Instead of proceeding to a Phase II expansion, any version of CJR–X must first be tested and evaluated as a Phase I model under subsection (b). They continued to state that CJR–X is an overreach of agency authority that contradicts the statutory mandate of section 1115A and raises concerns about impermissible delegation of lawmaking authority to the executive branch and unjust compensation for services provided to Medicare beneficiaries.

Response: We acknowledge the commenters' concerns. However, we do not agree that CJR–X exceeds the Innovation Center's authority, is ineligible for expansion, or is an overreach of agency authority. Section

[582] Comprehensive Care for Joint Replacement Model—Seventh Annual Report (*https://www.cms.gov/priorities/innovation/data-and-reports/2025/cjr-py7-annual-report*).

[583] Ibid.

1115A of the Act provides the Innovation Center with broad authority to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and CHIP beneficiaries. Additionally, under section 1115A(c) of the Act, taking into account the evaluation of a Phase I model test, the Secretary may, through rulemaking, expand (including implementation on a nationwide basis) the duration and scope of a model if certain criteria are met. We believe that CJR–X has met the requisite statutory criteria in 1115A(c) for expansion to a Phase II model test, and the Chief Actuary of CMS has certified that such expansion would reduce (or would not result in any increase in) net program spending under Medicare.

Comment: A commenter urged CMS to test CJR–X regionally rather than nationally.

Response: We thank the commenter for the suggestion. We do not believe a regional test would be appropriate for CJR–X because CJR–X represents the next step in the progression of testing LEJR episode-based payment, building directly from the CJR Model. The CJR Model was tested regionally, using selected metropolitan statistical areas. That regional test provided CMS with experience implementing mandatory LEJR episode accountability across a range of hospitals and geographic locations. Because CJR–X is predicated on the regional CJR Model test, we believe national implementation is the appropriate next step.

We also believe that national expansion would advance a more consistent approach to LEJR episode-based care coordination, quality accountability, and spending accountability across eligible hospitals. A regional approach could continue to produce variation between hospitals subject to LEJR episode accountability and hospitals not subject to the model, while a national approach would support broader standardization of LEJR episode management and reduce opportunities for geographic differences in model participation to affect care patterns or evaluation of the expanded model.

Comment: Many commenters recommended CMS not finalize CJR–X. A few commenters cited concerns of the potential impact it would have on beneficiaries' access to care and providers' success in the model. A commenter urged CMS to reconsider CJR–X and instead look to sources of Medicare spending other than joint replacements to garner meaningful savings and quality improvements. Another commenter cited their concerns with operational and financial impacts associated with broader mandatory bundled payment models, particularly as hospitals continue balancing quality reporting, interoperability investments, and adoption of new technologies across service lines.

Response: We recognize that there are many areas of Medicare spending that may present opportunities to improve quality and reduce expenditures, and we agree that continued innovation across a broad range of clinical conditions and payment models is important to advancing value-based care. We also note that CJR–X is only one component of the Innovation Center's broader portfolio of models and initiatives. CMS continues to test and implement models addressing other sources of Medicare spending and other clinical conditions through a variety of accountable care, specialty care, population-based, and episode-based payment approaches. We continue to believe that LEJR episodes are an appropriate area for model expansion under CJR–X as this builds upon the evidence generated through nearly a decade of experience with the CJR Model. LEJR episodes are high-volume procedures with well-defined clinical pathways, opportunities for care coordination across providers and settings, and a substantial evidence base demonstrating that episode-based payment approaches can improve efficiency while maintaining quality outcomes.

CJR–X includes safeguards and model features intended to address potential effects on beneficiaries and providers. For beneficiaries, CJR–X would not change Medicare coverage, eligibility, or benefits, and CJR–X participants would remain subject to applicable beneficiary protections, including requirements related to freedom of choice, access to medically necessary care, and monitoring for potential stinting or inappropriate changes in care. For providers, CJR–X includes financial risk protections, including stop-loss limits for all hospitals and lower stop-loss limits for certain categories of hospitals, to place a threshold on repayment responsibility while preserving incentives for care redesign and coordination.

Comment: Some commenters recommended that CMS provide up-front investments or implementation support to help essential hospitals and other resource-constrained hospitals participate successfully in CJR–X. Commenters suggested funding for staff such as nurse navigators, analytics capabilities, or care coordination infrastructure. Commenters stated that hospitals serving vulnerable populations may lack the capital needed to make early investments required for successful episode management. Commenters believed that upfront resources could help hospitals build care redesign capacity before bearing financial accountability.

Response: We appreciate the commenters' recommendation that CMS provide upfront investments or implementation funding to support hospitals with limited financial resources, including hospitals serving vulnerable populations. We believe that such an approach would introduce operational and financial complexities, including determining appropriate payment amounts, identifying eligible recipients, establishing permissible uses of funds, monitoring compliance, and addressing situations in which CJR–X participants subsequently fail to meet model requirements or do not achieve performance improvements. In addition, providing upfront funding would create challenges regarding the recovery of funds if a CJR–X participant were unable to successfully implement care redesign activities or if CMS later determined that the CJR–X participant was not entitled to retain all or a portion of the upfront payment. We believe recovering such payments could require additional administrative processes and could create uncertainty for both CMS and CJR–X participants.

We also note that, unlike models that rely on prospective infrastructure payments, CJR–X allows participants that successfully improve quality and reduce episode spending to retain savings through reconciliation payments. We believe this approach better aligns financial incentives with actual performance and care redesign results rather than providing funding in advance of demonstrated improvements in quality or efficiency.

Comment: Many commenters recommended that CMS provide additional implementation runway or a phased rollout before mandatory CJR–X accountability begins. Commenters stated that organizations need time to redesign workflows, build analytics infrastructure, establish post-acute partnerships, educate clinicians, and evaluate financial exposure. Commenters believed that compressed implementation could reduce readiness and divert resources from other strategic priorities. Some commenters recommended that CMS adopt a longer glide path before applying full downside risk under CJR–X, with a few commenters suggesting a 3-yearglide

path. Other commenters recommended different phased approaches such as a phased in discount factor, a phased in geographic expansion, and a phased in mandatory approach. A commenter suggested a one-year stop gain only performance period for any hospital without prior experience in a CMS-administered episode-based payment model. Another commenter recommended an informational only approach for the first year before introducing risk in the second performance year.

Response: We value commenters' recommendations to help CJR–X participants ease into participation and it was a motivating factor when deciding to finalize a 3-month delay to the model start, as discussed in section X.C.2.a of this final rule. However, we do not believe additional phased implementation approaches such as a multi-year glide path before downside accountability, phased geographic expansion, phased mandatory participation, or a phased-in discount factor are necessary for CJR–X. We believe these approaches would introduce additional complexity into model operations and delay the realization of potential improvements in care coordination and episode efficiency. We are also concerned that extended transition periods or informational-only phases could weaken incentives for CJR–X participants to establish and implement care redesign activities early in the model. Further, phased geographic or participation approaches could limit the consistency and comparability of model results across participants and reduce the ability to assess model performance at scale. We believe that maintaining a consistent accountability framework from the outset, while providing sufficient preparation time and targeted risk protections, better supports both participant readiness and the integrity of the model design.

In addition, we do not believe further reductions in accountability are necessary given the other protections finalized in this rule. We are finalizing a lower discount factor compared to the CJR Model discussed in section X.C.2.f.(3)(g) of this final rule, as well as improvements to risk adjustment discussed in section X.C.2.f.(4) of this final rule, a low-volume hospital policy discussed in section X.C.2.f.(3)(h) of this final rule, and stop-loss limits for all hospitals, with lower limits for certain hospitals, that reduce potential repayment exposure, as discussed in section X.C.2.f.(5)(g) of this final rule. We believe these policies directly address commenters' concerns regarding financial risk and participant readiness while preserving incentives for care redesign and efficient episode management. For these reasons, in combination with the January 1, 2028, start date, we believe there are sufficient protections that provide an appropriate balance between participant readiness and financial accountability.

We also note that CJR–X will not begin until January 1, 2028, and that participants will effectively have a pre-implementation year during calendar year 2027. During this period, CJR–X participants will have the opportunity engage physicians and post-acute care providers, establish governance and accountability structures, and develop episode management processes before model accountability begins. In addition, pursuant to an executed CJR–X data sharing agreement, CJR–X participants will receive baseline data and other model information that may be used to better understand historical performance and identify opportunities for care redesign and operational improvement. We believe calendar year 2027 will provide CJR–X participants with a meaningful opportunity to prepare for participation and gain familiarity with model requirements before being subject to financial accountability.

Comment: Many commenters recommended that CMS strengthen protections for rural, safety-net, Medicare-dependent, small rural hospitals, sole community hospitals, essential access, and other vulnerable hospitals. Commenters stated that these hospitals often operate with limited margins, limited capital, fewer post-acute resources, and less experience with bundled payment infrastructure. Some commenters indicated that immediate downside risk and regional target pricing could disproportionately affect hospitals serving medically underserved or rural communities. Commenters suggested excluding these hospitals from the model or providing exemptions from downside risk, reducing their discount factor, longer transition periods, or other safeguards until CMS has more information on how these hospitals perform under CJR–X and related models. Commenters linked these concerns to beneficiary access, financial stability, and the ability of vulnerable hospitals to invest in care redesign. Another commenter stated that given the lack of historical experience, CMS needs to collect more information through TEAM and CJR–X showing how sole community hospitals and Medicare-dependent hospitals perform under episode-based payment arrangements, including the impact on patient access and quality of care outside of metropolitan statistical areas before requiring participation. A commenter stated safety net hospitals fared poorly under the original CJR model and that on average, safety-net hospitals in the CJR Model performed worse financially than non-safety net hospitals and that safety net hospitals were substantially more likely than non-safety net hospitals to owe repayments to Medicare.

Response: We appreciate the commenters' recommendations regarding protections for rural hospitals, safety-net hospitals, Medicare-dependent, small rural hospitals, sole community hospitals, essential access community hospitals, and other hospitals that may face unique operational and financial challenges. We also acknowledge the CJR Model evaluation findings that demonstrated that safety net hospitals were overrepresented among hospitals with the highest per-episode repayments to Medicare.[584] We believe it is important to provide appropriate safeguards for hospitals that may face greater challenges under CJR–X and draw from lessons learned under the CJR Model. For this reason, we are finalizing several policies designed to improve pricing accuracy and limit financial exposure for hospitals that may have lower episode volumes, serve more complex patient populations, or are more financially vulnerable. These policies include improvements to the risk adjustment methodology intended to better account for differences in patient characteristics and episode complexity, a low-volume hospital policy that recognizes the additional variation associated with smaller episode volumes, and lower stop-loss limits that reduce potential repayment exposure, as discussed in sections X.C.2.f.(4), X.C.2.f.(3)(h), and X.C.2.f.(5)(g) of this final rule.

Improved risk adjustment helps ensure that target prices more accurately reflect differences in beneficiary characteristics and clinical complexity rather than holding hospitals accountable for factors outside of their control. This is particularly important for hospitals that serve medically underserved populations or beneficiaries with greater health and social needs, as more accurate risk adjustment can reduce the likelihood that target prices systematically

[584] Comprehensive Care for Joint Replacement Model—Safety Net Hospital Experience in Bundled Payment Model Report: *https://www.cms.gov/priorities/innovation/data-and-reports/2025/cjr-safety-net-hospital-exp-rpt.*

understate expected episode spending for these populations.

We also recognize that hospitals with lower episode volumes may experience greater year-to-year variation in spending and quality outcomes due to a relatively small number of episodes. A small number of unusually complex cases, complications, or high-cost episodes can have a proportionally larger effect on performance for low volume hospitals than for hospitals with hundreds of episodes. We believe the low volume hospital policy helps address this concern by recognizing the uncertainty associated with smaller episode counts and reducing the likelihood that financial outcomes are driven by random variation rather than underlying performance.

In addition, safety net hospitals, rural hospitals, Medicare-dependent hospitals, and sole community hospitals all receive lower stop-loss limits. Lower stop-loss limits provide important financial protection by capping the amount that a CJR–X participant may owe CMS in a given performance year. We believe these limits are particularly meaningful for hospitals with limited operating margins, fewer financial reserves, or less ability to absorb unexpected financial losses. By limiting repayment exposure, the stop-loss policy allows hospitals to participate in the model and pursue care redesign activities while reducing the risk that model participation could result in repayment obligations that are disproportionate to their size or financial capacity.

Taken together, we believe these policies improve pricing accuracy, reduce exposure to random variation, and limit financial risk while maintaining incentives for quality improvement and efficient episode management. Rather than exempting certain hospitals from accountability altogether, we believe these targeted protections better address the specific challenges identified by commenters while preserving the model's ability to encourage care coordination, evaluate performance across diverse hospital types, and test whether episode-based payment can improve quality and reduce Medicare spending in a broad range of communities.

With respect to discount factor reductions, we believe the existing protections through reduced stop-loss limits, rather than a reduced discount factor is the most appropriate mechanism for addressing vulnerable hospital concerns. The purpose of the discount factor is to represent Medicare's share of expected savings generated through improvements in care coordination, quality, and efficiency. We believe CJR–X participants should generally be subject to a consistent accountability framework that maintains a clear relationship between episode spending performance, quality performance, and Medicare savings. Reducing discount factors for broad categories of hospitals could weaken those incentives and reduce the model's ability to generate savings while maintaining consistency across participants.

We do not believe that exempting these hospitals from downside risk or delaying downside accountability beyond the start of the model is necessary or appropriate. We believe that accountability for both quality and spending from the outset of participation creates appropriate incentives for care coordination, discharge planning, post-acute care management, and other care redesign activities that are central to the goals of the model. Further, we believe that exempting broad categories of hospitals from downside accountability could reduce incentives for care redesign and limit the model's ability to evaluate whether episode-based payment can improve quality and reduce spending across a diverse range of hospitals and communities. Rather than exempting these hospitals from accountability, we believe it is more appropriate to provide targeted protections through risk adjustment improvements, low-volume policies, stop-loss protections, and additional implementation time while maintaining a consistent accountability framework across participants.

Lastly, we do not agree that these hospitals should be excluded from CJR–X until additional experience is collected. Including sole community hospitals and Medicare-dependent, small rural hospitals in CJR–X, subject to the model's applicable policies and protections, will allow CMS to better understand how these hospitals perform under LEJR episode-based payment arrangements in real-world settings. Excluding these hospitals from the model would limit CMS' ability to evaluate episode-based care coordination, quality, spending, patient access, and post-acute care patterns in the communities they serve. We also believe that participation by these hospitals can help inform more targeted policies and support over time. Monitoring and evaluation of CJR–X will allow CMS to assess whether certain hospitals, including sole community hospitals and Medicare-dependent, small rural hospitals, experience distinct operational challenges or access, quality, or financial impacts under the model. That information can help CMS identify whether additional guidance, technical assistance, model refinements, or other targeted policies may be warranted.

Comment: Some commenters stated that the proposed model structure did not adequately capture or emphasize downstream nonphysician services, including therapy services needed to support recovery and prevent secondary complications. A commenter stated that hospital should not be rewarded for reducing costs if savings are achieved by limiting post-acute care. Another commenter stated that patients should be able to pick which provider works best for them based on quality of care and provider location. Another commenter stated that it is best for patients to receive post-surgical care in their home community when possible and removing barriers to services locally helps maintain the fiscal health of rural providers.

Response: We agree that CJR–X should not limit access to care or restrict beneficiaries from seeking care from their preferred providers. As outlined in § 512.120, CJR–X participants must not restrict beneficiaries' ability to choose to receive care from any provider or supplier and also must make medically necessary covered services available to beneficiaries, including post-acute care services. Further, CJR–X includes the Telehealth and 3-Day SNF Rule waivers, discussed in section X.C.2.j of this final rule, that support CJR–X participants providing care closer to the beneficiary's home. Therefore, CJR–X does not dictate where beneficiaries receive care and provides flexibilities to help beneficiaries to receive care closer to home. However, if a beneficiary does elect to seek care from a CJR–X participant, they would not be able to opt-out of the model.

CJR–X participants are also held accountable for the quality of care provided to CJR–X beneficiaries. As discussed in section X.C.2.e of this final rule, CJR–X participants are assessed on five quality measures and performance on those measures is tied financial performance. While reductions in post-acute care services may help reduce Medicare expenditures, the CJR–X participant may not be eligible for a reconciliation payment if they performed poorly on quality.

We also recognize the role of downstream providers, including nonphysician services, in supporting beneficiary recovery. A CJR–X episode strives to be total-cost-of-care with limited exclusions, as discussed in section X.C.2.d.(3)(c) of this final rule, therefore many nonphysician services

are included in the episode. Given this inclusion, we believe it's important for CJR–X participants to have the ability to partner with these entities to help improve beneficiary outcomes and reduce Medicare expenditures. We are finalizing the ability for CJR–X participant to have sharing arrangements with CJR–X collaborators, as discussed in section X.C.2.i.(3) of this final rule, which would permit nonphysician entities, such as nonphysician practitioners, therapists in private practice, comprehensive outpatient rehabilitation facilities, providers or suppliers of outpatient therapy services, therapy group practices, and other entities to be CJR–X collaborators and support care redesign.

Comment: A commenter noted that, as Medicare Advantage (MA) enrollment increases, models such as CJR–X that apply only to Original Medicare will continue to cover a decreasing share of beneficiaries. While the commenter recognized that CMS and the Innovation Center face limitations in incorporating MA into payment models, they encouraged CMS to consider the implications of continued MA growth as it develops and evaluates future Innovation Center models.

Response: We appreciate the commenter's concern about the impact of increasing MA enrollment on models that only include Original Medicare beneficiaries. CMS recognizes that Medicare Advantage enrollment has continued to grow and that, although the rate of growth has slowed in recent years, MA now accounts for more than half of eligible Medicare beneficiaries. CMS will continue to consider how Medicare enrollment patterns, including the continued growth of MA, affect the reach, design, data availability, and evaluation of future Innovation Center models.

Comment: A commenter requested that CMS provide greater transparency about the composition of savings in the CJR Model, given that we cite these savings as part of our justification for model expansion. They request information including the number and mix of participating hospitals, distribution of savings and losses across participants, and whether the model improved or only maintained quality. They state their belief that the CJR Model did not demonstrate quality improvement and therefore may not have achieved its intended goal.

Response: We refer the commenter to the published evaluation reports of the CJR Model, including the Seventh Annual Report (*https://www.cms.gov/priorities/innovation/data-and-reports/2025/cjr-py7-annual-report*), which contain the information requested by the commenter. We note that we expect to publish the final evaluation report of the CJR Model in the fall of 2026. We confirm based on those evaluation results that the CJR Model maintained quality on claims-based and patient-reported outcomes while saving money for Medicare. As we noted earlier in this section of this final rule, the Innovation Center aims to test models that either reduce spending while maintaining quality of care or improve the quality of patient care without increasing spending. We note the finding in the Seventh Annual Report that the quality of LEJR care nationwide has improved since the beginning of the CJR Model, and CJR participants kept pace with those quality improvements while saving money, though they did not show significant increases in quality beyond non-CJR hospitals. However, saving money while maintaining quality aligns with Innovation Center model goals and, along with the CMS Chief Actuary's certification of expected savings and the Secretary's determination that expansion would not deny or limit coverage or benefits, fulfills CMS's statutory requirements for model expansion.

Comment: A few commenters offered recommendations related to how CMS should evaluate the CJR–X Model, share evaluation findings, and use those findings to refine the model. A commenter suggested that a phased or regionally stratified approach to implementation would allow CMS to build on prior CJR findings while addressing key evidence gaps, including impacts on access to care, referral patterns, risk modeling, and financial sustainability across different hospital types. They recommended that CMS conduct and publish evaluations of early implementation impacts, including access, patient selection, and financial impacts across hospital types and participation phases. They requested that CMS commit to an ongoing process to evaluate and incorporate findings into model refinement while working toward nationwide expansion. They also encouraged CMS to incorporate insights from the ongoing TEAM as part of the evaluation of CJR–X to inform future episode-based payment policy design.

Another commenter highlighted the importance of continuing to evaluate the impact of CJR–X on safety net hospitals. They stated their appreciation that CMS has acknowledged the need for additional protections for safety net hospitals in CJR–X, based on the challenges identified in CMS's evaluation of the CJR Model, but they expressed their concern that the proposed remedies would fall short of mitigating these challenges. They recommended that CMS conduct a formal evaluation to reassess how the model is affecting safety net hospitals and pause the model if it continues to find evidence of disproportionate harm to essential hospitals.

Response: We appreciate the commenters' concerns about continuing to monitor the impact of CJR–X on a range of outcomes including patient access to care, financial sustainability, and differential impacts on different categories of hospitals, including safety net hospitals. While we disagree with the suggestion of a phased or regionally stratified approach for reasons discussed above in this section of this final rule, we acknowledge the need for continued evaluation of the model's impacts and the application of lessons learned to refine the model as needed through notice and comment rulemaking. While nationwide expansion does not allow for a randomized control evaluation design as in the CJR Model, we plan to monitor hospitals' performance and look for evidence of disproportionate repayment impacts on subgroups of hospitals including safety net hospitals, rural hospitals, low volume hospitals, Sole Community Hospitals, and Medicare Dependent, small rural Hospitals. We will monitor year-over-year trends in outcomes including total episode spending, the percentage of hospitals that earn reconciliation payments and owe repayments, and improvement or maintenance of quality measures. We plan to post reports of these outcomes on a regular basis on the CJR–X website. We will work with the TEAM evaluation contractor to compare outcomes in 30-day TEAM LEJR episodes with 90-day CJR–X LEJR episodes. We note that we have made changes in CJR–X as a result of CJR evaluation findings that indicated the need for additional protections for certain types of vulnerable hospitals. We will evaluate the impact of those changes, if any.

Comment: A commenter stated that the pace and scale of the proposed model may limit the ability of organizations to test and stabilize care redesign strategies.

Response: We acknowledge the commenter's concern; however, we do not believe the proposed pace and scale of CJR–X would prevent organizations from iterating on care redesign strategies. As a nationally expanded model, CJR–X is intended to move LEJR episode-based care further toward a

standardized approach to care coordination, quality accountability, and episode spending accountability across eligible hospitals. We do not view care redesign as a one-time activity that must be fully completed before accountability begins. In ordinary clinical and operational practice, hospitals routinely assess outcomes, update care pathways, refine discharge planning, strengthen post-acute care coordination, and revise internal processes over time. The CJR–X framework would support that type of continued refinement while applying a consistent national episode-based payment methodology for LEJR episodes.

Comment: Many commenters expressed concern that CJR–X would hold hospitals financially accountable for spending that hospitals do not fully control. A commenter stated in the past, such models have not been mandatory and were successful at least partially because they included only hospitals ready and able to make such models successful. Another commenter recommended CMS adjust accountability methodologies to reflect the limited control hospitals have over post-acute utilization, particularly in non-employed physician models. Another commenter stated that hospitals do not have full control over services delivered by independent or post-acute care providers, or over beneficiary choice of post-acute providers, creating a misalignment between financial accountability and operational control.

Response: We acknowledge commenters' concerns and recognize that hospitals may not control beneficiary choice of post-acute care providers and that some hospitals may have less direct authority over physicians or post-acute care partners. We know voluntary models have produced important evidence and have shown that participating hospitals and other providers can improve care coordination and reduce episode spending. However, voluntary models are affected by self-selection and attrition which can limit the model's ability to generate broad-based, generalizable results and sustain savings across the Medicare program. We believe mandatory participation is important to advancing CJR–X as a nationally expanded model and as a step toward standardizing LEJR episode-based care coordination, quality accountability, and spending accountability.

We do not believe that hospitals must control every item or service furnished during an episode for episode-based accountability to be appropriate. CJR–X is predicated on the CJR Model, which tested mandatory LEJR episode-based accountability and demonstrated that hospitals can reduce episode spending while maintaining quality. Although hospitals may not control every item or service furnished during an episode, hospitals are well positioned to influence key aspects of LEJR episode performance, including discharge planning, care coordination, collaboration with physicians and post-acute care providers, beneficiary and caregiver education, internal care pathways, and processes that affect transitions of care, avoidable complications, readmissions, and post-acute recovery.

We also recognize that beneficiary freedom of choice remains an important protection under CJR–X. The model does not require beneficiaries to receive post-acute care from a particular provider or facility, and hospitals may not restrict beneficiaries' choice of Medicare-participating providers or suppliers. Instead, CJR–X relies on hospitals, treating clinicians, beneficiaries, and caregivers working together to identify clinically appropriate post-acute care arrangements that meet the beneficiary's needs and preferences. Hospitals may influence care through education, coordination, discharge planning, and collaboration, but CJR–X does not eliminate beneficiary choice or require hospitals to control independent providers.

We further acknowledge that hospitals operate under different structures, including non-employed physician models. CJR–X is designed to support care coordination across different organizational arrangements, including through collaboration with physicians, post-acute care providers, and other entities involved in LEJR episodes. The model's design recognizes that an episode of care is delivered across multiple settings, while encouraging hospitals to strengthen relationships, share information, and coordinate care with providers and suppliers that affect LEJR outcomes.

Comment: Some commenters suggested CMS include more accountability and monitoring to help address the post-acute care challenges. A few commenters expressed concerns over their view that CJR–X incentives may drive patients away from medically necessary inpatient rehabilitation facility (IRF) and long-term care hospital use. A commenter stated that essential hospitals serve patient populations with limited access to skilled nursing facilities and inpatient rehabilitation facilities and CMS should consider ways to better monitor post-acute care access barriers and provide technical assistance or modify the model if necessary. Another commenter believed CJR–X could drive blanket reductions in post-acute care utilization without adequate consideration of individual patient need and recommended the model include meaningful guardrails to ensure patients can continue to access appropriate levels of post-acute care. Another commenter encouraged CMS to monitor care patterns under CJR–X, including changes in site-of-care and post-acute utilization. They believed that while ongoing evolution in care delivery may be appropriate, treatment decisions should remain grounded in clinical appropriateness and patient-specific considerations. Another commenter was concerned about a potential impact on patient access to medically necessary IRF care, and that patients would be diverted to skilled nursing facilities (SNFs) or other settings due to their lower cost. They continued to state that the type and intensity of services provided by IRFs are distinctly not provided in SNFs and claimed that CJR–X would cause substitutions in the type of care received by beneficiaries. They further stated that recent oversight reports about major nursing home operators highlight inherent risks and patient safety concerns that could arise if patients are diverted to this setting.

Response: We recognize that post-acute care availability may vary across communities and that hospitals serving historically underserved populations are no exception. We agree that monitoring beneficiary access to post-acute care, post-acute care utilization, and site-of-care patterns is important under CJR–X. As noted in section X.C.2.m of this final rule, we intend to monitor CJR–X, including beneficiary access and safety. We reiterate that CJR–X does not require beneficiaries to receive post-acute care in any particular setting nor does it permit clinically inappropriate substitution of one post-acute care setting for another based on cost. CJR–X would not change Medicare coverage, eligibility, or benefits, and beneficiaries would retain freedom of choice to receive care from any Medicare-participating provider or supplier.

We acknowledge that some hospitals, including essential hospitals, may serve communities where beneficiaries face preexisting barriers to accessing post-acute care, including limited availability of skilled nursing facility or inpatient rehabilitation facility services. We also recognize that some beneficiaries undergoing lower-extremity joint

replacement procedures may have clinical, functional, or social needs that make access to an appropriate level of post-acute care especially important. For example, beneficiaries with multiple chronic conditions, mobility limitations, limited caregiver support, or a higher risk of complications or readmissions may need more intensive rehabilitation or other post-acute services to support recovery and functional independence.

However, we do not believe CJR–X would create those access limitations. Where a beneficiary's clinical condition supports the need for IRF care, LTCH care, SNF care, home health services, outpatient therapy, or another covered post-acute care service, treatment and discharge planning decisions should remain grounded in medical necessity, clinical appropriateness, and the beneficiary's individual circumstances.

We also recognize that changes in post-acute care use can be an important indicator of whether the model is operating as intended. Under CJR–X, hospitals may work to improve discharge planning, care transitions, and post-acute care coordination, and changes in post-acute utilization may reflect appropriate care redesign. However, reductions or shifts in post-acute care use must not result from stinting on medically necessary care, inappropriate steering, or barriers to clinically appropriate services. For that reason, monitoring post-acute care utilization, site-of-care changes, beneficiary access, quality of care, readmissions, complications, and other indicators of beneficiary safety will be important to CMS' oversight of CJR–X.

Consistent with standard discharge planning and care coordination practices, we expect hospitals, treating clinicians, beneficiaries, and caregivers to work together to identify clinically appropriate post-acute care options that meet the beneficiary's needs and preferences. Treatment decisions should remain grounded in clinical appropriateness and patient-specific considerations, including the beneficiary's functional status, medical needs, home support, caregiver availability, provider availability, and preferences. CJR–X does not authorize a CJR–X participant to force a CJR–X beneficiary into a lower-cost post-acute care setting when a different covered setting is medically necessary and clinically appropriate.

We also take seriously concerns about beneficiary safety in post-acute care settings, including concerns about potential adverse outcomes if beneficiaries are discharged to settings that are not equipped to meet their clinical and rehabilitation needs. As noted earlier, CMS' monitoring of CJR–X may include review of post-acute care utilization, patterns, and other indicators that could suggest inappropriate reductions in care or unsafe shifts in site of care.

We will continue to monitor CJR–X implementation, including beneficiary access to post-acute care, post-acute care utilization, site-of-care patterns, quality of care, and potential unintended consequences. If monitoring or evaluation identifies access barriers, inappropriate changes in post-acute care use, or other issues that warrant action, CMS may consider additional technical assistance or operational guidance. We may also consider this in future notice and comment rulemaking.

Comment: A commenter supported CMS's continued engagement with stakeholders as the CJR–X is implemented and suggested that mid-model changes should be minimized to the extent possible to provide stability and predictability for participating hospitals. Another commenter urged CMS to evaluate and work with stakeholders on the design and development of additional episodic payment options, particularly for surgical procedures.

Response: We recognize that participating hospitals need sufficient certainty regarding model policies to plan effectively, invest in care redesign, and manage LEJR episodes over time. At the same time, we believe CJR–X should remain responsive to beneficiary needs and to changes in clinical practice, care pathways, and health care delivery. Care for LEJR beneficiaries continues to evolve, including changes in surgical practice, discharge planning, post-acute care use, care coordination tools, quality measurement, and provider workflows. We believe it is important for CJR–X to retain the ability to respond to such developments where appropriate, so that the model continues to reflect how providers currently practice and how beneficiaries receive care.

With respect to commenters' suggestions of other surgical procedures, we are open to stakeholder feedback that may be appropriate to consider for future episodic payment models or payment options. We also note that TEAM is testing four surgical episode categories in addition to the LEJR episode category. Experience from TEAM may help inform CMS' broader understanding of surgical episode-based care, including how care redesign operates across different surgical procedures. We may consider lessons from TEAM, as well as feedback received through this and future rulemaking processes, as well.

Comment: A few commenters recommended expanding the episode to include upstream services to broaden the scope of the episode and strengthen the model's connection to longitudinal care. A commenter urged CMS to collaborate with stakeholders to design and test a longitudinal payment model that moves care upstream and directly addresses procedural appropriateness. Another commenter requested CMS to articulate how the model's episode structure can serve as building blocks for broader longitudinal accountability. Another commenter recommended that CMS should explicitly recognize and encourage the use of evidence based pre-surgical testing and diagnostic strategies as core components of episode optimization and quality assessment. A commenter recommended expanding the episode to include therapy interventions within the weeks prior to (and in connection with) the anchor surgery.

Response: We acknowledge that CJR–X is not designed to directly determine procedural appropriateness before an LEJR procedure occurs or to establish longitudinal accountability for care before and after multiple episodes or over an extended period of time. We believe it's important for episode-based payment models to have clear episode time periods and triggers and extending the episode to start before the anchor hospitalization or anchor procedure can make defining the episode challenging. Further, starting the episode before the anchor hospitalization or anchor procedure can make it difficult to avoid including unrelated items and is more likely to encompass costs that vary widely among beneficiaries, which would make the episode more difficult to price appropriately.

However, we agree that evidence-based pre-surgical evaluation, diagnostic strategies, shared decision-making, and care planning can be important to appropriate surgical care and successful episode outcomes. experience. For those reasons, we encourage providers to use clinically appropriate, evidence-based pre-surgical evaluation and diagnostic practices as part of patient-centered care, consistent with applicable Medicare coverage and payment rules.

Episode-based models can serve as important building blocks for broader accountability by encouraging providers to coordinate across settings, strengthen relationships with clinicians and post-acute care providers, and manage care beyond the inpatient stay. These capabilities may inform future

approaches to longitudinal accountability, including approaches that consider care pathways before a procedure occurs. We also believe the CJR–X overlap policy, as discussed in section X.C.2.h of this final rule, supports broader accountability by allowing CJR–X to operate alongside longitudinal or total-cost-of-care models, such as ACO models. When a beneficiary is included in both a longitudinal model and a CJR–X episode, the models can provide complementary forms of accountability. The longitudinal model participant may remain accountable for the beneficiary's broader care over time, including care before a surgical episode, while the CJR–X participant hospital is accountable for the quality and spending associated with the LEJR episode when surgery occurs. This overlap approach can help preserve upstream care-management incentives while maintaining focused accountability for the surgical episode and post-acute recovery period once an LEJR procedure is performed.

With respect to the request to design and test a longitudinal payment model that moves care upstream, we are open to stakeholder feedback on future model concepts. To the extent we propose a future model, we would provide opportunities for public input consistent with applicable rulemaking or model-development processes.

Comment: A commenter expressed significant concern and opposition to the expansion of the CJR model and stated that value-based models must align accountability with areas of influence and the CJR–X Model does not achieve this balance for community hospitals.

Response: We disagree that CJR–X may hold community hospitals accountable for aspects of care outside the hospital's influence. We believe CJR–X appropriately aligns accountability with areas that all hospitals can influence. Hospitals furnish the anchor procedure or anchor hospitalization, conduct discharge planning, communicate with treating clinicians, arrange or recommend post-acute care options, educate beneficiaries and caregivers, and can work with physicians, post-acute care providers, and other providers to improve care transitions and reduce avoidable complications, readmissions, and unnecessary utilization. While hospitals do not control every service furnished during an episode, they are well positioned to influence care coordination and care redesign across the episode.

We recognize that community hospitals vary in size, resources, episode volume, patient mix, local post-acute care capacity, and ability to absorb financial risk. For that reason, CJR–X includes policies intended to limit excessive financial exposure and support participation for hospitals that may face greater operational or financial constraints. These include a low volume hospital policy, as discussed in section X.C.2.f.(3)(h) of this final rule, and lower stop-loss limits for certain categories of hospitals, including safety net hospitals, rural hospitals, Medicare-dependent, small rural hospitals, and sole community hospitals, as discussed in section X.C.2.f.(5)(g) of this final rule. We believe these policies help address concerns that some community hospitals may have less capacity to absorb downside risk while preserving incentives to coordinate care, improve quality, and manage LEJR episode spending.

Comment: A commenter recommended that CMS, in coordination with the HHS Office of Inspector General, examine the scope of existing patient choice and discharge planning requirements as applied to CJR–X participants and provide clear regulatory guidance on the extent to which CJR–X participants may direct beneficiaries to higher performing post-acute care providers consistent with quality goals and clinical appropriateness. Without such guidance or appropriately scoped flexibility, hospital accountability for post-discharge and post-episode spending will be significantly mismatched with hospital authority to shape the care pathway.

Response: We agree that hospitals should be able to support beneficiaries and caregivers with information that helps them make informed post-acute care decisions, including information related to quality, care coordination, and clinical appropriateness. We indicated, as discussed in section X.C.2.c.(1) of this final rule, that CJR–X participants may recommend preferred providers to CJR–X beneficiaries, provided those recommendations are made within the constraints of current law. CJR–X participants may identify or recommend providers or suppliers that the hospital believes may support high-quality care transitions and appropriate post-acute care, including providers with whom the hospital has established care coordination relationships. However, CJR–X participants may not limit CJR–X beneficiaries to a preferred or recommended provider list.

We emphasize that CJR–X would not change Medicare beneficiary freedom of choice, Medicare coverage, or discharge planning requirements. Beneficiaries would retain the right to obtain care from any Medicare-participating provider or supplier, and CJR–X participants may not require beneficiaries to use a particular post-acute care provider, physician, or other provider or supplier as a condition of receiving care or participating in the model. Recommendations must be presented in a manner consistent with all applicable laws and regulations, including applicable requirements relating to patient choice and discharge planning, as well as applicable fraud and abuse laws.

We recognize the commenter's concern that hospitals are accountable for post-discharge episode spending while beneficiaries retain freedom of choice and post-acute care providers may operate independently. CMS continues to believe that hospitals can meaningfully influence LEJR episode outcomes through discharge planning, beneficiary and caregiver education, care coordination, information sharing, and collaboration with physicians and post-acute care providers, without restricting beneficiary choice. The ability to recommend preferred or high-performing providers, within the constraints of current law, supports care coordination and quality goals while preserving beneficiary protections.

We will continue to consider whether additional sub-regulatory guidance, operational materials, or beneficiary-facing resources would be useful to clarify how CJR–X participants may provide information about post-acute care options while complying with existing patient choice and discharge planning requirements.

Comment: A commenter encouraged CMS to focus on targeted refinements that enhance operational feasibility and provider sustainability. They stated such refinements will be essential to ensure that CJR–X achieves its intended goals while preserving access to high-quality care across diverse hospital settings. Another commenter stated the success of mandatory models is highly dependent on whether program design provides a realistic opportunity for providers to succeed across diverse market contexts.

Response: We believe the CJR–X design provides an opportunity for CJR–X participants to succeed by including targeted policies intended to support operational feasibility across diverse hospital settings. These policies include defined episode and participant criteria, a target price methodology that uses regional spending data, quality-based reconciliation, stop-loss protections,

monitoring and beneficiary protections, and opportunities for hospitals to coordinate with physicians, post-acute care providers, and other collaborators. We also include additional protections for hospitals that may face greater operational or financial constraints, including lower stop-loss limits for certain hospital categories and policies addressing low-volume hospitals.

We believe a nationally expanded model should be designed to operate across the range of eligible hospitals while incorporating safeguards and targeted policies that help participants manage accountability. CJR–X is a continuation of the CJR Model, which demonstrated that hospitals can improve LEJR episode efficiency while maintaining quality. At the same time, we will continue to consider monitoring data, evaluation findings, operational experience, and stakeholder feedback to determine whether refinements are needed to support implementation, protect beneficiary access, and preserve incentives for high-quality care.

Comment: A commenter recommended CMS view CJR–X as a long-term partnership with providers to improve patient outcomes, care coordination, and system efficiency.

Response: We recognize the importance that providers and suppliers bring to value-based care models. We will continue to engage CJR–X participants and other interested parties to support the model goals of improving quality of care and reducing Medicare spending.

Comment: A commenter did not support making CJR–X mandatory, particularly given the ongoing shift of joint replacement procedures to ambulatory surgical centers (ASCs). They stated that as more routine cases migrate to outpatient settings, hospitals are increasingly left caring for patients with greater medical and social complexity, which can significantly affect performance under a mandatory bundled payment model.

Response: We acknowledge the commenter's concern that the site of service for joint replacement procedures continues to evolve and that hospitals may treat beneficiaries with greater medical, functional, or social complexity as more routine cases shift to ambulatory surgical centers and other outpatient settings. However, we do not agree that these concerns warrant making CJR–X voluntary. CJR–X is predicated on the CJR Model, which tested mandatory LEJR episode-based accountability and demonstrated reduced Medicare spending while maintaining quality. We believe mandatory participation remains important to generating broad-based, generalizable results and supporting a consistent national approach to LEJR episode-based care coordination, quality accountability, and spending accountability.

We also believe that the CJR–X target price methodology is designed to remain responsive to changes in the population of beneficiaries receiving LEJR procedures in hospital settings. Because the baseline period rolls forward annually, target prices would reflect more recent episode spending and patient mix for beneficiaries receiving LEJR procedures in the inpatient hospital or hospital outpatient department setting. To the extent routine cases continue to shift to ASCs and hospitals treat a comparatively more acute or complex mix of beneficiaries, that changing case mix and associated spending would generally be reflected in future target prices. We believe this rolling baseline approach helps maintain alignment between target prices and current hospital LEJR practice patterns.

We will continue to monitor changes in joint replacement site of service, patient complexity, quality of care, beneficiary access, utilization, and episode spending under CJR–X. Monitoring and evaluation will help CMS assess whether the model is operating as intended across diverse hospital settings and whether future refinements may be appropriate to ensure that CJR–X remains responsive to evolving practice patterns and beneficiary needs.

Comment: Some commenters expressed concerns with CJR–X participant burden implementing the model. A commenter believed that CJR–X would create significant financial challenges and an unfunded workforce burden to manage 90-day episodes of care across a continuum that hospitals do not fully control. Another commenter stated that CJR–X Model introduces significant operational and financial uncertainty for academic medical centers. They stated the expansion increases both the scope and the accountability associated with bundled payments, including broader episode definitions, more aggressive cost benchmarks, and greater emphasis on post-acute care performance. While these goals align with care coordination efforts, they do not fully account for the clinical and social complexity of patients treated at institutions such as ours. Another commenter encouraged CMS to streamline requirements wherever possible.

Response: We disagree that CJR–X would result in unfunded workforce burden or result in greater burden for certain hospitals like academic medical centers. CJR–X does not require hospitals to hire additional staff. CJR–X holds hospitals accountable for LEJR episode quality and spending, but the model does not prescribe a specific staffing model or require CJR–X participants to create new positions to manage episodes. Hospitals retain flexibility to determine how best to organize care coordination, discharge planning, quality improvement, and post-acute care communication based on their existing resources, patient population, market conditions, and operational structure.

We also note that hospitals already have obligations under the Medicare hospital conditions of participation related to appropriate discharge planning, as described in 42 CFR 482.43. CJR–X builds on hospitals' existing role in planning for safe transitions from the hospital to the next care setting. CJR–X encourages hospitals to strengthen care coordination, communicate with treating clinicians and post-acute care providers, educate beneficiaries and caregivers, and support clinically appropriate transitions of care.

Further, CJR–X will not alter the way CJR–X participants bill Medicare. We believe that there will be no additional burden for CJR–X participants related to billing practices, even in cases where CMS waives certain policies for purposes of CJR–X (for example, the telehealth waivers discussed in section X.C.2j of this final rule). We do recognize the time and effort to establish financial arrangements, which may vary based on a CJR–X participant's experience and capabilities partnering with entities and setting up the terms and conditions of such partnerships. However, CJR–X participants are not required to engage in financial arrangements for the model. Additionally, we believe CJR–X will not be adding to quality measure reporting burden because we are using quality measures that CJR–X participants will already be reporting. However, we recognize there may be some CJR–X participants required to submit a financial arrangements list or clinician engagement list, as discussed in section X.C.2.i.(3) of this final rule, for which we've noted the associated estimate of burden in section I.G.12 of Appendix A of this final rule.

Lastly, we appreciate the commenter's recommendation that CMS streamline requirements wherever possible. We are committed to considering opportunities to reduce unnecessary administrative burden and improve operational clarity,

while maintaining the safeguards, beneficiary protections, and program accountability needed to implement and evaluate CJR–X effectively. We will continue to assess whether any requirements can be simplified, aligned with existing Medicare processes, or clarified through implementation guidance without undermining the goals of the model or the protections.

Comment: A commenter stated that CJR–X is at odds with the Rural Health Transformation Program (RHTP) because tertiary care facilities will be left with the difficult choice to divert post-surgical care away from CAHs or face financial performance penalties under the CJR–X.

Response: We agree that beneficiaries in rural communities should continue to have access to medically necessary, high-quality care, including post-surgical and post-acute care when clinically appropriate. We do not believe CJR–X discourages hospitals from referring beneficiaries to CAHs or other rural providers when those providers are clinically appropriate for the beneficiary's needs. CJR–X would not require a beneficiary to receive post-acute or follow-up care from any particular provider or facility, nor would it permit CJR–X participants to restrict beneficiary choice in a manner inconsistent with current Medicare requirements. CJR–X beneficiaries retain freedom of choice to receive care from Medicare-participating providers and suppliers, including rural providers, as applicable. Additionally, we note that CMS would use standardized payment amounts to calculate target prices and episode spending in CJR–X.

We also do not believe that CJR–X is at odds with efforts to support rural access to care. CJR–X is intended to improve care coordination, quality, and efficiency for LEJR episodes, including during the 90-day post-discharge period. For beneficiaries who return to rural communities after surgery, appropriate coordination with rural providers, including CAHs and other local providers, may be important to supporting recovery and avoiding unnecessary complications, emergency department visits, or readmissions. The model's incentives are intended to encourage clinically appropriate care coordination, not to divert care away from rural providers solely for financial reasons.

We also note that the SNF 3-day rule waiver, as discussed in section X.C.2.j.(4) of this final rule, is designed to support appropriate post-acute care access and care transitions. Under the waiver, CJR–X participants may discharge eligible beneficiaries to certain qualifying skilled nursing facilities or hospitals with swing bed arrangements, including Critical Access Hospitals, without a prior 3-day inpatient hospital stay, provided the applicable waiver conditions are met. Including Critical Access Hospitals in this waiver helps support access to post-acute care for beneficiaries in rural communities by allowing clinically appropriate discharge options closer to where beneficiaries live.

We recognize that tertiary care facilities may care for beneficiaries who live in rural areas and may need to coordinate with rural hospitals, Critical Access Hospitals, post-acute care providers, and other providers after discharge. We expect CJR–X participants to consider beneficiary needs, clinical appropriateness, provider availability, and beneficiary preferences when planning post-surgical care. CJR–X does not eliminate or reduce existing discharge planning obligations, beneficiary protections, or Medicare coverage of medically necessary services.

CJR–X also includes policies intended to support hospitals that may face greater rural or resource-related challenges, including lower stop-loss limits for certain hospital categories, such as rural hospitals, Medicare dependent hospitals, sole community hospitals, and safety net hospitals, as applicable. CMS will monitor CJR–X for effects on beneficiary access, quality of care, utilization, post-acute care patterns, and potential unintended consequences, including whether the model affects access to care for beneficiaries in rural communities or referrals to rural providers. If monitoring, evaluation, or stakeholder feedback identifies access concerns, CMS may consider whether additional guidance, technical assistance, or future policy refinements are warranted.

Comment: A few commenters requested CMS monitor the impact of post-acute care availability for CJR–X participants and make appropriate design changes to mitigate the impact of post-acute care shortages.

Response: We do not expect CJR–X will result in adverse results such as decrease in availability of services or disruption of patient care. In contrast, CMS believes that CJR–X may have the opposite effects. The financial incentives in the model are designed to incentivize innovative care delivery methods that focus on improving care and reducing Medicare spending. We believe CJR–X may spur partnerships between CJR–X participants and post-acute care providers, such as skilled nursing facilities and home health agencies, to share financial risk and collaborate on care redesign strategies. We recognize that partnerships with post-acute care providers could be a crucial driver of episode spending and quality, given that many beneficiaries in CJR–X may receive post-acute care services after discharge from the hospital. We believe the opportunities to find savings in post-acute care could be a motivator for these partnerships to help address some of the challenges with vacancies and capacities. Evaluation findings suggest episode-based payment model participants tend to find efficiencies in the post-acute care space such as reducing the length of stay in institutional post-acute care.[585] Reductions in the length of stay may free up institutional post-acute care beds, thereby allowing beneficiaries to not remain in the acute care setting unnecessarily. We also believe that model incentives could be a catalyst to financially support additional staffing needs through the sharing of reconciliation payment amounts established by financial arrangements between the CJR–X participant and post-acute care provider. We emphasize the importance of beneficiary quality and access to care in CJR–X and we will monitor the impact of the model, as described in section X.C.2.m of this final rule.

We also acknowledge that post-acute care can vary across different communities, regions, and states and may take into consideration policies, waivers, or pricing methodology adjustments that may address these variances. We may take this into consideration in future notice and comment rulemaking.

Comment: A commenter recommended CMS develop safeguards to ensure that hospitals are not penalized for spending variation that is unrelated to the quality or efficiency of the care they provide.

Response: We recognize that episode spending may be affected by sources of variation that may not directly reflect the quality or efficiency of a hospital's care. CJR–X includes safeguards intended to address these concerns. The pricing methodology, as discussed in section X.C.2.f of this final rule, includes policies designed to improve predictability and account for variation across hospitals and beneficiary populations, including regional target pricing, risk adjustment, trend and normalization policies, and stop-loss

[585] Comprehensive Care for Joint Replacement Model—Seventh Annual Report: *https://www.cms.gov/priorities/innovation/data-and-reports/2025/cjr-py7-annual-report.*

limits that cap repayment responsibility. Regional target prices help mitigate the effect of individual hospital-level variability by basing prices on broader regional episode spending experience rather than solely on a hospital's own historical episode spending. The high-cost outlier cap also limits the extent to which unusually expensive episodes affect episode spending calculations, helping reduce the influence of extreme cases that may not reflect typical hospital performance. In addition, the retrospective trend factor is capped to limit the difference between the prospective trend factor used in preliminary target prices and the retrospective trend factor applied at reconciliation. This cap helps maintain predictability and reduces the extent to which target prices may shift based on performance-year spending trends that participants could not fully anticipate.

Comment: Some commenters encouraged CMS to explore broader accountability mechanisms that more appropriately distribute risk among all parties contributing to patient outcomes, including physicians, implant manufacturers, and post-acute care providers.

Response: We appreciate commenters' recommendation to consider broader accountability mechanisms that recognize the role of multiple parties in LEJR episode outcomes. While we agree that hospitals are not the sole contributors in episodic care, we maintain the belief that hospitals are the most appropriate entity to place accountability. Hospitals furnish the anchor hospitalization or anchor procedure, manage discharge planning, coordinate transitions of care, and are generally positioned to engage physicians, and post-acute care providers involved in post-discharge recovery.

We recognize that episode outcomes depend on collaboration across the care continuum. For that reason, CJR–X includes policies that allow CJR–X to enter into financial arrangements and care redesign relationships with certain entities, subject to applicable requirements and safeguards, as discussed in section X.C.2.i of this final rule. These arrangements can help align incentives among hospitals, physicians, post-acute care providers, and other entities that contribute to LEJR episode quality and spending, while maintaining hospital accountability as the central model participant.

We are not permitting CJR–X participants to establish financial arrangements with all entities, such as implant manufacturers at this time. Doing so would implicate additional program integrity and beneficiary protection considerations. However, we agree that stakeholder feedback on broader accountability structures may be useful for future model design, including approaches that consider how best to align incentives among entities that contribute to patient outcomes.

Comment: Some commenters encouraged CMS to provide additional operational guidance, data-sharing support, implementation flexibility, and subregulatory compliance guidance prior to the model's start. CMS could consider providing additional technical assistance, implementation resources, and timely performance data to help providers adapt to CJR–X participation on a national scale. Another commenter recommended CMS consider providing additional technical assistance, implementation resources, and timely performance data to help providers adapt to CJR–X participation on a national scale.

Response: We value commenters' recommendations and we intend to provide learning and implementation support for CJR–X participants before the model begins. We anticipate engaging CJR–X participants before the model start date and sharing resources to help participants prepare for implementation. We also anticipate sharing technical specifications and data before the model begins, including information needed to understand model methodology, episode attribution, target prices, quality measures, reconciliation, and other operational requirements. Further, we will continue to make updated model resources publicly available, including the CJR–X Model-specific web page, frequently asked questions, fact sheets, and other implementation materials.

We welcome feedback on additional ways to educate and assist CJR–X participants and their care partners in care redesign, knowledge sharing, and model implementation.

Comment: Many commenters recommended that CJR–X emphasize patient-centered care. These comments included requests for individualized discharge planning, caregiver training services, appropriate post-acute care access, and monitoring of care patterns so that cost incentives do not override clinical needs. Other commenters requested CMS include specific providers in care decisions, such as occupational therapists during discharge planning, and acknowledging physiatrist's role in medically complex patients. A commenter encouraged CMS to take on a holistic view regarding the specific episode categories because bundled payment models run the risk of viewing a patient solely as their condition rather than through the whole person lens.

Response: We appreciate commenters' recommendations and agree that LEJR episode care should remain patient-centered, clinically appropriate, and responsive to each beneficiary's individual needs. CJR–X is intended to improve coordination, quality, and efficiency for LEJR episodes, but the model does not override clinical judgment, beneficiary choice, Medicare coverage rules, or the need for individualized care planning. We also note that CJR–X includes quality measures focused on patient experience and patient reported outcomes, as discussed in section X.C.2.e.(3) of this final rule.

Discharge planning and post-acute care decisions should be based on the beneficiary's medical condition, functional status, rehabilitation needs, home environment, caregiver availability, preferences, and other patient-specific circumstances. CJR–X does not require beneficiaries to receive post-acute care from any particular provider or facility, and beneficiaries retain freedom of choice to receive care from Medicare-participating providers and suppliers. Hospitals, treating clinicians, beneficiaries, and caregivers should work together to identify clinically appropriate care plans and post-acute care arrangements that support safe recovery.

We also recognize the important role of rehabilitation professionals, including occupational therapists, physical therapists, physiatrists, and other clinicians, in supporting recovery for LEJR beneficiaries. CJR–X does not prescribe a single discharge planning team or require that specific provider types participate in every care decision, because beneficiaries' needs vary and hospitals use different clinical staffing models. However, CMS expects CJR–X participants to involve appropriate clinical expertise, consistent with applicable Medicare requirements and the beneficiary's needs, when developing discharge plans, arranging rehabilitation services, coordinating post-acute care, and addressing medically complex cases.

We also agree that caregiver involvement and caregiver education can be important components of safe transitions and recovery after LEJR procedures. When caregivers are involved in a beneficiary's care, hospitals and other providers should consider the caregiver's role in supporting recovery, medication management, mobility, activities of daily living, transportation, follow-up

care, and the beneficiary's ability to safely remain in the intended care setting.

We agree that CJR–X beneficiaries should be treated holistically, not solely as episode categories. The CJR–X episode structure provides a framework for accountability for LEJR-related quality and spending, but it does not replace individualized clinical assessment or the need to consider comorbidities, functional limitations, social needs, caregiver support, and beneficiary preferences. We believe CJR–X can support whole-person care by encouraging hospitals to coordinate across settings and providers to support each beneficiary's recovery.

Comment: A commenter had concerns that CJR–X reconciliation and quality structure—among the only direct ways that physical therapists are discretely considered in the model—are skewed heavily toward large or multi-site outpatient physical therapy practices. They believe it is because the ability to evidence a practice's contribution to success is a prerequisite for gainsharing and it requires significant investment in both systems and personnel and simply is not realistic for most small or even mid-size practices.

Response: We recognize that physical therapists and other rehabilitation professionals play an important role in successful recovery for LEJR beneficiaries. We recognize that outpatient therapy practices vary in size, administrative capacity, data infrastructure, and ability to participate in formal care redesign or financial arrangements. CJR–X does not require outpatient physical therapy practices to participate in gainsharing or other financial arrangements, and it does not require CJR–X participants to enter into arrangements only with large or multi-site therapy practices. CJR–X participants retain flexibility to collaborate with providers and suppliers that support clinically appropriate, high-quality recovery for beneficiaries, including small and mid-size therapy practices, consistent with applicable model requirements and current law. We believe that safeguards for financial arrangements are necessary to ensure that any gainsharing payments or other distributions are tied to legitimate care redesign activities, quality improvement, or episode performance, and are not used in a manner that could compromise beneficiary choice, program integrity, or medically necessary care. These requirements are intended to protect beneficiaries and the Medicare program while permitting participant hospitals to align incentives with care partners that contribute to LEJR episode outcomes. Further, we do not believe that these safeguards are intended to favor large or multi-site outpatient therapy practices. Rather, they establish accountability requirements for any entity receiving financial distributions under the model. Hospitals may work with therapy practices of different sizes and structures, and beneficiaries retain freedom of choice to receive covered therapy services from Medicare-participating providers and suppliers. Decisions about rehabilitation services should remain based on clinical appropriateness, beneficiary needs and preferences, functional status, home environment, caregiver support, and provider availability.

Comment: Some commenters recommended that CJR–X include stronger mechanisms for physician and specialist engagement in episode management. A commenter recommended that CJR–X participant hospitals be required to establish a steering committee that includes physicians who perform joint replacement surgery at the hospital. Other commenters recommended that episodes triggered by surgical procedures be attributed to the operating surgeon, expressed concern about attribution conflicts across multiple CMS models, and stated that CJR–X may not hold surgeons equally accountable for episode costs even though surgeons influence patient selection, surgical care, and post-acute care decisions. A commenter recommended that CMS develop mechanisms to track and report specialist engagement in episode-based payment models so that specialist contributions to outcomes and resource use are reflected in performance measurement.

Response: We appreciate commenters' recommendations regarding physician and specialist engagement in CJR–X and agree they are critical partners in caring for CJR–X beneficiaries. Although physicians and other clinicians contribute to episode outcomes, we continue to believe that hospitals are best positioned to organize episode-level care coordination across the surgical setting, discharge transition, and recovery period. We strongly encourage CJR–X participants to engage surgeons and other relevant clinicians in episode management, care redesign, quality improvement, and post-acute care coordination. Hospitals may choose to establish physician-led or multidisciplinary committees, clinical workgroups, or other governance structures that support successful implementation of CJR–X. However, we do not believe in making specific organizational structures a CJR–X requirement. Hospitals vary in size, organizational structure, physician alignment, governance processes, and existing care redesign infrastructure. Requiring a uniform steering committee structure could create unnecessary administrative burden and may not reflect the most effective approach for every hospital.

We also do not believe that CJR–X episodes should be attributed to the operating surgeon rather than the participant hospital. CJR–X builds on the CJR Model's hospital-based episode accountability structure and changing that may jeopardize the ability for CJR–X expansion. We note that CJR–X includes financial arrangements that allow CJR–X participants to align incentives with certain collaborators, including physicians and physician group practices, subject to model requirements and safeguards. These arrangements can support physician engagement while maintaining hospital accountability as the central model participant. We believe this approach provides flexibility for hospitals to engage surgeons and other specialists without requiring a complex, multi-attribution model or a prescribed governance structure for all participants.

We will continue to consider whether data, monitoring, evaluation, or future model design can better capture the role of specialists in episode outcomes and resource use. However, we are not adding a separate specialist engagement reporting requirement at this time to avoid reporting burden. We will continue to consider ways of increasing specialist engagement in CJR–X.

Comment: A commenter recommended that CMS ensure CJR–X does not undermine statutory requirements for appropriate pain medication prescribing, which they said included statutory requirements for temporary separate payments for certain non-opioid treatment for pain relief under the OPPS and ASC payment system.

Response: We recognize that pain management is an important component of recovery following LEJR procedures. CJR–X is not intended to influence providers to avoid medically necessary or clinically appropriate pain management services or therapies. The model would not change Medicare coverage, eligibility, or benefits for beneficiaries, and it would not alter the ability of clinicians to prescribe or furnish pain management therapies that are medically appropriate for a beneficiary.

Further, CJR–X Model will not undermine statutory requirements under Section 4135 of Consolidated Appropriations Act (CAA), 2023 which amended section 1833(t)(16) and section 1833(i) of the Act, also known as the NO PAIN Act, because the temporary additional payments for certain non-opioid treatments for pain relief are authorized in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs)on or after January 1, 2025 and before January 1, 2028. The CJR–X Model has a start date of January 1, 2028 such that there would be no overlap.

We will continue to consider whether and how drugs, biologicals, devices, or other treatments subject to separate statutory payment requirements, may affect episode spending, prescribing behavior, and beneficiary access under CJR–X. CMS may consider these issues in future monitoring, evaluation, or rulemaking, as appropriate.

Comment: A commenter recommended that CMS include incentives to encourage adoption of evidence-based testing protocols, including rapid molecular testing for pathogens associated with surgical complications.

Response: We appreciate the recommendation and agree that clinically appropriate testing and diagnostic strategies may help identify beneficiary-specific risks, inform perioperative planning, support infection prevention efforts, and improve outcomes for some beneficiaries. However, we are not establishing a separate CJR–X incentive or requirement for any specific testing protocol or diagnostic technology at this time. Testing needs may vary based on beneficiary-specific risk factors, clinical presentation, local practice patterns, provider judgment, and applicable evidence-based guidelines, and we believe providers should retain clinical flexibility to determine when particular pre-surgical or perioperative testing is appropriate.

Comment: A commenter believes CJR–X will be a race to the bottom and CMS recognizing the ''ratchet effect'' is not akin to CMS fixing the ''ratchet effect,'' which refers to the idea that target prices will continually decrease over time as hospitals decrease their spending in response to the model.

Response: We recognize that if target prices are based only on a hospital's own historical performance, repeated use of improved performance to set future prices could create a ratchet effect by continually lowering benchmarks for hospitals that reduce spending. We believe the CJR–X target price methodology helps mitigate, though not eliminate, this concern by using regional prices rather than relying solely on a participant hospital's own historical spending. Regional pricing assesses episode spending across a broader group of hospitals within the applicable region, rather than basing each hospital's target price only on its own prior performance. This approach helps reduce the extent to which an individual hospital's own care redesign success or spending reductions are immediately incorporated into that same hospital's future target prices. We believe this broader regional benchmark promotes more stable and comparable pricing while maintaining incentives for hospitals to improve LEJR episode efficiency and quality.

We also note that CJR–X includes additional pricing and reconciliation safeguards intended to improve predictability and reduce the effect of unusual spending variation. These include trend and normalization policies, high-cost outlier caps, quality-based reconciliation, and stop-loss limits that cap repayment responsibility. The retrospective trend factor cap limits the difference between the prospective trend factor used in preliminary target prices and the retrospective trend factor applied at reconciliation, which helps reduce the extent to which target prices shift based on performance-year spending trends that participants could not fully anticipate.

We will continue to monitor CJR–X participant performance in relation to spending trends and assess whether the target price methodology creates realistic opportunities for hospitals to achieve savings while providing high-quality beneficiary care.

Comment: A commenter was concerned that the CJR–X Model continues to be built on the FFS framework, with providers largely continuing to bill Medicare on a FFS basis followed by an annual retrospective reconciliation some months after the conclusion of the performance year. This structure creates significant lags between when care is delivered and when performance is recognized. We encourage CMS to explore mechanisms that more closely tie value into the initial payment structure.

Response: We are considering ways to move away from relying solely on a fee-for-service framework and the traditional approach of retrospective reconciliation, including approaches that could bring financial incentives closer to the time care is delivered or closer to when a CJR–X participant receives payment. We agree that payment approaches that more directly incorporate value into the initial payment structure may, in some circumstances, strengthen incentives for timely care redesign, quality improvement, and episode management.

At the same time, the CJR–X reconciliation methodology builds on the tested CJR Model structure and provides a clear framework for assessing LEJR episode spending and quality across the 90-day episode. Retrospective reconciliation allows CMS to account for actual episode spending and quality performance after the episode and performance year are complete. We believe this approach remains appropriate for CJR–X while CMS continues to evaluate potential future approaches to value-based payment.

Comment: A commenter recommended that CMS should consider how technologies that improve visibility into patient condition, support care coordination, and assist with earlier clinical intervention may contribute to reduced complications, lower readmissions, and improved episode performance across the continuum of care. They also stated that CMS should also ensure that payment and quality policies appropriately support technologies that facilitate safe discharge planning, care coordination, and transitions across care settings.

Response: We are not requiring or endorsing any specific technology, vendor, platform, or tool under CJR–X. Hospitals vary in their resources, workflows, patient populations, care partners, and local market conditions, and we believe CJR–X participants should retain flexibility to determine which technologies or operational tools best support their care redesign activities and beneficiary needs. A technology-neutral approach allows hospitals to adopt or continue using tools that are appropriate for their circumstances without creating a uniform technology mandate or disadvantaging participants that use different approaches. However, we support the use of technology to help CJR–X participants improve care for beneficiaries. For example, tools that help identify changes in patient condition, facilitate timely follow-up, support care teams in coordinating with post-acute care providers, or help beneficiaries understand recovery instructions may contribute to improved episode performance when used appropriately.

Comment: A comment stated that they believe that target-price models that lack sufficient guardrails inappropriately incentivize hospitals to make discharge decisions based on short-term cost

concerns—rather than patients' individual clinical needs, functional recovery, and long-term outcomes.

Response: We agree that care redesign under CJR–X must not result in stinting on medically necessary care, inappropriate steering, or discharge decisions that are inconsistent with a beneficiary's clinical circumstances. CJR–X is designed to align financial incentives with high-quality, clinically appropriate care, rather than reductions in utilization alone. Under CJR–X, participants would not be rewarded for reducing spending alone. The payment methodology incorporates quality performance into reconciliation through the composite quality score, as discussed in section X.C.2.f.(5)(e) of this final rule, which would affect the CJR–X participant's financial performance under the model. For example, poor quality performance would result in a CJR–X participant not being eligible for a reduced discount factor or a reconciliation payment, while stronger quality performance could allow a CJR–X participant to receive more favorable reconciliation outcome. As a result, CJR–X participants would have a financial incentive to make discharge planning and post-acute care decisions that support quality of care, functional recovery, and beneficiary-specific clinical needs.

In addition, poor quality care may lead to avoidable spending during the episode, including spending associated with complications, hospital visits, readmissions, or other additional services. Those avoidable costs would increase episode spending and could adversely affect a CJR–X participant's reconciliation performance under CJR–X. Accordingly, the model's financial incentives are designed to encourage CJR–X participants to coordinate care, support appropriate recovery, and avoid preventable complications, rather than to make discharge decisions based solely on short-term reductions in post-acute care use.

We will monitor CJR–X implementation, including whether changes in discharge patterns or post-acute care use raise concerns about beneficiary access, safety, quality, or outcomes.

Comment: A commenter suggested for CMS to move beyond approaches that focus solely on discrete episodes of care and consider incorporating population health strategies aimed at reducing inequities in access to appropriate and timely services.

Response: We appreciate the commenter's recommendation. While CJR–X focuses on LEJR episodes, which represent high-volume procedures with significant opportunities to improve care coordination and reduce Medicare spending while maintaining quality, the model is intended to complement broader population-based care initiatives rather than operate independently. As discussed in section X.C.2.h of this final rule, CJR–X would permit beneficiary and provider overlap with certain population-based models and would allow savings generated under both models to be retained by the respective participants. We believe this approach supports coordinated care by allowing CJR–X participants to focus on improving the quality, coordination, and efficiency of care surrounding the LEJR episode while enabling beneficiaries who are aligned to an ACO or other total cost of care model to transition to ongoing, longitudinal care beyond the episode. We believe this will promote collaboration across complementary value-based payment models while avoiding unnecessary complexity and preserving the integrity of each model.

Comment: A commenter was concerned that the ''target rates'' for CJR–X participants hospitals assume a level of access to a range of services that does not always exist. They believe it would unfairly penalize the hospital performing the procedure but could also prevent patients from receiving care in the most appropriate and often cost-effective available clinical setting within the episode of care

Response: We disagree that the CJR–X target pricing methodology assumes that every hospital has the same access to the same range of services or is intended to penalize hospitals for factors outside their control. We believe the CJR–X target pricing methodology helps account for regional variation in care patterns and beneficiary characteristics. As described in section X.C.2.f of this final rule, CJR–X target prices are based on regional episode spending for the applicable MS–DRG or HCPCS episode type, rather than a single national price. To the extent hospitals in a region have different patterns of access to post-acute care or other episode services, those regional spending patterns would be reflected in the regional data used to construct target prices. CJR–X target prices also incorporate beneficiary-level risk adjustment, including factors related to age, CJR HCC count, and dual eligibility, so that episodes involving older, more medically complex, or socioeconomically disadvantaged beneficiaries may receive corresponding adjustments to the target price.

2. Provisions of the Proposed Comprehensive Care for Joint Replacement Expanded (CJR–X) Model

a. Scope of Proposed Model

We proposed that CJR–X would begin on October 1, 2027. Under this proposal, CJR–X performance years would align with fiscal years (FYs). In contrast, the CJR Model aligned with calendar years (CYs). While we considered proposing a January 1, 2028 start date to align with CY and be consistent with the CJR Model, we stated our belief that changing to FY is more appropriate given that the IPPS is aligned to an FY cycle, and we anticipate potential future policy changes to CJR–X would be proposed in the IPPS rulemaking cycle. Therefore, we proposed that the first PY of CJR–X would run from October 1, 2027 through September 30, 2028, and the proceeding performance years would follow the same cadence.

We also considered a later start date to allow additional time for CJR–X participants to prepare for the model. However, we believe it beneficial to limit the amount of time between the final CJR Model PY and the continuation of the model test as CJR–X. In addition, the proposed start date provides more lead time for participants than the CJR Model did when finalized in November 2015. Despite the CJR Model beginning when hospitals had less experience with episode-based payment models, participants were able to successfully implement the model for the first performance year in April 2016. With the October 1, 2027 start date, hospitals would have more than 1 year to prepare for CJR–X participation. We also anticipate that many hospitals will have prior experience with LEJR episodes given that the Innovation Center has tested episode-based payment models for over a decade and Medicare Advantage organizations and commercial insurers often include episode-based contracts for high-volume procedures.

The CJR Model was a mandatory model for acute care hospitals within certain selected MSAs. However, for CJR–X, we proposed that all eligible acute care hospitals nationwide would be required to participate, as described in section X.C.1.b. of this final rule. As we stated in section X.C.1.c. of this final rule, the CJR Model has met the requirements for expansion as a nationwide model by reducing spending and maintaining quality of care among mandatory hospitals, and the CMS Chief Actuary has certified its nationwide expansion as a mandatory model.

We sought comment on our proposal at § 512.605 to define ''performance

year'' as aligning with FYs and our proposal at § 512.630(a) to begin the model on October 1, 2027. We also sought comment on alternative start dates.

The following is a summary of the public comments received on our performance year and model start date proposals, and our responses to these comments:

Comment: Numerous commenters recommended that CMS delay the proposed October 1, 2027 CJR–X start date. Commenters stated that the proposed timeline would not provide enough lead time for hospitals to prepare for mandatory nationwide participation and two-sided financial accountability. Commenters cited the need to build analytics infrastructure, hire or train care management staff, engage physicians, develop post-acute partnerships, and understand model methodology. Some commenters recommended that CMS delay implementation of CJR–X altogether. Commenters stated that CMS should address stakeholder concerns, methodological questions, or operational issues before the model begins. Commenters believed that additional time would allow hospitals and partners to prepare for workflow, data, and care coordination changes. Some commenters recommended that implementation not proceed until key issues are resolved. A commenter cited other CMS models that allowed more time for hospitals to prepare for mandated implementation, including the two years to prepare for mandated for Inpatient Quality Reporting (IQR) of Patient- Reported Outcomes (PRO) and three years to prepare for mandated Outpatient Quality Reporting (OQR) PRO. A few commenters urged CMS to hold off on implementing a potential expanded CJR model at least until after the initial performance years for TEAM have been completed or postponing implementation of the CJR–X until several key design elements can be verified through TEAM. Another commenter stated that CMS has not afforded TEAM the ability to illustrate results prior to mandating CJR–X.

Response: We appreciate the commenters' recommendations regarding the timing of CJR–X implementation. We recognize that mandatory participation in a nationwide episode-based payment model requires substantial preparation and that hospitals may need time to develop operational, clinical, financial, and data infrastructure to support successful participation.

After considering the public comments, we are persuaded that CJR–X participants would benefit from additional implementation time before the start of mandatory participation in CJR–X. Commenters described the operational work necessary to prepare for model participation, including developing care management capabilities, enhancing data and analytics infrastructure, engaging physicians and post-acute care providers, and establishing episode management processes. We agree that additional preparation time will support participant readiness and facilitate more effective implementation of the model.

At the same time, we continue to believe that lower extremity joint replacement is an appropriate area for model expansion given the extensive experience generated through prior episode-based payment initiatives. Accordingly, rather than delaying the Phase II model indefinitely, we believe a targeted three-month implementation delay appropriately balances commenters' readiness concerns with the benefits of continuing care transformation efforts in this clinical area.

Therefore, we are finalizing at § 512.630(a) to begin the Phase II model on January 1, 2028 rather than the proposed October 1, 2027 start date. We are also finalizing at § 512.605 that performance years will be based on the calendar year rather than the fiscal year. We believe these modifications provide CJR–X participants with meaningful additional time to prepare while creating a more predictable framework for annual planning, budgeting, performance monitoring, and operational implementation.

The revised implementation timeline will allow hospitals and their partners additional time to strengthen governance and accountability structures, assess reporting capabilities, and implement operational changes necessary to support successful participation. We believe this additional preparation period will be particularly valuable for organizations with less experience in episode-based payment models or those continuing to build care coordination and episode management infrastructure.

However, we do not believe that delaying implementation beyond January 1, 2028 or postponing CJR–X until all stakeholder concerns are resolved is necessary. We believe approximately 17 months between publication of the final rule and the January 1, 2028 model start date provides participants sufficient time to prepare for model implementation. During this period, CMS will produce resources to support CJR–X understand model requirements and methodologies and CJR–X participants will have the opportunity to review baseline performance data and establish care redesign processes. In addition, lower extremity joint replacement is among the most common and clinically standardized procedures in Medicare and has been the focus of extensive care redesign efforts through the CJR Model, BPCI Advanced, Medicare Advantage arrangements, and commercial bundled payment initiatives. As a result, many hospitals, physicians, and post-acute care providers have already developed experience with care coordination, discharge planning, utilization management, and episode-based approaches that are directly relevant to CJR–X.

We recognize that CMS has provided longer implementation periods for other certain quality reporting initiatives, including requirements related to patient-reported outcome measures. However, we do not believe those initiatives are directly comparable to CJR–X. The implementation activities associated with establishing new patient-reported outcome reporting requirements differ from those associated with an episode-based payment model focused on lower extremity joint replacement. While PRO reporting initiatives often require the development of new data collection processes, survey administration workflows, vendor relationships, and reporting infrastructure, CJR–X builds upon a clinical episode that has been the subject of extensive care redesign and episode-based payment efforts for many years.

Lastly, we do not believe it is necessary to delay CJR–X implementation pending further experience with TEAM. TEAM is a separate episode-based payment model that will have two full years of testing prior to CJR–X and three full years where both models are tested simultaneously. We believe this provides a unique opportunity to test TEAM in different scenarios while generating evidence to compare a 30-day episode to a 90-day episode. Additionally, CJR–X is being implemented as an expansion of the Comprehensive Care for Joint Replacement (CJR) Model under section 1115A(c) of the Act. As a result, CJR–X is grounded primarily in the experience, evaluation findings, and tested design elements of the CJR Model rather than in future findings from TEAM. We believe the evidence supporting expansion of the CJR Model provides a sufficient basis for moving forward with CJR–X without waiting for

additional years of experience under TEAM. We also note that the CJR–X implementation timeline provides a meaningful opportunity for CMS to gain operational experience from TEAM before CJR–X begins. TEAM began on January 1, 2026, and CJR–X will begin on January 1, 2028, providing TEAM two full years of implementation before CJR–X begins.

Comment: Some commenters recommended that CMS align CJR–X performance and reporting periods with the calendar year. Commenters stated that calendar-year alignment would simplify data management, abstraction workflows, validation processes, cross-program analytics, resource allocation, and budgeting. Commenters noted that overlapping or conflicting timelines across programs increase the risk of data errors and administrative burden. Some commenters also cited alignment with the Outpatient Prospective Payment System (OPPS), TEAM performance years, and other reporting programs. A few commenters recommended standardized calendar-year periods wherever feasible.

Response: After considering the public comments, we agree that aligning CJR–X performance years with the calendar year will simplify model administration and CJR–X participant operations. Therefore, in conjunction with finalizing a January 1, 2028 model start date rather than the proposed October 1, 2027 start date, we are also finalizing at § 512.605 to define ''performance year'' that align with the calendar year rather than the fiscal year. Under this approach, each performance year will run from January 1 through December 31.

We believe calendar-year performance periods will provide several advantages for CJR–X participants. Aligning performance years with a single annual reporting cycle may simplify financial forecasting, performance monitoring, and operational planning activities. We also believe calendar-year performance periods create a more intuitive framework for CJR–X participants to monitor episode performance and evaluate year-over-year trends. In addition, as a growing share of lower extremity joint replacement procedures are furnished in outpatient settings, calendar-year alignment may simplify CJR–X participants' efforts to monitor performance across inpatient and outpatient episodes within a single calendar year performance year.

We also note that calendar-year alignment will better align CJR–X with TEAM performance years and certain other CMS reporting and payment initiatives. While we recognize that complete alignment across all CMS programs and initiatives is not always possible given differing statutory, regulatory, and operational requirements, we agree that reducing unnecessary differences in performance periods where feasible may help reduce administrative burden and improve operational efficiency for participants. Further, consistent performance periods across initiatives may support the sharing of operational lessons learned across episode-based payment initiatives. Common performance periods may also improve the comparability of operational and performance information across episode-based payment initiatives and facilitate the identification of successful care redesign strategies.

Finally, we believe the combination of a January 1, 2028 start date and calendar-year performance years provides participants with a clearer and more predictable implementation timeline while supporting participant readiness. Together, these modifications provide additional preparation time before model accountability begins and establish a performance year structure that is easier for participants to administer and integrate into existing planning and reporting processes.

Comment: Numerous commenters recommended that CMS make the first CJR–X performance year upside-only or waive downside risk during the first year. Commenters stated that PY1 upside-only risk would allow hospitals to gain experience with target prices, data, episode management, post-acute coordination, and reconciliation methods before being subject to repayment obligations. Commenters compared this approach to prior episode-based models and stated that it would be especially important for hospitals without prior bundled payment experience. They believed that a one-year transition would reduce immediate financial strain while preserving incentives to identify savings opportunities and improve care processes.

Response: We recognize the commenters' concerns regarding participant readiness, particularly for hospitals without prior experience in bundled payment models, and we agree that participants need sufficient time to understand all the requirements and methodologies associated with model participation. However, we do not believe that an upside-only first performance year is necessary or appropriate for CJR–X. As a result of public comments regarding implementation readiness, we are finalizing a January 1, 2028 model start date rather than the proposed October 1, 2027 start date and are aligning performance years with the calendar year. We believe this additional three-months, resulting in a 17-month implementation period, provides CJR–X participants meaningful additional time to prepare for model participation, establish governance structures, engage physicians and post-acute care providers, develop care management workflows, evaluate historical performance, and implement operational processes necessary to manage episodes effectively before financial accountability begins.

We also note that lower extremity joint replacement is among the most common and well-established episode categories in Medicare and has been the focus of episode-based payment initiatives for nearly a decade. During that time, hospitals, physicians, post-acute care providers, and other stakeholders have gained substantial experience with episode management, care coordination, discharge planning, post-acute care optimization, and performance monitoring related to LEJR episodes. Further, CJR Model evaluation data has demonstrated that non-participating hospitals also reduced LEJR episode spending over the years and suggests market-wide adoption of care efficiency practices.[586] We believe the widespread attention given to LEJR episodes through the CJR Model and similar initiatives has contributed to the development of standardized care pathways, established best practices, and operational capabilities that are broadly available across the health care system, including among organizations that did not directly participate in prior bundled payment models.

We further believe that downside risk plays an important role in encouraging CJR–X participants to establish care redesign processes, monitor utilization, and coordinate care across providers and settings from the outset of model participation. While upside-only risk participation may reduce financial exposure during the first year, it may also reduce incentives for CJR–X participants to implement operational changes necessary to improve efficiency and manage episode spending. We believe CJR–X participants are best positioned to begin developing these capabilities prior to the start of the model, particularly given the additional implementation time provided through January 1, 2028.

[586] Comprehensive Care for Joint Replacement Model—Fifth Annual Report: *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cjr-py5-annual-report.*

Comment: A commenter recommended that CMS coordinate CJR–X implementation with FY 2027 IPPS MS–DRG restructuring. The commenter stated that target prices and baseline episode definitions should be stable, transparent, and not subject to disruptive midcourse changes. The commenter believed that beginning CJR–X before hospitals understand the effects of coding and grouping changes could undermine pricing predictability and participant planning. The commenter requested that CMS time implementation to avoid instability in episode definitions, baseline construction, and target-price calculations.

Response: We note that CMS routinely updates Medicare payment policies through an annual rulemaking process, including changes to MS–DRG classifications, relative weights, coding policies, grouper logic, HCPCS codes, and other payment system parameters. These annual updates are a longstanding feature of the Medicare payment environment and are intended to ensure that payment methodologies appropriately reflect current clinical practice, coding, resource use, and health care delivery. As a result, hospitals regularly adapt to these updates as part of their normal operational and financial planning activities.

We further note that CJR–X is designed with the expectation that annual payment system updates will continue to occur throughout the model. For this reason, we are finalizing our proposed policy, as discussed in section X.C.2.f.(5)(d), under which reconciliation target price construction will account for applicable MS–DRG and HCPCS coding changes so that target prices reflect the most current payment methodologies and rates available. We believe incorporating these updates into target price construction improves pricing accuracy and helps ensure that reconciliation target prices remain reflective of current episode spending patterns rather than historical payment structures that may no longer align with current Medicare payment policy.

In addition, in response to public comments regarding participant readiness, we are finalizing a January 1, 2028 start date for CJR–X rather than the proposed October 1, 2027 start date and are aligning performance years with the calendar year. We believe this additional implementation period provides participants with additional time to understand and operationalize any finalized FY 2027 IPPS payment policy changes before the start of model accountability. The revised implementation timeline also provides participants with additional time to evaluate baseline performance, assess operational impacts, and prepare internal systems and processes for participation in CJR–X.

Comment: Some commenters stated that CMS did not identify a fixed end date for CJR–X. Commenters expressed concern that hospitals could remain subject to mandatory financial accountability indefinitely, including hospitals that perform poorly or face persistent structural challenges. Commenters stated that the absence of a defined endpoint or formal evaluation milestone could reduce transparency and predictability. Some commenters recommended that CMS implement CJR–X as a time-limited demonstration or establish clear milestones for continued operation, modification, or termination. Commenters requested greater clarity regarding the duration of CJR–X and how CMS would assess ongoing model performance. A commenter stated that CMS has not included an end date for the CJR–X Model and this would mean a poorly performing hospital could lose reimbursement on every eligible LEJR patient in perpetuity, especially since CMS has not included a floor after which penalties stop. Another commenter believed that Innovation Center authority is limited to models of defined duration, and the proposal to implement CJR–X without any end date and with only the prospect of unilateral termination is unlawful. They believed all models under section 1115A(b) and (c) must have a defined duration (that is, a completion date).

Response: CJR–X is a national expansion of the CJR Model under section 1115A(c) of the Act, rather than a new time-limited Phase I model test. As discussed in section X.C.1.c of this final rule, section 1115A(c) authorizes the Secretary, through rulemaking, to expand the duration and scope of a model, including nationwide implementation, when the statutory expansion criteria are met.

We disagree with the commenters' views that section 1115A requires every model to have a fixed completion date. We also disagree that CJR–X would be unlawful because it would not include a fixed end date. The absence of a fixed completion date does not mean CJR–X would operate without accountability or without a mechanism for modification or termination. Rather, CJR–X would be subject to the standard provisions, including monitoring and evaluation, as discussed in section X.C.2.m of this final rule. CMS will continue to assess whether expanded implementation is reducing Medicare spending without reducing quality of care or improving quality without increasing spending.

We recognize commenters' concerns regarding transparency, predictability, and the possibility that hospitals could remain subject to mandatory financial accountability for an extended period. We believe CJR–X provides transparency through the policies established in regulation and continued monitoring and evaluation.

We disagree with the commenter's statement that CJR–X would allow hospitals to lose reimbursement on every eligible LEJR patient without a floor. Under the reconciliation methodology, CJR–X would include stop-loss and stop-gain limits on the total amount a CJR–X participant could owe CMS as a repayment or receive from CMS as a reconciliation payment, as discussed in section X.C.2.f.(5)(g). These limits ensure that CJR–X participants would not be subject to an unmanageable level of risk and would not be incentivized to stint on care to achieve savings. Most CJR–X participants will be subject to a 20 percent stop-loss and stop-gain limit; however, safety net hospitals, rural hospitals, Medicare-dependent, small rural hospitals, and sole community hospitals are subject to a 5 percent stop-loss.

Comment: A couple of commenters recommended alignment of CJR–X performance years with TEAM performance years to ensure hospitals currently in TEAM would have an immediate transition to CJR–X upon the conclusion of TEAM, rather than a 9-month holding period to transition to CJR–X on October 1, 2031.

Response: We agree that aligning CJR–X performance years with calendar years would better support continuity for hospitals transitioning from TEAM to CJR–X. We also agree that such a gap could create unnecessary operational discontinuity for hospitals that have already been managing LEJR episodes under TEAM. While a seamless transition was not a driving factor, we are finalizing our proposal with modification such that the CJR–X performance year aligns with calendar years, which would permit TEAM participants that become CJR–X participants after TEAM ends to begin CJR–X participation on January 1, 2031.

After consideration of the public comments, we are finalizing with modification the proposals at § 512.605 to define ''performance year'' to mean a calendar year, the ''model start date'' to mean January 1, 2028. We are also finalizing with modification our

proposal at § 512.630(a) to begin the model on January 1, 2028.

b. Participants

(1) Background

The CJR Model incentivized coordination between hospitals, clinicians, and post-acute care providers (that is, home health agencies (HHAs), skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs), as defined at section 1899B(a)(2) of the Act) to improve outcomes and reduce spending for beneficiaries undergoing an LEJR procedure. The model required participation by most acute care hospitals in selected geographical areas, unless they met certain exceptions. Based on the CJR Model evaluations, participant hospitals were able to decrease spending while maintaining quality. Therefore, we believe expanding the CJR Model nationally to all eligible hospitals will increase its impact.

(2) CJR–X Participant Definition

Consistent with the CJR Model, we proposed that hospitals would be the model participants in CJR–X. Because it is the hospital that furnishes the surgical procedure, we believe it is most straightforward and appropriate for the hospital to be the model participant. Hospital staff already manage discharge needs and placement recommendations as part of post-procedural or post-discharge care for beneficiaries. In addition, hospitals are more likely than other providers or suppliers to have access to the resources to appropriately manage and coordinate care throughout the episode and have an adequate volume of episodes to warrant investment in more robust care coordination. For the purposes of CJR–X, the term ''hospital'' means a hospital as defined in section 1886(d)(1)(B) of the Act, which includes only acute care hospitals and excludes certain specialty hospitals, such as psychiatric and cancer hospitals. Although the CJR Model was confined to certain geographic areas, we proposed at § 512.610(a) that CJR–X participation would be mandatory for all acute care hospitals nationwide, provided they meet the ''CJR–X participant'' definition.

We proposed to define a ''CJR–X participant'' as an acute care hospital located in any of the 50 United States, District of Columbia, or U.S. Territories that initiates LEJR episodes and is paid under both the IPPS and OPPS, unless it meets an exception described in section X.C.2.b.(2)(a) of this final rule. We believe that only including acute care hospitals that bill for services under both the IPPS and OPPS is necessary to avoid potential challenges related to constructing target prices for episodes that initiate in either the inpatient or outpatient department of a hospital but are not paid under the IPPS or OPPS, respectively. Specifically, this policy would exclude Indian Health Service (IHS) and Tribal hospitals from CJR–X participation as they are paid under the IPPS but not the OPPS, as described in § 419.20 of this chapter. Similarly, hospitals participating in the Rural Community Hospital Demonstration, Critical Access Hospitals, and Rural Emergency Hospitals would also be excepted because they are not paid under IPPS.

Further, we proposed at § 512.610(a)(2) that CJR–X participants will remain CJR–X participants, unless they no longer meet the definition of CJR–X participant, CMS terminates CJR–X, or the CJR–X participant receives notice of termination from CJR–X in accordance with § 512.165.

We considered but did not propose including Ambulatory Surgery Centers (ASCs) as CJR–X participants. Including ASCs would present a significant departure from the CJR Model test.

We sought comment on our proposal at § 512.605 to define ''hospital'' as defined in section 1886(d)(1)(B) of the Act and ''CJR–X participant'' as a hospital located in any of the 50 States, District of Columbia, or U.S. Territories that initiates LEJR episodes and is paid under both the IPPS and OPPS. We also sought comment on our proposals at § 512.610(a) that CJR–X participation would be mandatory for all eligible acute care hospitals nationwide and that CJR–X participants will remain CJR–X participants, unless they no longer meet the definition of CJR–X participant, CMS terminates CJR–X, or the CJR–X participant receives notice of termination from CJR–X in accordance with § 512.165.

The following is a summary of the public comments received.

Comment: A commenter supported the proposal to define ''hospital'' for purposes of CJR–X by reference to section 1886(d)(1)(B) of the Act, which excludes certain specialty hospitals, such as psychiatric and cancer hospitals.

Response: We appreciate the commenter's support for excluding specialty hospitals.

Comment: Some commenters supported CMS' proposed ''CJR–X participant'' definition and the exclusion of Critical Access Hospitals and other acute care hospitals that do not bill for services under both the IPPS and OPPS. Commenters generally agreed that these exclusions were appropriate for CJR–X participant eligibility. A commenter stated that CJR–X may incentivize hospitals to better coordinate with post-acute care providers.

Response: We appreciate the commenters' support of our proposal to exclude certain hospitals from the ''CJR–X participant'' definition and related exclusions. As previously discussed in this section of the final rule, we proposed that a CJR–X participant must be paid under both the IPPS and OPPS. This policy is to account for the inclusion of both inpatient and outpatient episodes and the challenges that including hospitals not paid under both payment systems would create in constructing target prices. This approach will exclude, among others, IHS and Tribal hospitals paid under IPPS but not OPPS, hospitals participating in the Rural Community Hospital Demonstration, Critical Access Hospitals, and Rural Emergency Hospitals that are not paid under IPPS. We maintain that these exclusions will provide a workable and consistent pricing methodology for inpatient and outpatient LEJR episodes. We note that to be a CJR–X participant, we proposed that a hospital must be paid under both the IPPS and OPPS. That is, a hospital must not be excluded from either of those payment systems. Hospitals are not required to receive payment through both payment systems in a given performance year to be a CJR–X participant. Therefore, to be more precise, we are updating the wording of the ''CJR–X participant'' definition to reflect IPPS and OPPS payment eligibility rather than actual payment.

Comment: Some commenters recommended that CMS permit physician group practices (PGPs), physician-owned hospitals (POHs), and others that have participated in bundled payment models and other APMs to manage or initiate episodes in CJR–X, as convening or collaborative participants. A few commenters stated that orthopedic PGPs are a natural fit for CJR–X because of their experience in bundled payment models and their role in clinical decision-making for LEJR procedures. A commenter stated that, specifically for hip and knee replacements, orthopedic PGPs generated savings for Medicare and quality improvements for patients. They recommended that CMS give operating surgeons and physician groups the ability to oversee the bundle, including collecting payments and accepting two-sided risk across the spectrum of care.

Commenters stated that PGPs and POHs have demonstrated success in BPCI, BPCI Advanced, and CJR by improving outcomes, increasing care efficiency, and reducing Medicare costs. Another commenter stated that more must be done to recognize and favor the physician's role as the individual responsible for clinical care.

Response: We appreciate commenters' recommendations to include physicians and physician-led organizations in CJR–X. We recognize that physicians, including orthopedic surgeons, play an important role in clinical care, selection of surgical setting, beneficiary engagement, and episode performance. We also acknowledge the contribution of PGPs in BPCI Advanced and other voluntary models and do not doubt that many PGPs would be equally successful participants in CJR–X. We recognize that many PGPs would have the necessary infrastructure and episode volume to drive care redesign activities and coordinate care throughout the 90-day episode. However, as previously stated in this section of the final rule, CMS proposed to define a CJR–X participant as an acute care hospital that is paid under both the IPPS and OPPS to avoid challenges related to constructing target prices for episodes that initiate in either the inpatient or outpatient setting. Because physicians are paid under the Physician Fee Schedule, target price construction would be subject to additional challenges.

Finally, commenters recommended including PGPs as voluntary participants, although CJR–X is being finalized as a mandatory model. However, we did not propose to make PGPs model participants or episode initiators. Nevertheless, physicians, PGPs, and other providers and suppliers may participate through CJR–X collaborator arrangements, including sharing arrangements and distribution arrangements, subject to model requirements and applicable fraud and abuse safeguards, as described in section X.C.2.i. of this final rule.

Comment: A few commenters urged CMS to allow ASCs to be voluntary participants, as they are optimized for elective total joint replacements. They stated surgeons are able to shift appropriate procedures to these lower-cost settings, while maintaining or improving quality outcomes. Other commenters disagreed stating that including ASCs would enable surgeons who own ASCs to draw preferred patients away from hospitals, leaving only the more challenging and costly patients to receive hospital treatment.

Response: We thank commenters for these suggestions. We considered but did not propose including ASCs as participants in the CJR–X Model. However, we do recognize that the role of ASCs in episode-based payment models continues to evolve. Accordingly, we issued a request for information regarding the potential inclusion of ASCs in TEAM in section X.A.2.d. of the proposed rule. Information received through that request, together with evidence generated through TEAM implementation and subsequent evaluation reports, may provide additional insight into the feasibility and implications of including ASCs as accountable participants in episode-based payment models.

Comment: Many commenters supported mandatory participation for eligible acute care hospitals in CJR–X. Commenters stated that a mandatory model could reduce selection bias and produce more reliable evidence than a voluntary model. They suggested that mandatory participation could broaden accountability for LEJR episodes, support care coordination, and advance value-based care. Some commenters viewed mandatory participation as an opportunity to create a stronger glidepath toward accountable care and specialist accountability.

Response: We appreciate commenters' support for mandatory participation for eligible acute care hospitals in CJR–X. We agree that mandatory participation is an important feature of CJR–X because it will broaden accountability for LEJR episodes and support a more robust assessment of the model's impact across eligible acute care hospitals. Accordingly, CJR–X participation will be mandatory for acute care hospitals that meet the CJR–X participant definition, subject to the proposed participant exceptions, including TEAM participants and Maryland hospitals.

Comment: Many commenters did not support mandatory participation and recommended that CMS make CJR–X voluntary. Commenters stated that a mandatory model would impose substantial administrative, operational, and compliance costs on hospitals. A commenter also raised concerns about data analysis, care redesign, and financial risk management costs related to model implementation. Many commenters suggested that hospitals differ significantly in size, resources, infrastructure, local markets, patient populations, and post-acute care access, and that a mandatory nationwide model may not account for those differences. Some commenters stated that hospitals with limited prior bundled payment experience may need time to build infrastructure and partnerships before assuming downside risk.

Other commenters recommended opt-in participation, broader exemptions, or hospital discretion to determine whether the model is feasible for their communities. Many commenters recommended that CMS provide voluntary or phased participation for specific hospitals, such as rural, safety net, smaller, sole community, and Medicare-dependent, small rural hospitals. A commenter recommended that CMS incorporate tiered participation tracks, including an option for safety net providers to participate without downside risk. Commenters stated that these hospitals often operate with thinner margins, fewer staff, lower episode volumes, and fewer resources for analytics and care redesign. They expressed concern that even limited downside risk could be difficult for financially-fragile hospitals to absorb. Commenters suggested that mandatory participation could worsen access challenges in communities that rely on these hospitals.

Response: We appreciate commenters' requests for additional flexibilities for certain hospitals. Although we believe that many hospitals have prior experience with LEJR episodes or episode-based payment models, we recognize that readiness may vary across hospitals. Therefore, as discussed in section X.C.2.a of this final rule, we are finalizing a start date of January 1, 2028 to increase the preparation time for hospitals that do not already have processes in place to meet the model requirements. We note that the CJR Model was implemented with significantly less lead time and hospital participants were able to successfully meet the model requirements. We continue to believe that CJR–X participants will have ample time and capacity to prepare for CJR–X, particularly with a later start date. In addition, we will be providing educational guidance and implementation support prior to the model start. We encourage readers to visit the CJR–X website at *https://www.cms.gov/priorities/innovation/innovation-models/cjr-x* for model updates. For reasons discussed in the proposed rule, we are not considering voluntary participation at this time.

Comment: Some commenters stated that integrated health systems may have some hospitals participating in TEAM and other hospitals participating in CJR–X. These commenters stated that this could require the same health system to manage different LEJR episode lengths, attribution rules, workflows,

and model requirements across facilities. A commenter stated that requiring health systems to participate in multiple mandatory episode-based payment models simultaneously, including TEAM and CJR–X, creates significant operational and clinical confusion. They stated that under the proposed framework, health systems would be required to manage patients across distinct bundles with different attribution rules, episode durations, post-acute responsibility, and financial risk structures.

Response: We are implementing CJR–X based on the previous test and belief that it is appropriate for the majority of acute care hospitals. We also continue to test new Innovation Center payment models, such as TEAM, and iterate upon previous policies based on ongoing model evaluations and stakeholder feedback. We recognize that many hospitals are part of larger health systems and may operate differently than other hospitals within that system depending on patient population, available services, location, or other factors. However, health systems regularly manage and successfully implement various programs with different payment policies and rules in a subset of their hospitals. For instance, it is not uncommon for specialty-designated hospitals, such as cancer hospitals, to be part of a larger health system. Therefore, we do not believe that ownership of several hospitals should preclude a systems' participation in applicable CMS' programs and policies.

Final response: After consideration of the public comments we received, we are finalizing without modification our proposal at § 512.605 to define ''hospital'' as defined in section 1886(d)(1)(B) of the Act. We are finalizing with modification the ''CJR–X participant'' definition at § 512.605 to be a hospital located in any of the 50 States, District of Columbia, or U.S. Territories that initiates LEJR episodes and is eligible to be paid under both the IPPS and OPPS. We are also finalizing without modification our proposal at § 512.610(a)(1) that CJR–X participation is mandatory for any hospital that meets the CJR–X participant definition. We did not receive comment on our proposal at § 512.610(a)(2) that CJR–X participants will remain CJR–X participants, unless they no longer meet the definition of CJR–X participant, CMS terminates CJR–X, or the CJR–X participant receives notice of termination from CJR–X in accordance with § 512.165. However, we realized we introduced a technical error by including the reference to § 512.165, which relates to notices of termination provided to model participants only in the event of the termination of the model test in its entirety. To provide clarification on when a model participant may receive a notice of termination, outside of the termination of CJR–X, and to avoid including duplicative provisions in § 512.610(a)(2), we have inserted a separate provision addressing the notice of termination at § 512.610(c), which is discussed in section X.C.2.m. of this final rule. Accordingly, we are finalizing with modification our proposal at § 512.610(a)(2) that CJR–X participants will remain CJR–X participants, unless they no longer meet the definition of CJR–X participant, CMS terminates the CJR–X participant in accordance with § 512.610(c), or CMS terminates CJR–X in accordance with § 512.165. As we did in the CJR model, we expect to post a list of the CJR–X participants on the CJR–X website for the 2028 performance year/2030 payment year by the end of 2026. We anticipate this list would be updated on a quarterly cadence, to account for hospital mergers, closures, or other instances that would result in a hospital being added or removed from CJR–X participation.

(a) CJR–X Participant Exclusions

We proposed at § 512.610(b)(1) to exclude hospitals that are TEAM participants. Although LEJR episodes in TEAM are similar to LEJR episodes in CJR–X, there are a few key differences. Most notably, TEAM tests 30-day episodes, while CJR–X would continue testing the 90-day episodes that demonstrated savings in the CJR Model. Excluding TEAM participants from CJR–X would allow us to compare the impacts of 30- and 90-day episodes on savings and quality of care while maintaining a consistent methodology across all five TEAM episodes. Moreover, we believe that subjecting TEAM participants to CJR–X rules for LEJR episodes and TEAM rules for the remaining four TEAM episodes would create confusion for providers and deviate from a consistent testing methodology.

We note that the TEAM exclusion applies to both mandatory and voluntary TEAM participants, as voluntary TEAM participants must remain in the model until its conclusion per § 512.510(a). We also note that this exclusion would expire at the conclusion of the TEAM test or if at any point a TEAM participant no longer meets the TEAM participant definition, at which point TEAM participants that meet CJR–X participant definition at § 512.605 would become CJR–X participants. In addition, while it is too early to make assumptions about the model test, should TEAM be expanded in the future, we would evaluate whether to continue LEJR in either TEAM or CJR–X, as we do not envision LEJR episodes being expanded in both concurrently.

We proposed at § 512.610(b)(2) to exclude acute care hospitals in the State of Maryland because of its unique rate-setting authority, as described in section X.C.2.f.(3)(a) of this final rule. We do not believe that the regional pricing methodology used in CJR–X would accurately reflect episode spending for Maryland hospitals. We acknowledge that the State of Maryland is participating in the Achieving Healthcare Efficiency through Accountable Design (AHEAD) model, with which CJR–X would allow concurrent participation. Further, we are aware that Maryland's rate setting authority is in transition and will conclude at the end of 2027. As stated in the proposed rule, we may consider, through future notice and comment rulemaking, modifications to our finalized policy to exclude Maryland from CJR–X and our finalized policy to permit concurrent participation with the AHEAD model.

We sought comment on our proposals at § 512.610(b) to exclude TEAM participants and Maryland hospitals from CJR–X. The following is a summary of the public comments received.

Comment: Many commenters supported CMS' proposal to exclude hospitals participating in TEAM from CJR–X during their TEAM participation. Commenters stated that this exclusion would avoid duplicative episode accountability, beneficiary confusion, reporting burden, and reconciliation complexity for overlapping LEJR episodes. Some commenters also supported CMS' proposed attribution approach under which TEAM generally supersedes CJR–X for TEAM hospitals, except where a TEAM-qualifying procedure occurs during an existing CJR–X episode and is included in the CJR–X episode instead. Commenters asked CMS to continue coordinating TEAM and CJR–X overlap policies and to provide clear examples in subregulatory guidance.

Response: We appreciate commenters' support for excluding TEAM participants from CJR–X during the TEAM test period. We believe avoiding duplicative episode accountability will reduce beneficiary confusion and provider burden. Under the CJR–X proposal, hospitals participating in TEAM would be exempt from CJR–X

until the end of the TEAM model test. We also proposed episode cancellation and precedence rules for beneficiaries whose care could otherwise overlap across TEAM and CJR–X, as discussed in section X.C.2.d.(3) of this final rule. These policies are intended to avoid duplicative calculations for the same procedure, preserve clear accountability for the anchoring provider, and reduce model-overlap complexity for participants and beneficiaries. In addition, excluding TEAM participants preserves the ability to evaluate the models' differences. To help participants prepare for implementation, clear guidance regarding model policies will be maintained on the CJR–X website at *https://www.cms.gov/priorities/innovation/innovation-models/cjr-x.*

Comment: Many commenters raised concerns regarding transitioning TEAM hospitals into CJR–X in future years. A few commenters stated that late-entering hospitals would be disadvantaged compared to hospitals that had participated in CJR–X from the beginning. They requested clarity on how we would ensure equitable benchmarking and target price setting across cohorts entering at different times and whether historical TEAM performance would be incorporated into CJR–X benchmarking. Commenters stated that TEAM hospitals will have invested in TEAM-specific care redesign, data systems, quality reporting, care coordination, and workflows, and that immediate transition into CJR–X could create administrative burden and structural disadvantage. Some commenters urged CMS to allow TEAM hospitals to voluntarily elect whether to participate in CJR–X after TEAM ends. Because TEAM hospitals may already have implemented LEJR care redesign and achieved efficiencies under TEAM, they should be allowed to choose whether CJR–X participation is appropriate after TEAM ends. Some commenters requested phase-in options for health systems with hospitals in both TEAM and CJR–X. Commenters requested that CMS publish a clear transition framework before the end of the TEAM test.

Response: We appreciate commenters' concerns regarding the proposed transition of TEAM hospitals into CJR–X after TEAM ends or when a hospital no longer meets the TEAM participant definition. We recognize that hospitals may make model-specific investments and may have questions about operational readiness and treatment of prior TEAM experience. However, we believe that any TEAM care redesign activities will continue to benefit and be applicable to care pathways under CJR–X. Accordingly, we will strive to align CJR–X and TEAM policies wherever possible to effectuate as smooth a transition as possible when TEAM concludes.

We continue to believe it is reasonable that hospitals participating in a geographically- and time-limited model, such as TEAM, would become subject to the participation requirements applicable under a mandatory national model, such as CJR–X, once they no longer qualify for a particular participant exclusion. As discussed in the proposed rule, voluntary participation by hospitals that meet the ''CJR–X participant'' definition, is not supported by experience with the original CJR Model.

Our goal is to test multiple value-based methodologies and adopt the most beneficial and effective policies, even if that means iterating on previously implemented CJR–X Model design. Therefore, we recognize that the design of either model could change over time, including policies related to participation, benchmarking, financial methodology, or model duration. As implementation experience accumulates, there may be additional approaches that better facilitate transitions between the models than those currently contemplated. While we continue to believe that defaulting TEAM hospitals to the participation requirements applicable under CJR–X is appropriate under the models as currently designed, we remain open to considering alternative transition approaches in the future should experience, evaluation results, or future policy considerations warrant them. We also intend to provide appropriate operational guidance to support hospitals in advance of any future transition. Any future modifications to the relationship between TEAM and CJR–X, including transition policies or participation options following the conclusion of TEAM, would be proposed through future notice and comment rulemaking, as appropriate.

Comment: Some commenters supported CMS' proposal to exclude Maryland hospitals from CJR–X. Commenters stated that Maryland's rate-setting authority provides a basis for excluding those hospitals from the model. They supported CMS' recognition that Maryland hospitals are subject to a distinct payment environment. A commenter recommended that CMS consider excluding hospitals in AHEAD states from CJR–X. The commenter stated that hospitals preparing for an AHEAD global budget payment methodology may need to focus on that transition. The commenter suggested that overlap between CJR–X and hospital global budgets could create operational or payment complexity.

Response: We appreciate commenters' support for the proposed exclusion of Maryland hospitals from CJR–X. We proposed this exclusion because Maryland's unique rate-setting authority would make the proposed CJR–X regional pricing methodology unsuitable for accurately reflecting episode spending for Maryland hospitals. We acknowledge that Maryland is participating in AHEAD and that Maryland's rate-setting authority is in transition. As stated in the proposed rule, we may consider, through future notice and comment rulemaking, modifications to our finalized policy to exclude Maryland from CJR–X and our finalized policy to permit concurrent participation with the AHEAD model.

Comment: Many commenters recommended additional participant exceptions. Many commenters recommended that CMS exclude rural, low-volume, or otherwise resource-constrained hospitals. A commenter stated many hospitals will have had limited direct experience with bundled payment models. Many commenters stated that hospitals with limited episode volume and infrastructure capability would have difficulty with mandatory CJR–X participation. A commenter asked that CMS test CJR–X with rural and smaller hospitals on a more limited scale. Another commenter stated that hospitals with fewer than 100 lower extremity joint replacements per performance year should not be subject to mandatory CJR–X participation. Several commenters stated that rural hospitals are already experiencing financial pressure, including Medicare payment rates below the cost of care, Medicare Advantage losses, Medicaid payment reductions, and limited staffing and resources. The commenters expressed concern that mandatory downside risk under CJR–X could further strain financially fragile rural hospitals and could contribute to hospital closures or reduced access to care in the communities they serve. A commenter stated that sole community hospitals are the sole source of care for Medicare beneficiaries in large rural areas and are currently facing numerous financial challenges. Some commenters recommended that CMS create an exception or flexibility process based on post-acute care access, community resources, or local market constraints. Commenters stated that hospitals that

face major deficits in post-acute care access or other community should not be penalized when patient needs and community resources make care in a particular setting appropriate. Commenters recommended exceptions, hardship processes, or flexibility where local resources limit a hospital's ability to manage the episode. Commenters stated that reduced stop-loss limits may not be sufficient protection for hospitals with small or negative margins and recommended categorical exclusions, hardship exemptions, modified participation, delayed participation, or optional participation for these hospitals.

Response: We appreciate concerns regarding potential burden and financial impact of mandatory downside risk for rural hospitals, sole community hospitals, Medicare-dependent, small rural hospitals, and low volume hospitals. We disagree that additional hospitals that perform more than 31 episodes in the baseline period should be excluded from the model. Many low volume hospitals were able to successfully implement and perform well in the CJR Model.

To reduce burden, we are finalizing policies which eliminate CJR–X specific quality reporting and are relying on data submitted to other hospital quality reporting programs. In addition, we are finalizing the model in the FY 2027 IPPS to give CJR–X participants additional time to prepare for implementation. We found that low-volume status and performance were correlative, but volume was not a necessarily causative factor of poor performance. However, if the hospital also provided care to a high-proportion of dual-eligible beneficiaries, there was a greater risk of poor performance. In light of this, we considered the combination of those factors when determining the payment methodology for CJR–X. We are finalizing as proposed a low-volume threshold of 31 episodes for reconciliation, as discussed in section X.C.2.f.(3)(h) of this final rule, and a hospital-level safety net risk-adjuster for hospitals with a higher proportion of dual-eligible beneficiaries, discussed in section X.C.2.f.(4) of this final rule. To clarify, hospitals that meet the CJR–X participant definition will be participants and the low-volume threshold is not a criterion of that definition. However, we will exclude from reconciliation CJR–X participants that don't meet the low-volume threshold.

We recognize the importance of rural access considerations in designing a national episode-based payment model and that some hospitals may have fewer resources than others. We also recognize that post-acute care access, community resources, and local market constraints may affect how hospitals manage LEJR episodes. However, quality outcomes for rural beneficiaries are affected by cost variation, care transitions, and post-acute care patterns and including these hospitals will help us to understand how the model works for hospitals with different resources, patient populations, and post-acute care access. In addition, including rural hospitals with lower volume or fewer post-acute options enables us to monitor these issues directly rather than assuming the model effects in rural communities.

Nevertheless, given these challenges, we have included policies that help to protect rural hospitals from significant financial loss. For example, we are finalizing as proposed a lower stop-loss limit for rural hospitals to minimize extreme losses in repayment amounts, as discussed in section X.C.2.f.(5)(g) of this final rule. Since some hospitals, including many rural hospitals, may have low LEJR volume, we are also finalizing the proposal to exclude low volume hospitals from reconciliation, as discussed in section X.C.2.f.(3)(h) of this final rule. The low volume hospital policy effectively eliminates upside and downside risk so that low volume CJR–X participants are not disadvantaged by their limited capacity to distribute financial risk or implement efficient operational processes.

We will monitor rural hospital experience, including effects on quality, beneficiary access, and operational burden, and may take this into consideration in future notice and comment rulemaking.

After consideration of the public comments we received, we are finalizing without modification our proposal at § 512.610(b) to exclude TEAM participants and Maryland hospitals from CJR–X.

c. Beneficiary Population

We proposed at § 512.620(a) that the beneficiaries whose care would be included in CJR–X would include those who meet the following beneficiary inclusion criteria at the time of their anchor procedure or anchor hospitalization:

- Is enrolled in Medicare Part A and Part B;
- Has Medicare as their primary payer;
- Is not eligible for Medicare on the basis of end-stage renal disease, as described at § 406.13;
- Is not enrolled in any managed care plan (for example, Medicare Advantage, Health Care Prepayment Plans, cost-based health maintenance organizations);
- Is not covered under a United Mine Workers of America health plan, which provides health care benefits for retired mine workers; and
- Is in an episode, as defined at § 512.605.

We believe this is the most appropriate Medicare population to include in CJR–X because it aligns with the CJR Model population tested. Excluding beneficiaries enrolled in managed care or covered by payment systems other than the IPPS and OPPS ensures that CMS has complete and consistent claims data across the full episode of care, including inpatient, outpatient, physician, and post-acute services, which is essential for setting target prices, calculating episode spending, and assessing quality performance. In addition, excluding beneficiaries with Medicare eligibility based on end-stage renal disease and those with other primary payers helps reduce clinical and financial heterogeneity that could compromise comparability across episodes and participant hospitals. Together, these eligibility criteria ensure that CJR–X hospitals are held accountable only for episodes for which Medicare has primary payment responsibility and complete data visibility.

We recognize that a CJR–X episode could be initiated for a beneficiary who ceases to meet the beneficiary inclusion criteria at some point during the episode. In this case, we proposed at § 512.620(b) that we would cancel the episode. We sought comment on the proposed beneficiary inclusion criteria and the proposal to cancel episodes if a beneficiary no longer meets that criteria at § 512.620.

The following is a summary of the public comments received on our proposed beneficiary inclusion criteria and the proposal to cancel episodes if a beneficiary no longer meets those criteria.

Comment: Several commenters requested that CMS clarify and explicitly require that beneficiaries meet the inclusion criteria throughout both the clinical episode period and the 180-day lookback period used for risk adjustment. Specifically, they asked that Medicare explicitly codify the regulation to include the continuous enrollment in Medicare Part A and Part B, as primary payer and exclude managed care enrollment, for the entirety of the 180-days prior to the procedure. Since risk adjustment relies on HCC diagnoses, prior post-acute care use, and economic risk captured during the 180-day period preceding the

procedure, without continuous enrollment, risk adjustment may be incomplete or inaccurate. The commenters urged CMS to refine eligibility for concordance with the proposed risk adjustment policy.

Response: We appreciate the comments and are happy to clarify that the beneficiary inclusion criteria would require continuous enrollment in Medicare Part A and B for the 180 days prior to the episode start date. In addition, we are finalizing updated language for the beneficiary inclusion criteria to reflect the 180-day lookback period.

Comment: A commenter stated it is not obvious to hospitals and providers whether patients are enrolled in Medicare as a result of end-stage renal disease (ESRD). They asked CMS to provide additional information for which patients are excluded due to their enrollment in Medicare's ESRD benefit.

Response: We appreciate the commenter's concern. CJR–X participants may request and receive beneficiary-identifiable claims data during the performance year which can help CJR–X participants identify those beneficiaries that are initiating episodes in the model and which beneficiaries may be excluded due to not meeting the inclusion criteria. Our data sharing provisions are further discussed in section X.C.2.k.(2) of this final rule.

Comment: A commenter urged CMS to prioritize and work toward including Medicare Advantage (MA) enrollees in the CJR–X beneficiary population because more than half of Medicare beneficiaries are enrolled in a Part C plan. They stated excluding MA enrollees who receive total joint replacements means the agency is not capturing relevant data on the costs and outcomes for more than 50% of these high-cost surgical interventions.

Response: We appreciate the commenter's concerns. To reduce participant burden, CJR–X is relying solely on the quality data submitted to the existing hospital quality reporting programs. Although the measure specifications are out of scope for this model, we do note that the Medicare Advantage program is itself a value-based program. As such, Medicare Advantage has its own cost reporting and quality requirements which aid in capturing data on the costs and outcomes of enrollees.

After consideration of the public comments we received, we are finalizing with modification the proposed beneficiary inclusion criteria at § 512.620(a) as follows:

''An individual is a CJR–X beneficiary if, based on a 180-day lookback period that ends on the day prior to an anchor procedure or anchor hospitalization, the individual—

(1) Is enrolled in Medicare Parts A and B;

(2) Has Medicare as their primary payer;

(3) Is not eligible for Medicare on the basis of having end stage renal disease, as described at § 406.13 of this chapter;

(4) Is not enrolled in any managed care plan (for example, Medicare Advantage, health care prepayment plans, or cost-based health maintenance organizations);

(5) Is not covered under a United Mine Workers of America health care plan; and

(6) Is in an episode.''

(1) Beneficiary Notification

We proposed CJR–X because we believe it offers an opportunity to improve quality of care. We believe that the policies of the model would make care more easily accessible to consumers when and where they need it and increase beneficiary engagement and choice. For example, we proposed certain waivers which would offer CJR–X participants additional flexibilities with respect to furnishing telehealth services and care in SNFs, as discussed in section X.C.2.j. of this final rule. In the proposed rule, we noted that these same opportunities could also be used to try to steer beneficiaries into lower cost services without an appropriate emphasis on maintaining or increasing quality given the incentives to reduce Medicare spending in the model.

We stated that existing Medicare provisions would be effective in protecting beneficiary freedom of choice and access to appropriate care under CJR–X. Further, since CJR–X would be expanded nationally, diverting care to hospitals not in the model would be less of an issue given CJR–X's broad scale. Because we proposed mandatory hospital participation, individual beneficiaries would not be able to opt out of CJR–X when they receive care from a CJR–X participant. Moreover, allowing beneficiaries to opt out would be inconsistent with other Medicare policies. For example, we do not allow beneficiaries to opt out of a payment system, such as the IPPS, but we do not believe that to be a critical factor in upholding beneficiary choice if other safeguards are in place. Specifically, we do not believe this would be an issue for CJR–X, given that this model does not increase beneficiary cost-sharing. However, CJR–X beneficiaries are not precluded from seeking care from providers or suppliers who do not participate in CJR–X. We stated in the proposed rule that full notification and disclosure of the payment model and its possible implications would be critical for CJR–X beneficiary understanding and protection and important to create safeguards for CJR–X beneficiaries to ensure that care recommendations are based on clinical needs and not inappropriate cost savings. It is also important for CJR–X beneficiaries to know that they can raise any concerns with their clinicians, 1–800–MEDICARE, or their local Quality Improvement Organizations (QIOs).

We stated that the CJR–X Model will neither limit a CJR–X beneficiary's ability to choose providers nor limit Medicare's coverage of items and services available to the CJR–X beneficiary. CJR–X beneficiaries may continue to choose any Medicare participating provider, or any provider who has opted out of Medicare, with the same costs, copayments, and responsibilities as they have with other Medicare services. As discussed in section X.C.2.(m) of this final rule, CJR–X participants will be subject to the standard provisions at §§ 512.100 through 190, including the beneficiary protections noted in § 512.120 that cover beneficiary freedom of choice, availability of services, and descriptive model materials and activities.

Further, the model will allow CJR–X participants to enter into CJR–X sharing arrangements with certain providers, as proposed in section X.C.2.i.(4) of this final rule, and these preferred providers may be recommended to CJR–X beneficiaries as long as those recommendations are made within the constraints of current law. However, CJR–X participants may not limit CJR–X beneficiaries to a preferred or recommended providers list.

This model does not create any restriction of beneficiary freedom to choose providers, including surgeons, hospitals, post-acute care or any other providers or suppliers. Moreover, we anticipate that care pathway redesign that occurs in response to the model will increase coordination of care, improve the quality of care, and decrease cost for all patients, not just Medicare beneficiaries. As it would be unlikely that providers would treat individuals differently based on health care insurance, we anticipate care delivery impacts to promote consistent treatment of all beneficiaries.

We proposed at § 512.622(a)(1) that every CJR–X participant must provide written notification to each CJR–X beneficiary of his or her inclusion in the CJR–X Model. We stated that appropriate beneficiary notification should explain the model, advise

patients of both their clinical needs and their care delivery choices, and should clearly identify any CJR–X collaborator, as defined at § 512.605. That is, we proposed that the CJR–X participant would be required to disclose any providers, suppliers, or other entities with which the CJR–X participant holds a sharing arrangement as a ''financial partner of the hospital for the purposes of participation in CJR–X.''

We stated that the notification would enhance CJR–X beneficiaries' understanding of their care and is an important safeguard for ensuring CJR–X beneficiaries receive all medically necessary services. We also highlighted it as an important clinical opportunity to better engage CJR–X beneficiaries in shared decision-making and understanding competing benefits, even as they are presented with cost-saving recommendations. Therefore, we proposed at § 512.622(a)(4) that the CJR–X beneficiary notification must:

- Explain the CJR–X Model and how it might be expected to affect the CJR–X beneficiary's care;
- Inform CJR–X beneficiaries that they retain freedom of choice to choose providers, suppliers, and services;
- Explain how the CJR–X beneficiary can access care records and claims data through an available patient portal and through sharing access to care-givers to their Blue Button® electronic health information;
- Explain that CJR–X participants may receive beneficiary-identifiable claims data;
- Advise CJR–X beneficiaries that all standard Medicare beneficiary protections remain in place, including the ability to report concerns of substandard care to QIOs and 1–800–MEDICARE; and
- Provide a list of the CJR–X collaborators with which the CJR–X participant has a sharing arrangement.

We recognized that an exhaustive list of CJR–X collaborators may lengthen the beneficiary notification, unnecessarily. Therefore, we stated this requirement may be fulfilled by the CJR–X participant including in the detailed notification a publicly available web address where CJR–X beneficiaries may access the CJR–X collaborators list.

After carefully considering the appropriate timing and circumstances for the necessary CJR–X beneficiary notification, we proposed at § 512.622(a)(2) that CJR–X participants must provide the CJR–X beneficiary notification prior to discharge from either the anchor hospitalization or the anchor procedure for a Medicare beneficiary who would be included under the model. The purpose of the proposed policy was to ensure that all CJR–X beneficiaries received the beneficiary notification materials, and that they received such materials as early as possible but no later than discharge from the hospital or hospital outpatient department. We stated that the proposal would increase the likelihood that patients would become engaged and seek to understand CJR–X and its potential impact on their care, particularly in the post-discharge period.

We also considered whether to require CJR–X participants to provide this information at the point of admission, as hospitals provide other information concerning patient rights and responsibilities at that time. However, we recognized that, due to a CJR–X beneficiary 's condition, it may not be feasible to provide notification at such time. We invited comments on ways in which the timing and source of beneficiary notification could best serve the needs of CJR–X beneficiaries without creating unnecessary administrative work.

In addition, we proposed at § 512.622(b) that CJR–X participants would have to require every CJR–X collaborator to provide written notice to applicable CJR–X beneficiaries describing the existence of a sharing arrangement with the CJR–X participant and the basic quality and payment incentives under the model. We proposed that the notice be provided no later than the time at which the beneficiary first receives an item or service from the CJR–X collaborator during an episode. We recognized that due to the patient's condition, it may not be feasible to provide notification at such time, in which case the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. We stated that if the beneficiary notification policy was finalized, CMS would post a CJR–X collaborator template for use by CJR–X participants on the CJR–X website.

We considered, but did not propose, requiring the CJR–X beneficiary notifications only during the years that both CJR–X and TEAM are implemented. Under such a policy, after TEAM ended, we would no longer have required CJR–X beneficiary notifications since all hospitals nationwide, barring any excluded hospitals from CJR–X, would be held accountable for LEJR episodes. We also considered, but did not propose, not requiring the CJR–X beneficiary notifications. We acknowledged other CMS initiatives, such as the Hospital Value Based Purchasing Program or the Expanded Home Health Value-Based Purchasing Model, do not require entities participating in those initiatives to provide beneficiary notifications. We recognized a model that is expanded nationally, such as CJR–X, would become standard practice for hospitals to manage beneficiaries in a LEJR episode of care. Therefore, the beneficiaries' experience or treatment options should not materially change between participating hospitals, nor should beneficiaries' or out-of-pocket costs, freedom of choice, or access to care differ. Further, we recognized that beneficiaries already receive a significant amount of information on discharge from the hospital or hospital outpatient department and a beneficiary notification may go unnoticed or be redundant. We stated that we believed the CJR–X participant would already be communicating to the CJR–X beneficiary the hospital's responsibility to manage the CJR–X beneficiary during the episode, including in the 90-day post-discharge period. Thus, we stated that the administrative burden of notification may outweigh its value.

We invited public comment on our proposed requirements for notification to CJR–X beneficiaries at § 512.622. We also sought comment on our consideration to not require CJR–X beneficiary notifications. The following is a summary of the public comments received on the proposed CJR–X notification requirements.

Comment: Many commenters opposed or recommended narrowing the proposed CJR–X beneficiary notification requirements. Commenters stated that requiring hospitals and collaborators to provide CJR–X-specific written notices would create unnecessary administrative burden, duplicate existing patient education and discharge communications, and provide little practical value to beneficiaries because CJR–X is mandatory and beneficiaries cannot opt out. A commenter stated that such notification is difficult to implement consistently across high-volume inpatient and outpatient surgical settings. Several commenters stated the notices could confuse or alarm beneficiaries even though model participation would not change cost-sharing or standard Medicare rights. A commenter suggested limiting notices to those with a direct care, financial impact, or actionable implication for the patient.

Response: We appreciate commenters' concerns about the administrative burden that may be associated with providing CJR–X Model information to beneficiaries. However, the Innovation Center has employed a similar

requirement for other mandatory models and model participants have successfully operationalized similar beneficiary notifications. We also acknowledge CMS' goal of eliminating unnecessary burden when possible and appropriate. While we do not wish to further confuse or overwhelm beneficiaries, we believe it necessary that beneficiaries are aware of the model, how it would or would not impact their care, and their continued beneficiary rights, including their freedom of choice to choose providers, suppliers, and services. The notification also provides beneficiaries with important information relating to their claims data.

Comment: Many commenters who opposed the hospital-level notice requirement did not oppose beneficiary education altogether. Instead, many commenters suggested CMS-led communication would be more consistent, less duplicative, and less burdensome than requiring each hospital and collaborator to maintain and distribute model-specific notices. Many commenters suggested vehicles such as the Medicare & You Handbook, an annual blanket notification, or a broad beneficiary communication campaign. Other commentors suggested CMS provide standardized templates and protocols if the requirement is finalized.

Response: We appreciate the recommendation for a CMS-directed beneficiary notification. As a Phase II model test, we are still distinct from the Medicare program. As such, including information in the Medicare & You Handbook would not be appropriate. However, as was done for the CJR Model, we plan to provide templates for the beneficiary notifications, which will be posted to the CJR–X website prior to the model start date.

Comment: A commenter stated that some episodes will not be coded as an LEJR MS–DRG until after the patient is discharged, so the patient would not get the notification before they leave the hospital. Another commenter strongly recommended that any notification be delivered during pre-operative conversations and/or patient joint education and that CMS permit electronic delivery. They stated that earlier disclosure allows beneficiaries freedom of choice to seek a provider who is not in the CJR–X Model and receiving the information after the service defeats this purpose.

Response: We believe there is sufficient time to identify CJR–X beneficiaries once the decision is made to furnish a joint replacement procedure, enabling CJR–X participants to provide CJR–X beneficiaries with the beneficiary notification prior to discharge. The notifications may be provided prior to or at any point during admission to reduce administrative and clinical burden on the discharging team. We also recognize that it may be easier for some CJR–X participants to provide the information as part of pre-operative planning, while, for others, more operationally feasible as part of discharge planning. Moreover, we agree that providing any information that may impact beneficiary choice or their recovery is preferable during the pre-operative period. We believe hospitals will have sufficient opportunity to provide notification prior to discharge, as the need will be known at the time of the LEJR procedure, despite any delay in coding the MS–DRG.

Comment: Some commenters support beneficiary notification requirements as a safeguard for transparency, beneficiary choice, and patient understanding. These commenters stated their belief that CJR–X financial incentives could encourage hospitals to steer beneficiaries toward lower-cost settings that may not align with patient wishes or treating clinician judgment. They stated that written notice could help beneficiaries understand their care options, their inclusion in the model, and their freedom to choose providers. A commenter urged CMS to inform beneficiaries about the CJR–X Model as it will be a mandatory, nationwide program. Another commenter stated that alignment with the content required for the TEAM model would decrease administrative burden. Another commenter stated CMS should at minimum require documentation of the beneficiary's post-acute care preference, the clinical basis for the discharge plan, and any reason the beneficiary's preferred setting was not selected.

Response: We thank commenters for providing their support of the beneficiary notification requirement. We agree that the CJR–X participants must not limit a beneficiary's access to care and must continue to make treatment decisions in the best interest of the beneficiary. We also expect that hospitals discuss with beneficiaries the clinical basis for discharge plans and reasons why a beneficiary's preferred setting may not be selected. However, we are not requiring further documentation for CJR–X participants. CJR–X participants may document beneficiary preferences, the clinical basis for the discharge plan, and related discussions in the beneficiary's electronic health record or other medical record documentation.

We agree that transparency remains necessary for beneficiary choice and engagement and continue to recognize the importance of disclosing financial relationships between participant hospitals and the service providers to whom they refer patients.

After consideration of the public comments we received, we are finalizing the beneficiary notification requirements for CJR–X at §§ 512.622(a), 512.622(b), and 512.622(d) as proposed.

However, we remain committed to reducing the administrative burden associated with the beneficiary notification policy and will consider updates to this policy through future notice and comment rulemaking, provided the change would not fundamentally alter beneficiary protections.

d. Episode

(1) Background

A key design feature of episode-based payment models is the definition of the episodes included in the model. The episode definition has two significant dimensions—(1) a clinical dimension that describes which clinical conditions and associated services are included in the episode; and (2) a time dimension that describes the beginning and end of the episode, its length, and when the episode may be cancelled prior to the end of the episode.

In testing payment models, we recognize the importance of there being clear potential for participating hospitals to successfully drive care improvements by streamlining care pathways and transitions between clinical settings. We aim to design models with episodes that are clinically similar, for which episode spending is more predictable. We also note that episodes with a greater proportion of spending in the post-acute period relative to the anchor hospitalization or anchor procedure offer greater opportunity for improved care transitions for beneficiaries to reduce unnecessary hospitalizations and emergency care.

Given the promising findings for LEJR in the CJR Model and BPCI Advanced, we believe there is value in an expansion of the CJR Model test through CJR–X, particularly given the high volume of LEJR procedures among the Medicare population. Based on 2021 Medicare claims data, LEJR episodes were the highest volume, highest cost of the BPCI Advanced surgical episode categories. There were 204,160 episodes with a total cost of $5.01 billion, with more than 40 percent of spending occurring in the post-acute period.

Moreover, based on the CJR Model evaluation, LEJR episodes continue to offer opportunities for improvement.

(2) Clinical Dimension of Episode

(a) Episode Definition (LEJR)

We proposed to define ''episode'' to mean all Medicare Part A and B items and services described in § 512.625(b) (and excluding the items and services described in § 512.625(c)) that are furnished to a beneficiary described in § 512.620 during the time period that begins on the date of the beneficiary's admission to an anchor hospitalization or the date of the anchor procedure, as described at § 512.625(a), and ends on the 90th day following the date of discharge from the anchor hospitalization or anchor procedure, with the date of discharge or date of the anchor procedure itself being counted as the first day in the 90-day post-discharge period, as described at § 512.630.

As discussed in section X.C.2.d.(3) of this final rule, in the case that an anchor hospitalization for the same episode type occurs within 3 days of an anchor procedure (that is, an outpatient procedure is later converted to an inpatient admission), the anchor procedure episode is not initiated, and the episode start date for the anchor hospitalization is the same as the outpatient procedure. This episode definition aligns with the CJR Model and TEAM, at § 510.2 and § 512.505, respectively, providing consistency across Innovation Center models. In addition, this policy aligns with Medicare's 3-day payment guidelines that require hospitals to bundle the technical component of outpatient services with the inpatient claim if they are related to the same condition and occur in the 3 days preceding inpatient admission, in compliance with section 1886 of the Act.

We proposed at § 512.605 to define ''anchor hospitalization'' as the initial hospital stay upon admission for a lower extremity joint replacement included in CJR–X, as described in § 512.625(a), for which the institutional claim is billed through the inpatient prospective payment system (IPPS). Anchor hospitalization also includes an inpatient hospital admission within 3 days after an outpatient Total Knee Arthroplasty (TKA) or Total Hip Arthroplasty (THA). We also proposed at § 512.605 to define ''anchor procedure'' as a TKA or THA procedure related to an episode, as described in § 512.625(a), included in CJR–X that is permitted and paid for by Medicare when performed in a hospital outpatient department (HOPD) and billed through the Hospital Outpatient Prospective Payment System (OPPS), except when the beneficiary is admitted to an inpatient hospital stay within 3 days after the TKA or THA.

We sought comment on our proposed ''episode'' definition at § 512.605. The following is a summary of the public comments received.

Comment: Some commenters supported the proposed CJR–X episode definition and maintaining a focused and clinically appropriate LEJR episode category. Commenters supported including inpatient and outpatient procedures in the model to reflect evolving care delivery patterns, but cautioned that it introduces complexity in achieving site-neutral payments. In addition, patient variability across care settings may significantly influence outcomes and episode costs. Another commenter stated that rigid episode definitions could misalign incentives if they do not reflect current practice patterns.

Response: We appreciate the support for the proposed CJR–X episode definition and acknowledge concerns about shifts between inpatient and outpatient settings. The proposed definition aligns with the CJR Model and TEAM to provide consistency across Innovation Center models. CMS will monitor for unwarranted shifts in setting, site-of-service variation, and other unintended effects as part of the CJR–X evaluation activities.

As stated in the proposed rule, if an outpatient procedure is later converted to an inpatient admission, we would not consider the outpatient procedure to be the episode initiator. Rather, we would consider the anchor hospitalization to be the initiator. This would only occur if the inpatient admission occurs at the same CJR–X participant as the outpatient procedure. This is further discussed in section X.C.2.d.(3)(a) of this final rule and at § 512.630(c).

After consideration of the public comments we received, we are finalizing with modification our proposed ''episode'' definition at § 512.605 as all Medicare Part A and B items and services described in § 512.625(b) (and excluding the items and services described in § 512.625(c)) that are furnished to a CJR–X beneficiary during the time period that begins on the date of the beneficiary's admission to an anchor hospitalization or the date of the anchor procedure, as described at § 512.630(c), and ends on the 90th day following the date of discharge from the anchor hospitalization or anchor procedure, as described at § 512.630(d).

We also recognize that the ''anchor hospitalization'' and ''anchor procedure'' definitions include unnecessary cross-references and policy. Therefore, we are removing extraneous text from the finalized definitions. We are finalizing with modification the ''anchor hospitalization'' definition at § 512.605 as the initial hospital stay upon admission for a lower extremity joint replacement for which the institutional claim is billed through the inpatient prospective payment system (IPPS). We are finalizing with modification the ''anchor procedure'' definition at § 512.605 as a TKA or THA procedure that is permitted and paid for by Medicare when performed in a hospital outpatient department (HOPD) and billed through the Hospital Outpatient Prospective Payment System (OPPS).

(b) Episode Identification (MS–DRG/HCPCS)

We believe that a straightforward approach for identifying CJR–X episodes is important for the care redesign that is required for model success. As was done in the CJR Model, hospitals participating in CJR–X will be able to identify episodes through the MS–DRG of the anchor hospitalization or by the Healthcare Common Procedure Coding System (HCPCS) codes for hospital outpatient procedures, allowing active coordination of beneficiary care during and after the anchor procedure or anchor hospitalization. We believe identifying LEJR episodes with MS–DRGs or HCPCS codes is a reasonable approach especially given LEJR is a procedural episode, making CJR–X beneficiary identification easier at the time of hospital inpatient or hospital outpatient department admission. This approach offers operational simplicity for providers and CMS and is consistent with the approach taken by BPCI Advanced and the CJR Model to identify beneficiaries whose care is included in those episodes. We note that there may be times an episode initiating code, such as an included MS–DRG, changes after the CRJ–X beneficiary is discharged. For example, the inpatient LEJR procedure generally determines the ultimate MS–DRG assignment for the hospitalization. However, depending on the beneficiary's principal and secondary diagnoses and other procedures received during the inpatient stay, the final MS–DRG assigned to the inpatient stay may not be the LEJR procedure, in which case the episode would not be picked up for

CJR–X.[587] In those instances, CJR–X participants could rely on data shared by CMS, in accordance with a CJR–X data sharing agreement and attestation, to confirm episode attribution, as described in section X.C.2.k. of this final rule.

We proposed to identify LEJR episodes by certain MS–DRGs and HCPCS codes included on claims. Specifically, IPPS discharges under MS–DRG 469, 470, 521, or 522; and OPPS claims for HCPCS codes 27130 or 27447, would trigger LEJR episodes in CJR–X. This approach offers operational simplicity for both providers and CMS and is consistent with the approach taken by previous models to identify episodes.

We sought comment on our proposal at § 512.625(a) to identify LEJR episodes with MS–DRGs and HCPCS in CJR–X. The following is a summary of the public comments received.

Comment: Several commenters supported identifying CJR–X episodes by the proposed codes, that is MS–DRGs 469, 470, 521, and 522 and CPT codes 27447 and 27130. A few commenters agreed with CMS's decision to focus the model on selected DRGs and not require participants to manage an entire orthopedic service-line, as was done in BPCI Advanced. A commenter supported excluding procedures that had not previously been tested under CJR, including CPT code 27446 (unicompartmental, or partial, knee replacement).

Response: We appreciate commenters' support for defining CJR–X episodes using the proposed MS–DRGs and CPT codes, which maintains the model's focused LEJR episode scope and excludes procedures not previously tested under CJR.

Comment: A commenter stated that the codes for identifying CJR–X episodes would not capture surgical complexity, such as differences between routine TKA and complex conversion cases involving prior fractures, retained hardware, multiple incisions, or contractures. The commenter stated that treating these cases as comparable episodes could discourage hospitals and surgeons from operating on beneficiaries who need complex reconstructions and create access concerns. Another commenter stated that more complicated admissions, specifically those that would fall under MS–DRGs 469 and 521, present significant coding and documentation challenges, especially regarding hard-to-code social risk factors that strongly condition post-discharge outcomes like hospital readmissions. Another commenter stated CMS should clearly and broadly define trauma to differentiate between a patient who needs a hip replacement to repair a fracture and a patient who is having an elective hip replacement.

Response: We proposed MS–DRG/HCPCS-based episode identification because it would be straightforward, operationally simple, and consistent with prior episode-based payment models for LEJR. While we acknowledge that MS–DRG/HCPCS episode triggers may not distinguish between routine and more complex joint replacement procedures, we believe variation within a particular code would be captured in the baseline spending used to produce target prices.

After consideration of the public comments we received, we are finalizing without modification our proposal at § 512.625(a) to identify LEJR episodes with MS–DRGs and HCPCS codes.

(3) Scope of Episode

We proposed that, consistent with the CJR Model, LEJR episodes in CJR–X would include inpatient hip, knee, and ankle replacement procedures paid through the IPPS under select MS–DRGs and hospital outpatient hip and knee replacement procedures billed under select HCPCS codes through the OPPS. We proposed to exclude from CJR–X ankle replacements performed in the outpatient setting. Total ankle arthroplasty (TAA) was on the IPO list until 2021 and, therefore, was not included in BPCI Advanced or the CJR Model. Although we did consider including outpatient TAAs in CJR–X, to do so at this time would represent too great a departure from the CJR Model to meet the limits of OACT certification. However, we are currently testing outpatient TAAs, as identified by HCPCS code 27702, in TEAM. If we consider adding outpatient TAAs to CJR–X at some point in the future based on TEAM evaluations, we would propose that change through notice and comment rulemaking.

We sought comment on the MS–DRG and HCPCS codes proposed for inclusion in CJR–X at § 512.625(a) and our proposal to exclude outpatient TAA from the LEJR episode category. The following is a summary of the public comments received.

Comment: A commenter supported the proposal to exclude outpatient total ankle arthroplasty in CJR–X. The commenter agreed that adding the procedure would represent a significant change from the prior CJR Model test. Another commenter stated that inpatient total ankle arthroplasty volume is relatively low and that inpatient TAA cases tended to be more complex and higher risk. The commenter stated that expanding a low-volume, higher-acuity procedure into a nationwide mandatory episode model without adequate data could create benchmarking instability and financial volatility and recommended that CMS assess publicly available volume data before advancing any expansion.

Response: We appreciate commenters' support for excluding outpatient total ankle arthroplasty from the CJR–X episode definition and acknowledge concerns that including TAA procedures could create benchmarking instability and financial volatility. However, this policy maintains the LEJR episode scope that was previously tested under the CJR Model. We did not see inherent issues with including these procedures in the CJR Model, but will monitor these procedures for untoward effects in CJR–X.

Comment: Some commenters raised concerns about including fracture-related THA cases in CJR–X. Commenters stated that hip fracture cases involve elderly, medically complex, and vulnerable beneficiaries whose outcomes, post-acute needs, and long-term disability risks differ from primary arthroplasty populations. They stated that patients with hip fractures are more likely to have complications or readmissions. They also stated that because these procedures are not elective, patients cannot be optimized prior to surgery and hospitals have minimal opportunity conduct presurgical interventions. Specifically, the care pathway redesign strategies that drive cost reduction in elective lower extremity joint replacement episodes, including presurgical patient optimization, scheduled rehabilitation pathways and predictable discharge planning, are not available for fracture patients. Moreover, a patient presenting with an acute hip fracture has a fundamentally different risk profile and post-acute trajectory than an elective joint replacement patient. Commenters stated that including these cases could affect access to clinically appropriate care and treatment decisions.

Response: We acknowledge commenters' concerns regarding hip fracture episodes in CJR–X. We understand that the clinical complexity of beneficiaries discharged under different DRGs or CPT codes is varied. We also recognize that presurgical

[587] Medical Severity Diagnosis Related Groups (MS–DRGs): Definitions Manual. Version 33.0A. 3M Health Information Systems. (October 1, 2015). *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html.*

optimization is not always possible. However, as benchmarking and risk adjustment are applied at the episode-level, the baseline spending for fractures would reflect patient complexity, higher costs, and distinct post-acute care needs associated with fracture-related THA episodes.

Comment: Some commenters questioned the rationale for testing LEJR episodes under TEAM and CJR–X at the same time. Commenters stated that doing so could create methodological inconsistencies and operational confusion. A commenter recommended removing LEJR episodes from TEAM and consolidating LEJR episodes under CJR–X. Other commenters supported excluding TEAM participants from CJR–X specifically to enable a clean comparison of the episode designs.

Response: We recognize commenters' concerns that testing LEJR episodes under both TEAM and CJR–X could create operational confusion or methodological inconsistencies if the same hospitals were subject to both sets of model rules. For that reason, CMS proposed to exclude TEAM participants from CJR–X while TEAM is being tested. As discussed in the proposed rule, TEAM and CJR–X test different LEJR episode designs. Most notably, TEAM tests a 30-day LEJR episode, while CJR–X will continue testing the CJR Model's 90-day episode. Maintaining LEJR in TEAM allows CMS to preserve TEAM's consistent methodology across its five surgical episode categories, while CJR–X allows CMS to continue testing the 90-day episode nationally, rather than only 34 MSAs.

We agree with commenters who supported the proposed exclusion of TEAM participants from CJR–X because it offers greater simplicity and reduced burden. It also allows CMS to compare the effects of different episode durations and other episode designs on Medicare spending and quality. We do not believe it would be appropriate to remove LEJR from TEAM and consolidate all LEJR episodes under CJR–X, because doing so would eliminate the opportunity to evaluate the TEAM episode design. We also note that we will continue to monitor and evaluate TEAM and CJR–X and will consider changes to this policy should data signal alternatives are warranted.

After consideration of the public comments we received, we are finalizing without modification the proposed MS–DRG and HCPCS codes at § 512.625(a) to trigger CJR–X episodes.

(a) Episode Initiation

We proposed that, if a beneficiary meets the beneficiary inclusion criteria at § 512.620, an LEJR episode would begin when a beneficiary is admitted for an anchor hospitalization for one of the following MS–DRGs or an anchor procedure indicated by one of the following HCPCS codes on an outpatient claim (specifically, a hospital's institutional claim for an included outpatient procedure billed through the OPPS):

MS–DRGs and HCPCS–

- 469 (Major joint replacement or reattachment of lower extremity with major complications or comorbidities (MCC))
- 470 (Major joint replacement or reattachment of lower extremity without MCC)
- 521 (Hip replacement with principal diagnosis of hip fracture with MCC)
- 522 (Hip replacement with principal diagnosis of hip fracture without MCC)
- 27447 (Total knee arthroplasty)
- 27130 (Total hip arthroplasty)

We proposed that the episode start date would be the day of the anchor procedure for outpatient procedures and the date of admission for an inpatient hospitalization. However, if an anchor hospitalization is initiated on the same day as or within 3 days of an outpatient LEJR procedure, we proposed to begin the episode on the date of the outpatient procedure rather than the date of the inpatient admission.

We recognize there could potentially be episodes initiated as a result of a beneficiary being transferred from one CJR–X participant hospital to another. In this case, and in alignment with the CJR Model and TEAM, these would be viewed as two separate hospitalizations. Specifically, if the initial inpatient admission is for an MS–DRG in CJR–X, then a transfer to another hospital would not initiate a new anchor hospitalization, rather it would be included in the LEJR episode initiated from the first hospitalization. However, if a beneficiary is admitted to a hospital for an MS–DRG not included in CJR–X and subsequently transferred to another CJR–X hospital, from which they are discharged under an MS–DRG that is included in CJR–X, the second hospitalization would initiate the LEJR episode at the second CJR–X hospital.

We sought comment on our proposal at § 512.630(c) for initiating CJR–X episodes. The following is a summary of the public comments received.

Comment: A few commenters supported using the anchor hospitalization admission date or anchor procedure date to define when an episode begins.

Response: We appreciate commenters' support of this policy.

Comment: A commenter supported alignment with the CJR transfer policy and agreed that linking the transfer admission to the initial hospitalization is appropriate. However, they did recommend that CMS cancel the episode if the discharge MS–DRG from the receiving hospital is not a CJR–X episode trigger. Another commenter requested further clarification of episode attribution when a beneficiary receives an outpatient LEJR procedure at a CJR–X hospital and is then transferred to another CJR–X hospital and admitted for care related to the procedure.

Response: We thank commenters for their support of the policy to continue a CJR–X episode if a beneficiary is transferred to another hospital. As discussed in the proposed rule, once a CJR–X episode is initiated, it will continue for 90-days unless it is canceled in accordance with § 512.630(e). Therefore, the initial CJR–X episode would continue, the transfer to the receiving hospital would be considered a readmission, and the spending for the readmission at the transfer hospital would be attributed to the initial CJR–X episode. The policy is the same for an outpatient procedure that results in an admission to another CJR–X participant.

As we stated in the proposed rule, we will begin an episode on the date of the outpatient procedure if an anchor hospitalization is initiated on the same day as or within 3 days of an outpatient LEJR procedure. Under the CJR Model, there were occasions when anchor hospitalizations for LEJR procedures did not have a corresponding claim for the surgeon. This occurred when a beneficiary underwent an outpatient procedure and was later admitted to the hospital. As an administrative fix for not having a surgeon's claim for the procedure linked to the admission, we did a 3-day lookback to determine when the episode began. We proposed a similar policy for CJR–X. As we stated in the proposed rule, this policy applies to an outpatient procedure that is later converted to an inpatient admission. This policy is distinguishable from and unrelated to the transfer policy, as the admission must be at the same CJR–X participant and for the same episode type. Therefore, we are clarifying the language of the proposed policy to state that it only applies if an anchor hospitalization occurs at the same hospital an anchor procedure and for the same episode type.

After consideration of the public comments we received, we are finalizing without modification the proposal at § 512.630(c) that an episode is initiated by a beneficiary's admission

to a CJR–X participant for an anchor hospitalization that is paid under a MS–DRG specified in § 512.625(a) or an anchor procedure billed under a HCPCS code specified in § 512.625(a) and that the episode start date would be the day of the anchor procedure for outpatient procedures and the date of admission for an inpatient hospitalization. We are finalizing § 512.630(c)(2) with modification to state if an anchor hospitalization is initiated on the same day as or within 3 days of an outpatient procedure for the same episode type at the same CJR–X participant, the episode start date will be that of the outpatient procedure rather than the admission date, and an anchor procedure will not be initiated.

(b) Items and Services Included in the Episode

Like previous episode-based payment models, CJR–X would incentivize comprehensive, coordinated, patient-centered care through inclusive episodes. We proposed to include in the episode all items and services paid under Medicare Part A and Part B during the performance year, unless such items and services fall under an exclusion described in section X.C.2.d.(3)(c) of this final rule.

We proposed to include all Part A services furnished during the 90-day post-discharge period of the episode, other than certain excluded hospital readmissions; to ensure the episode is comprehensive in nature. In particular, we believe that claims for services with diagnosis codes that are directly related to LEJR episodes or the quality and safety of care furnished during the episode (for example, surgical would infection) should be included in an episode. Thus, we proposed at § 512.625(b) that items and services for episodes would include all items and services paid under Medicare Part A and Part B, subject to the exclusions at § 512.625(c). For example, the following is a non-exhaustive list of services included in episodes:

- Physicians' services.
- Inpatient hospital services, including services paid through IPPS operating and capital payments.
- Inpatient psychiatric facility (IPF) services.
- Long-Term Care Hospital (LTCH) services.
- Inpatient Rehabilitation Facility (IRF) services.
- Skilled Nursing Facility (SNF) services.
- Home Health Agency (HHA) services.
- Hospital outpatient services.
- Outpatient therapy services.
- Clinical laboratory services.
- Durable medical equipment.
- Part B drugs and biologics except for those excluded under § 512.625(c).
- Hospice services.
- Part B professional claims dated in the 3 days prior to an anchor hospitalization if a claim for the surgical procedure is not detected as part of the hospitalization because the procedure was performed by the participant on an outpatient basis but the patient was subsequently admitted as an inpatient.

These items and services are similar to those included in the CJR Model and reflect the full range of Medicare-covered services that would be furnished to a CJR–X beneficiary during an episode. As joint replacement episodes frequently involve services across multiple providers and settings, we believe excluding these services would fragment financial accountability and undermine the model's ability to promote care coordination and cost containment. Moreover, including these services aligns incentives for hospitals to manage transitions of care, post-acute utilization, and complication-related services.

We sought comment on the items and services we did propose to include in CJR–X at § 512.625(b). The following is a summary of the public comments received.

Comment: A commenter supported the proposed broad accountability structure for Medicare Part A and Part B spending during the recovery period, subject to specified exclusions, because it could encourage coordinated recovery management.

Response: We appreciate the commenter's support for a broad episode accountability structure. We proposed to include most Medicare Part A and Part B items and services furnished during the episode, subject to specified exclusions, because LEJR episodes often involve care across multiple providers and settings. We believe this approach will support comprehensive, coordinated, patient-centered care and reduce fragmentation during the recovery period.

Comment: Some commenters urged CMS to provide additional clarity on which services would be included in a CJR–X episode. Commenters recommended that CMS include only services clinically related to the LEJR procedure. Another commenter asked for clarification on whether emergency department visits or hospital admissions during a CJR–X episode would be included in the episode or if they would initiate a new episode. Another commenter stated that CMS should consider only specific MS–DRGs when considering whether a readmission is attributed to the episode, as many readmissions from post-acute care facilities and providers are well outside the direct control of the CJR–X participant.

Response: We acknowledge requests for additional clarity regarding the items and services included in a CJR–X episode. We proposed a broad episode definition that would include all Medicare Part A and Part B items and services furnished during the episode, unless the item or service is among the exclusions in section X.C.2.d.(3)(b) of this final rule. We elected to adopt this broad policy because joint replacement episodes frequently involve care across multiple providers and settings and because excluding services could fragment accountability. We will maintain the exclusions lists on the CJR–X website at *https://www.cms.gov/priorities/innovation/innovation-models/cjr-x.*

Comment: Some commenters stated that unintentional inclusion of trauma-related or other unrelated high-cost services could distort target prices, dilute episode accountability, and undermine the model's ability to reward efficiency in joint replacement care. Commenters requested that CMS clarify guardrails so that unrelated costs do not inflate benchmarks or create financial volatility for participants. A commenter stated that including high cost therapy, such as IVIG for primary immunodeficiency, CIDP, or other chronic conditions in episode spending could create inappropriate financial pressure on hospitals to manage, defer, or substitute necessary unrelated therapy. Another commenter stated that by including post-acute care delivered in a critical access hospital, CMS is unfairly comparing the episode costs of rural populations against those of urban populations. Specifically, CAH swing beds and outpatient services are paid higher rates than those paid under SNF and PFS payment systems.

Response: We appreciate commenters' concerns about the potential inclusion of trauma-related, chronic-condition-related, rural post-acute care, or other high-cost services in episode spending. We recognize that commenters are concerned that such spending could introduce volatility, dilute accountability, or create inappropriate incentives regarding services that are clinically necessary but not directly related to the LEJR procedure. However, we have generally included all Medicare Part A and Part B spending during the episode because a central purpose of the model is to test whether hospitals can

improve coordination, quality, and efficiency across the full episode of care.

Nevertheless, we believe the model includes safeguards to help address these concerns. Where we have determined that an exclusion is appropriate, those services are added to the exclusions list and removed from spending calculations. With respect to high-cost services that are not on the exclusions lists, including services associated with trauma, chronic conditions, IVIG therapy, or post-acute outpatient care in rural settings, we note that the target price methodology is based on historical spending for comparable episodes. As a result, high-cost services that occur in the performance year are not considered only on one side of the calculation; comparable outlier costs are also present in the historical baseline and are therefore reflected in the benchmark used to establish target prices. This helps mitigate the concern that participants would be measured against benchmarks that do not account for historical episode spending variation.

For these reasons, we believe the proposed episode and pricing methodology appropriately balances episode accountability with protections against undue volatility, including by reflecting historical outlier costs in the benchmark. We will continue to monitor episode spending patterns, including high-cost services and rural post-acute care utilization, as part of model oversight and will revisit the exclusions lists when warranted.

Comment: A commenter recommended expanding the episode to include pre-operative therapy as related to surgical preparation and recovery planning furnished in the weeks before the anchor surgery. Another commenter encouraged CMS to consider coverage of other services in the bundle that would enable care at home, including custodial care and other activities of daily living support, caregiver training codes, and virtual care services such as telehealth, remote physiologic monitoring, or remote therapeutic monitoring.

Response: We appreciate the recommendation to include certain pre-operative therapy interventions connected to the anchor surgery. However, two of the benefits of CJR–X and other episode-based payment models are clear, easily identifiable triggers for initiating episodes and concrete rules for defining what is included in the episode. We believe that retroactively identifying therapy services delivered before a triggering event as prehabilitation or optimization in preparation of an upcoming surgery, rather than a continuation of previous conservative treatment, would not be consistently achievable on a large scale.

We appreciate the value of home-based care and note that virtual care services, such as telehealth, remote physiologic monitoring, or remote therapeutic monitoring, are included items and services in CJR–X. However, expanding Medicare coverage of items and services not currently authorized, such as custodial care, is out of scope for this rulemaking. Should Medicare expand Part B coverage to additional services supporting home-based care, such services would be included in CJR–X episodes, unless the services fall under the episode exclusions.

After consideration of the public comments we received, we are finalizing without modification the proposal at § 512.625(b) to include in a CJR–X episode all items and services paid under Medicare Part A and Part B, subject to the exclusions at § 512.625(c).

(c) Excluded Items and Services

We proposed to exclude from episodes certain Part A and B items and services that are clinically unrelated to an LEJR procedure. The exclusions would be applicable to episodes included during the baseline period, the three-year historical period used to construct target prices, as described in section X.C.2.f.(3)(a) of this final rule, and episodes initiated during a performance year. We proposed to use these exclusions based on several years of experience with them and their suitability for LEJR episodes. The rationale for the exclusions is consistent with the CJR Model (80 FR 73303) and TEAM (89 FR 69722) but differ slightly from both.

We proposed to exclude from episodes all Part A and B items and services for hospital admissions and readmissions, for both the baseline period and performance years, for specific categories of diagnoses, such as oncology, trauma medical admissions, organ transplant, and ventricular shunts determined by MS–DRGs, as well as all of the following excluded Major Diagnostic Categories (MDC):[588]

- MDC 02 (Diseases and Disorders of the Eye)
- MDC 14 (Pregnancy, Childbirth, and Puerperium)
- MDC 15 (Newborns)
- MDC 25 (Human Immunodeficiency Virus)

We proposed to exclude from episodes IPPS new technology add-on payments for drugs, technologies, and services identified by value code 77 on IPPS hospital claims for episodes in the baseline period and performance years.[589] New technology add-on payments are made separately and in addition to the MS–DRG payment under the IPPS for specific new drugs, technologies, and services that substantially improve the diagnosis or treatment of Medicare beneficiaries and would be inadequately paid under the MS–DRG system. We believe this exclusion would reduce the potential for CJR–X to diminish beneficiaries' access to new technologies or burden hospitals with concern about the payments for these new drugs, technologies, or services counting toward CJR–X participants' actual episode spending. Additionally, new drugs, technologies, or services approved for the add-on payments vary unpredictably over time in their application to specific clinical conditions. In addition, maintaining this exclusion from CJR–X episodes would align with the CJR Model (80 FR 73303 through 73304 and 73315).

We also proposed to exclude from episodes OPPS transitional pass-through payments for medical devices as identified through OPPS status indicator H for episodes in the baseline period and performance years. Through the established OPPS review process, we have determined that these technologies have a substantial cost but also lead to substantial clinical improvement for Medicare beneficiaries. This is consistent with the CJR Model final exclusions policy (80 FR 73308 and 73315).

We proposed to exclude hemophilia clotting factors (§ 412.115), identified through HCPCS code, diagnosis code, and revenue center on IPPS claims for episodes in the baseline period and performance years. In contrast to other drugs and biologics that are administered during an inpatient hospitalization and paid through the MS–DRG, hemophilia clotting factors are paid separately by Medicare in recognition of clotting factors being costly, yet essential, to care for certain beneficiaries. Because we do not believe that there are any spending efficiencies to be gained by including hemophilia clotting factors, we proposed to exclude these high-cost drugs from episodes initiated during the baseline period and performance year.

[588] MDCs are formed by dividing all possible principal diagnoses (from ICD–10–CM) into 25 mutually exclusive diagnosis areas. The diagnoses in each MDC correspond to a single organ system or etiology and in general are associated with a particular medical specialty.

[589] This exclusion is applied during the payment standardization process.

We also proposed to exclude from episodes certain Part B payments for high-cost drugs and biologics, low-volume drugs, and blood clotting factors for hemophilia patients billed on outpatient, carrier, and durable medical equipment claims for episodes in the baseline period and initiated in the performance years.[590] These high-cost items are essential to appropriate care of certain beneficiaries and we do not believe including them in the episode would improve any spending or quality of care efficiencies. Specifically, the list would include all of the following:

- For episodes included during the baseline period—

++ Drug/biologic HCPCS codes that are billed in fewer than 31 episodes in total across all episodes in CJR–X during the baseline period;

++ Drug/biologic HCPCS codes that are billed in at least 31 episodes in the baseline period, and have a mean allowed cost of greater than $25,000 per episode in the baseline period; and

++ HCPCS codes corresponding to clotting factors for hemophilia patients, identified in the quarterly average sales price file for certain Medicare Part B drugs and biologics as HCPCS codes with clotting factor = 1, HCPCS codes for new hemophilia clotting factors not in the baseline period, and other HCPCS codes identified as hemophilia.[591]

- For episodes initiated during a performance year, in addition to those listed in the previous bullet, Part B payments for high-cost drugs and biologics, low-volume drugs, and blood clotting factors for hemophilia billed on outpatient, carrier, and durable medical equipment (DME) claims, including, but not limited to—

++ Drug/biologic HCPCS codes that were not included in the baseline period, and appear in 10 or fewer episodes in the performance year;

++ Drug/biologic HCPCS codes that were not included in the baseline period, appear in more than 10 episodes in the performance year, have a mean cost of greater than $25,000 per episode in the performance year;

++ Drug/biologic HCPCS codes that were not included in the baseline period, appear in more than 10 episodes in the performance year, have a mean cost of $25,000 or less per episode in the performance year, and correspond to a drug/biologic that appears in the baseline period list but was assigned a new HCPCS code between the baseline period and performance year; and

++ HCPCS codes for new hemophilia clotting factors not in the baseline period.

Complete lists of excluded MS–DRGs for readmissions and excluded HCPCS codes for Part B services furnished during episodes after beneficiary discharge from an anchor hospitalization will be posted on the CMS CJR–X web page within the Innovation Center website at *https://innovation.cms.gov.* The methodology to identify excluded items and services would apply to all performance years of the model, and lists would be shared with CJR–X participants on the CJR–X web page around the time preliminary target prices are released. Lists would be updated after the performance year concludes to account for the performance year exclusions proposed in the previous paragraph. We proposed that revisions to the exclusion lists, such as adding MS–DRGs not covered by oncology, trauma medical admissions, organ transplant, and ventricular shunts, would be initiated through notice and comment rulemaking to allow for public input.

We sought comment on the proposed excluded services, the lists of excluded services, and the process for updating the lists of excluded services at §§ 512.625(c), (d), and (e). The following is a summary of the public comments received.

Comment: A commenter supported the exclusion of certain categories of unrelated services, including specified oncology, trauma, transplant, ventricular shunt, and related major diagnostic categories. Another commenter agreed with excluding trauma-related and other unrelated high-cost services, as their inclusion could distort target prices, dilute episode accountability, and undermine the model's ability to reward efficiency in joint replacement care. Another commenter requested more information on what is considered a ''trauma medical'' exclusion.

Response: We thank commenters for their support of an episode exclusion policy. We also recognize that the ''trauma medical'' terminology may cause confusion. In aligning with the CJR Model, we adopted similar episode exclusions, including the ''trauma medical'' exclusion at § 510.200(d)(4)(i)(B). However, we believe this language to be an artifact of MS–DRG and ICD coding changes that have occurred, particularly since the CJR exclusions lists included both medical and surgical trauma MS–DRGs. Therefore, we are updating the language to encompass all trauma admissions that would be considered unrelated to the episode.

Comment: Some commenters requested that CMS publish the complete excluded-service lists, with rationale for each exclusion, and operational processes for identifying and removing unrelated services from episode spending. A commenter also asked CMS to publish the methodology for determining readmission exclusions and establish a participant petition process by which CJR–X participants can request additional exclusions based on clinical evidence.

Response: CJR–X excludes certain items and services that are clinically unrelated to the LEJR procedure, or that are high-cost, low-volume, separately paid, or unpredictable in ways that would not create meaningful opportunities for care redesign or spending efficiency. For example, CJR–X excludes hemophilia clotting factors and certain hospital readmissions, such as a readmission for oncology, given their high cost and not being clinically related to the LEJR procedure. Additionally, CJR–X excludes new technology add-on payments and transitional pass-thru payments because these are temporary payments that we do not want to discourage adoption of.

Further, CJR–X aims to limit the items and services excluded from an episode in an effort for episode spending to be close to total-cost-of care. Given this principle, we are continuing a similar exclusion framework used in the CJR Model and other episode-based payment models for CJR–X. We believe the list of exclusions, which was developed through a collaborative effort between CMS and external stakeholders and informed by several years of experience testing episode-based payment models, appropriately captures the items and services that may be unrelated to the episode. We believe this approach would hold CJR–X participants accountable for services they can reasonably influence during the episode while avoiding accountability for unrelated or atypical services that do not reflect the quality or efficiency of LEJR care.

The lists of exclusions will be maintained on the CJR–X website at *https://www.cms.gov/priorities/innovation/innovation-models/cjr-x.* We intend to publicly post the CJR–X exclusions list closer to the time when CMS constructs preliminary target prices. We cannot publish the complete CJR–X exclusions list at this time because certain items and services on the exclusions list are based on how frequently they appear during the

[590] To determine if a drug HCPCS meets the cost or volume thresholds for exclusion, the episodes are pooled across all episode categories.

[591] *https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files.*

baseline period. For performance year 1, the baseline period is CY 2024 through CY 2026, and CY 2026 has not yet concluded. Therefore, the complete baseline-period claims experience needs to finish with sufficient claims runout before we can publish the full exclusions list for CJR–X.

Comment: Some commenters recommended that CMS consider additional exclusions to address variable clinical characteristics and resource needs. A commenter requested that CMS reconsider exclusions, carve-outs, or separate benchmarking approaches for clearly atypical or highly complex episodes. Another commenter stated that non-elective and emergent episodes have materially different clinical characteristics and resource requirements than elective joint replacement procedures. Another commenter recommended excluding joint revision procedures or placing them in a separate category because revision cases may have greater clinical complexity, higher complication risk, and more variable costs than primary joint replacements. Another commenter stated CMS should carve out episodes with periprosthetic joint infections from the standard episode. They stated that hospitals should be held accountable for infections that present up to 12 months after the surgery and that the current episode construction would miss these complications.

Response: We recognize that LEJR episodes can vary in clinical complexity, complication risk, and resource use. The proposed CJR–X methodology is intended to account for this variation through the episode definition, separate MS–DRG episode types, risk adjustment, and outlier protections, rather than by excluding broad categories of clinically complex cases from the model. CJR–X episodes would be initiated using specified MS–DRGs and HCPCS codes, including separate inpatient episode types that reflect major complications or comorbidities and hip fractures. We also proposed risk adjustment and normalization to account for beneficiary-level factors that affect episode spending, as discussed in section X.C.2.f.(4) of this final rule.

We disagree that excluding all non-elective, emergent, or otherwise complex episodes would be appropriate for CJR–X. We believe excluding broad categories of higher-complexity episodes could reduce the comprehensiveness of the model, weaken accountability for care coordination, and create operational complexity in identifying which cases should or should not be included. The model is designed to test accountability for the full LEJR episode of care, including post-acute care, transitions of care, and complications that may arise following the anchor hospitalization or procedure, while excluding certain clinically unrelated items and services where appropriate. That said, we do note that CJR–X episode identification does not include revision joint replacement DRGs.

We also note that the pricing methodology includes protections for unusually high-cost episodes, through a high-cost outlier cap to both baseline episode spending and performance year episode spending, as discussed in section X.C.2.f.(5)(g) of this final rule. In addition, outlier costs are not considered only in the performance year; comparable high-cost episodes are also present in the historical baseline and are reflected in the benchmark. This approach helps prevent high-cost outlier spending from artificially inflating benchmarks while also limiting participant responsibility for catastrophic episode spending that hospitals could not reasonably have been expected to prevent.

We acknowledge the commenter's concern that prosthetic joint infections may arise after the proposed CJR–X episode ends. However, extending accountability to 12 months for a specific complication category would represent a substantial departure from the CJR Model and proposed CJR–X Model. Moreover, the retrospective identification of episodes with delayed or late infections would add significant operational complexity to pricing, reconciliation, quality measurement, and overlap policies. However, we will continue to monitor complications associated with LEJR episodes and episode spending patterns for clearly atypical and highly complex cases as part of model oversight. Should we consider additional model refinements, they will be proposed through future notice-and-comment rulemaking if warranted.

Comment: A couple of commenters recommended excluding critical care transport including by air ambulance. A few commenters recommended excluding patients that are discharged to hospice. A commenter recommended excluding patients leaving against medical advice.

Response: We acknowledge these requests but disagree that these services warrant exclusions. These services reflect discharge dispositions that would be reflected in the baseline spending when determining target prices and would, therefore, not artificially penalize participants.

Comment: Some commenters requested additional exclusions for services that are not clinically related to the LEJR episode. Several commenters were concerned that unrelated services, including trauma-related costs, chronic dialysis services, and high-cost chronic maintenance therapies would be attributed to the CJR–X episode despite no clinical relationship to the joint replacement or recovery. Another commenter requested exclusions for substance use disorder treatment, including inpatient psychiatric facility services, chronic conditions, such as auto-immune disorders, and previously existing wounds or pressure ulcers. A commenter stated such services should be excluded from episode spending calculations to avoid penalizing hospitals that serve medically complex patient populations. Another commenter recommended broader protections for unrelated spending because a 90-day episode could still capture unrelated post-acute utilization.

Several commenters recommended CMS exclude Part B payments for drugs and biologicals that are for diagnoses unrelated to the anchor procedure or hospitalization, whether the patient was receiving them prior to the anchor or started during the post-discharge period. Several commenters recommended excluding all infusion services. Another commenter recommended that CMS explicitly exclude all items related to oncology and cancer-related treatment cases, as these treatments lack Medicare savings potential. The commenter stated that excluding oncology treatments will help ensure that performance measurements and financial accountability remain fair and clinically appropriate. Another commenter recommended an exclusion for Fracture Liaison Services (FLS) for osteoporotic patients, which they stated are widely underutilized despite their demonstrated value in reducing secondary fractures. They stated uptake of these services would be further disincentivized as they would be largely absent from the historical spending data used in setting target prices for LEJR episodes. The commenter asked that CMS work with stakeholders to develop flexibilities or a pathway that encourages FLS adoption and actively monitor hospitals to ensure that FLS uptake is not discouraged or delayed due to financial pressures imposed by the CJR–X Model.

Response: We acknowledge commenters' concerns that certain services furnished during the episode may be unrelated to the joint replacement and could affect episode spending for hospitals treating

medically complex beneficiaries. CJR–X episodes will include all Medicare Part A and Part B items and services furnished during the episode, subject to specified exclusions for clinically unrelated services, including certain readmissions and high-cost Part B drugs and biologicals. The lists of exclusions will be maintained on the CJR–X website at *https://www.cms.gov/priorities/innovation/innovation-models/cjr-x.* We proposed this inclusive approach because broad exclusions could fragment accountability for care coordination, post-acute care, and complication management. We also recognize commenters' requests for additional exclusions for other services they view as unrelated to LEJR care, and may take these recommendations under consideration should we draft future rulemaking.

Comment: Several commenters urged CMS to adopt cost exclusions for the IceMan device and other non-opioid pain management treatments. Commenters stated the Non-Opioid Policy for Pain Relief (NO PAIN) Act provides for temporary additional payments for certain non-opioid treatment for pain relief under the Medicare hospital OPPS and ASC Payment System. They stated that, similar to other transitional pass-through payments, CJR–X should exclude the cost of these medical devices from the episode to ensure beneficiary access to these critical therapies.

Response: We support efforts to improve access to alternative pain control options that reduce the need for opioid treatment. We also appreciate the recommendation to exclude non-opioid therapies from the episode. Section 4135 of the Consolidated Appropriations Act, (CAA), 2023, also known as the NO PAIN Act, which amended section 1833(t)(16) and section 1833(i) of the Act, provides temporary additional payments for certain non-opioid treatments for pain relief which are authorized in the HOPDs and ASCs on or after January 1, 2025 and before January 1, 2028. Because we are finalizing a January 1, 2028 start date for CJR–X, we don't anticipate any policy overlap or need for an additional exclusion.

After consideration of the public comments we received, we are finalizing with modification the proposal at § 512.625(c) to exclude from CJR–X episodes certain Part A and B items and services that are clinically unrelated to an LEJR procedure or essential to appropriate care of certain beneficiaries. Specifically, we are updating § 512.625(c)(1)(i)(B) to say ''Trauma unrelated to the CJR–X episode'' rather than the proposed ''Trauma medical.'' We are also finalizing, without modification, the proposal at § 512.625(d) to post the lists of excluded services on the CJR–X website and the process at § 512.625(e) for updating the lists of excluded services.

(d) Episode Duration

We proposed that episodes would cover the surgical procedure and a subsequent period that is marked by significant post-acute care needs, potential complications of surgery, and short-term, intense management of chronic conditions that may be destabilized by a joint replacement. We believe that hospitals have substantial ability to influence the quality and efficiency of care that Medicare beneficiaries receive over the weeks and months following a procedure. For this reason, the CJR Model utilized a 90-day post-discharge episode duration. It is during this period that beneficiaries are provided the most intensive care for their recovery, including physical therapy and interventions to prevent complications. Notably, the professional payments to the surgeon under the Physician Fee Schedule for the procedures included in LEJR are also paid as a global payment covering a 90-day period.

The 90-day episode tested under the CJR Model demonstrated savings while maintaining quality, although some stakeholders have stated a shorter episode length would be more appropriate. Specifically, shorter episodes exhibit less spending variability due to medical events outside the intended scope of the model and conditions unrelated to the joint replacement become more prevalent in the later stage of an episode. In addition, longer episodes increase the potential for ACO overlap (where a beneficiary aligned or assigned to an ACO has an episode included in CJR–X). In the TEAM final rule (89 FR 69727), we agreed that a 30-day episode could position the specialist as the principal provider near the anchor event with a hand-off back to the primary care provider for longitudinal care management and we believe that ACOs are better equipped to address the population health needs of Medicare beneficiaries. For these reasons, the Innovation Center is currently testing a 30-day episode duration in TEAM. Through future evaluations and direct comparison between TEAM and CJR–X, we can determine the optimal episode length to balance spending reductions and outcomes.

Based on the rationale noted earlier, we proposed to end episodes 90 days after discharge from the anchor hospitalization or anchor procedure and that day 1 of the 90-day post-acute portion of the episode is the date of the anchor procedure or the date of discharge from an anchor hospitalization. To the extent that a Medicare payment for services included in an episode spans a period of care that extends beyond the episode duration, we proposed that these payments would be prorated so that only the portion attributable to care during the fixed duration of the episode is attributed to the episode spending.

We sought comment on our proposal at § 512.630(d) to maintain a 90-day post-discharge episode length. The following is a summary of the public comments received.

Comment: Many commenters recommended that CMS shorten the proposed CJR–X episode from 90 days to 30 days. They stated that hospitals have the greatest ability to influence surgical recovery, discharge planning, early complications, and readmissions during the first month after discharge. Commenters expressed concern that a longer episode window may hold hospitals accountable for unrelated medical events, chronic conditions, and less controllable factors, such as social risk. Several commenters also stated that a 30-day window would align CJR–X with TEAM and other Medicare programs and reduce operational burden, financial exposure, and potential access concerns. A commenter stated that holding hospitals responsible for the costs of care for every comorbid condition in 90 days will result in rationing and poorer outcomes for patients. Another commenter stated that patients will need to delay care for other issues and visits with other providers for 90 days after the procedure.

Response: We acknowledge commenters' concerns that a 90-day episode may capture spending later in the recovery period that commenters view as less controllable by the hospital. In fact, we believe the longer episode is beneficial as it will capture later complications and increased management needs for chronic conditions that are directly linked to the care delivered during the early days of the episode. A shorter episode would not capture these complications. We also remind readers that care delivered for chronic comorbid conditions is captured in the risk adjustment and baseline spending used in constructing target prices and participants would not

be penalized for delivering such care to beneficiaries.

We continue to believe hospitals have substantial ability to influence the quality and efficiency of care furnished during the later stages of the post-acute period through discharge planning, care coordination, physical therapy, and post-acute care management. The CJR Model evaluation demonstrated that 90-day episodes were successful for providing adequate incentives to engage hospitals in care redesign and greater engagement with beneficiaries and post-acute care providers. The 90-day duration maintains continuity with the tested CJR approach and allows us to compare results with TEAM, which tests a shorter episode duration.

Importantly, we are not ruling out the effectiveness of a 30-day episode and are testing TEAM for that very reason. We purposely designed TEAM to differ from the CJR Model, and by extension CJR–X, so that it could be adequately evaluated. We aligned with TEAM for many of the risk adjustment and other policies, but total alignment would undermine the TEAM test. Testing CJR–X and TEAM concurrently will provide a unique opportunity to understanding episode length and identify whether a certain length may be more effective at reducing complications, improving outcomes, and lowering spending. However, we believe it is important to adopt the same episode length that was tested in the CJR Model for CJR–X at this time.

Finally, we do not believe patients will delay care as that was not the case for the CJR Model or BPCI–A, both of which used 90-day episodes. Moreover, we have post-episode spending safeguards in place to ensure this does not happen, as discussed in section X.C.2.f. (5)(h) of this final rule. After consideration of the public comments we received, we are finalizing without modification the proposal at § 512.630(d) to utilize a 90-day post-discharge episode length.

(e) Episode Termination

Similar to the CJR Model, we proposed that, once an episode begins, the episode would continue until the end of the episode as described in section X.C.2.d.(3)(d) of this final rule, unless the episode is cancelled for certain reasons.

First, an episode would be canceled if the beneficiary ceases to meet any of the general beneficiary inclusion criteria described in section X.C.2.c. of this final rule. When a beneficiary's status changes during the episode, the episode target price would still reflect full payment for the episode. However, we would not have full Medicare episode payment data for the beneficiary to reconcile against the target price. Therefore, the episode would be canceled.

Second, in the case that a beneficiary has a subsequent inpatient admission for an episode on the same day as or within 3 days of an outpatient LEJR procedure, the outpatient episode would not initiate an anchor procedure and the outpatient procedure would instead initiate an anchor hospitalization. That is, the anchor hospitalization start date will be that of the outpatient procedure. We proposed this policy because we believe that an inpatient episode should take precedence over an outpatient procedure performed on the same day, given the likelihood of higher spend associated with the inpatient episode and potential for higher clinical acuity.

Third, we proposed to cancel the episode if a beneficiary dies at any point during the CJR–X episode. As discussed in the EPM proposed rule (81 FR 50841), we consider mortality to be a harmful beneficiary outcome that should be targeted for improvement through care redesign. We also believe holding participants responsible for episodes during which a beneficiary dies could encourage participants to actively reduce beneficiaries' risk of death. However, we acknowledge that the likelihood that a death that is unrelated to an LEJR procedure occurs is increased the further out from the anchor procedure or anchor hospitalization. Therefore, we believe that holding participants responsible for death during a 90-day episode would create too much uncertainty and variability for participants.

We note that TEAM only cancels episodes if death occurs during the anchor hospitalization or anchor procedure, but not if the death occurs in the post-discharge period (89 FR 69730). As we discussed in the CJR final rule (80 FR 73318), there would be limited incentive for efficiency that could be expected when death occurs during the anchor hospitalization itself. We considered aligning the CJR–X policy with TEAM but believe while this policy is appropriate for a 30-day episode where the cause of death during the post-discharge period is more likely to be related to the index procedure, it is inappropriate for than in a 90-day episode. Therefore, we did not propose for CJR–X to only cancel episodes for a death that occurs during the anchor hospitalization or anchor procedure. Rather, we would cancel any episode during which a death occurs during the anchor hospitalization, anchor procedure, or post-discharge period.

Finally, we proposed that episodes subject to extreme and uncontrollable circumstances (EUC) would be canceled, meaning that the services associated with the episode would continue to be paid through Original Medicare, but the episode would not be reconciled against a target price. We proposed to base the CJR–X EUC definition on the definition finalized in the CJR 2018 final rule (83 FR 26604), which was designed to address the extreme and uncontrollable costs associated with natural disasters such as hurricanes, flooding, and wildfires. Specifically, we proposed that the EUC policy would apply to CJR–X participants with a CCN address located in a county where both: (1) a major disaster has been declared under the Stafford Act; and (2) section 1135 waivers have been issued. We believe that it is appropriate for our EUC policy to apply only in the narrow circumstance of a major disaster, which is catastrophic in nature and tends to have significant impacts on infrastructure, rather than the broader grounds for which an emergency could be declared.

We considered alternative approaches to EUC policy that would allow mandated participants to meet the model's objectives when one or more campuses of a hospital system is in a disaster area but would fail to meet the requirements set forth here. Specifically, we recognize that some hospital systems span across regions or state lines and a location that is not identified by the ''CCN address'' could be in a disaster area. Therefore, we considered alternative methods of identifying CJR–X participants at an individual level using NPI, TIN, or a combination of CCN and another identifier. However, we proposed to continue using CCN address until and unless an alternative is determined to be appropriate. We also stated that any potential change to the identification method used for the EUC policy would first be proposed through notice and comment rulemaking.

Separately, we acknowledge that stakeholders have requested that emergency flexibilities be extended to cybersecurity attacks. We also realize that the difficulties such a scenario would cause for CJR–X participants would extend well beyond this model. Therefore, we would consider conforming to any future CMS policy that addresses emergent cybersecurity issues, as needed, through future notice and comment rulemaking.

We acknowledge this EUC policy deviates from how the CJR Model

addressed the COVID–19 PHE which fell under a major disaster declaration. During the PHE, the CJR Model effectively waived downside risk, which resulted in substantial losses to Medicare. We believe canceling the episode, rather than waiving downside risk, is a better long-term policy to avoid significant risk to the government, while maintaining flexibility for the CJR–X participant. In regard to determining the start date of episodes to which the EUC would apply, we believe that episodes initiated during an emergency period or in the 30 days before the start date of an emergency period (as defined in section 1135(g) of the Act) should reasonably capture those beneficiaries whose high episode costs could be attributed to extreme and uncontrollable circumstances.

We also proposed canceling a CJR–X episode if the beneficiary is in in the 30-day post-discharge period following a TEAM anchor hospitalization or anchor procedure (that is, for an episode at a non-CJR–X hospital). Further discussion of this proposal is discussed in section X.C.2.h.(2) of this final rule.

In summary, we proposed that the following circumstances would cancel an episode:

- The beneficiary no longer meets the criteria for inclusion.
- The beneficiary dies during the episode.
- The CJR–X participant is subject to the EUC policy.
- The beneficiary is in a TEAM episode and has a LEJR procedure at a CJR–X participant during the 30-day post-discharge period after a TEAM anchor hospitalization or anchor procedure.

When an episode is canceled, we proposed that the services furnished to beneficiaries prior to and following the episode cancellation would continue to be paid by Medicare as usual but there would be no episode spending calculation that would be reconciled against the target price (see section X.C.2.f.(5) of this final rule). As discussed in section X.C.2.j. of this final rule, waivers of program rules applicable to beneficiaries in episodes would apply to the care of beneficiaries who are in episodes at the time the waiver is used to bill for a service that is furnished, even if the episode is later canceled.

We sought comment on our proposal at § 512.630(e) to cancel episodes once they have begun but prior to the end of the 90-day post-discharge period under certain conditions. The following is a summary of the public comments received.

Comment: Many commenters asked that CMS clarify how CJR–X would handle overlapping or subsequent LEJR episodes during an active 90-day episode. Commenters described situations involving staged bilateral procedures, a second joint replacement, or overlap between CJR–X and TEAM episodes. Many commenters recommended that CMS follow prior CJR Model policy by canceling or ending the first episode when a subsequent qualifying procedure begins a new episode. Commenters stated that clear precedence rules are necessary for attribution, reconciliation, quality measurement, beneficiary notices, and operational administration.

Response: CMS appreciates requests for clear rules for subsequent and overlapping LEJR episodes. We proposed that once an episode is initiated, all Medicare Part A and B services, with some exceptions, would be included in the episode until the episode ends 90-days post-discharge, or until the episode is canceled in accordance with § 512.630(e).

We acknowledge the need for a policy that addresses a subsequent CJR–X LEJR procedure during the course of an CJR–X LEJR episode. We recognize that it is common for a beneficiary to receive a joint replacement and then undergo a second joint replacement during the 90-day post-discharge period and our intention is to maintain the CJR Model policy without modification. In the CJR Model, if a beneficiary was readmitted for another LEJR procedure during a CJR episode, such as occurs for a staged contralateral procedure, we stated our belief that it would not be appropriate to include both episodes in the model with overlapping time periods. Therefore, we canceled the first LEJR episode and allowed the subsequent LEJR procedure to initiate a new episode, superseding the first.

We recognize that TEAM does not have a policy to cancel one of the episodes when two episodes overlap and there may be instances when a beneficiary may have a subsequent admission for a second TEAM LEJR episode during the 30-day discharge period. Our belief is that such occurrences will be infrequent within TEAM's shorter 30-day episode, assuming the need for beneficiaries to be medically optimized before undergoing a second procedure. However, with a 90-day CJR–X episode, we believe a second LEJR procedure during the post-discharge period will be a more frequent occurrence and it may be more appropriate to cancel the first LEJR episode, consistent with original CJR policy. While we are not finalizing a policy for a second LEJR episode at this time, we may address these situations in future rulemaking.

With respect to episode overlap between CJR–X and TEAM, we proposed to allow the first episode initiated to continue and not initiate a subsequent episode. That is, we proposed to cancel a CJR–X episode that is initiated for a beneficiary that is already in the 30-day post-discharge period of a TEAM episode and allow the spending for the procedure at the CJR–X hospital to be included in the TEAM episode. We note that the overlap policy would apply to any TEAM episode category and is not limited to LEJR episodes. The CJR–X overlap policy is discussed in greater detail in section X.C.2.h.(2) of this final rule. Similarly, as discussed in section X.A.2.a.(3) of this final rule, if a beneficiary is in a CJR–X episode and has a subsequent procedure during the 90-day post-discharge period, the procedure would not initiate a TEAM episode and any spending from that procedure would be included in the CJR–X episode.

Comment: A couple of commenters appreciated the inclusion of an EUC policy. A few commenters requested that CMS also include a cybersecurity-related EUC flexibility. A commenter stated that the prevalence and sophistication of security risks is increasing with the advent of AI and the attacks are both disruptive and take considerable time to remedy.

Response: We appreciate support for the EUC policy. The COVID–19 PHE was an unprecedented situation and policy choices made during that time warranted changes for future situations. We acknowledge that the CJR EUC policy only covered major disasters, although other circumstances, such as cyberattacks, could be equally disruptive to hospital operations. We stated in the proposed rule that such disruptions would likely extend beyond the CJR–X and indicated our intention to conform to CMS policy that would expand the EUC to other instances outside of the control of the CJR–X participant. We stated we would consider changing the policy to address emergent cybersecurity issues, as needed, through future notice and comment rulemaking. However, in light of comments received we are finalizing the addition of cyberattacks to the EUC policy. Similar to policies for the Quality Payment Program at § 414.1380(c)(2)(i)(C), the MSSP, and the Ambulatory Specialty Model at § 512.780(a) to allow CMS to determine, based on information known to the Agency prior to the beginning of the relevant reconciliation calculation for

the performance year in which the cyberattack occurred, that data for a CJR–X participant are inaccurate, unusable, or otherwise compromised due to circumstances outside of the control of the CJR–X participant and its agents, including third-party intermediaries.

Comment: A commenter proposed that CJR–X episodes be canceled if a beneficiary receives any services at a swing bed, outpatient CAH or Rural Health Clinic during the 90-day episode.

Response: We acknowledge the commenter's recommendation, but do not believe that CJR–X episodes should be canceled solely because a beneficiary receives services from a swing bed, outpatient CAH, or Rural Health Clinic during the 90-day episode; excluding such episodes could remove clinically appropriate rural care from episode accountability and reduce the model's ability to evaluate LEJR care across the full post-discharge period.

After consideration of the public comments we received, we are finalizing with modification the proposal at § 512.630(e) to cancel episodes and not perform an episode spending calculation for reconciliation against the target price if the beneficiary no longer meets the criteria for inclusion at § 512.620; the beneficiary dies during the episode; the CJR–X participant is subject to the EUC policy, including due to a cyberattack; or the beneficiary is in a TEAM episode and has a LEJR procedure at a CJR–X participant during the 30-day post-discharge period after a TEAM anchor hospitalization or anchor procedure.

e. Quality Measures and Scoring

(1) Background

The Medicare Modernization Act of 2003, the Affordable Care Act of 2010, and the Tax Relief and Healthcare Act of 2006 led to the implementation of several hospital quality reporting programs where payment reflects the quality of care delivered to Medicare beneficiaries. The CJR Model also tied quality to payment. We believe that future episode-based payment models, including CJR–X, should continue to link quality and payment to ensure ongoing incentives to improve patient outcomes and lower health care spending. This is particularly important in an expanded model where some CJR–X participants will be new to episode-based payment models.

The CJR Model relied on data already reported to the Hospital Inpatient Quality Reporting (IQR) Program (section 1886(b)(3)(B)(viii) of the Act) to assess quality without additional reporting burden for CJR participants. Measures used in the CJR Model included a joint replacement-specific measure and a general patient experience survey of the hospital stay. Specifically, the CJR Model utilized the Hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure, further discussed in Section X.C.2.e.(3) of this final rule. In addition to the two HIQR measures, the CJR Model offered participants an opportunity to receive additional points towards their quality score for voluntarily submitting THA/TKA patient-reported outcomes (PROs) and limited risk variable data following eligible elective primary THA/TKA procedures.

(2) Selection of Quality Measures

We expect CJR–X will incentivize hospitals to engage in care redesign activities to reduce post-surgical complications and hospital readmissions and enhance patient experience and outcomes for Medicare beneficiaries undergoing joint replacement surgery. Moreover, achieving savings while continuing to ensure high-quality care for Medicare beneficiaries will require close collaboration among hospitals, physicians, post-acute care providers, and other clinicians.

The quality measures we proposed for CJR–X are a natural outgrowth of the CJR Model and maintain focus on patient safety, patient experience, and health outcomes for beneficiaries undergoing hip and knee arthroplasty. The proposed measures sustain ongoing efforts to improve quality and health outcomes across a beneficiary's care journey and incentivize hospitals to better align and coordinate care across various programs and care settings. We believe the measures used for CJR (80 FR 73465 through 73507) remain appropriate for assessing care and proposed to continue utilizing those measures for inpatient LEJR episodes in CJR–X. However, we proposed two notable variations from the CJR Model measures, which are discussed in detail in section X.C.2.e.(3) of this final rule.

First, we proposed to weight the THA/TKA PROs more heavily by forgoing voluntary PRO submission and relying on the required data submitted through the quality reporting programs. CMS is committed to increased use of PROs, whenever possible, as these measures provide valuable insights into the patient's perspective of care received. PROs assessing health status as a result of care are a critical type of outcome needed for health care quality assessment. The use of PRO measures (PROMs), standardized instruments that query patients' self-assessments of their health, provide a direct way to capture patients' experience of care and the results of that care. PROMs can assess multiple health domains, including physical health, emotional well-being, and social functioning by measuring outcomes relevant to each domain, such as symptoms, functional status, and mental status. As a result, they provide rich information on how care affects multiple dimensions of patients' well-being.

Broadly, patient-reported data includes PROs and electronic PROs (ePROs), which is the electronic capture of this data; PROMs, which reflect how the PRO data is reported (for example, a survey or questionnaire); and patient-reported outcome-based performance measures (PRO–PMs), which are reliable and valid quality measures of aggregated PRO data reported through a PROM and potentially used for performance assessment. In support of this goal, the HIQR now includes a THA/TKA PRO–PM, which was developed using the PRO data voluntarily submitted under the original CJR Model. Therefore, CJR–X would use THA/TKA PRO–PM data submitted to the HIQR for the purpose of scoring model performance.

Second, CJR–X would adopt two additional measures to account for the high percentage of hospital outpatient LEJRs procedures. Outpatient same-day surgery has become commonplace in the United States. Nearly 70 percent of all THA and TKA surgeries are now performed in the outpatient setting. By the end of the CJR Model, outpatient procedures accounted for nearly three in four THA and TKA episodes. For this reason, we believe it necessary to supplement the previous measure set to include metrics which capture complications and patient experience related to outpatient surgery. Therefore, we proposed to use additional quality measures that are currently reported under the Hospital Outpatient Quality Reporting (HOQR) Program (section 1833(t)(17)(C) of the Act).

The proposed measures would be used to determine hospital quality of care in the form of a composite quality score (CQS), as described in section X.C.2.e.(5) of this final rule. As observed in the 7th annual evaluation of the CJR model, the proportion of hospitals achieving ''Good'' or ''Excellent'' quality ratings has increased over the course of

the CJR Model.[592] However, there is continued opportunity for quality improvement. Similar to the CJR Model, the CQS would be used to adjust the discount factor, as described in section X.C.2.f.(3)(g) of this final rule, that is applied to the CJR–X participants' reconciliation target price, as specified in section X.C.2.f.(5)(e) of this final rule, during the reconciliation process to tie quality performance to payment.

The measures we proposed are as follows:

- Hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)
- Hospital Visits Within 7 days of Hospital Outpatient Department (HOPD) Surgery
- Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS)
- Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems Survey (OAS CAHPS)
- Hospital-Level Total Hip and/or Knee Arthroplasty (THA/TKA) Patient Reported Outcome (PRO)-Based Performance Measure

We believe the CJR–X proposed measure set would provide CMS with sufficient information to monitor quality performance related to care provided to beneficiaries undergoing a hip or knee replacement and for the purposes of model evaluation. However, should we determine the need to adjust the measure set in future performance years, we would propose any changes through notice and comment rulemaking.

We sought comment on additional measures that should be considered for CJR–X. The following is a summary of the public comments received.

Comment: Some commenters supported CMS's proposed direction for CJR–X quality measurement, including consistency with CJR and alignment with TEAM and existing CMS quality programs. Some commenters recommended that CMS better align CJR–X quality performance measurement with TEAM and other Medicare quality reporting programs, such as IQR, OQR, ASCQR, HVBP. Other commenters stated that consistency across measure specifications and baseline periods can improve methodological coherence and reduce duplicative administrative burden. They appreciated CMS's effort to align quality measurement in value-based care models with broader quality reporting programs. The comments generally favored maintaining alignment rather than creating a separate quality measurement system for CJR–X. Another commenter appreciated alignment but had concerns about the limited differentiation and duplicative nature of the proposed quality measures, which largely overlap with existing programs.

Response: We appreciate commenters' support for aligning CJR–X quality measurement with existing CMS programs and prior CJR experience. We proposed the CJR–X quality framework to maintain accountability using measures that are applicable to LEJR episodes and aligned with existing reporting programs. We recognize concerns about overlapping measures, but this is a product of meeting our goal to reduce duplicative reporting requirements and support national comparability across hospitals. We believe that maintaining continuity with prior CJR policies where appropriate can support participants' understanding of model requirements while allowing targeted improvements in CJR–X.

Comment: Some commenters stated that using different measures for LEJR populations in CJR–X and TEAM could lead to confusion about how CMS defines quality. They stated that this creates unnecessary complexity, reduces clarity for multidisciplinary teams, and undermines coordination among stakeholders working to improve outcomes. Commenters stated the growing complexity of program requirements has created substantial operational burden for providers that may undermine efforts to modernize measurement through electronic clinical quality measures (eCQMs). Many commenters supported using the Information Transfer measure to better align CJR–X with TEAM and create a more balanced inpatient and outpatient framework.

Response: We recognize that coordinating quality measures between CJR–X and TEAM LEJR episodes is preferable, whenever possible. However, model alignment must be balanced with the need for measures that are particularly meaningful for CJR–X. By necessity, TEAM uses measures that are able to be reasonably applied to all five of its episode categories, not just LEJR episodes. In addition, TEAM, as a Phase I test, has greater flexibility to employ measures that have not yet generated performance data through implementation, such as the Information Transfer Patient-Reported Outcome-based Performance Measure. Although we considered using the Information Transfer Measure, it will not become mandatory under the HIQR until CY 2027 and there is currently insufficient historical data to reasonably estimate CJR–X participant performance on the measure. As discussed in section X.C.2.e.(3)(d) this final rule, the CMS Actuary requires such data to estimate model performance as a condition of certification. Therefore, we were unable to propose the Information Transfer measure at this time. However, we did indicate in the proposed rule that we will consider stakeholder feedback on the quality measure set and may make adjustments as data availability and implementation experience mature.

Comment: Some commenters recommended that CMS use quality measures that are directly attributable to LEJR episodes and the care redesign activities evaluated under CJR–X. A commenter stated that other measures would fall outside the scope of metrics that should be considered in determining total joint arthroplasty quality. Commenters believed that more episode-specific measures would give CMS, hospitals, and beneficiaries a clearer picture of the care furnished during joint replacement episodes. Another commenter stated some of the measures are not fully within provider control during a 90-day episode that spans multiple care settings. Some commenters suggested CMS delay the model until reliable, valid, and equitable quality measures can be developed to specifically measure care associated with lower extremity joint replacements.

Response: We agree that CJR–X quality measurement should be closely connected to the episode population and care redesign goals wherever possible. For this reason, we selected lower extremity joint replacement-specific outcome and PRO measures. Both the THA/TKA complications measure and THA/TKA PRO–PM are directly and solely related to LEJR episodes. In addition, CAHPS measures reflect patient experience for inpatient and outpatient care settings, which is relevant to all hospital care, including care provided during LEJR episodes. While the Hospital Visits within 7 days of HOPD Surgery measure is not limited to LEJR procedures, it captures common complications that may arise following outpatient THA and TKA procedures. Moreover, the complications specified in the measure largely crosswalk to the inpatient THA/TKA complications measure. We believe this measure set appropriately captures episode-specific accountability and patient experience and is relative to the care associated

[592] *Comprehensive Care for Joint Replacement Model—Seventh Annual Report, December 3, 2025. https://www.cms.gov/priorities/innovation/innovation-models/cjr.*

with joint replacement procedures. However, we will consider stakeholder feedback on the quality measure set and may make additional adjustments prior to the model start date.

Comment: Some commenters stated that broad hospital-wide measures may be influenced by unrelated service lines, patient populations, or system-level conditions and, therefore, may not accurately reflect joint replacement quality. Several commenters suggested that CJR–X should target complications, outcomes, and patient experience associated with LEJR rather than relying on general facility performance.

Response: We thank commenters for feedback regarding assessment of quality for outpatient LEJR episodes in the absence of a fully-implemented LEJR-specific HOQR measure. As stated in the proposed rule, although the vast majority of LEJR episodes are now outpatient, the HOQR doesn't include a THA/TKA complications measure and outpatient THA/TKA PROs are currently only being reported on a voluntary basis. Until such time as the reporting for LEJR-specific measures is mandatory under the HOQR, including such measures as a CJR–X requirement would create additional administrative burden for model participants. We also note that the CMS Chief Actuary requires sufficient performance data to estimate CJR–X participant performance on the measures before we are unable to adopt them in CJR–X. Therefore, the options available to us are to (1) assess participants only for inpatient episodes, using the HIQR measures; or (2) assess participants at the facility level, by generalizing inpatient THA/TKA Complications and PRO–PMs to encompass all LEJR regardless of setting. We believe the first option would unfairly minimize the work that CJR–X participants put into administering and reporting pre- and post-operative PRO surveys, particularly for those voluntarily reporting the outpatient PROs in anticipation of the mandatory start in CY 2028. The second option avoids additional burden, while allowing overall facility quality to serve as a proxy for outpatient LEJR-specific quality. Because the measure assesses the same CJR–X participant, we disagree that it will inaccurately reflect HOPD quality. Moreover, HOPD and inpatient procedures often utilize the same operating rooms, anesthesia teams, post-operative care units, and perioperative staff.

Comment: Some commenters suggested using a wider range of quality measures to support the delivery of high-quality, safe, patient-centered care. A commenter encouraged CMS to ensure that quality metrics remain sufficiently robust to discourage stinting on medically-necessary services. Many commenters recommended that CMS add a cross-setting care coordination measure, such as documented structured electronic care plan transfer to a skilled nursing facility or home health agency, the Information Transfer Patient-Reported Outcome-based Performance Measure (OP–46), or a patient-centered home time outcome measure. They stated that LEJR episode success often depends on transitions after discharge and that CJR–X should better reflect care coordination across the 90-day post-discharge period. Another commenter supported measures of patient experience, patient and workforce safety and reliability, clinical quality, and caregiver engagement that are evidence-based, targeted, and meaningful to patients and caregivers.

Response: We appreciate commenters' recommendations to adopt a broader set of quality measures, including those that guard against incentives to stint on medically-necessary services and place greater emphasis on care coordination throughout the full length of the episode. In selecting measures for CJR–X, we sought to balance comprehensiveness with feasibility, reliability, alignment with existing CMS quality reporting programs, and participant reporting burden. We believe the proposed quality domains—complications, patient experience, and patient-reported outcomes—provide a balanced framework for assessing whether participants are improving efficiency while maintaining or improving quality. In addition, CJR–X includes post-discharge flexibilities, such as home visits and telehealth waivers, to support safe recovery and care management during the episode.

We agree that LEJR episode performance often depends on whether beneficiaries receive clear discharge instructions, timely communication among providers, appropriate post-acute care, and support during the 90-day recovery period and believe the patient experience measures adequately address communication, discharge information, and care coordination. We also agree that utilizing PROs and aligning with TEAM are preferable and did both, whenever possible. For this reason, we considered using the Information Transfer Patient-Reported Outcome-Based Performance Measure. However, there is insufficient historical data to reasonably estimate CJR–X participant performance on the measure. Therefore, we proposed to use OAS CAHPS to assess outpatient episode quality performance until adequate data are available. We may consider the Information Transfer measure for future use in CJR–X as measure specifications, data availability, and implementation experience mature.

Comment: Some commenters recommended that CMS monitor long-term outcomes, readmissions, mortality, infections, or functional recovery beyond the CJR–X 90-day episode. Commenters stated that some outcomes important to LEJR quality, including non-elective joint replacement outcomes and functional recovery, may extend beyond the episode period. They suggested that CMS collect post-episode patient data up to one year after surgery. Commenters believed longer-term monitoring could provide insight into recovery, downstream utilization, and care quality. Another commenter requested that CMS adopt a quality measure for tracking prosthetic joint infections with a longer performance window, as delayed and late presenting infections are not currently captured in the 90-day measure.

Response: We appreciate commenters' recommendations regarding longer-term outcome monitoring. We proposed a 90-day CJR–X episode duration consistent with the CJR Model and the period during which beneficiaries often receive the most intensive post-acute care. We recognize that certain outcomes, including readmissions, infections, mortality, and functional recovery, may be informative beyond the 90-day episode. However, extending accountability or required reporting beyond the proposed episode would impact attribution, clinical relevance, data availability, burden, and the relationship between longer-term outcomes and hospital episode management. Therefore, we don't believe extending quality monitoring for CJR–X specifically, would maintain operational feasibility for national implementation at this time.

Comment: Some commenters raised concerns about relying on survey-based patient experience measures for CJR–X. Commenters stated that survey response rates are low, survey fatigue is persistent, and facility-wide surveys may not represent Medicare beneficiaries undergoing LEJR procedures. A commenter stated that CAHPS surveys do not stratify by MS–DRG or outpatient procedure code and, therefore, cannot be applied directly to LEJR episodes. A commenter questioned the relevance and applicability of CAHPS given the significant time lag between the admission or procedure and survey completion and its subsequent use for determining CJR–X

performance. Other commenters stated that patient satisfaction or all-payer facility experience scores are not precise proxies for clinical quality or LEJR episode experience. Several commenters recommended minimizing the relative importance of CAHPS survey measures and instead focus on outcomes-based and PRO-based clinical outcome measures.

Response: We appreciate commenters' concerns about using survey-based patient experience measures in CJR–X and agree that patient experience measures should not serve as the sole proxy for clinical quality. For that reason, we proposed a composite quality score that balances patient experience with outcomes-based and PRO measures, including complication measures and the THA/TKA PRO–PM. The proposed methodology weights clinical outcomes most heavily while still recognizing that communication, discharge planning, care coordination, and recovery information are important to LEJR episode quality.

We recognize that HCAHPS and OAS CAHPS are facility-level measures and are not stratified by MS–DRG or outpatient procedure code. However, these measures are standardized, validated, and already reported through existing CMS quality programs. Using these surveys allows us to assess patient experience without creating new CJR–X-specific survey burden. Therefore, we disagree that survey-based measures should be removed from the CJR–X quality methodology, as they are the only method by which we are able to incorporate patient voice into performance assessment. Removing them would reduce accountability for beneficiary communication and care transitions.

Moreover, we do not believe it necessary to limit potential to improve care and efficiencies beyond a particular episode-based payment model. For example, previous model tests have inspired many of the care coordination activities that have become standard practice for hospitals, such as pre-surgical patient education and post-discharge outreach, and there is demonstrated benefit to such spill-over effects.

Comment: Several commenters felt the measure set placed too much emphasis on measures that are not yet fully established or reliable. A couple of commenters stated many of the measures considered are challenged by the current case minimums and patient acuity changes with procedures shifting to outpatient and ASC settings. Commenters recommended the measure set be revised to address reliability, data collection burden, and survey response rate concerns before being used for accountability. Another commenter raised the issue of using highly technical metrics in the CJR–X measure set.

Response: We appreciate commenters' concerns about the inclusion of measures that are new to the Medicare quality reporting programs. We recognize some of these measures are still voluntary or in the first year of reporting and we are still gathering data on provider performance. Therefore, we will continue to evaluate the reliability of the measures to ensure they remain appropriate for inclusion in CJR–X when the model begins in CY 2028. We selected the measures because of their applicability to LEJR episodes and to avoid creating additional reporting burden for participants, as these are measures already required under the HIQR and/or HOQR. However, should CMS determine that providers are not able to meet the case minimums or the measures are not providing sufficiently reliable data, we will certainly consider alternatives.

Comment: A commenter recommended that CMS monitor for unintended consequences associated with the proposed CJR–X quality measures. The commenter stated that the quality performance aspects of CJR–X should fairly and appropriately reflect relevant care. The commenter expressed conceptual concerns because several measures may be used for the first time as part of a pay-for-performance model. Another commenter stated that, as designed, the model effectively creates overlapping penalties by mandating a second pay for performance penalty using similar data already used to calculate payment structures for LEJR procedures.

Response: We appreciate the recommendation to monitor for unintended consequences. We recognize that applying measures in a payment accountability context can raise fairness, reliability, and behavioral incentive concerns, particularly when measures are newly incorporated into a model's financial methodology. We proposed to monitor the effects of CJR–X on model participants and beneficiaries to ensure the model does not create adverse incentives. Monitoring activities may include evaluating measure performance, participant behavior, and beneficiary outcomes. We will also take into account participant and stakeholder feedback to assess whether future refinements are warranted through notice-and-comment rulemaking.

Comment: Some commenters urged CMS to ensure measures are appropriately adjusted for patient complexity and socioeconomic factors outside the direct control of providers. Some commenters were concerned that hospitals with a higher percentage of low-income patients or at higher social risk will do worse on quality measures. They stated that those hospitals struggled in CJR and CJR–X should take steps to adequately account for these populations. A few commenters encouraged CMS to evaluate whether patient experience measures accurately reflect the quality of the full episode of care rather than isolated inpatient encounters.

Response: We appreciate concerns about social risk, patient complexity, and fair quality measurement. In the proposed rule, we proposed payment methodology features, including risk adjustment and policies for safety net and low-volume hospitals, to address differences in hospital and beneficiary characteristics in the model's financial accountability framework. We recognize that social risk and clinical complexity may affect quality performance and we will continue to assess the measures to ensure reliability and fairness. We note that CMS quality reporting programs generally rely on the tested specifications and applicable risk-adjustment approach established in development and throughout the maintenance of each measure.

Comment: Many commenters recommended that CMS consider additional measures for inclusion in the CJR–X quality measure set. Some commenters recommended that CMS include functional status, functional recovery, therapy utilization, or Section GG data in the CJR–X quality framework. Commenters stated that functional outcomes are important to understanding whether LEJR beneficiaries recover mobility and self-care ability after surgery. A commenter recommended that CMS utilize a more reliable and more objective measure to evaluate functional recovery where performance represents all episodes based upon standardized data collection that is performed by licensed professionals such as therapists. They suggested that standardized functional data collected across post-acute care settings, including Section GG information, could help CMS assess patient recovery and therapy needs. A commenter suggested measures of timeliness and quality of rehabilitative care to better capture patient recovery in the post-acute period of an episode. Another commenter suggested that CMS use existing validated measures, such as 30-day readmissions following primary THA/TKA. Other commenters

recommended that CMS collect and analyze therapy utilization and patient outcome data to better understand the services CJR–X beneficiaries need to achieve the best outcomes. Some commenters recommended including a surgical site infections (SSI) measure, such as the measure used in the MIPS Clinical Quality Program for Surgical Site Infections (Quality #357), to encourage improved care of closed surgical incisions while lowering costs. Another commenter stated that CMS should consider future quality and safety measures that better recognize timely identification and intervention for postoperative deterioration, particularly during the high-risk period immediately following discharge. Another commenter recommended adopting an ankle-specific patient-reported outcome measure, such as the Foot and Ankle Outcome Score (FAOS), which is conceptually similar to the HOOS and KOOS instruments used for hip and knee episodes.

Response: We thank commenters for their suggestions of other quality measures CMS should consider for the CJR–X quality measure set. In developing the CJR–X quality measure set, we prioritized measures that CJR–X participants already report through existing CMS quality reporting programs. This approach is intended to minimize additional reporting burden while still allowing CMS to assess important dimensions of quality for LEJR episodes. Accordingly, we are finalizing as proposed to use measures reported through established CMS quality reporting programs, including measures related to complications, patient experience, and patient-reported outcomes, to calculate the composite quality score in CJR–X.

We also believe it is important to maintain a focused quality measure set when calculating the composite quality score. The composite quality score methodology is intended to allow performance on each required quality measure to be meaningfully valued in the model's pay-for-performance methodology, while combining multiple complementary measures into a single assessment of hospital performance across the episode of care. Adding numerous additional measures could reduce the relative weight and interpretability of each individual measure within the composite score and make it more difficult for CJR–X participants and CMS to assess meaningful quality improvement across the measure domains.

We recognize commenters' interest in additional measures that directly assess functional recovery, therapy needs, and post-acute rehabilitation outcomes. We agree that recovery of mobility, self-care, and function after LEJR procedures is an important aspect of episode quality. We note that the THA/TKA complications measure includes both wound and periprosthetic joint infections and the THA/TKA PRO–PM is a functional outcomes measure that captures patient-reported pain and functional status following THA/TKA, so the measures assess distinct and complementary dimensions of quality relevant to LEJR episodes.

We also recognize commenters' recommendations regarding therapy utilization, rehabilitative care, surgical site infections, postoperative deterioration, and readmissions. We believe the CJR–X quality measure set reflects the appropriate quality domains while balancing the value of additional quality information against the burden of requiring new data collection from CJR–X participants. However, we will take these quality measure recommendations into consideration. Any changes to the CJR–X quality measure set would first be proposed through notice and comment rulemaking.

(3) Quality Measures

(a) Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (CMIT ID #350)

THA and TKA are commonly performed procedures that improve quality of life for the Medicare population and are generally considered safe. However, as discussed in the 2015 CJR final rule (80 FR 73473 through 73477), post-operative complications related to these procedures do exist. The hospital-level risk-standardized complication rate (RSCR) following elective primary THA and/or TKA, also referred to as the THA/TKA Complications measure, was finalized for use in the CJR Model to measure a hospital's rate of mortality, myocardial infarction, pneumonia, sepsis, pulmonary embolism, bleeding, infection, and mechanical failure following inpatient surgery.[593] [594]

The goal of this measure is to improve patient outcomes by providing patients, physicians, hospitals, and policy makers with information about complication rates following inpatient primary elective THA and/or TKA at a given hospital. Measurement of patient outcomes allows for a broad view of quality of care that encompasses more than what can be captured by individual process-of-care measures. Complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient environment, all contribute to patient outcomes but are difficult to measure by individual process measures. The goal of outcomes measurement is to risk-adjust for patient conditions at the time of hospital admission and then evaluate patient outcomes. The measure was developed to identify institutions whose performance is better or worse than would be expected based on their patient case-mix, promote quality improvement, and better inform consumers about care quality.

The THA/TKA Complications measure captures the most common complications following inpatient THA and TKA. The outcome (complication) is defined as any one of the specified complications (not already present on admission) that occurs from the date of admission to 90 days following admission. Complications are counted in the measure only if they occur during the index hospital admission or during a readmission. The complication outcome is a dichotomous (yes/no) outcome. If a patient experiences one or more of these complications in the applicable time period, the complication outcome for that patient is counted in the measure as a ''yes'': acute myocardial infarction (AMI), pneumonia or other acute respiratory complication, or sepsis/septicemia/shock during the index admission or within seven days of the start of the index admission; surgical site bleeding or other surgical site complication, pulmonary embolism, or death during the index admission or within 30 days of the start of the index admission; mechanical complication or periprosthetic joint infection/wound infection or other wound complication during the index admission or within 90 days of the start of the index admission.[595]

[593] ''Primary'' refers to an initial joint replacement. The measure does not assess revision joint replacement procedures.

[594] Hospital-Level, Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA), Centers for Medicare & Medicaid Services Measures Inventory Tool, CMIT Measure ID 350. *https://cmit.cms.gov/cmit/#/FamilyView?familyId=350.*

[595] Exception: Subsequent inpatient admissions with a principal diagnosis code of COVID–19 (U07.1) or with a secondary diagnosis code of COVID–19 coded as present on admission on the claim within the seven/30-day time frames are not eligible for use by the measure (and are excluded) in determining whether AMI, pneumonia or other

Continued

In the 2015 CJR final rule (80 FR 73473 through 73477), we described our reasoning for adopting the THA/TKA Complications measure. We shared historical information about the development of the measure, its implementation in CMS programs, and its public display. Our rationale for its continued use is unchanged. Given the clinical alignment with the LEJR episode and its use in the CJR Model, the measure is well established and minimizes complexity since it is familiar to hospitals. Further, the measure reflects the full episode of care, and, given it is risk-standardized, reduces the incentive to avoid higher-risk patients. We believe this measure is beneficially actionable, at both the hospital and care team level, to influence performance through preoperative optimization, standardizing perioperative protocols, and incorporating post-acute care coordination and early complication management.

Therefore, we proposed at § 512.635(a)(1) to use hospital-level RSCR following elective inpatient primary THA and/or TKA (CMIT ID #350) to assess episode quality performance starting in PY1 of CJR–X. We sought comment on the inclusion of this measure in the CJR–X measure set. The following is a summary of the public comments received.

Comment: Some commenters supported adopting the Hospital-Level Risk Standardized Complication Rate (RSCR) following elective primary Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA) as part of the CJR–X quality measure set. A commenter stated that the long-established quality measure is well-suited to track the quality of LEJR procedures.

Response: We agree and thank the commenters for their support.

Comment: Some commenters urged CMS to reconsider use of the THA/TKA complications measure because inpatient LEJR volume has declined, the measure may be topped out or produce insufficient-volume results, and it may not meaningfully distinguish performance under CJR–X. A couple of commenters stated that the shift of LEJR procedures to the outpatient setting has reduced inpatient volume at many hospitals, resulting in a growing number of hospitals unable to meet case volumes, thereby reducing the measure's usefulness for distinguishing performance or driving improvement. Some commenters stated that the THA/TKA complications measure should be revised before use. A commenter stated that hospitals with robust coding practices and resources may capture more ''Present on Admission'' comorbidities and, therefore, perform better through administrative superiority rather than clinical excellence. A couple of commenters stated that the risk adjustment methodology does not account for social factors that contribute to complication rates such as income, level of home support, access to outpatient follow-up care, or affect a patient's ability to recover successfully at home. A commenter suggested that CMS align the measure's risk adjustment with the methodology adopted for CJR–X pricing to account for social factors that materially.

Response: We disagree that the THA/TKA complications measure is topped-out or no longer useful, particularly when applied to an episode-based payment methodology. Many of the hospitals that will be CJR–X participants will be new to CMMI models and we believe there is continued benefit to emphasizing LEJR outcomes on performance. We note that the complications included in the measure only if they occur during the index hospital admission or during a readmission and we do not believe that the significant conditions included in the measure (for example, acute myocardial infarction, acute respiratory illness, sepsis, surgical site bleeding or infection, or death) would be overlooked during coding diagnoses on admission. Finally, we acknowledge the concerns about risk adjustment, coding, and reliability. However, the THA/TKA complications measure is risk-standardized and is intended to compare hospital performance while accounting for patient case mix.

Comment: A commenter recommended adapting the THA/TKA complications measure to account for outpatient total joint arthroplasty rather than relying on a less joint-specific outpatient measure.

Response: We appreciate the commenter's recommendation to adapt the Hospital-level RSCR following elective primary THA and/or TKA measure for outpatient total joint arthroplasty. We included this measure because it is well established, clinically aligned with LEJR episodes, familiar to hospitals, risk-standardized, and actionable through perioperative and post-acute care coordination efforts. Since this measure is designed to assess elective inpatient primary THA/TKA complications, we included the Hospital Visits within 7 days of HOPD Surgery measure as an outpatient proxy to assess complications for outpatient episodes. While not clinically specific to THA/TKA procedures, it does capture events associated with postoperative safety and care coordination, including emergency department visits, observation stays, and unplanned inpatient admissions shortly after discharge. We also included the measure because it can be reported through existing Hospital Outpatient Quality Reporting Program processes without additional CJR–X-specific data submission.

We also note that adapting or re-specifying an existing complications measure to include outpatient THA/TKA would require additional measure development, testing, and validation to ensure that the measure accurately captures the intended clinical outcomes, is reliable across care settings, and is appropriate for use in CJR–X. That process would take significant time, require separate reporting or data collection specifications, and would likely not be completed in time for implementation at the start of CJR–X. We may consider whether a more joint-specific outpatient complications measure could strengthen the CJR–X quality measure set in future rulemaking, particularly as outpatient THA/TKA data and measure experience mature.

After consideration of the public comments we received, we are finalizing without modification the proposal at § 512.635(a)(1) to include the hospital-level RSCR following elective inpatient primary THA and/or TKA (CMIT ID #350) in the CJR–X quality measure set.

(b) Hospital Visits Within 7 days of Hospital Outpatient Department (HOPD) Surgery (CMIT ID #344, OP–36)

There are well-described and potentially preventable adverse events that occur after outpatient surgery, such as uncontrolled pain, urinary retention, infection, bleeding, and venous thromboembolism, which can result in unexpected hospital visits. Similarly, non-clinical patient considerations, such as lack of transport home upon discharge and delayed start of surgery, are primary causes of unanticipated yet preventable hospital admissions following same-day surgery.

National estimates of hospital visit rates following surgery vary from 0.5 to 9.0 percent based on the type of surgery, outcome measured (admissions alone or admissions and emergency department

acute respiratory complication, sepsis/septicemia/shock, or pulmonary embolism occurred. The code list used to define the ''Mechanical Complication'' outcome includes 26 codes that reflect fractures of the pelvis, femur, tibia or fibula, or other bone following insertion of an orthopedic implant as well as periprosthetic fractures around the internal prosthetic joint.

visits), and timeframe for measurement after surgery. Additionally, these rates may vary among HOPDs, suggesting variation in surgical and discharge care quality. Therefore, using a quality measure of hospital visits following outpatient same-day surgery can improve transparency, inform patients and providers, and foster quality improvement.[596]

The Hospital Visits within 7 days of Hospital Outpatient Department (HOPD) Surgery measure assesses quality of care following surgery or cystoscopy performed in the hospital outpatient setting for Medicare beneficiaries. The measure outcome is any of the following hospital visits: (1) an inpatient admission directly after the surgery; or (2) an unplanned hospital visit (inpatient admission, observation stay, or emergency department visit) occurring after discharge or within 7 days of the surgery. The measure score is a ratio of the predicted to expected number of post-surgical hospital visits among the HOPD's patients. The denominator is the expected number of hospital visits given the HOPD's case mix and surgical procedure mix. The numerator is the number of hospital visits predicted for the HOPD's patients accounting for its observed rate, the number of surgeries performed at the HOPD, the case mix, and the surgical procedure mix. A score of less than one indicates the HOPD's patients were estimated as having fewer post-surgical visits than expected compared to HOPDs with similar surgical procedures and patients. A ratio of greater than one indicates the HOPD's patients were estimated as having more visits than expected.

Although it is not specific to outpatient LEJRs, we believe the Hospital Visits within 7 Days of HOPD Surgery measure is an appropriate quality measure for inclusion in CJR–X Model because it captures early, unplanned hospital utilization following outpatient surgical procedures, including elective THA and TKA. It assesses complications similar to several of those included in the THA/TKA Complications measure and, for that reason, is a good complement to the original CJR inpatient measure. As joint replacement care is primarily furnished in outpatient settings, we believe this measure would help ensure that quality accountability under CJR–X reflects current clinical practice across care settings. The measure assesses early post-operative safety and care coordination by identifying emergency department visits, observation stays, and unplanned inpatient admissions shortly after discharge—events that are often associated with potentially preventable complications or gaps in discharge planning and post-operative support. We believe performance on this measure is actionable for hospitals and clinicians and complements the existing CJR–X inpatient complications measure in supporting the model's goals of improving quality, enhancing patient safety, and reducing avoidable episode spending.

We proposed at § 512.635(a)(2) to use the Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP–36) measure to assess outpatient episode quality performance starting in PY1 of CJR–X. We sought comment on the inclusion of this measure in the CJR–X measure set. The following is a summary of the public comments received.

Comment: A couple of commenters supported including the Hospital Visits within 7 Days of HOPD Surgery measure in the CJR–X quality measure set.

Response: We thank the commenters for their support.

Comment: Some commenters did not believe the Hospital Visits within 7 days of HOPD Surgery measure would fairly and appropriately reflect quality performance relevant to CJR–X. The commenter stated that the measure is minimally suitable given that it tracks exceedingly rare events. Several commenters said the measure uses an overly broad denominator that includes all outpatient surgeries rather than joint replacements, so that the weight of the measure would be disproportionate to actual performance on LEJR procedures.

Response: We recognize that the Hospital Visits within 7 days of HOPD Surgery measure may not fully reflect quality performance specific to LEJR episodes under CJR–X. However, we are not aware of another outpatient measure currently being reported by hospitals to CMS that would capture complications related to THA and TKA procedures. We believe the Hospital Visits within 7 days of HOPD Surgery measure is the most appropriate, available measure to assess outpatient episodes because the complications specified in the measure largely crosswalk to the inpatient THA/TKA complications measure, including unplanned hospital visits shortly after outpatient procedures, observation stays, and unplanned inpatient admissions, as well as emergency department visits. We also believe this measure would provide information about short-term postoperative outcomes and care coordination for the outpatient episodes included in CJR–X.

We may consider whether a more joint-specific outpatient complications measure would be appropriate for CJR–X in future rulemaking as outpatient THA/TKA data and measure experience continue to develop.

After consideration of the public comments we received, we are finalizing without modification the proposal at § 512.635(a)(2) to include the Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP–36) measure in the CJR–X quality measure set.

(c) Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (CMIT ID #338)

The Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS) is a national, standardized, publicly-reported survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience.[597] Since 2008, HCAHPS has allowed valid comparisons to be made across hospitals locally, regionally, and nationally. Three broad goals have shaped HCAHPS. First, the standardized survey and implementation protocol produce data that allow objective and meaningful comparisons of hospitals on topics that are important to consumers. Second, public reporting of HCAHPS results creates new incentives for hospitals to improve quality of care. Third, public reporting enhances accountability in health care by increasing transparency. With these goals in mind, CMS and the HCAHPS Project Team have taken substantial steps to assure that the survey is credible, practical and actionable.

HCAHPS is a 32-item survey instrument that produces 11 publicly reported measures: 7 multi-item measures (communication with doctors, communication with nurses, restfulness of hospital environment, care coordination, responsiveness of hospital staff, communication about medicines, and discharge information); and 4 single-item measures (cleanliness of the hospital environment, information about symptoms, overall rating of the hospital, and recommendation of hospital). The FY 2025 IPPS/LTCH PPS final rule describes HCAHPS survey measure updates starting with January 2025 discharges.

[596] National Coverage Analysis (NCA) Decision Memo CAG–00157R4. *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=288.*

[597] Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS), Centers for Medicare & Medicaid Services Measures Inventory Tool, CMIT Measure ID 338. *https://cmit.cms.gov/cmit/#/FamilyView?familyId=338.*

The HCAHPS Survey asks recently discharged patients about aspects of their hospital experience that they are uniquely suited to address. The core of the survey contains 20 items that ask how often or whether patients experienced a critical aspect of hospital care, rather than whether they were satisfied with their care and two global questions about rating and recommending the hospital. Also included in the survey are three screener items that direct patients to relevant questions, five items to adjust for the mix of patients across hospitals, and two items that support Congressionally-mandated reports. Hospitals may include additional questions after the core HCAHPS items. HCAHPS is administered to a random sample of adult inpatients between 2 to 42 days after discharge. Patients admitted in the medical, surgical, and maternity care service lines are eligible for the survey; HCAHPS is not restricted to Medicare beneficiaries. Hospitals may use an approved survey vendor or collect their own HCAHPS data if approved by CMS to do so. HCAHPS can be implemented in six survey modes: mail, telephone, mail with telephone follow-up, web with mail follow-up, web with telephone follow-up, or web with mail and telephone follow-up, each of which requires multiple attempts to contact patients. Hospitals must survey patients throughout each month of the year. IPPS hospitals must achieve at least 300 completed surveys over four calendar quarters.[598]

We believe the HCAHPS survey (CMIT ID #338) is an appropriate quality measure for inclusion in CJR–X because it relies on patient-reported experiences of hospital care, including communication with providers, responsiveness of staff, and discharge information, which are critical to successful joint replacement episodes. We believe patient experience is particularly relevant in the context of episode-based payment models, as effective communication and care transitions are closely associated with adherence to post-acute care plans, rehabilitation participation, and reduced risk of avoidable utilization. Because HCAHPS is a standardized, nationally-validated survey, it allows for consistent comparison of hospital performance. Moreover, the current use of this measure in the HIQR removes the need for CJR–X to introduce additional reporting burden. Including this measure would help ensure that incentives under CJR–X continue to support patient-centered care and balance cost containment with accountability for quality and beneficiary experience.

For the reasons specified previously, we proposed at § 512.635(a)(3) to use the HCAHPS (CMIT ID #338) survey to assess inpatient episode quality performance starting in PY1 of CJR–X. We sought comment on the inclusion of this measure in the CJR–X measure set. The following is a summary of the public comments received.

Comment: A few commenters raised concerns that HCAHPS changes, low response rates, or lack of recent Consensus-Based Entity review could affect reliability and validity. A commenter stated that fracture patients, who are more likely to be discharged to SNFs, are excluded from HCAHP surveys. Commenters stated that HCAHPS depend heavily on patient participation to generate performance data, but response rates are critically low at just above 30 percent. Commenters stated that CMS needs time to address these structural problems before tying the measure to financial consequences.

Response: We acknowledge commenters' concerns. However, the HCAHPS was used in the original CJR Model and reflects overall patient experience for inpatient care settings which is relevant to care provided during LEJR episodes. We believe this measure appropriately captures patient experience and is relative to the care associated with joint replacement procedures. However, we will consider whether additional validation or transition considerations are needed when determining the CJR–X composite quality score.

Comment: Many commenters stated that HCAHPS or other broad patient experience measures may not capture meaningful LEJR-specific quality, may be influenced by broader patient populations, or may not be fully within provider control during the episode. Commenters expressed concern that extrapolating limited HCAHP data to broader populations creates questions of validity of calculating upside and downside risk payments. Commenters suggested CMS drop the care experience measures and redistribute the weighting to outcome metrics capturing rates of infection, readmissions, complications, and revisions.

Response: We disagree that the patient experience domain should be removed and continue to believe it is appropriate to include measures, such as HCAHPS, in the CJR–X quality methodology. These measures capture dimensions of care that are central to recovery from LEJR procedures, including communication, discharge planning, care coordination, and how well patients understand and experience care transitions. These domains are directly relevant to a 90-day episode in which successful recovery depends on coordination across the hospital, physician, and post-acute care settings. Clinical outcome measures are important and receive substantial weight in the CJR–X quality methodology, but they do not fully capture whether beneficiaries received coordinated, understandable, patient-centered care during an episode.

Consistent with the CJR Model's ''quality first'' approach, we believe incorporating HCAHPS-based patient experience into the composite quality score reflects our view that quality in an episode-based model should be multidimensional and not limited to avoidable complications alone. Removing patient experience measures would narrow the quality assessment and could weaken incentives for hospitals to focus on communication, discharge readiness, and care transitions that affect beneficiary recovery.

Comment: A commenter stated that the influence of the HCAHPS survey will be compounded because it is also used to evaluate performance in the Hospital Value-based Purchasing program.

Response: We do not believe the inclusion of HCAHPS in CJR–X would inappropriately compound the measure's influence because the programs use HCAHPS for different purposes and within different payment methodologies.

In CJR–X, HCAHPS would be one component of the composite quality score, which is used to determine the CJR–X participant's eligibility for reconciliation payments and the applicable quality adjustment to repayment responsibility. By contrast, the Hospital Value-Based Purchasing Program uses HCAHPS as part of a separate quality pay-for-performance program that applies its own scoring methodology and payment adjustment rules. In addition, the use of HCAHPS in CJR–X would not change how HCAHPS is scored or applied in the Hospital Value-Based Purchasing Program. The same underlying patient experience measure may therefore inform more than one CMS program without duplicating the same payment adjustment or measuring the same performance construct in the same way.

[598] For full details, see the current HCAHPS Quality Assurance Guidelines, V.19.0, under the Quality Assurance button on the official HCAHPS On-Line website at *https://www.hcahpsonline.org/en/quality-assurance/*.

We also believe that using existing, nationally-implemented measures, such as HCAHPS promotes consistency across CMS quality programs and initiatives. In addition, it benefits CJR–X participants by reducing burden because it relies on established quality reporting infrastructure and processes. Including HCAHPS in CJR–X allows the model to account for patient experience with hospital care without creating a new CJR–X-specific inpatient patient experience survey or reporting requirement.

Comment: Several commenters asked for clarification on which version of the HCAHPS would be used, as CMS is currently transitioning to the updated version. A commenter requested more detail on how HCAHPS would be scored for CJR–X, including the survey version, measure point estimate, sub-measures or composites, calculation method, and national distribution used for percentile assignment.

Response: CMS acknowledges the request for more detail on HCAHPS scoring. CMS began administering the updated HCAHPS in the HIQR for discharges beginning January 1, 2025. Because we are finalizing a January 1, 2028 start date for CJR–X, the HCAHPS performance period for PY 1 of CJR–X will be January 1, 2028–December 31, 2028. Therefore, all surveys for discharges under the HIQR, and by extension CJR–X, will be the updated version.

Comment: A couple of commenters supported including the HCAHPS survey in the measure set.

Response: We thank the commenters for their support.

Comment: A commenter stated that compact performance percentiles for patient experience measures could make meaningful improvement difficult to distinguish and could limit participants' ability to affect their composite quality score.

Response: We believe the scoring approach remains appropriate for the HCAHPS measure because the patient experience percentiles are generally commensurate with the percentiles used for the HCAHPS measure under the CJR Model. This continuity supports use of a familiar quality-scoring framework and is consistent with CMS' prior experience incorporating patient experience into the CJR Model quality methodology.

We also do not intend for any single patient experience measure to determine overall quality performance under CJR–X. Patient experience measures would be one component of the broader composite quality score, together with other measures relevant to LEJR episodes. Including patient experience measures in this broader quality score will allow us to account for beneficiary experience while limiting the effect of compact percentile distributions on the overall CJR–X quality methodology.

We will monitor the distribution and performance of patient experience measures used in the CJR–X quality methodology and may consider refinements through future rulemaking if measure performance does not adequately distinguish quality differences among participants.

After consideration of the public comments we received, we are finalizing without modification the proposal at § 512.635(a)(3) to include the HCAHPS (CMIT ID #338) survey in the CJR–X quality measure set.

(d) Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems Survey (OAS CAHPS) (CMIT ID #162)

The OAS CAHPS is the complement to the HCAHPS used for inpatient episodes. The OAS CAHPS survey collects feedback on patients' experiences and care in Medicare-certified HOPDs and ASCs.[599] Though the surveyed population is all adults rather than solely Medicare beneficiaries, it still provides relevant information about the quality of care provided at a particular facility. The survey assesses key domains such as communication with providers, information provided before and after surgery, pain management, and care coordination, all of which are critical to safe recovery and successful post-operative outcomes. It includes questions about patients' experiences with their preparation for the surgery or procedure, check-in processes, cleanliness of the facility, communications with the facility staff, discharge from the facility, and preparation for recovering at home. The survey also includes questions about whether patients received information about what to do if they had possible side-effects during their recovery.[600] Outcomes are proportions of patients in HOPDs or ASCs that responded ''Yes'' to survey questions.

We believe the OAS CAHPS survey is an appropriate quality measure for inclusion in CJR–X because it captures beneficiaries' experiences with care in outpatient surgery settings, which are the primary setting for elective total hip and total knee arthroplasty. The inclusion of this measure would ensure that patient experience accountability is measured under CJR–X, regardless of setting. OAS CAHPS is a standardized, nationally developed instrument that allows for consistent comparison of performance and its inclusion supports CJR–X's goals of promoting patient-centered care, care coordination, and high-quality outcomes across the episode.

We considered but did not propose the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery PRO–PM (OP–46), rather than the OAS CAHPS for outpatient LEJR episodes.[601] The measure, also referred to as the Information Transfer PRO–PM, aims to assess the level of clear, personalized recovery information provided to patients who had surgery or a procedure at an HOPD. It reports the average score of a patient's ratings on a three-domain, 9-item survey to evaluate the clarity of the clinical information patients are given before, during, and after an outpatient surgery or procedure. While reporting to the HOQR is voluntary for procedures in CY 2026 (CY 2028 payment determination), the Information Transfer PRO–PM will be mandatory beginning with the CY 2027 reporting period (CY 2029 payment determination).[602]

This measure was considered because it is used in TEAM and, as we have previously stated, we attempted, where feasible, to align CJR–X policies with TEAM to ensure a more reliable and valid comparison between the two models. Moreover, for reasons previously discussed, we strive to use PROs wherever possible to ensure patient voice is appropriately reflected in assessing quality of care. However, as a new measure, there is insufficient data available to reasonably estimate how CJR–X participants might perform on the Information Transfer PRO–PM.

[599] Centers for Medicare & Medicaid Services. (December 1, 2023). 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsxhttps://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[600] Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf. https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf.*

[601] Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (PRO–PM), Version 1.0 Methodology Report, April 2024. *https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf.*

[602] Hospital Outpatient Quality Reporting (OQR) Program Measures. *https://qualitynet.cms.gov/2outpatient/oqr/measures.*

Because the CMS Chief Actuary requires a high level of certainty for estimating participant performance in order to certify a model for expansion, we were limited to established measures with sufficient historical data available for analysis. Until adequate data for the Information Transfer PRO–PM is available (which could potentially be attained through TEAM evaluations), we will use the OAS CAHPS measure. Should we proposed to utilize the Information Transfer PRO–PM in the future, we would propose such a change through notice and comment rulemaking.

Therefore, we proposed at § 512.635(a)(4) to use the OAS CAHPS (CMIT #162, OP–46) to assess outpatient episode quality performance starting in PY1 of CJR–X. We sought comment on the inclusion of this measure in the CJR–X measure set. The following is a summary of the public comments received.

Comment: Some commenters supported including OAS CAHPS in the CJR–X quality measure set. A commenter appreciated CMS' effort to include outpatient measures in CJR–X, particularly given the continued migration of lower acuity joint replacement cases to outpatient settings.

Response: We appreciate the support for the inclusion of the OAS CAHPS. As LEJR procedures have largely shifted to outpatient settings, we believe it is a good complement to the inpatient measures.

Comment: A few commenters stated that broad patient experience measures, including the OAS CAHPS may not capture meaningful LEJR-specific quality. A commenter questioned whether the volume distribution of procedures underlying a facility's OAS CAHPS score is sufficiently weighted toward LEJR to make the score a meaningful proxy for LEJR episode quality. Another commenter requested that CMS provide insight into how it can ensure that the measure will fairly and appropriately reflect LEJR care. Another commenter stated the survey responses may not be fully within provider control during a 90-day episode that spans multiple care settings. Another commenter expressed concern that patient participation is necessary to generate performance data. A commenter stated that meaningful performance improvement is difficult to achieve because performance percentiles are often tightly compacted.

Response: We acknowledge commenters' concerns that OAS CAHPS is a broad outpatient surgical patient experience measure and is not LEJR-specific. Because of the large number of CJR–X outpatient THA/TKA procedures being performed, we believe it is necessary to include a patient experience measure relevant to outpatient surgical care. We note that the CJR Model quality measure set did not include a measure that assessed patient experience for outpatient episodes. Given the importance of assessing quality performance and the increasing proportion of outpatient sites of care for these procedures, we believe it is prudent to include a measure that captures patient experience in outpatient surgical care. Although OAS CAHPS is not LEJR-specific, it provides an available and established tool for incorporating outpatient patient experience into the CJR–X quality methodology.

While patient experience remains an important dimension of quality for CJR–X, the OAS CAHPS would not be the sole determinant of quality performance; rather, it would be one component of the composite quality score, together with other measures related to inpatient and outpatient LEJR episode quality. This broader scoring approach helps account for patient experience while limiting the effect of any single measure on a participant's overall quality score.

With respect to concerns that performance percentiles for patient experience measures may be compact, we believe the current approach remains reasonable because the patient experience percentiles used for CJR–X are generally commensurate with the percentiles used for the HCAHPS measure under the CJR Model. This continuity supports use of a familiar scoring framework and is consistent with prior experience incorporating patient experience into the CJR quality methodology.

We recognize that patient involvement is essential for survey-based performance data. Therefore, we avoided creating new surveys or reporting processes that might overwhelm patients or CJR–X participants. We will continue to monitor the performance, distribution, and usefulness of patient experience measures in the CJR–X quality methodology and may consider future refinements through notice and comment rulemaking.

Comment: Some commenters stated that the proposed use of the OAS CAHPS places too much emphasis on a measure that is not yet fully standardized or been submitted for Consensus-Based Entity review. They stated that, therefore, hospitals, patients and policymakers have no independent assurance of its appropriateness, either generally or for use in CJR–X. A commenter stated that fewer than 1 percent of facilities administering the survey by mail with phone follow-up achieve response rates above 36 percent, representing a fundamental challenge to the representativeness and validity of the underlying data. Commenters asked CMS to provide evidence of the survey's reliability before it requires survey administration.

Response: We value commenters feedback on their concerns with the OAS CAHPS. As a measure that assesses patient experience in outpatient settings, we believe its inclusion in CJR–X is appropriate, especially as more THA/TKA procedures are performed in outpatient settings. Therefore, it would be an oversight to rely so heavily on inpatient quality measures when outpatient episode volume far exceeds inpatient volume. Because CJR–X holds CJR–X participants accountable for the quality of care throughout the LEJR episode, we believe it is important to include a measure that reflects the beneficiary's experience of care, including communication, preparation for discharge and recovery, and coordination of outpatient surgical care.

We also believe that relying on an established patient experience measure may provide a broader and more patient-centered assessment of quality than a narrowly focused process measure. While process measures can play an important role in quality measurement, they may not fully capture the aspects of outpatient surgical care that beneficiaries are best positioned to assess. Including a patient experience measure in the CJR–X composite quality score helps ensure that the model evaluates not only whether certain care processes occurred, but also whether beneficiaries experienced care in a manner consistent with high-quality, coordinated, patient-centered care.

We are also mindful of CJR–X participant burden. We included OAS CAHPS because it aligns with existing CMS quality reporting infrastructure. We also believe that including OAS CAHPS in a nationally expanded model may support broader use of the measure and promote greater standardization in outpatient surgical patient experience reporting. Increased use of the measure could provide CMS, hospitals, patients, and other stakeholders with more opportunity to evaluate OAS CAHPS performance across outpatient surgical settings.

As previously noted, we recognize that survey-based measures depend on patient participation and that response rates may affect representativeness. We

also recognize commenters' concern that a broad outpatient surgical survey may not fully capture LEJR-specific quality. For these reasons, OAS CAHPS would not be the sole determinant of a CJR–X participant's quality performance under CJR–X. It would be one component of the broader composite quality score, together with other measures related to inpatient and outpatient LEJR episode quality.

We will continue to consider the reliability, validity, response rates, and usefulness of OAS CAHPS for CJR–X as additional experience with the measure becomes available. We may also consider refinements to the CJR–X quality measure set through future rulemaking if the measure does not adequately support assessment of outpatient patient experience for CJR–X episodes.

Comment: Some commenters stated that the use of the OAS CAHPS in CJR–X is premature in a pay-for-performance context. A commenter noted that CJR–X would represent the first time OAS CAHPS is used to directly determine payment consequences based on performance. A couple of commenters requested that CMS implement the measure as pay-for-reporting during year one of CJR–X. A commenter stated that the measure was only made mandatory for hospital outpatient departments beginning January 1, 2025, meaning hospitals will have limited experience with this measure at the time CJR–X performance years begin. Another commenter requested that CMS delay use of OAS CAHPS in quality scoring until hospitals have completed at least two full years of mandatory reporting experience.

Response: We acknowledge commenters' concerns that hospitals may have limited mandatory reporting experience with the OAS CAHPS measure before the start of CJR–X. However, the OAS CAHPS is already used in a pay-for-reporting context under existing CMS quality reporting infrastructure. Using OAS CAHPS in the CJR–X quality methodology would build on that existing reporting framework and would place greater emphasis on patient experience as a component of quality in an episode-based payment model since CJR–X is a pay-for-performance approach. We believe this is appropriate because patient experience is an important part of the quality of care hospitals provide for outpatient surgical episodes.

We recognize that OAS CAHPS is newer in mandatory reporting. However, because mandatory reporting for OAS CAHPS began on January 1, 2025, hospitals will have had three years of reporting experience prior to the launch of CJR–X on January 1, 2028, as finalized in section X.C.2.a of this final rule. We also note that given the updated model start date, we have made conforming edits to the quality measure performance periods, in section X.C.2.e.(3)(4)(a) of this final rule. The updated quality measure performance period for the OAS CAHPS is January 1, 2028–December 31, 2028, which follows three years of mandatory reporting. We believe three years of mandatory reporting will provide hospitals with sufficient experience collecting and reporting the measure before its use in CJR–X.

We will continue to consider hospitals' reporting experience with OAS CAHPS, the measure's reliability and usefulness, and whether any phase-in or scoring refinements are necessary through future rulemaking as additional experience with the measure becomes available.

After consideration of the public comments we received, we are finalizing without modification the proposal at § 512.635(a)(4) to include the OAS CAHPS (CMIT #162, OP–46) survey in the CJR–X quality measure set.

(e) Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO–PM) (CMIT ID #1618)

Administrative claims-based THA/TKA Complications and hospital readmission measures have been publicly reported since 2013. However, these measures do not capture the reasons for which patients undergo elective THA and TKA (for example, Will quality of life be improved after undergoing the procedure?). Therefore, a quality measure based on PRO data provides both patients and providers with a unique and critical perspective on care.

As the goal of the procedures is to improve quality of life, THA and TKA are ideal candidates for assessing PROs. The original CJR model included voluntary reporting of PRO data. In order to meet the CJR Model requirements for successful submission of PRO data, hospitals had to submit the Veterans RAND 12 Item Health Survey (VR–12) or Patient-Reported Outcomes Measurement Information System (PROMIS) Global-10 generic PRO survey; and the (HOOS Jr.)/(KOOS Jr.) or HOOS/KOOS subscales PRO survey for patients undergoing eligible elective primary THA/TKA procedures.

Using the data collected from CJR participants, CMS developed the THA/TKA PRO–PM (CMIT ID #1618) to assess the quality of care delivered to Medicare beneficiaries undergoing elective THA or TKA.[603] As described in the FY 2023 IPPS/LTCH PPS Final rule (87 FR 48780), the THA/TKA PRO–PM became a mandatory requirement for hospitals included in the Hospital IQR Program beginning July 1, 2025. Therefore, voluntary PRO submission is no longer a relevant incentive. Rather, inclusion of the PRO–PM in the HIQR provides an opportunity for CJR–X to access this data without additional burden to CJR–X participants.

The Hospital-Level THA/TKA PRO–PM measure is an appropriate quality measure for inclusion in CJR–X because it directly assesses improvements in patients' pain, physical function, and health-related quality of life following elective joint replacement. Unlike utilization- or complication-based measures, this measure captures outcomes that matter most to beneficiaries. The measure evaluates change in patient-reported outcomes from before surgery to after recovery, which provides a meaningful assessment of episode-level effectiveness and complements existing CJR–X quality measures. In addition, because the measure is risk-adjusted and allows for fair comparison across hospitals, it would support accountability while minimizing incentives to avoid higher-risk patients. Including this measure would strengthen alignment between the CJR–X financial incentives and patient-centered care and support the model's goals of improving quality, value, and beneficiary experience throughout the episode of care.

As stated, THA/TKA PRO–PM reporting is currently only mandatory in the HIQR. However, we believe the inpatient measure provides an overall reflection of hospital performance related to LEJR care and can appropriately be used to infer quality of care for outpatient episodes even in the absence of outpatient-specific PRO collection. Therefore, we do not propose to require PRO submission for outpatient CJR–X episodes but will use the inpatient THA/TK PRO–PM to assess quality of care for all LEJR episodes, regardless of setting.

We note that voluntary THA/TKA PRO reporting to the HOQR (OP–42) has already begun for procedures performed in CY 2025 and will be mandatory for procedures performed in CY 2028 (2031

[603] Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure, Centers for Medicare & Medicaid Services Measures Inventory Tool, CMIT Measure ID 1618. *https://cmit.cms.gov/cmit/#/FamilyView?familyId=1618.*

payment determination).[604] CJR–X may rely on data from the HOQR when it becomes available, but only after proposing such a change through CJR–X notice and comment rulemaking.

Therefore, we proposed at § 512.635(a)(5) to use the Hospital-Level THA/TKA PRO–PM (CMIT ID #1618) to assess inpatient and outpatient LEJR episode quality performance starting in PY1 of CJR–X. We sought comment on the inclusion of this measure in the CJR–X measure set and alternatives to our proposal to apply the PRO–PM to outpatient episodes. The following is a summary of the public comments received.

Comment: Some commenters supported including the THA/TKA PRO–PM in CJR–X. A commenter stated it is appropriate for CJR–X because it directly assesses improvements in patients' pain, physical function, and health-related quality of life following elective joint replacement. Another commenter recommended CMS continue developing patient-reported outcome measures as part of quality assessment. Another commenter stated that PRO measures have the potential to meaningfully inform clinical decision-making and improve patient outcomes. Another commenter stated that THA/TKA PRO–PM represents the type of patient-centered outcome data that could bridge acute episode accountability and longitudinal chronic care management and asked CMS to describe how these measures could be linked to other models, such as ACCESS and CARA arrangements within LEAD, to enable specialists and/or ACCESS participants to track functional status longitudinally for the same patient population.

Response: We thank commenters and agree that the measure is appropriate for CJR–X.

Comment: Many commenters stated that PROs should be implemented in a manner that is both realistic and achievable to ensure their long-term effectiveness and to avoid unintended burden on participating providers. They further stated that, at this time, the operational burden and resource intensity of administering and reporting the PROs will exceed the capabilities of many hospitals. Many commenters stated the operational realities present substantial barriers for hospitals and health systems. A commenter urged CMS to address website issues which frequently result in uploading rejections. They stated that the data elements required for reporting and the timelines for data collection are incredibly complex and require painstaking review of data formatting. Some commenters stated that hospitals in rural and medically-underserved settings do not employ their surgeons, and post-discharge follow-up is conducted with the surgeons, limiting hospitals access to PROs and control over survey administration. Commenters cautioned that the CJR Model demonstrated that even highly engaged and clinically sophisticated organizations struggled to successfully report this measure. They stated that administering PROs diverts resources both pre- and post-operatively from patient care, as it requires significant clinical and quality staff time for patient outreach, tracking, and data entry. Further, post-operative PRO collection at 90–365 days requires long-term tracking outside standard workflows, reliance on third-party tools or manual processes that increase duplication and risk of error. Many commenters asked CMS to provide flexibility, technical support, or refinements. A commenter expected that there will be limited consistency and completeness in the early years of implementation until systems can build sustainable workflows. The commenter requested that CMS align PRO requirements across programs and allow flexibility in the initial performance years.

Response: We acknowledge commenters' concerns that PRO collection and reporting creates operational burden. However, we note that the HIQR reporting requirement for the Hospital-Level THA/TKA PRO–PM is outside the scope of this model. As hospitals must already report the measure to the HIQR, CJR–X will not create additional burden. We also note that there are several differences between the CJR Model PRO reporting experience and the PRO–PM requirements. First, the CJR Model PRO submissions were voluntary, so it is difficult to estimate how many hospitals would have successfully reported PROs under mandatory conditions. Second, the CJR Model instituted increasing minimum reporting thresholds over the course of the model, beginning at 50% in PY 1 and ending at 90% in PY 8. However, in PY 1, 67% of CJR hospitals successfully met the 50% threshold, which is the same threshold currently in use for the PRO–PM under the HIQR.

We acknowledge that collecting both pre-operative and post-operative PRO data may require hospitals to develop or refine workflows for patient outreach, tracking, data submission, and coordination with surgeons and other providers involved in post-discharge care. We also recognize commenters' concerns that hospitals in rural or medically underserved areas, or hospitals that do not employ their orthopedic surgeons, may face additional challenges obtaining PRO data after discharge. These operational considerations are important, and we will consider whether technical assistance, clarification of specifications, or additional implementation flexibility is needed to support feasible reporting.

We continue to believe that including the Hospital-Level THA/TKA PRO–PM in CJR–X is important because it provides a patient-centered measure of surgical recovery and functional improvement that cannot be fully assessed through administrative data alone. We will continue to consider ways to reduce unnecessary burden, improve reporting reliability, and support hospitals in collecting meaningful PRO data for LEJR episodes.

Comment: Many commenters urged CMS to delay mandatory performance-based use of the THA/TKA PRO–PM. Commenters requested that CMS keep the measure voluntary to allow time for participants to establish reporting processes and for CMS to assess response rates, and feasibility. Many commenters asked that CMS make the measure ''pay-for-reporting'' only for the first few years of the model. A commenter requested that CMS not begin ''pay-for-performance'' until the FY2030 Hospital IQR payment determination period. Other commenters suggested offering bonus points for voluntary reporting, as was done in the CJR Model, or removing the PRO–PM.

Response: We thank the commenters for their recommendations and acknowledge concerns about using the THA/TKA PRO–PM in CJR–X for assessing performance.

We note that the THA/TKA PRO–PM is currently in use in a pay-for-reporting context under the HIQR. Using the measure in CJR–X under a pay-for-performance approach would build on that existing reporting framework and strengthen the importance of PROs in evaluating the quality of care hospitals provide. We believe this is appropriate because CJR–X would link financial accountability to both cost and quality for LEJR episodes, and patient outcomes are an important part of assessing the quality and value of care delivered during those episodes.

We further believe that including the THA/TKA PRO–PM in a national episode-based payment model may increase the incentive to report and

[604] Patient-Reported Outcome Performance Measures Overview, CMS QualityNet. *https://qualitynet.cms.gov/outpatient/measures/PRO-PM.*

support broader, more consistent use of PRO data for LEJR care. Increased use of the measure could provide more experience evaluating PRO–PM performance across hospitals and support more reliable reporting practices over time.

We believe that delaying performance-based use of the Hospital-Level THA/TKA PRO–PM for several years could slow progress toward incorporating patient-centered outcomes into value-based care for LEJR episodes. At the same time, we recognize the importance of implementing the measure in a manner that is operationally feasible, reliable, and fair to participating hospitals. We will continue to consider hospitals' reporting experience, data completeness, response rates, and operational feasibility as the THA/TKA PRO–PM is implemented in CJR–X.

Comment: Many commenters suggested making refinements to measure specifications before implementation and taking a measured approach to allow for further evaluation of measure reliability. A commenter stated that the small sample sizes at low-volume hospitals increase variability, limit meaningful comparisons, and require substantial administrative effort with limited value. Other commenters strongly recommend that CMS establish a minimum sample size threshold for the THA/TKA PRO–PM, as a single patient could materially affect results. Another commenter did not believe that comparing participants with lower response rates to others with 90–100% of patients responding was a meaningful incentive. Another commenter urged CMS to implement social risk adjustment methodologies to ensure outcome benchmarks are appropriately adjusted for patient demographics and baseline function before linking them to payment.

Response: We acknowledge commenters' concerns about measure reliability and the lack of social factors in the THA/TKA PRO–PM measure risk adjustment methodology. However, as previously discussed, CJR–X is relying on data that is mandatorily submitted to the HIQR and changes to the measure are out of scope for this model.

We also note that re-specifying an existing measure is not simply an operational change. Additional testing and validation would be needed to assess whether proposed refinements improve fairness and reliability without introducing unintended bias, reducing comparability, or undermining the measure's ability to evaluate outcomes. That process would take significant time. However, we will continue to assess the response rates, sample sizes, and reliability of the HIQR measure as it matures and may consider future refinements to the THA/TKA PRO–PM specifications as appropriate.

Comment: Many commenters recommended lowering the case minimums for the measure. The commenters stated the measure disproportionately affects rural, safety-net, and low-volume facilities because it lacks feasible case minimums. Many commenters noted that completion rates are impacted by factors beyond provider control, including digital literacy, access issues, language barriers, and limited patient awareness. Commenters also urged CMS to account for the population-level factors that drive collection gaps at essential hospitals independent of care quality. Another commenter suggested CMS restore improvement-based quality scoring to allow hospitals to demonstrate meaningful progress in PRO–PM collection and performance over time. Several recommended setting the case minimums at 25 for larger, urban hospitals and 10 for small and/or rural hospitals. Commenters also recommended patient-exclusion criteria or the ability to report patient refusals to capture the volume of patients who decline to participate or are in hospice. A commenter stated their post-op response rates are 28% lower, on average, compared to the pre-op response rates. Other commenters recommended a data-collection framework with an evidence-based response rate less than 50% for low-volume and rural settings and clinically realistic data-collection timelines that align with everyday clinical workflows.

Response: We believe the 25-case minimum is reasonable because it is commensurate with case minimums used for other CMS quality measures. A case minimum helps ensure that measure results are based on enough observations to support more reliable performance assessment and to reduce the effect that a very small number of patient responses may have on a hospital's quality score. We recognize, however, that case minimums must balance reliability with the need to allow participating hospitals, including low-volume and rural hospitals, to be fairly assessed for quality performance in the model.

We also note that the 50 percent minimum reporting threshold currently in use for the PRO–PM under the HIQR corresponds to the reporting threshold in the first CJR performance year. Although submission was voluntary, 67 percent of CJR participants who submitted PROs in PY 1 were successful. We do recognize that hospital reporting under mandatory conditions may differ, but we anticipate that the mandatory requirement would increase engagement among model participants.

Nevertheless, we will continue to monitor the effects of including the measure in CJR–X and may take these recommendations into consideration in the future. *Comment:* We received a few comments about the measure cohort. A commenter requested that CMS limit the cohort to Medicare as primary payor only. They stated that it is nearly impossible, at the time of survey enrollment, to know whether Medicare is the secondary or tertiary payer, resulting in the enrollment of many more patients than will qualify just to avoid a penalty. Another commenter stated that because this is difficult to determine, the measure should not include only those for whom Medicare is the primary payer. Another commenter urged CMS to expand the THA/TKA PRO–PM cohort to include Medicare Advantage beneficiaries, as a FFS-only restriction captures only a minority of joint replacement volume, producing small, non-representative denominators.

Response: We proposed to use the same Hospital-Level THA/TKA PRO–PM measure specifications used in the HIQR to maintain consistency and alignment across CMS programs. We do note that the Medicare Advantage program is itself a value-based program with its own quality requirements which aid in capturing data on the outcomes of enrollees.

At this time, we believe that using the HIQR specifications will support standardization, comparability, and alignment across CMS quality measurement efforts. We will continue to consider whether future refinements to the THA/TKA PRO–PM cohort are warranted as we evaluate measure reliability, feasibility, and representativeness across hospitals.

After consideration of the public comments we received, we are finalizing without modification the proposal at § 512.635(a)(5) to include the Hospital-Level THA/TKA PRO–PM (CMIT ID #1618) in the CJR–X quality measure set.

(4) Quality Measure Reporting

(a) Display of Quality Measures and Performance Periods

We stated in the proposed rule that we believe that the display of measure results is an important way to educate the public on hospital performance and increase the transparency of the model.

We proposed at § 512.635(f) to display quality measure results on the publicly available CMS website in a form and manner consistent with other publicly reported measures. CMS would share each CJR–X participants' quality metrics with the hospital prior to display on the CMS website. The timeframe for when CJR–X participants would receive data on our proposed measures aligns with the Care Compare schedule that can be found here: *https://data.cms.gov/provider-data/topics/hospitals/measures-and-current-data-collection-periods.* We noted that all measures under the statutory hospital quality programs have a 30-day preview period prior to results being posted on the Care Compare web page. CJR–X participant measure scores would be delivered to CJR–X participants confidentially. We proposed to publicly report PY 1 measure scores in calendar year 2029 and we would continue to publicly report scores every performance year with an approximate 1-year lag. We believed this approximate 1-year lag period would be a sufficient amount of time to ensure accuracy of the measures data.

We also recognized in the proposed rule that measure performance periods would not align perfectly with performance years based on availability of data needed to assess quality performance in CJR–X. We proposed the following measure performance periods, summarized in Table X.C.–01. While only 5 performance years are displayed in the table, we proposed that the measure performance periods would continue at the same cadence each performance year. We stated in the proposed rule that where possible, these proposed measure performance periods align with existing CMS quality reporting program measure performance periods to minimize CJR–X participant confusion. We also acknowledged in the proposed rule that the measure performance periods do not exactly line up with the performance years used in CJR–X. While this creates some disparity between measure performance periods and model performance years, we believed this approach is the least burdensome to CJR–X participants because it does not require them to report on these measures separately for CJR–X. Additionally, we stated in the proposed rule that this approach is similar to how some measures were captured in the original CJR model as well as TEAM.

TABLE X.C-01: SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR IN CJR-X

Quality Measure	CJR-X Performance Year (PY)				
	PY1	PY2	PY3	PY4	PY5
Hospital-Level RSCR Following Elective Primary THA and/or TKA (CMIT ID #350)	April 1, 2026- March 31, 2028	April 1, 2027-March 31, 2029	April 1, 2028-March 31, 2030	April 1, 2029-March 31, 2031	April 1, 2030-March 31, 2032
Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP-36)	January 1, 2027-December 31, 2027	January 1, 2028-December 31, 2028	January 1, 2029-December 31, 2029	January 1, 2030-December 31, 2030	January 1, 2031-December 31, 2031
HCAHPS Survey (CMIT ID #338)	January 1, 2027-December 31, 2027	January 1, 2028-December 31, 2028	January 1, 2029-December 31, 2029	January 1, 2030-December 31, 2030	January 1, 2031-December 31, 2031
OAS CAHPS Survey (CMIT ID #162)	January 1, 2027-December 31, 2027	January 1, 2028-December 31, 2028	January 1, 2029-December 31, 2029	January 1, 2030-December 31, 2030	January 1, 2031-December 31, 2031
Hospital-Level THA/TKA PRO-PM (CMIT ID #1618)	July 1, 2026-June 30, 2027	July 1, 2027-June 30, 2028	July 1, 2028-June 30, 2029	July 1, 2029-June 30, 2030	July 1, 2030-June 30, 2031

We sought comment on our proposals at § 512.635(e) on how quality measures in CJR–X would be displayed and the quality measure performance periods.

The following is a summary of the public comments received on our proposals to display quality measure performance and align quality measure performance with existing CMS quality reporting programs, and our responses to these comments:

Comment: A commenter supported the timing and display of measures being publicly reported.

Response: We thank the commenter for their support.

Comment: A commenter objected to the measure performance periods because some of the measure performance periods will begin before CJR–X implementation and asked CMS to revise the timing.

Response: We recognize the commenter's concern that CJR–X participants may be assessed using quality data from periods before the model starts. This approach is consistent with the CJR Model and we continue to believe is appropriate at this time because the CJR–X quality methodology relies on established CMS quality measures and existing reporting timelines. Using available measure performance periods supports timely calculation of the CQS and avoids creating new CJR–X-specific reporting timelines that could increase burden and reduce consistency with other CMS quality reporting programs. Therefore, when we are performing reconciliation calculation, we will be using quality measure data that are the most currently available and aligns with measure data available through the Hospital Inpatient Quality Reporting Program and Hospital Outpatient Quality Reporting Program. We believe that aligning the measure performance periods with measure periods used in CMS quality reporting programs will reduce the potential for confusion and ensures that CJR–X uses the most currently available measure results for calculating participant hospital reconciliation payment determinations.

We also believe that using existing quality reporting periods promotes transparency and comparability across participant hospitals. These measures reflect ongoing hospital quality performance and are already part of hospitals' quality reporting obligations, rather than new requirements created solely for CJR–X. Delaying the use of quality measure data until only post-implementation periods are available could delay reconciliation calculations and disbursement or collection of reconciliation payment or repayment amounts.

We do note that the model start date has shifted by three months, as described in section X.C.2.a of this final rule, which means CJR–X performance years run on the calendar year and reconciliation calculations would be pushed back three months as well. Given this timing change, we are making conforming changes to the measure performance periods in this final rule. TABLE X.C–02 summarizes the finalized quality measure

performance periods by performance year in CJR–X.

TABLE X.C-02: SUMMARY OF QUALITY MEASURE PERFORMANCE PERIODS BY YEAR IN CJR-X

Quality Measure	CJR-X Performance Year (PY)				
	PY1 (1/1/28-12/31/28)	PY2 (1/1/29-12/31/29)	PY3 (1/1/30-12/31/30)	PY4 (1/1/31-12/31/31)	PY5 (1/1/32-12/31/32)
Hospital-Level RSCR Following Elective Primary THA and/or TKA (CMIT ID #350)	April 1, 2027-March 31, 2029	April 1, 2028-March 31, 2030	April 1, 2029-March 31, 2031	April 1, 2030- March 31, 2032	April 1, 2031-March 31, 2033
Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP-36)	January 1, 2028-December 31, 2028	January 1, 2029-December 31, 2029	January 1, 2030-December 31, 2030	January 1, 2031-December 31, 2031	January 1, 2032-December 31, 2032
HCAHPS Survey (CMIT ID #338)	January 1, 2028-December 31, 2028	January 1, 2029-December 31, 2029	January 1, 2030-December 31, 2030	January 1, 2031-December 31, 2031	January 1, 2032-December 31, 2032
OAS CAHPS Survey (CMIT ID #162)	January 1, 2028-December 31, 2028	January 1, 2029-December 31, 2029	January 1, 2030-December 31, 2030	January 1, 2031-December 31, 2031	January 1, 2032-December 31, 2032
Hospital-Level THA/TKA PRO-PM (CMIT ID #1618)	July 1, 2027-June 30, 2028	July 1, 2028-June 30, 2029	July 1, 2029-June 30, 2030	July 1, 2030-June 30, 2031	July 1, 2031-June 30, 2032

Additionally, we see the value of aligning measure performance periods and model performance years and will monitor the timing and use of quality data under CJR–X and may consider refinements to measure performance periods in future notice and comment rulemaking.

Comment: A commenter recommended shortening the lag between measure performance and CQS calculation at reconciliation so that within performance year improvements are reflected in the reconciliation amount for the year in which they occur, using hybrid claims plus eCQM data already submitted under Hospital Inpatient Quality Reporting Program.

Response: We are using quality measure data from the Hospital Inpatient Quality Reporting Program, and we aim to use the most currently available data such that measure performance periods may overlap as much as possible with a performance year. Shortening the lag substantially could create operational and methodological challenges. Specifically, we would need to ensure that the measure data were sufficiently complete, risk adjusted where applicable, validated, and available for all participant hospitals on a consistent timeline. Using incomplete or preliminary data could reduce reliability, create inequities across hospitals, and increase the risk that reconciliation amounts are based on unstable or non-comparable quality results.

We may monitor the relationship between measure performance periods and reconciliation timing.

After consideration of the public comments, we are finalizing without modification the proposal at § 512.635(e) on how quality measures in CJR–X would be displayed. We are also finalizing with modification the quality measure performance periods used to assess quality performance. The modification accounts for the updated model start date and performance years now aligned with calendar years.

(b) Data Submission Criteria

As discussed in the proposed rule, we believe it is important to be transparent and to outline the form, manner, and timing of quality measure data submission so that accurate measure results are provided to hospitals, and that timely and accurate calculation of measure results are consistently produced to determine reconciliation payment amounts and repayment amounts. We proposed that data submission for the Hospital-Level RSCR Following Elective Primary THA and/or TKA (CMIT ID #350), the HCAHPS survey (CMIT ID #338), and the Hospital-Level THA/TKA PRO–PM (CMIT #1618) would be accomplished through existing Hospital Inpatient Quality Reporting Program processes. Since these measures are reported to the Hospital IQR or other CMS quality reporting programs, CJR–X participants would not need to submit additional data for CJR–X.

For measures in the outpatient setting, we proposed that data submission for the Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP–36) and the OAS CAHPS (CMIT #162) survey be accomplished through the existing Hospital Outpatient Quality Reporting Program. Therefore, CJR–X participants would not need to submit additional data for CJR–X.

The following is a summary of the public comments received on our proposals to collect quality measure data from existing CMS quality reporting programs, and our responses to these comments:

Comment: Some commenters supported CMS' effort to minimize the reporting burden for hospitals by

selecting a parsimonious set of measures that hospitals already report to other CMS quality programs.

Response: We thank the commenter for this support.

Comment: Some commenters urged CMS to rely on existing data sources wherever possible, and suggested CMS continue to ensure alignment with the Hospital Inpatient Quality Reporting Program and Hospital Outpatient Quality Reporting Programs. Another commenter suggested that CMS consider the potential data collection burden of the Hospital-Level THA/TKA PRO–PM and ways to leverage technology to minimize reporting burden.

Response: We agree that minimizing reporting burden is an important consideration in designing and implementing the CJR–X quality methodology. We believe CJR–X reflects this goal because the CQS relies on measures and reporting processes already used in existing CMS quality reporting programs, rather than creating a separate CJR–X-specific quality reporting framework. This approach supports consistency across CMS programs, reduces duplicative reporting, and allows participant hospitals to focus on quality improvement rather than new administrative requirements.

We also acknowledge commenters' concerns about the potential data collection burden associated with the Hospital-Level THA/TKA PRO–PM. We continue to believe in the value of including this measure because patient-reported outcomes provide important information about pain, function, and recovery that is not fully captured through claims-based or patient experience measures. At the same time, we recognize that collecting PRO–PM data requires patient engagement, follow-up workflows, and reporting infrastructure.

We will continue to be mindful of reporting burden as CJR–X is implemented and may consider opportunities to leverage existing processes, technology, and alignment with broader CMS quality reporting efforts. We may monitor participant experience with PRO–PM data collection.

Comment: A commenter stated that implementation of CJR–X will require significant investments in quality reporting.

Response: We disagree because CJR–X is relying on quality measures that hospitals must already report to CMS in existing CMS quality reporting programs. Absent CJR–X, hospitals must report on the five quality measure in the Hospital Inpatient Quality Reporting Program and Hospital Outpatient Quality Reporting program. As a result, CJR–X does not require hospitals to make significant investments in quality reporting beyond what they already have allocated. We believe this approach is the best way to incorporate quality into reconciliation while minimizing new administrative burden, because it uses familiar reporting channels without creating duplicative submissions for CJR–X.

Comment: A commenter suggested that registry reporting could reduce administrative burden for hospitals new to value-based care, support quality and safety improvement, improve patient outcomes, and strengthen measurement. The commenter also noted that a registry could share facility-level metrics or support integration of registry-based metrics into the CQS, and that a registry's benchmarking functionality could help CMS refine the model over time.

Response: We thank the commenter for the suggestion and willingness to partner with CMS to support hospital reporting efforts. At this time, we believe the CJR–X quality methodology is the most appropriate approach because it relies on measures that are already reported through existing CMS quality reporting programs. We note that not every hospital may have access or resources to work with quality registry and we want to ensure hospital reporting can be applied consistently across participant hospitals. We recognize the value of a registry, especially in supporting hospitals that are new to value-based care that may not have experience with reporting quality measures or clinical data elements. We also recognize reporting flexibility may be important to meet the needs of CJR–X participants. We may consider incorporating registry reporting but also acknowledge it would require CMS to assess the availability, completeness, standardization, validation, and feasibility of registry data. Any such changes would be considered through future notice and comment rulemaking.

Comment: A commenter recommended that CMS require hospitals to report infections to the American Joint Replacement Registry and make aggregate product-line infection rates publicly available.

Response: We agree that surgical infections are important patient safety and quality concerns for LEJR beneficiaries, and that information about infection rates can support quality improvement efforts. However, we are not requiring CJR–X participants to report infections to a registry or to publicly report aggregate product-line infection rates as part of CJR–X at this time. We recognize that registries may provide valuable information for clinical quality improvement, including information related to joint replacement outcomes, complications, implants, and infection-related concerns. In addition to burden concerns, we would need to consider, among other issues, whether such reporting would be feasible for all CJR–X participants, whether the data would be standardized and sufficiently comparable, how product-line infection rates would be attributed and risk adjusted, how public reporting would protect beneficiary privacy, and how any new requirement would interact with existing hospital quality reporting and infection surveillance requirements.

We will continue to monitor quality of care and will continue to consider stakeholder feedback, registry data opportunities, measure-development work, monitoring results, and evaluation findings when assessing whether additional infection-related reporting or quality measures would be appropriate for CJR–X or future LEJR payment initiatives.

After consideration of the public comments, we are finalizing without modification the proposal to collect quality measure data from existing CMS quality reporting programs.

(5) Composite Quality Score (CQS)

(a) Overview

We stated in the proposed rule that we believe that CJR–X provides another mechanism for CJR–X participants to improve quality of care, while also achieving cost efficiency. Incentivizing high-value care through episode payments for LEJR is a primary objective of the model. Therefore, incorporating quality performance into the episode payment structure is an essential component of CJR–X, just as it was for the CJR Model (80 FR 73370) and for TEAM (89 FR 69774). We believe it is important for CJR–X to link the financial reward opportunity with performance in the quality of care for Medicare beneficiaries in a LEJR episode.

As discussed in section X.C.2.f. of this final rule, which outlines the pricing methodologies for CJR–X, we discuss the approach for setting a target price for LEJR episodes. We stated in the proposed rule that we would apply the CJR–X participant's discount factor, based on the participant's quality performance for the performance year, to calculate the reconciliation target price for LEJR episodes. We refer to section X.C.2.f.(5)(e). of this final rule for further discussion of the relationship between a CJR–X participant's quality

performance and the discount factor. A CJR–X reconciliation target price would represent expected spending on all related Part A and Part B items and services furnished during a LEJR episodes and would incorporate the CJR–X participant's discount factor for the performance year. CJR–X participants that achieve actual FFS spending below the reconciliation target price for a given performance year may be eligible for a reconciliation payment from CMS, subject to the proposed stop-gain limit policy as discussed in section X.C.2.f.(5)(g). of this final rule. CJR–X participants that achieve actual FFS spending that exceed the reconciliation target price for a given performance year would be required to pay CMS a repayment amount, subject to the stop-loss limit policy as discussed in section X.C.2.f.(5)(g). of this final rule.

We proposed a composite quality score methodology for linking quality and payment in CJR–X that is similar to, but not the same, as the methodology that was finalized for the CJR Model (80 FR 73363 through 73381). We proposed to define the ''composite quality score'' at § 512.605 as a score computed for each CJR–X participant to summarize the CJR–X participant's level of quality performance on specified quality measures as described in § 512.635. We indicated in the proposed rule that notably different is the inclusion of outpatient quality measures in CJR–X and thus the assessment of these measures in the composite quality score. The CJR–X composite quality score methodology would allow performance on each required quality measure to be meaningfully valued in the CJR–X's pay-for-performance methodology, incentivizing and rewarding cost savings in relation to the quality of episode care provided by the CJR–X participant.

We stated that although performance on each measure would be valued in the CJR–X composite quality score methodology, it is the CJR–X participant's overall quality performance under the CJR–X that would be considered in the pay-for-performance approach, rather than performance on each quality measure individually determining the financial opportunity under CJR–X. We noted in the proposed rule that the composite score methodology also provides a framework for incorporating additional measures of meaningful outcomes in the future. Finally, we stated that while we believe that high performance on all of the quality measures represents goals of clinical care that should be achievable by all CJR–X participants that heighten their focus on these measures, we appreciated that many CJR–X participants would have room for significant improvement in their current measure performance. The composite score methodology would provide the potential for financial reward for CJR–X participants that reach ''good'' or ''excellent'' quality performance, thus incentivizing their continued efforts to improve the quality and efficiency of LEJR episodes.

(b) Determining Quality Measure Performance

In the proposed rule we believed that assessing measure performance by comparing CJR–X participants against a national distribution for the proposed CJR–X measures would be the most appropriate way to incorporate quality performance into CJR–X. Moreover, we believed that hospitals nationally are currently working to improve their performance on quality measures on an ongoing basis as some of these measures are included in other CMS programs such as the Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs. Therefore, we expected that CJR–X participants would have a heightened focus on performance on these measures as a result of the financial incentives resulting from the CJR–X payment methodology.

Thus, at the time of reconciliation for a performance year, we proposed at § 512.635(c) to assign each CJR–X participant's measure point estimate from the measure performance period, as discussed in section X.C.2.e.(5)(d). of this final rule, to a performance percentile based on the national distribution of measure results for hospitals that are eligible for payment under the IPPS reporting the measure, as discussed in section X.C.2.e.(5)(d). of this final rule, that meets the minimum patient case or survey count. We indicated in the proposed rule that this proposal applies to the Hospital-Level RSCR Following Elective Primary THA and/or TKA (CMIT ID #350); the Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP–36); the HCAHPS Survey (CMIT ID #338); the OAS CAHPS Survey (CMIT #162); and the Hospital-Level THA/TKA PRO–PM (CMIT #1618). The measure-specific parameters for minimum case/survey count that would apply to developing the national distributions are displayed in Table X.C–03.

TABLE X.C-03: MINIMUM REQUIREMENTS FOR USE IN NATIONAL DISTRIBUTION

Measure Requirements for use in national distribution
Hospital-Level RSCR Following Elective Primary THA and/or TKA (CMIT ID #350) At least 25 patient cases in the measure performance period.
Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP-36) At least 25 patient cases in the measure performance period.
HCAHPS Survey (CMIT ID #338) At least 100 completed surveys in the measure performance period.
OAS CAHPS Survey (CMIT ID #162) At least 100 completed surveys in the measure performance period.
Hospital-Level THA/TKA PRO-PM (CMIT ID #1618) At least 25 patient cases in the measure performance period.

We proposed at § 512.635(d) to assign any CJR–X participant without a reportable value for the measure, new hospitals that are identified as CJR–X participants, or CJR–X participants where CMS has suppressed the measure value due to an error in the data used to calculate the measure to the 50th performance percentile of the measure

result, so as not to disadvantage a CJR–X participant based on its lack of applicable cases because that CJR–X participant may in actuality provide high quality care. We noted in the proposed rule that we believe that relative measures of quality performance are most appropriate for CJR–X as hospitals continue to make progress nationally on improving patient outcomes and experience. This approach is also consistent with the CJR Model.

We sought comment on our proposals at §§ 512.635(c) and (d) to determine quality measure performance based on assigning the CJR–X participant's measure point estimate to a measure performance percentile based on the national distribution of measure results from hospitals eligible for payment under the IPPS.

The following is a summary of the public comments received on our proposal to determine quality measure performance, and our responses to these comments:

Comment: A commenter was concerned that the minimum cases needed for a quality score may not align with the model's low-volume threshold, creating uncertainty for hospitals with enough episodes to participate but too few cases for stable quality scores.

Response: We thank the commenter for raising concerns that the minimum case thresholds needed to calculate quality measure results may not always align with the CJR–X low-volume threshold for participation. We recognize that this could create uncertainty for hospitals that have enough episodes to participate in the model but too few cases for one or more quality measures to generate stable or reportable results.

We believe the current approach remains appropriate because the low volume hospital threshold and the quality measure case minimums serve different purposes. The low volume hospital threshold is used to determine whether a hospital has sufficient CJR–X episode volume to bear financial risk and have their episodes included in reconciliation, while quality measure case minimums are used to ensure that reported quality results are reliable and consistent with the specifications for the applicable measures. Aligning these thresholds exactly could either exclude hospitals that are otherwise appropriate for participation or require CMS to rely on quality results that may not be sufficiently stable for payment purposes. Therefore, we do not believe it is appropriate to align both the minimum patient case threshold and low volume hospital threshold. However, we will monitor how the quality methodology applies to low volume hospitals, including whether hospitals have sufficient measure data to support stable composite quality scores.

Comment: Some commenters said the Hospital-Level RSCR Following Elective Primary THA/TKA measure's case minimum of 25 cases was insufficient and recommended increasing it so the measure would meet a minimum reliability threshold appropriate for accountability.

Response: We appreciate the commenter's recommendation regarding minimum case thresholds for nationally benchmarked quality measures. The minimum case thresholds in CJR–X are predicated from the CJR Model and align with thresholds used in CMS quality reporting programs. Using these established thresholds supports alignment with the Hospital Inpatient Quality Reporting Program and Hospital Outpatient Quality Reporting Program and allows CMS to apply a consistent, transparent approach across CJR–X participants and avoids creating a separate CJR–X-only measurement system that could increase burden and reduce comparability. We recognize the commenters' concerns about reliability for accountability purposes and may consider whether additional analysis of case minimums is warranted.

Comment: A commenter stated that the 50% threshold is too high for hospitals without a reportable value and was not tested in a variety of US hospitals before implementation.

Response: We thank the commenter for raising concerns about the policy to calculate the measure to the 50th performance percentile when there may be insufficient data for a reportable value, in particular for the patient experience and patient reported outcome measures. We recognize the commenter's concern that response rates may be low for some hospitals and that low response rates could make it difficult for hospitals to obtain stable or representative patient experience data during the initial years of CJR–X.

We agree that quality measures used for payment purposes should be reliable, feasible, and based on sufficient data to support meaningful comparisons across participants. However, we believe the current approach, which mimics the CJR Model, is appropriate at this time because the patient experience measures included in the CQS are established measures used in existing CMS quality reporting programs. Using these measures allows CMS to incorporate patient experience into the model through standardized survey instruments and existing reporting infrastructure, rather than creating new CJR–X-specific reporting requirements that could result in additional reporting burden.

We also believe it is important to maintain the 50 percent threshold because the purpose of the threshold is to not disadvantage a CJR–X participant based on its lack of applicable data or cases because that CJR–X participant may in actuality provide high quality care. Lowering the threshold too substantially could unfairly disadvantage hospitals.

We acknowledge that survey response rates and implementation experience may vary across hospitals, particularly during early model years and for outpatient episodes. We may monitor response rates, measure reliability, data completeness, and the effect of the application of the 50th percentile on CQS calculation and payment adjustments.

Comment: A commenter requested CMS to describe the time period and data sources that will be used to construct the national distribution for OAS CAHPS, and confirm that the distribution reflects a stable, consistently reported version of the measure.

Response: We will be using the OAS CAHPS data available through the Hospital Outpatient Quality Reporting Program where hospitals currently report this measure. We note that the CJR–X Model has shifted the model start date to January 1, 2028, as discussed in section X.C.2.a of this final rule, and therefore we have made conforming changes to measure performance periods, including the measure performance period for the OAS CAHPS, as discussed in section X.C.2.e.(4)(a) of this final rule. For example, for performance year 1, we will be using a January 1, 2028–December 31, 2028 OAS CAHPS measure performance period which is the same time period as the performance year. Given our reliance on using the Hospital Outpatient Quality Reporting Program infrastructure to construct the applicable national distribution for the OAS CAHPS measure, we believe this produces consistent and standardized survey data that supports construction of the national distribution.

We may also monitor OAS CAHPS data availability, stability, and reporting consistency in connection with the quality scoring methodology.

Comment: A commenter suggested CMS should publish minimum data completeness thresholds, provide hospital-level PROM benchmarking dashboards with national and peer-

group comparisons no less than quarterly, standardize the PROM instruments and EHR-extractable specifications to reduce administrative burden, particularly for low-volume participants.

Response: We thank the commenter for their recommendation. We agree that patient-reported outcome measures are most useful when participants have timely feedback, meaningful benchmarks, and efficient data collection processes. We also recognize that participant-facing data can help hospitals use PROM results not only for payment methodology purposes, but also for care redesign, patient engagement, and quality improvement. We anticipate sharing data with CJR–X participants to support quality improvement during the model. We will take the commenter's recommendations into consideration as we develop participant-facing reports, including whether and how to provide information on PROM performance, data completeness, benchmarking, and comparisons to relevant peer and national groupings.

Comment: Some commenters stated concerns over scoring participants relative to each other, rather than against a clear, external performance standard. They indicated that a methodology that relies on forced distribution risks penalizing hospitals that are delivering high-quality care or demonstrating meaningful year-over-year improvement, simply because they fall into a lower decile compared to peers. They believed this approach undermines the intent of CJR–X to encourage continuous improvement.

Response: We recognize commenters' concern that a percentile-based methodology could result in hospitals receiving fewer quality points even when they are furnishing high-quality care or improving over time, if their performance remains in a lower decile compared to other hospitals. However, we believe the national distribution-based scoring approach is appropriate at this time because it provides a standardized, transparent, and comparable method for assessing quality performance across participant hospitals. Scoring participants against the national distribution allows CMS to compare quality performance using a common benchmark, rather than creating hospital-specific standards that could vary based on each hospital's starting point.

We also note that because CJR–X is a national model, identifying a separate external performance standard that is broadly representative, current, and applicable across the range of CJR–X participants would be challenging. Any national hospital benchmark for the relevant measures would likely include many hospitals participating in CJR–X, and excluding those hospitals could make the benchmark less representative of current national performance. For that reason, CMS believes that using the national distribution for the applicable measures provides a transparent and administrable reference point that supports comparability across participants while preserving a common quality standard.

We also do not believe the methodology undermines continuous improvement. The decile-based point structure rewards higher performance with additional quality points and creates an ongoing incentive for hospitals to improve their performance relative to national benchmarks. While year-over-year improvement is important, we believe reconciliation payment eligibility and discount factor reductions should remain tied to whether a participant's overall quality performance meets the model's quality expectations, not solely to whether the participant improved from its own baseline. A methodology based only on improvement could allow hospitals to receive quality-based financial benefits even where their overall quality performance remains below standard.

We will monitor participant quality performance, including whether the percentile-based methodology appropriately captures meaningful quality improvement over time.

Comment: A commenter requested CMS clarify how the HCAHPS and OAS CAHPS measure point estimates will be derived given neither measure is a single measure, but rather a larger measure that encompasses many measures. Further they want to know whether the scoring approach uses top-box proportions (percent of patients responding ''definitely yes''), a combined positive proportion, or some other calculation.

Response: We acknowledge the need for clarification regarding how a single measure point estimate is derived for the HCAHPS and OAS CAHPS survey measures for purposes of assigning quality performance percentiles under CJR–X.

For the HCAHPS, we intend to align with the scoring approach used in the CJR model. Under that approach, CMS summarized performance on the HCAHPS Survey measure using a HCAHPS Linear Mean Roll-up (HLMR) score. The HLMR summarizes performance across the publicly reported HCAHPS measures, excluding Pain Management, by averaging the linear mean scores for the HCAHPS measures, with a weight of 1.0 for each composite measure and a weight of 0.5 for each single-item measure. CMS then used that HLMR value as the HCAHPS measure value for assigning the CJR participant hospital to a performance percentile based on the national distribution of hospitals meeting the applicable survey-count threshold.

Therefore, consistent with the CJR methodology, we would derive the HCAHPS point estimate for CJR–X from the applicable HCAHPS linear mean scores, rather than treating each HCAHPS component as a separate CJR–X quality measure. We would assign each CJR–X participant's measure point estimate to a performance percentile based on the national distribution of measure results for hospitals that meet the applicable minimum survey count.

For OAS CAHPS, we also recognize that the survey includes multiple patient-experience domains. We view the OAS CAHPS as the outpatient complement to HCAHPS and will use it to assess outpatient episode quality performance. We intend to apply a parallel approach for CJR–X scoring: the OAS CAHPS measure point estimate would be derived as a single patient-experience measure value using the applicable OAS CAHPS publicly reported measure results, and that single value would then be assigned to a performance percentile for purposes of the CJR–X composite quality score. This approach is consistent with the CJR model's use of a single rolled-up HCAHPS value for patient experience and with the CJR–X proposal to score HCAHPS and OAS CAHPS as patient-experience measures within the composite quality score, rather than as separate component measures.

We anticipate providing additional resources to help CJR–X participants understand the calculation of measure point estimates and the construction of the composite quality score.

Comment: A commenter stated that the use of OAS CAHPS in a pay-for-performance context represents a significant expansion of this measure's role, and the proposed rule does not appear to address whether OAS CAHPS has the distributional properties necessary to support reliable percentile-based payment scoring.

Response: We appreciate the commenter's concern about the OAS CAHPS measure generally being used in pay-for-reporting contexts. We acknowledge that OAS CAHPS has generally been used in pay-for-reporting programs, where the emphasis has been on promoting standardized measurement and public reporting of

patient experience. We believe that a pay-for-performance approach is appropriate for CJR–X because the model is intended not only to measure quality, but also to encourage participants to improve quality while reducing Medicare expenditures for lower extremity joint replacement episodes. As more LEJR procedures are performed in hospital outpatient departments, it is important that the model incentivize CJR–X participants to deliver a high-quality patient experience in addition to achieving favorable clinical outcomes and efficient resource use. Including OAS CAHPS as a performance measure advances this objective by creating an incentive for participants to improve patients' experiences with outpatient surgical care, including communication, care coordination, and preparation for recovery, rather than solely report these experiences.

We recognize the commenter's concern regarding the distribution of OAS CAHPS scores and whether the measure provides sufficient differentiation to support percentile-based scoring. However, we do not believe that the appropriateness of including a patient experience measure in CJR–X depends on maximizing variation across CJR–X participants. Patient experience measures, including CAHPS surveys more broadly, are designed to assess aspects of care that are important to beneficiaries and are not captured by clinical outcome or cost measures. As providers improve performance over time, it is not unexpected that scores on patient experience measures may become concentrated at the upper end of the distribution. We do not view this, by itself, as evidence that the measure is unsuitable for inclusion in a value-based payment model.

Moreover, we believe that a percentile-based methodology remains an appropriate approach for CJR–X because it recognizes relative performance among CJR–X participants and maintains incentives for continuous quality improvement as national performance evolves. The purpose of the composite quality score is to distinguish performance across CJR–X participants using multiple complementary dimensions of quality, of which patient experience is one. OAS CAHPS contributes to a broader assessment of quality alongside clinical outcome measures, rather than serving as the sole determinant of CJR–X participants' quality performance or reconciliation payments.

At the same time, we acknowledge that CJR–X represents the first application of OAS CAHPS in a Medicare pay-for-performance model. Accordingly, we intend to closely monitor CJR–X participant performance on this measure throughout the model, including the distribution of scores, measure reliability, and movement across performance percentiles over time. We may evaluate whether the measure and scoring methodology appropriately differentiate CJR–X participant performance and support the objectives of the model.

Comment: A commenter stated that the Discharge and Recovery composite in the OAS CAHPS captures care coordination and post-discharge preparation, which CMS itself identifies as central to successful joint replacement episodes, making it the OAS CAHPS domain most clinically aligned with CJR–X goals. They further stated that its recent reinstatement to public reporting is therefore a welcome development in this context. They asked CMS to describe the basis for that reinstatement and to address what the data collected during the suppression period suggests about the composite's current reliability and readiness for use in a payment context. They also wanted to know if this composite was not publicly reported for the period that would form the baseline national distribution for CJR–X, there may be a discontinuity in the historical data underlying that distribution. Lastly, they also requested CMS clarify whether the Discharge and Recovery composite will be included in the OAS CAHPS ''measure point estimate'' used for CJR–X scoring, and if so, whether the national distribution will be constructed from a period when this composite was fully operational, suppressed, or transitional.

Response: We appreciate the commenter's support for the OAS CAHPS Survey and the request for additional information regarding the Preparation for Discharge and Recovery composite. We recognize the commenter's interest in its prior public reporting status and subsequent return to public reporting. The current OAS CAHPS measure specifications, including the Preparation for Discharge and Recovery composite, reflect the survey as it is presently specified and publicly reported by CMS, and we believe it is appropriate to rely on those current specifications for purposes of CJR–X.

We agree with the commenter that patients' preparation for discharge and recovery is highly relevant to the goals of the model. As an increasing share of LEJR procedures are performed in hospital outpatient departments, effective discharge preparation, patient education, and care coordination are important components of high-quality, patient-centered care that may contribute to improved recovery following surgery. Accordingly, we believe that this aspect of the patient experience is appropriately reflected as part of the OAS CAHPS measure used in CJR–X.

We also clarify that, given the modified start date of January 1, 2028 for CJR–X, as discussed in section X.C.2.a of this final rule, we have made conforming changes to the quality measures performance periods. As discussed in section X.C.2.e.(4)(a) of this final rule, the updated OAS CAHPS measure performance period for performance year 1 will be January 1, 2028–December 31, 2028. Accordingly, CJR–X participants in performance year 1 will be evaluated based on OAS CAHPS measure data from January 1, 2028 through December 31, 2028 performance period, and the national performance distribution used to assign performance percentiles will be derived from the same contemporary performance period using the finalized OAS CAHPS measure specifications in effect for that period. Because CJR–X will rely on contemporaneous performance data collected under the current OAS CAHPS measure specifications, rather than historical data collected during the period in which certain OAS CAHPS survey results were not publicly reported, we do not believe the prior public reporting status of the Preparation for Discharge and Recovery composite or other OAS CAHPS survey results has implications for the implementation of the finalized CJR–X scoring methodology.

Finally, as with other quality measures included in CJR–X, we will continue to monitor the performance of the OAS CAHPS measure over the course of the model, including its reliability, distribution of scores, and ability to meaningfully distinguish participant performance.

Comment: A commenter recommended that CMS score the HCAHPS surveys as pay-for-reporting measures during the first performance year of CJR–X.

Response: We appreciate the commenter's recommendation, but we continue to believe that HCAHPS is an appropriate pay-for-performance measure because it captures an important dimension of quality from the patient's perspective that is not reflected in clinical outcome or cost measures alone. Patient experience is a key component of high-quality, patient-centered care, and the HCAHPS Survey

assesses aspects of the inpatient experience, including communication with clinicians, responsiveness of hospital staff, care transitions, and overall hospital experience, that are particularly relevant to beneficiaries undergoing inpatient lower extremity joint replacement procedures.

HCAHPS is a mature, nationally standardized measure that has been widely implemented across Medicare programs for many years. We believe it is appropriate to maintain consistency with the CJR Model, which incorporated HCAHPS as a pay-for-performance measure in the composite quality score. Continuing this approach in CJR–X provides established policy continuity, while preserving a balanced quality framework that recognizes patient experience alongside clinical outcomes and episode spending.

After consideration of the public comments, we are finalizing without modification the proposal at §§ 512.635(c) and (d) to determine quality measure performance based on assigning the CJR–X participant's measure point estimate to a measure performance percentile based on the national distribution of measure results from hospitals eligible for payment under the IPPS.

(c) Quality Improvement

We recognized in the proposed rule that the CJR Model rewarded CJR participant hospitals for quality improvement, similar to the pay-for-performance policies under other programs such as the Hospital Value-Based Purchasing Program, in order to provide an incentive for quality improvement for CJR participant hospitals at all levels of quality performance (70 FR 73379). As in the CJR Model, we believed the heightened focus on episode spend and quality performance by CJR–X participants may lead to substantial year-over-year quality measure improvement. Nevertheless, we believe that the actual level of quality performance achieved in CJR–X should be most highly valued in the composite quality score to reward those CJR–X participants furnishing high-quality care to CJR–X beneficiaries.

We considered in the proposed rule, but did not propose, to include a policy that provides CJR–X participants quality improvement points when there is improvement of 2 deciles or more in comparison to the national distribution of measure results from the prior year, based on a comparison of relative quality measure performance over the most recent 2 years of available quality measure result data. CJR–X participants who are able to demonstrate quality improvement, could be awarded 10 percent of the maximum measure performance score, with a cap for the overall composite quality score at 20 points. This is the same methodology as was used in the CJR Model.

However, we did not propose to include quality improvement points in CJR–X because we believed CJR–X is structured to emphasize absolute quality performance on clinically meaningful outcomes, rather than short-term year-over-year changes that may reflect random variation or changes in case mix. Further, we stated in the proposed rule that we believe focusing on achievement-based performance promotes consistent accountability for patient safety, experience, and outcomes across CJR–X participant hospitals.

In addition, we noted in the proposed rule that CJR–X already provides incentives for improvement through its financial reconciliation structure, as hospitals can benefit from lower episode spending while maintaining quality thresholds. Excluding improvement points also supports transparency and predictability in quality scoring, allowing hospitals to better understand how quality performance affects reconciliation payments and to invest in sustained, long-term care redesign strategies. Lastly, this approach aligned with TEAM as quality improvement points are not included in the model's composite quality score calculation. Thus, we believed not including quality improvement points aligns with the goals of the model by balancing fairness, administrative simplicity, and accountability for high-quality, patient-centered care.

We sought comment on not including a policy for quality measure improvement for CJR–X.

The following is a summary of the public comments received on our proposal to not include a policy for quality improvement, and our responses to these comments:

Comment: A commenter supported the proposal to not include quality improvement points. They believed the current quality measure set is composed of measures with known challenges or low variation in performance resulting in little opportunity for improvement. They also noted that if CMS develops quality measures targeted to LEJR, inclusion of improvement points may be warranted.

Response: We thank the commenter for their support. We would consider reassessing the need for quality improvement points if different quality measures would be proposed for inclusion in CJR–X in future notice and comment rulemaking.

Comment: Many commenters recommended that CMS add quality improvement points or an improvement pathway, stating that hospitals should receive credit for year-over-year improvement and should not be judged only on absolute performance. A couple of commenters believed assigning points to quality measures based on relative performance compared to the national distribution of hospitals will always create winners and losers, even if a hospital has improved its performance over time and thus a separate approach to quality improvement is needed. A commenter believed that including quality improvement points rewards progress and prevents permanently disadvantaging hospitals that serve more complex patient populations. Another commenter recommended allowing CJR–X participants to qualify for a reconciliation payment based on quality improvement.

Response: We agree that encouraging quality improvement is an important overarching important goal of CJR–X. This includes CJR–X participants improving the quality of care provided to beneficiaries, improving the quality of collaboration between other providers and suppliers, and improving ways to reduce Medicare spending. However, we do not believe it is necessary or appropriate at this time to add separate quality improvement points when assessing quality performance. The CJR–X quality methodology is designed to provide a standardized, transparent, and comparable framework for assessing quality across participant hospitals. The purpose of the CJR–X quality methodology is not only to recognize whether a hospital improved relative to its own prior performance, but also to determine whether the hospital's quality performance is sufficient to support payment incentives under a nationwide episode payment model. A national distribution-based methodology gives CMS and CJR–X participants a common benchmark for assessing quality performance across hospitals, rather than creating hospital-specific standards that could vary based on each CJR–X participant's starting point.

We believe this approach is preferable for several reasons. First, it supports comparability across CJR–X participants by measuring performance against the same national reference point. This is especially important because CJR–X would apply nationally to eligible acute care hospitals, with limited exceptions, and the quality methodology must be administrable, transparent, and consistently applied across a broad set of participants. Second, the composite quality score methodology considers

overall quality performance across multiple complementary measures, rather than allowing performance on any single measure to determine the financial opportunity under the model. Third, linking reconciliation payment eligibility and discount factor reductions to composite quality score categories helps maintain a clear connection between financial incentives and the quality of episode care.

By contrast, a separate improvement pathway could allow a CJR–X participant to receive payment incentives based on relative improvement even if its overall quality performance remained below the standards CMS for CJR–X. While year-over-year improvement is important, CMS believes that payment incentives in CJR–X should remain tied to whether the CJR–X participant's overall quality performance meets the model's minimum quality expectations. This preserves accountability for beneficiary outcomes and avoids creating separate standards that could make results less comparable across CJR–X participants. We acknowledge some hospitals may serve more complex beneficiary populations, but beneficiaries in those hospitals should also continue to be protected by a meaningful minimum quality standard. A separate improvement-points pathway could allow a hospital to receive additional payment credit based on relative progress even if its overall quality performance remains below the thresholds CMS proposed for CJR–X.

We also believe the methodology already creates incentives for improvement given the link of quality performance to financial rewards through the adjustment of the discount factor. CJR–X participants that achieve at least ''Acceptable'' quality performance may be eligible for a reconciliation payment, and CJR–X participants with ''Good'' or ''Excellent'' performance may receive a reduced discount factor. Thereby through the structure of including quality levels, CJR–X participants are incentivized for continued efforts to improve the quality and efficiency of LEJR episodes.

Accordingly, we believe the national distribution-based composite quality score methodology is the better approach for CJR–X at this time because it maintains a uniform quality standard, supports comparability and transparency, links payment incentives to overall quality performance, and preserves beneficiary protections by ensuring that reconciliation payment eligibility is conditioned on meeting minimum quality expectations. CMS will monitor participant quality performance in connection with the quality methodology.

Comment: A commenter suggested that that certain hospitals, such as safety net, rural, and high acuity hospitals, should be provided quality improvement scoring pathway for the first few years of the model because they believe these hospitals may be penalized for starting further behind compared to other hospitals.

Response: We appreciate the commenter's recommendation to provide a quality improvement pathway for certain hospitals and recognize that all hospitals captured in CJR–X may not be providing same level of quality of care. However, we do not believe a separate quality improvement scoring pathway is necessary at this time. Applying a separate pathway only for certain hospital types could introduce additional complexity and may make quality performance less comparable across participant hospitals. We believe not including a separate quality improvement pathway is the better framework because it maintains a uniform quality standard across the model and preserves incentives for all CJR–X participants to improve quality.

We will monitor the quality performance of all CJR–X participants, including safety net, rural, high-acuity, and other participant hospitals during the model.

Comment: A couple of commenters recommended CMS include quality improvement points in CJR–X with specific recommendations. A commenter suggested adopting an quality improvement approach similar to the Skilled Nursing Facility Value-Based Purchasing Program where hospitals earn improvement points for better outcomes versus a baseline. Another commenter suggested providing partial credit for one-decile improvement because they believed partial credit for one-decile improvement would extend the benefit to a broader range of hospitals.

Response: We recognize the value of considering approaches that could better account for differences across participant hospitals, including differences in baseline performance, patient populations, and operational circumstances. At this time, we believe the current approach provides an appropriate framework for assessing quality performance in CJR–X because it applies a consistent methodology across participant hospitals, supports comparability, and preserves incentives for all participants to improve quality during the model. We believe adding separate partial credit for a one-decile improvement could increase complexity and reduce comparability across participants without clearly improving the model's ability to distinguish meaningful quality performance. We acknowledge the value of aligning quality assessment approaches with existing CMS quality programs, such as the Skilled Nursing Facility Value-Based Purchasing Program. We will monitor CJR–X quality performance, including whether there are shifts in quality improvement.

After consideration of the public comments, we are finalizing without modification the proposal to not include a policy for quality improvement. However, we may revisit this concept in future notice and comment rulemaking.

(d) Calculating the Composite Quality Score

We proposed adopting a similar calculation of the CJR Model composite quality but with modifications to account for outpatient quality measures. We stated in the proposed rule that the CJR Model CQS was constructed based on the performance of two inpatient quality measures and one voluntary inpatient measure. The measures were weighted 50 percent for the complications measure, 40 percent for patient experience measure, and 10 percent for the patient reported outcomes measure with the sum of quality points capped at 20 points. Given the greater proportion of episodes initiating in the outpatient setting, we proposed adopting two outpatient quality measures to capture quality performance for episodes in the outpatient setting. We indicated in the proposed rule that the CJR–X CQS methodology would account for these two measures by constructing an outpatient measure composite quality score that mimics the CJR Model weighting and quality point cap. Specifically, we proposed placing each of the five quality measures, as described in section X.C.2.g. of this final rule, into one of three quality domains. The domains would be complications, patient experience, and patient reported outcomes. We proposed for inpatient measures and outpatient measures to weight the complications domain at 50 percent, the patient experience domain at 40 percent, and the patient reported outcomes domain at 10 percent. We noted in the proposed rule that we believe the approach to weighting the quality domains represents a balanced and equitable approach to assessing hospital performance under CJR–X and aligns with the CJR Model. We stated the complications quality domain would be weighted most heavily because it reflects serious, clinically

significant outcomes that directly affect patient safety, recovery, and episode spending, and are supported by mature, well-validated, claims-based measures. We noted that patient experience measures receive substantial weight because effective communication, discharge planning, pain management, and care coordination are critical drivers of post-acute utilization and successful recovery in joint replacement episodes. Lastly, we sated that patient-reported outcome measures are included to capture improvements in pain and function that matter most to beneficiaries, while being weighted more modestly to reflect ongoing considerations related to response rates, data completeness, and measure stability. We stated in the proposed rule that together, this weighting approach promotes accountability for safety and outcomes while ensuring that patient-centered perspectives meaningfully inform quality performance, supporting a fair, reliable, and comprehensive assessment aligned with the goals of CJR–X. Table X.C–04 displays the quality measures and associated quality domain weights.

TABLE X.C-04: MEASURES AND QUALITY DOMAIN WEIGHTS FOR THE COMPOSITE QUALITY SCORE

Quality Domain	Quality Measures		Domain Weight in Composite Quality Score
	Inpatient Measure	Outpatient Measure	
Complications	Hospital-Level RSCR Following Elective Primary THA and/or TKA (CMIT ID #350)		50%
		Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP-36)	
Patient Experience	HCAHPS Survey (CMIT ID #338)		40%
		OAS CAHPS Survey (CMIT ID #162)	
Patient Reported Outcomes	Hospital-Level THA/TKA PRO-PM (CMIT ID #1618)		10%

Under this approach, we proposed we would score each CJR–X Model participant on the five proposed quality measures based on the CJR–X participant's performance percentile as compared to the national distribution of hospitals that are eligible for payment under the IPPS measure performance, assigning points according to the point values displayed in Table X.C–05.

TABLE X.C-05: POINT VALUES FOR CJR-X QUALITY MEASURES

Performance Percentile	Hospital-Level RSCR Following Elective Primary THA and/or TKA (CMIT ID #350)	Hospital Visits within 7 days of HOPD Surgery (CMIT ID #344, OP-36)	HCAHPS Survey (CMIT ID #338)	OAS CAHPS Survey (CMIT ID #162)	Hospital-Level THA/TKA PRO-PM (CMIT ID #1618)
$\geq 90^{th}$	10.00	10.00	8.00	8.00	2.00
$\geq 80^{th}$ and $< 90^{th}$	9.25	9.25	7.40	7.40	1.85
$\geq 70^{th}$ and $< 80^{th}$	8.50	8.50	6.80	6.80	1.70
$\geq 60^{th}$ and $< 70^{th}$	7.75	7.75	6.20	6.20	1.55
$\geq 50^{th}$ and $< 60^{th}$	7.00	7.00	5.60	5.60	1.40
$\geq 40^{th}$ and $< 50^{th}$	6.25	6.25	5.00	5.00	1.25
$\geq 30^{th}$ and $< 40^{th}$	5.50	5.50	4.40	5.40	1.10
$< 30^{th}$	0.00	0.00	0.00	0.00	0.00

We noted in the proposed rule that we believe that small point increments related to higher measure performance deciles would be the most appropriate way to assign more points to reflect meaningfully higher quality performance on the measures. The absolute differences for each decile among the five measures reflected the intended weight of the measure in the composite quality score.

After determining the point value for each measure, we proposed summing the performance points for the inpatient measures to construct the inpatient measure composite quality score and sum the outpatient measures to construct the outpatient measure composite quality score. We proposed at § 512.605 to define the ''inpatient measure composite quality score'' as the sum of inpatient quality measure point values capped at 20 points. Likewise, we proposed at § 512.605 to define the ''outpatient composite quality score'' as the sum of outpatient quality measure points values, capped at 20 points.

We proposed to assign each CJR–X participant an ''overall composite quality score,'' defined at § 512.605 as the sum of the weighted average of the inpatient measure composite quality score and the outpatient measure composite quality score, capped at 20 points. The inpatient and outpatient composite quality score would be weighted based on the proportion of inpatient to outpatient episodes. For example, if a CJR–X participant with 90 percent outpatient episode volume earned a 17.00 on their inpatient composite quality score and a 14.00 on their outpatient composite quality score, then their overall composite quality score would be calculated as follows:

- Inpatient measure composite quality score = 17.00
- Outpatient measure composite quality score = 14.00
- Inpatient/outpatient episode volume proportion—

++ 10 percent inpatient; and

++ 90 percent outpatient

- Overall composite quality score = ((0.10)*(17.00)) + ((0.90)*(14.00)) = 14.3

We stated in the proposed rule that we believe the proposed composite quality score methodology for CJR–X is a sound approach because it combines multiple, complementary quality measures into a single assessment of hospital performance across the episode of care, reflecting the multidimensional nature of quality in joint replacement. We noted that by incorporating measures of patient safety, patient experience, and patient-reported outcomes, the composite score avoids over-reliance on any single metric and improves the reliability and stability of quality assessment by mitigating the effects of random variation in individual measures. We indicated in the proposed rule that the methodology recognizes quality achievement and incentivizes meaningful progress across all CJR–X participants. We noted this standardized and transparent approach promotes equitable comparisons across CJR–X participants, enhances predictability in reconciliation outcomes, and aligns financial incentives with the patient-centered quality goals of the model.

We sought comment on our proposed methodology to calculate the composite quality score at § 512.635(b)(1) and (2) and on our definitions for the composite quality scores at § 512.605.

The following is a summary of the public comments received on our proposal to calculate the composite quality score, and our responses to these comments:

Comment: A few commenters supported the weighting of the complications, patient experience, and patient reported outcomes measures.

Response: We thank the commenters and we agree that these measures reflect important and complementary dimensions of quality for lower extremity joint replacement episodes.

Comment: Many commenters said the patient experience measures, the CAHPS and OAS CAHPS, were too heavily weighted. Of these commenters, some mentioned that patient experience measures captures hospital experience broadly rather than focusing on the LEJR procedure and does not capture a person's outcomes from surgery. Some commenters indicated the patient experience measures weighting is disproportionate and introduces risk that is largely outside hospitals' clinical control. A commenter recommended placing more emphasis on the complications or PRO–PM measures. Another commenter suggested dropping the patient experience measures assigns the 40 percent weight to an established readmission measure. A commenter suggested an alternative scoring approach such as an achievement threshold rather than a full percentile ranking to reflect the measure's distributional properties.

Response: We recognize commenters' concerns that patient experience measures may capture the hospital or outpatient facility experience broadly rather than focusing exclusively on the LEJR procedure. The CJR Model used the CAHPS for patient experience and as an expanded model we believe continuing this approach, along with the 40 percent weighting is appropriate until a more episode-specific patient experience measure is available.

Patient experience is a core component of quality in an episode-based payment model because communication, discharge planning, pain management, preparation for recovery, responsiveness, and care coordination directly affect whether beneficiaries understand and follow post-discharge instructions, participate in rehabilitation, avoid preventable complications, and transition safely across settings. The HCAHPS and OAS CAHPS are standardized survey instruments that allow consistent comparison across hospitals and outpatient settings and that their current use in existing CMS quality reporting programs avoids creating new CJR–X-specific reporting burden.

We do not agree that 40 percent weight is disproportionate. The complications domain is most heavily at weighted at 50 percent, patient experience at 40 percent, and patient-reported outcomes at 10 percent in the CQS methodology. This structure gives the greatest weight to clinically significant safety outcomes, while still giving substantial weight to the patient-centered processes that support successful recovery from LEJR episodes. We believe this is a balanced approach because complications, patient experience, and patient-reported outcomes measure different but complementary aspects of quality. Reducing patient experience weighting would place too much emphasis on clinical events alone and would not fully capture whether the episode was coordinated, understandable, and patient-centered.

We also do not agree that the patient experience measures capture matters that are largely outside hospitals' control. Although patient experience measures may reflect more than the technical performance of the surgical procedure, they assess domains that hospitals can meaningfully influence, including communication with providers and staff, discharge information, preparation for surgery and recovery, care coordination, and information about what to do if side effects occur. These factors are particularly important in CJR–X because the model holds participants accountable for care across the episode, including transitions after the anchor hospitalization or anchor procedure.

We appreciate the recommendation to place more weight on complications or the THA/TKA PRO–PM. The complications domain is already weighted most heavily at 50 percent because it reflects serious outcomes affecting patient safety, recovery, and episode spending. The PRO–PM is included at 10 percent because it captures pain, function, and health-related quality of life, but it is not heavily weighted to account for considerations related to response rates, data completeness, and measure stability.

We also do not believe it would be preferable to drop the patient experience measures and assign the 40 percent weight to an established readmission measure. Readmissions and hospital visits can be important indicators of safety and care coordination, but they do not capture beneficiaries' experience with communication, discharge preparation, pain management, and recovery instructions.

Finally, we appreciate the suggestion to use an achievement threshold rather than full percentile ranking. We believe the national distribution-based scoring approach is appropriate because it provides a transparent and comparable method for assessing CJR–X participants against a common benchmark. We also believe the minimum case or survey-count standards for inclusion in the national distribution and a 50th-percentile assignment for CJR–X participants without reportable measure values, new hospitals, or suppressed measure values, ensures these participants are not disadvantaged based on lack of applicable cases.

We will monitor measure performance under CJR–X in connection with the CQS methodology.

Comment: A commenter stated that concerns about the THA/TKA PRO–PM denominator are especially significant for CJR–X because the model would be mandatory and nationwide for many acute care hospitals. The commenter stated that CJR–X would give the THA/TKA PRO–PM greater weight than the original CJR model and also asserted that a small or non-representative PRO–PM denominator could produce an unstable quality estimate that directly affects a hospital's reconciliation payment eligibility and effective discount factor.

Response: We acknowledge the commenter's concerns and agree that CJR–X places more emphasis on the PRO–PM as compared to the CJR Model. The CJR Model helped to establish the PRO–PM and submission of patient reported data was voluntary in that model and therefore it would not have been appropriate to require a 10 percent weight in the CQS for CJR participants.

We believe the current CJR–X CQS approach is appropriate at this time because patient-reported outcomes are an important component of assessing quality for lower extremity joint replacement episodes. Claims-based measures and patient experience measures provide important information, but they do not capture beneficiaries outcomes. Including the THA/TKA PRO–PM in the CQS, and giving it meaningful, but not substantial, weight helps ensure that the model's financial incentives remain tied to outcomes that matter directly to beneficiaries. We also believe the CQS methodology mitigates the concern if unstable quality estimates because the PRO–PM is one component of a broader composite score, rather than the sole determinant of quality performance.

CMS may monitor the operation of the THA/TKA PRO–PM in CJR–X, including denominator size, representativeness, score stability, and effects on reconciliation payment eligibility and discount factor reductions.

Comment: A few commenters stated that CMS's increased emphasis on patient-reported outcome measures is significant because giving these measures greater weight than in prior models transforms patient engagement and longitudinal follow-up into a direct financial performance variable. Other commenters suggested placing more weight on the PRO–PM in the CQS.

Response: We agree that patient-reported outcome performance is an important component of assessing quality in an episode-based payment model because lower extremity joint replacement care is intended not only to avoid complications and readmissions, but also to improve beneficiaries' pain, function, mobility, and overall recovery experience. We believe weighting the Hospital-Level THA/TKA PRO–PM at 10 percent of the CQS is appropriate because it gives meaningful weight to outcomes that matter directly to beneficiaries while maintaining balance across the broader quality framework. A 10-percent weight creates a clear incentive for CJR–X participants to engage patients and monitor recovery after surgery, but it does not make the PRO–PM the dominant driver of the quality score. This balance is important because the CQS should reflect multiple dimensions of quality, including patient safety, patient experience, and patient-reported outcomes.

We also believe the 10-percent weight is appropriate because it supports continued movement toward more patient-centered quality measurement without creating an excessive or abrupt burden for hospitals. Patient-reported outcome collection requires workflow development, patient engagement, follow-up processes, and data submission infrastructure. By assigning the PRO–PM a meaningful but limited weight, CMS can encourage hospitals to build and strengthen these capabilities while preserving a stable and administrable quality methodology for CJR–X.

Comment: A couple of commenters identified a typographical error in Table X.C–05, for the HCAHPS and OAS CAHPS measures where ''5.40'' was used for the ≥30th and <40th percentile when it should have been ''4.40''.

Response: We thank the commenters for identifying this error. We have corrected this error in TABLE X.C–05 such that it reads ''4.40'' for the ≥30th and <40th percentile for the HCAHPS and OAS CAHPS measures.

Comment: A couple of commenters believed that the CQS was based on fragmented data or measures hospitals cannot reliably control and expressed concern about tying such measures to financial consequences. A commenter stated that the CQS methodology is derived from fragmented data that does not represent the proposed patient populations, specifically that hip fractures are unplanned and not included or represented in the PRO data. The commenter also noted that a substantially larger outpatient THA/TKA population will not have PRO data reported until 2029, well after the first performance year reconciliation. Another commenter indicated that approximately half of the CQS depends on measures, including the patient experience and patient reported outcome measures, that hospitals cannot reliably control under current specifications.

Response: The CQS is designed to evaluate CJR–X participants quality performance using measures that are already available through CMS quality reporting programs and that reflect important dimensions of care, including patient safety, patient experience, and patient-reported outcomes. Using existing measures supports reduces additional reporting burden and allows CMS to link payment incentives to quality domains that are relevant to episode-based care. Given the CJR–X Model uses measures hospitals already report to CMS, we believe adjusting the measure specifications would increase complexity and may lead to CJR–X participant confusion by deviating from existing, established specifications.

We acknowledge the commenter's concern that patients with a hip fracture are not included in the patient population for the Hospital-Level THA/TKA PRO–PM. However, we are not aware of a measure that best captures quality measurement for hip fracture cases, let alone a measure that hospitals currently report to CMS through existing CMS quality reporting programs that is specific to hip fracture and that would be available for use in the CJR–X quality methodology at this time. We note that participant submitted data from the CJR Model supported development of the Hospital-Level THA/TKA PRO–PM and we may consider how CJR–X could support the development of more clinically meaningful measures, such as ones that focus on fractures, for the model or for use in CMS Quality programs more broadly. We believe the current measure set for CJR–X is the most appropriate measure set that balances clinically appropriate measures while being mindful to participant reporting burden.

We also want to clarify that the outpatient hospital-level THA/TKA PRO–PM is not included in CJR–X at this time because we want hospitals to have some experience mandatorily reporting the measure in the Hospital Outpatient Quality Reporting Program before it would be included in CJR–X. We may consider this measure in future performance years of the model in order to capture an outpatient PRO–PM and improve our CQS methodology for outpatient episodes.

We will continue to assess whether additional or alternative measures could better capture quality of care for hip fracture episodes. If we identify an appropriate hip fracture-specific or otherwise more clinically relevant measures that are feasible for use in CJR–X, we may consider proposing changes to the quality methodology through future notice-and-comment rulemaking.

Comment: A few commenters wanted clarification on how the CQS was calculated. Specifically, if it was the sum of the two scores (inpatient measure composite quality score and the outpatient measure composite quality score) or the volume-weighted average of both scores. Another commenter requested clarification on whether the inpatient and outpatient composite scores are each capped and then weighted based on episode mix, or

whether a different methodology applies.

Response: We appreciate the commenters' requests for further clarification. The inpatient and outpatient measure composite quality scores are each calculated separately and capped at 20 points. CMS then calculates the overall composite quality score as a volume-weighted average of those two capped scores, based on the hospital's proportion of inpatient and outpatient CJR–X episodes. The overall composite quality score is also capped at 20 points.

Under this approach, CMS first calculates an inpatient measure composite quality score and an outpatient measure composite quality score, each capped at 20 points. CMS then weights those scores by the participant's inpatient and outpatient episode volume proportions to determine the overall CQS, also capped at 20 points. We believe this volume-weighted approach is appropriate because it accounts for the mix of inpatient and outpatient episodes at each hospital, rather than over-weighting either setting or treating hospitals with different episode distributions the same. This methodology better aligns the overall CQS with where the participant furnishes CJR–X episode care, supports fairer comparisons across hospitals with different inpatient and outpatient volume patterns, and preserves a single transparent score for determining the applicable CJR–X quality category. Like the CJR Model, we will be creating specifications for CJR–X participants that detail the CQS methodology and will make these specifications available before reconciliation.

Comment: A commenter wanted clarification on the methodology for the measure point estimate.

Response: A CJR–X participant would receive measure points based on the participant's performance percentile for each applicable quality measure compared to the relevant national distribution. The assigned measure points would correspond to the point values specified for each performance percentile range in TABLE X.C–05. Those measure points would then be summed to calculate the applicable inpatient measure composite quality score and outpatient measure composite quality score. As noted previously, we will be creating specifications for CJR–X participants that detail the CSQ methodology and will make these specifications available before reconciliation.

Comment: A commenter recommended CMS align performance measurement with quality of care to support equitable participation and accurate evaluation of episode outcomes.

Response: We believe the CQS methodology supports these goals by using multiple, complementary quality domains, including complications, patient experience, and patient-reported outcomes. This approach is intended to assess quality more comprehensively than any single measure could, while maintaining a standardized and transparent framework for comparing participant hospitals. The methodology also supports equitable participation by relying on measures already used in CMS quality reporting programs, which avoids creating new CJR–X-specific reporting requirements and promotes consistent application across participants.

We recognize the importance of continuing to evaluate whether the CQS measures accurately reflect care quality and episode outcomes for all participant hospitals and beneficiary populations. We will monitor measure performance, participant experience, and model outcomes, including whether refinements are needed to better align quality measurement with clinically meaningful outcomes.

Comment: A commenter requested whether procedure-specific or service-line-specific patient experience data specific to joint replacement could be made available and if not, does CMS view movement toward more targeted patient experience measurement for episode-based payment models as a longer-term program goal. They also inquired whether CMS conducted any analysis of the degree to which facility-wide, all-payer survey scores correlate with the specific Medicare LEJR patient experience that CJR–X is designed to improve.

Response: We agree that more targeted patient experience measurement could provide useful information for episode-based payment models, including CJR–X. Procedure-specific or service-line-specific patient experience data could help assess aspects of care that are especially relevant to LEJR episodes, such as preparation for surgery, communication about recovery expectations, discharge planning, rehabilitation coordination, and post-discharge follow-up.

At this time, we have not conducted all-payer analyses on this data, but we appreciate the suggestion may consider doing so in the future. At this time, we believe the use of HCAHPS and OAS CAHPS is the most appropriate approach for CJR–X because these measures are already established, standardized, and reported through existing CMS quality reporting programs. Using these measures supports national comparability, avoids creating new CJR–X-specific reporting burden, and allows CMS to incorporate patient experience into the Composite Quality Score using data infrastructure that is already available for hospitals and outpatient settings. Although these measures are not specific only to joint replacement, they capture important aspects of the care experience that are relevant to successful LEJR episodes, including communication, care coordination, discharge preparation, and responsiveness.

We did not propose nor are we aware of a separate procedure-specific patient experience measure for CJR–X that hospitals are already reporting. Before adopting such a measure, we would need to evaluate whether the data are available or could be collected consistently through existing survey infrastructure, whether the measure would be reliable and valid for Medicare LEJR beneficiaries, whether case volumes would support stable facility-level measurement, and whether implementation would impose additional burden on participants. CMS would also need to consider how any new or more targeted measure would interact with the existing CQS methodology and payment adjustments.

Comment: A commenter stated that a hospital scoring below the 30th percentile on OAS CAHPS receives zero quality performance points for that measure, while a hospital at the 70th percentile receives 6.80 points—that swing, driven by a 1-to-2 point absolute score difference on a 100-point scale, could meaningfully affect a hospital's composite quality score and downstream discount factor.

Response: We recognize the commenter's concern that relatively small absolute differences in scores may correspond to different percentile rankings and, therefore, different quality point values. These percentile rankings are commensurate with the CJR Model and we continue to believe this approach remains appropriate because percentile-based scoring provides a standardized and transparent method for comparing participant performance against the national distribution of hospitals reporting the measure. The point values are designed to reflect the intended weight of the patient experience domain in the CQS, while recognizing that higher performance on patient experience measures should contribute meaningfully to a participant's overall quality performance.

We also believe it is appropriate for OAS CAHPS to have a meaningful effect on the outpatient composite quality score because patient experience is an important dimension of quality for outpatient LEJR episodes. At the same time, OAS CAHPS is not the only determinant of the outpatient composite quality score. The proposed methodology balances patient experience with outpatient complications and patient-reported outcomes, so that no single measure fully determines overall quality performance. This structure helps ensure that the CQS reflects multiple dimensions of care, including safety, patient experience, and recovery outcomes.

We acknowledge that percentile-based scoring can be sensitive when the national distribution of measure scores is narrow. However, we believe this methodology is preferable to a less differentiated scoring approach because it preserves meaningful incentives for participants to improve patient experience and supports consistent comparisons across participants. We will monitor OAS CAHPS score distributions, score stability, and the effect of patient experience measure points on CQS categories and discount factor adjustments.

After consideration of the public comments, we are finalizing without modification the proposals at § 512.605 for the definitions of ''composite quality score'', ''inpatient measure composite quality score'', ''outpatient measure composite quality score'', and ''overall composite quality score''. We are also finalizing without modification our proposals at § 512.635(b)(1) and (2) to calculate the composite quality score.

f. Pricing and Payment Methodology

(1) Background

Given that we proposed CJR–X as an expansion of the CJR Model, as opposed to a new model concept, our pricing and payment methodology is fundamentally the same as the CJR Extension. However, as initially discussed in section X.C.1.b. of this final rule, we proposed a few minor modifications for CJR–X that would not fundamentally alter the methodology of the CJR Extension but would improve the accuracy of target prices and be responsive to concerns raised by the CJR evaluation results and stakeholder feedback. These minor adjustments would align with some of the policies we enacted in TEAM.

As stated in the proposed rule, we developed the methodologies for the CJR and BPCI Advanced Models, and refined them over time in response to observed changes in nationwide spending trends and payment system changes (such as the removal of TKA and THA from the IPO list, and the reclassifications of certain MS–DRGs), each new iteration drew from lessons learned in the previous iteration. With TEAM, we aimed to find a balance between simplicity and predictive accuracy of target prices, blending and building upon methods from both the original CJR Model and BPCI Advanced Model. Our goal was to choose a payment methodology that was as transparent and understandable as possible for participants of varying levels of statistical background and knowledge, but robust and statistically sophisticated enough to accurately predict performance year spending.

For CJR–X, we aimed to achieve a similar balance between simplicity and predictive accuracy, but with an added focus on long-term sustainability. As an expanded, national model, CJR–X is unique from the other models discussed here in that it is not being proposed as a finite, model test that will occur over a relatively short period of time. Therefore, we stated that when evaluating the different approaches to pricing and payment that have been used in other models, both past and present, we must also consider how each approach would perform in the long-term. We stated in the proposed rule that we believe that a pricing and payment methodology that is transparent, accurate, and adaptable to evolving payment and health care industry trends will be crucial for achieving our goals of improving quality and lowering costs over the long term.

We also noted that, whereas the goal for new (Phase I) models is to test and generate evidence on a novel payment policy design, the goal of model expansion (Phase II) is to take a payment policy design that has already proven effective and apply it to a larger scope of episodes. Thus, while we proposed several minor adjustments to the CJR Model pricing and payment methodology, in order to improve upon the policies that were tested, we must adhere to the general design and structure that was tested in and for which we can confidently predict the long-term effects on both quality and spending.

(a) CJR Model Pricing Methodology

We stated in the proposed rule that when designing the CJR Model payment methodology, some of the primary goals were simplicity and clarity, given that it was a mandatory model covering only one episode category. The original CJR Model payment methodology included a 3-year baseline period that rolled forward every 2 years. Target prices used a blend of participant-specific and regional spending, which shifted towards 100 percent regional spending for PYs 4 and 5. Downside risk was waived for the first performance year of the model to allow participants time to enact practice changes that would help them succeed in the model. Beginning in PY 2, participants were subject to both upside and downside risk, within stop-loss and stop-gain limits that increased to a maximum of 20 percent by PY 3 for most hospitals. The stop-loss and stop-gain limits were designed to ensure that participants would neither be subject to an unmanageable level of risk, nor be incentivized to stint on care to achieve savings. The original CJR Model payment methodology is described in detail in the 2015 CJR final rule, (80 FR 73324 through 73554).

We noted in the proposed rule that the original CJR Model payment methodology was modified in the 2021 CJR 3-Year Extension final rule. The CJR Model's 3-year extension and modification was due to a number of factors, as described in detail starting at 86 FR 23508. A principal reason for the modifications to the payment methodology was the fact that the original CJR Model target price methodology did not account for changing downward trends in spending on LEJR episodes, both among CJR participant hospitals and non-participant hospitals. The resulting reconciliation payments under the initial methodology rewarded participants for spending reductions that likely would have happened regardless of the model, which led to concerns that target prices could be too high for Medicare to achieve savings in the model over time.

The changes to the model increased the complexity in some ways (for example, the addition of risk adjustment multipliers) while simplifying it in other ways (for example, the removal of update factors) in order to calculate target prices that would more accurately reflect performance year spending. A retrospective Market Trend Factor was applied to target prices at reconciliation to capture changes in spending patterns that occurred nationally during the performance year. This market trend factor, in combination with the change from a 3-year baseline to a 1-year baseline, negated the need for setting-specific update factors that we had used previously to set purely prospective target prices. At the same time, our added risk adjustment increased target prices for episodes with more complex

patients, to better reflect the higher costs associated with those patients. The changes to the original CJR Model payment methodology are described in detail in the 2021 CJR 3-Year Extension final rule (86 FR 23508).

(b) TEAM Pricing Methodology

The TEAM methodology, as discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69748) and FY 2026 IPPS/LTCH PPS final rule (90 FR 37092), was designed with the goal of blending the most successful elements from the different CJR and BPCI Advanced Model iterations in order to strike a balance between predictability and accuracy. TEAM sets preliminary target prices at the MS–DRG/HCPCS episode type- and region-level using a 3-year baseline, trended forward to the performance year. Preliminary target prices are updated using the performance year data during the reconciliation process to account for updated spending trends (subject to a 3 percent cap) and normalization factor (subject to a 5 percent cap) and by adjusting for each participant's realized performance year case mix.

We stated in the proposed rule that TEAM's risk adjustment includes adjusters for age group, Hierarchical Condition Category (HCC) count, and beneficiary economic risk, as well as episode category-specific HCC adjusters and hospital-level adjusters including a hospital bed size factor and a safety net hospital factor. The risk adjustment factors will be calculated at the MS–DRG/HCPCS level using a weighted linear regression where episodes are weighted differentially based on whether they belong to year 1, 2, or 3 of the baseline periods. After risk adjusting for the performance year case mix, target prices are normalized to ensure that the average of the total risk-adjusted preliminary target price does not exceed the average of the total non-risk adjusted preliminary target price.

We indicated that TEAM participants will have the opportunity to achieve a reconciliation payment amount, after accounting for quality performance, if their performance year spending is below the reconciliation target price, or they may owe a repayment amount if their spending is above the reconciliation target price.

(2) Overview of CJR–X Pricing and Payment Methodology

We stated in the proposed rule, that while we describe each element of the pricing and payment methodology in detail in the following sections, here we present an overview of the proposed CJR–X pricing and payment methodology. At proposed § 512.640, we proposed to use 3 years of baseline data, trended forward to the performance year, to calculate target prices at the level of MS–DRG/HCPCS episode type and region. We proposed to group episodes from the baseline period by applicable MS–DRG for episode types that include only inpatient hospitalizations, and by applicable MS–DRG or HCPCS code for episode types that include both inpatient hospitalizations and outpatient procedures. We indicated that for episode types that include both inpatient hospitalizations (identified by MS–DRGs) and outpatient procedures (identified by HCPCS codes), HCPCS codes are combined for purposes of target pricing with the applicable MS–DRG representing an inpatient hospitalization without Major Complications and Comorbidities, as we expect those beneficiaries to have similar clinical characteristics and costs. After capping high-cost outlier episodes at the 99th percentile for each of the 4 proposed MS–DRG/HCPCS episode types, we proposed to use average standardized spending for each MS–DRG/HCPCS episode type in each region as the benchmark price for that MS–DRG/HCPCS episode type for that specific region, resulting in 36 MS–DRG/HCPCS episode type/region-level benchmark prices. We proposed to apply a prospective trend factor and a discount factor to benchmark prices (as well as a prospective normalization factor, described later in this section) to calculate preliminary target prices. We stated the prospective trend factor would represent expected changes in overall spending patterns between the most recent calendar year of the baseline period and the performance year, based on observed changes in overall spending patterns between the earliest calendar year of the baseline period and the most recent year of the baseline period. We stated that the discount factor would represent Medicare's portion of potential savings from the episode. At § 512.645(a), we proposed to risk adjust episode-level target prices at reconciliation by facility bed-size and safety net status, as defined in § 512.605, along with the following beneficiary-level variables: age group, Hierarchical Condition Category count (a measure of clinical complexity), beneficiary economic risk (the components of which are described in more detail in section X.C.2.f.(4). of this final rule), prior post-acute care use, disability status as reason for initial Medicare enrollment, and recent medical history (represented as 22 separate, binary variables indicating relevant services or HCC flags during the 180-day lookback). We proposed to calculate risk adjustment multipliers prospectively at the MS–DRG/HCPCS episode type level based on baseline data and hold those multipliers fixed for the performance year. To ensure that risk adjustment does not inflate target prices overall, we further proposed to calculate a prospective normalization factor based on the data used to calculate the risk adjustment multipliers. We proposed to apply the prospective normalization factor, in addition to the prospective trend factor and discount factor described previously, to the benchmark price to calculate the preliminary target price for each MS–DRG/HCPCS episode type and region. We proposed that the prospective normalization factor would be subject to a limited adjustment at reconciliation based on CJR–X participants' observed performance year case mix, such that the final normalization factor would not exceed +/− 5 percent of the prospective normalization factor. We stated we would use standardized payment data to perform these target price calculations. We indicated that a simplified equation for the construction of preliminary target prices would be—

Preliminary Target Price = Benchmark Price * Prospective Trend Factor * Prospective Normalization Factor * Risk Adjustment Multipliers * Discount Factor

We noted that construction of the reconciliation target price, as discussed in section X.C.2.f.(5)(d). of this final rule, would account for realized patient case mix and spending trends and result in updates to the trend factor and normalization factors.

As described in detail in the following sections, many of the payment and pricing policies that we proposed for CJR–X represent minor deviations from the policies that were tested in the original CJR Model and the CJR Extension. Many of the proposed policy adjustments reflect lessons learned from the CJR Model that were informed by CJR evaluation, which we believe would improve upon the CJR Model methodology in a manner that was predictable and would not fundamentally alter the general structure of the model that was tested. As discussed in section X.C.2.f.(1)(b). of the final rule, these same lessons informed the design of TEAM.

The following is a summary of general comments about our proposed pricing and payment methodology for CJR–X, and our responses to these comments:

Comment: Many commenters expressed concern that the proposed CJR–X pricing and payment methodology could create a ratchet effect in which prior savings and efficiency gains are incorporated into future benchmarks, resulting in progressively lower target prices over time. Commenters stated that this concern was especially important because CJR–X is proposed as an expanded national model without a defined end date. Commenters believed that annual rebasing, rolling regional benchmarks, heavier weighting of more recent baseline years, trend methodology, and application of the discount factor could operate together to reduce opportunities for continued savings, particularly for hospitals, regions, or providers that have already achieved efficiencies through prior participation in CJR, BPCI Advanced, TEAM, or other value-based care initiatives.

Commenters stated that continued downward pressure on target prices could penalize high-performing or historically efficient hospitals, create a ''race to the bottom,'' reduce financial predictability, and make it difficult for hospitals to sustain investments in care redesign, care coordination staff, data infrastructure, post-acute care relationships, physician alignment strategies, and quality improvement programs. Some commenters also expressed concern that, if LEJR spending has stabilized or if remaining savings opportunities are limited, further target price reductions could undermine access to medically necessary care, post-acute care, or high-quality care for higher-need beneficiaries. Commenters recommended that CMS adopt safeguards to mitigate the ratchet effect, including target price floors, limits on annual target price reductions, pricing protections for historically efficient hospitals, longer target price stability periods, glide paths, inflation-based updates, recognition of prior efficiency gains, additional stakeholder engagement, or ongoing monitoring of whether LEJR episode spending has reached a clinically sustainable level.

Response: We acknowledge commenters' concerns about target price sustainability and the potential for price ratcheting in a long-term expanded model. In the proposed rule, we recognized that CJR–X differs from prior finite model tests because it is proposed as an expanded national model and, therefore, the pricing and payment methodology must be transparent, accurate, and adaptable to evolving payment and health care industry trends over the long term. We also specifically recognized that participants in episode-based payment models have expressed concern about the ratchet effect, including the concern that participants could be penalized for achieving lower spending if those savings lead to lower target prices in subsequent years.

We proposed the CJR–X pricing and payment methodology to balance target price accuracy, predictability, long-term sustainability, and Medicare savings. Several features of the proposed methodology were intended to address these concerns while maintaining the general structure of the CJR Model payment policy that we have tested and are proposing to expand. These features include using a 3-year baseline period rather than a 1-year baseline period, using regional rather than hospital-specific target prices so that participants are not directly competing only against their own historical performance, applying prospective and limited retrospective trend factors to account for spending changes between the baseline and performance period, applying risk adjustment and normalization policies to account for differences in case mix, capping high-cost outlier episodes, and proposing a 2 percent discount factor rather than the 3 percent discount factor used for LEJR episodes in prior CJR and BPCI Advanced pricing.

We agree that target price sustainability will be important for CJR–X, particularly because CJR–X is intended to operate over a longer time horizon than a finite model test. We will continue to monitor CJR–X implementation, including target price sustainability, quality of care, beneficiary access, and potential unintended consequences, and may consider additional technical assistance, operational guidance, or future model modifications through notice and comment rulemaking if monitoring or evaluation identifies price ratcheting, unrealistic target prices, access barriers, or other concerning trends that warrant changes to the model.

However, we must also balance these concerns against the need to set target prices that reflect current spending patterns and do not overstate savings that would have occurred absent the model. Using older spending data, limiting rebasing too significantly, or establishing floors that are not tied to episode-specific spending patterns could reduce target price accuracy and could limit Medicare's ability to achieve savings under the model. We address the commenters' more specific recommendations regarding baseline rebasing in section X.C.2.f.(3)(a), regional target prices in section X.C.2.f.(3)(b), trend methodology in section X.C.2.f.(3)(f), discount factors in section X.C.2.f.(3)(g), and other pricing safeguards in the policy-specific sections that follow.

(3) Target Prices

(a) Baseline Period for Benchmarking

We proposed using 3 years of baseline episode spending to calculate benchmark prices, which we would further adjust as described in section X.C.2.f.(4). of this final rule to create preliminary target prices. Specifically, at § 512.605, we proposed to define ''baseline period'' as the 3-year historical period used to construct the preliminary target price and reconciliation target price for a given performance year. We also proposed to define ''baseline episode spending'' as total episode spending by all providers and suppliers associated with a given MS–DRG/HCPCS episode type for all hospitals in a given region during the baseline period. We proposed to roll this 3-year baseline period forward every year. Specifically, we proposed the following:

- To determine baseline episode spending for PY1, CMS would use baseline episode spending for episodes with anchor hospitalization start dates or anchor procedure dates beginning on or after October 1, 2023 and anchor hospitalization discharge dates or anchor procedure dates between October 1, 2023 and September 30, 2026.
- To determine baseline episode spending for PY2 and future performance years, CMS would use same 3-year cadence to roll the baseline period forward a year.
- For example, to determine baseline episode spending in PY2, CMS would use baseline episode spending for episodes with anchor hospitalization start dates or anchor procedure dates beginning on or after October 1, 2024 and anchor hospitalization discharge dates or anchor procedure dates between October 1, 2024 and September 30, 2027.

We stated in the proposed rule that the use of 3 years of baseline episode spending is consistent with our initial CJR methodology, as described in the 2015 CJR final rule (80 FR 73340). In that case, the 3-year baseline period moved forward every 2 years. However, in combination with the lack of a retrospective trend factor, the use of a 3-year baseline period that only moved forward every 2 years meant that our methodology was not able to capture the degree to which spending on LEJR episodes was decreasing nationwide,

both among CJR and non-CJR hospitals. As a result, we believed our target prices partially reflected spending decreases that were not due specifically to participation in CJR.

We stated in the proposed rule that subsequently, in the 2021 CJR 3-Year Extension final rule, we finalized a policy to use a 1-year baseline period that would move forward every year (with the exception of skipping data from 2020 due to COVID–19 irregularities) (86 FR 23514). In combination with a retrospective market trend factor, using 1 year of baseline episode spending updated every year meant that our target prices would not be inflated as they had been under the initial CJR methodology. BPCI Advanced employed a strategy that blends elements of both CJR approaches, with a longer baseline period (4 years) similar to the initial CJR methodology, but shifting forward every year, as we do in the CJR extension.

We noted in the proposed rule that participants in episode-based payment models have expressed concerns about a concept known as the ''ratchet effect'' when choosing the baseline period from which to calculate target prices. That is, participants do not want to be penalized for achieving lower spending by having lower target prices in subsequent years. We stated the use of fewer years of the most recent baseline episode spending, as well as more frequent rebasing, will generally decrease target prices more quickly year over year if overall episode spending decreases, as opposed to a longer, fixed baseline. However, we noted that we must balance this concern against the likelihood of having inaccurate target prices if we use older baseline episode spending or rebase less frequently.

We indicated in the proposed rule that in TEAM, we finalized a revised version of the BPCI Advanced strategy with a shorter, 3-year baseline that was rebased annually and temporally weighted to place greater emphasis on more recent years. As initially described in final rule establishing TEAM (89 FR 69748), we believe this approach will achieve a balance between providing target prices that sufficiently reflect up-to-date spending trends and mitigating the ratchet effect by allowing prices to adjust more gradually over time. Additionally, as discussed in section X.C.2.f.(3)(b). of this final rule, we proposed regional target prices based on regional average spending making CJR–X an achievement-based model. We noted in this framework, CJR–X participants would not compete against their historical selves but rather strive to outperform their regional peers. We also noted that individual improvements will not affect future target prices in a substantive way as the future benchmark is being calculated based on the performance of several hospitals. We believed a 3-year baseline period constructed using all hospital's spending would help produce a fair pricing approach that balances accuracy, simplicity, and mitigates CJR–X participants being penalized for successful past performance.

For CJR–X, we proposed to adjust baseline episode spending to trend all episode spending to the most recent year of the baseline period. We stated the adjustment would reflect the impact of inflation and any changes in episode spending due to evolving patterns of care, Medicare payment policies, payment system updates, and other factors during the baseline period. At § 512.605(e) we proposed to define a ''baseline year'' as any of the 3 fiscal years during a given baseline period. For example, baseline year 1 for PY 1 will be FY 2024 (October 1, 2023–September 30, 2024), baseline year 2 will be FY 2025 (October 1, 2024–September 30, 2025), and baseline year 3 will be FY 2026 (October 1, 2025–September 30, 2026). We proposed to calculate the adjustment factors for baseline years 1 and 2 by dividing average episode spending for baseline year 3 episodes by average episode spending for episodes from baseline years 1 and 2, respectively. We would then apply the applicable adjustment factors to the episode spending of each episode in baseline years 1 and 2. We indicated that this adjustment would bring all baseline episode spending forward to the most recent baseline year, so that baseline year 1 and 2 spending would be expressed in baseline year 3 dollars. We noted in the proposed rule that this method would be consistent with how we calculated the baseline trend factor for CJR in the performance years that used the 3-year baseline period, as described in the 2015 CJR final rule (80 FR 73342). We proposed to calculate these baseline trend factor adjustments at the MS–DRG/HCPCS episode type and region level.

In recognition of the fact that baseline episode spending from more recent years are likely to be a better predictor of performance year spending, we proposed to weight recent baseline episode spending more heavily than episode spending from earlier baseline years. Specifically, we proposed to weight episode spending from baseline year 1 at 17 percent, baseline year 2 at 33 percent, and baseline year 3 at 50 percent. We stated in the proposed rule that this method of weighting would mean that the most recent episode spending patterns, expected to be the most accurate predictor of performance year spending, would contribute most strongly to the benchmark price at 50 percent. The remaining 50 percent would be divided into thirds, with baseline year 2 contributing approximately ⅔, while baseline year 1, which is likely to be the least accurate predictor of performance year spending, would contribute ⅓.

We sought comment on our proposed definitions at § 512.605 and our proposals at § 512.640(b)(2) and (3) to use 3 years of baseline episode spending, rolled forward for each performance year, with more recent baseline years weighted more heavily, to calculate CJR–X target prices.

The following is a summary of the public comments received on our proposals to use a rolling 3-year baseline period, with more recent baseline years weighted more heavily, and our responses to these comments:

Comment: Many commenters expressed concern that the proposed use of a rolling 3-year baseline period, annual rebasing, and heavier weighting of the most recent baseline year would contribute to price ratcheting over time. Commenters stated that, as hospitals and regions reduce LEJR episode spending, those reductions would be incorporated into future benchmarks, resulting in lower target prices and reduced opportunities to earn reconciliation payments in subsequent performance years. Commenters stated that this effect could be particularly problematic for hospitals that have already achieved efficiencies through prior participation in CJR, BPCI Advanced, TEAM, or other value-based care initiatives.

Commenters recommended that CMS modify the baseline methodology to reduce the effect of annual rebasing on future target prices. Commenters suggested alternatives such as using a longer baseline period, rebasing less frequently, maintaining target prices for multiple performance years, weighting baseline years equally, applying inflation or other update factors instead of annually rebasing to more recent spending, limiting the frequency or magnitude of target price reductions, or adopting safeguards to prevent target prices from falling below sustainable levels.

Response: We acknowledge commenters' concerns that annual rebasing and recent-year weighting could contribute to price ratcheting if LEJR episode spending continues to decline over time. We considered these concerns in developing the CJR–X

baseline methodology. In the proposed rule, we recognized that using fewer years of more recent baseline episode spending and rebasing more frequently will generally decrease target prices more quickly year over year if overall episode spending decreases, as compared to using a longer or fixed baseline. We also recognized that this concern must be balanced against the likelihood of setting inaccurate target prices if older spending data are used or if rebasing occurs less frequently.

We proposed to use a rolling 3-year baseline period because we believe this approach balances target price accuracy, predictability, and mitigation of the ratchet effect. A 3-year baseline period allows target prices to reflect more than a single year of spending experience, which reduces the effect of year-to-year variation, outlier patterns, or unusual temporary changes in utilization. At the same time, rolling the baseline forward each year helps ensure that target prices remain connected to current LEJR episode spending patterns, changes in site of service, changes in Medicare payment policy, and evolving care delivery patterns. We believe that using substantially older data or freezing target prices for multiple years could cause target prices to diverge from current expected episode spending and could reduce the model's ability to generate Medicare savings.

We also proposed to weight the most recent baseline year more heavily because more recent spending is generally more predictive of performance-year spending than older spending. We believe the weighting methodology, under which baseline year 1 is weighted at 17 percent, baseline year 2 is weighted at 33 percent, and baseline year 3 is weighted at 50 percent, appropriately balances the predictive value of recent data with the stability provided by a multi-year baseline. Equal weighting or a longer fixed baseline would place more weight on older spending patterns that may no longer reflect current LEJR care delivery, post-acute care use, outpatient procedure volume, coding, or payment system changes.

We do not believe it would be appropriate to replace annual rebasing with inflation-only updates or to maintain target prices for multiple performance years without updating the underlying baseline. While these approaches could increase pricing stability for participants, they could also cause target prices to overstate expected episode spending if LEJR spending continues to decline or if care delivery patterns change. We believe that the rolling baseline methodology better supports the goals of CJR–X by maintaining a closer relationship between target prices and current regional episode spending while still smoothing spending experience across 3 baseline years.

We also note that CJR–X target prices are based on regional spending rather than hospital-specific spending. As a result, CJR–X participants are not competing only against their own historical performance, and an individual participant's efficiencies would not, by themselves, substantially determine that CJR–X participant's future target prices. We believe that using a 3-year baseline constructed from regional spending across hospitals helps mitigate concerns that a participant would be directly penalized for its own prior success, while preserving an achievement-based methodology that rewards participants for delivering efficient, high-quality LEJR episode care relative to regional spending patterns.

We acknowledge commenters' concerns that annual rebasing and recent-year weighting could contribute to price ratcheting if LEJR episode spending continues to decline over time. We considered these concerns in developing the proposed CJR–X baseline methodology. In the proposed rule, we recognized that using fewer years of more recent baseline episode spending and rebasing more frequently will generally decrease target prices more quickly year over year if overall episode spending decreases, as compared to using a longer or fixed baseline. We also recognized that this concern must be balanced against the likelihood of setting inaccurate target prices if older spending data are used or if rebasing occurs less frequently.

We proposed to use a rolling 3-year baseline period because we believe this approach balances target price accuracy, predictability, and mitigation of the ratchet effect. A 3-year baseline period allows target prices to reflect more than a single year of spending experience, which reduces the effect of year-to-year variation, outlier patterns, or unusual temporary changes in utilization. At the same time, rolling the baseline forward each year helps ensure that target prices remain connected to current LEJR episode spending patterns, changes in site of service, changes in Medicare payment policy, and evolving care delivery patterns. We believe that using substantially older data or freezing target prices for multiple years could cause target prices to diverge from current expected episode spending and could reduce the model's ability to generate Medicare savings.

We also proposed to weight the most recent baseline year more heavily because more recent spending is generally more predictive of performance-year spending than older spending. We believe the proposed weighting methodology, under which baseline year 1 is weighted at 17 percent, baseline year 2 is weighted at 33 percent, and baseline year 3 is weighted at 50 percent, appropriately balances the predictive value of recent data with the stability provided by a multi-year baseline. Equal weighting or a longer fixed baseline would place more weight on older spending patterns that may no longer reflect current LEJR care delivery, post-acute care use, outpatient procedure volume, coding, or payment system changes.

We do not believe it would be appropriate to replace annual rebasing with inflation-only updates or to maintain target prices for multiple performance years without updating the underlying baseline. While these approaches could increase pricing stability for participants, they could also cause target prices to overstate expected episode spending if LEJR spending continues to decline or if care delivery patterns change. We believe that the proposed rolling baseline methodology better supports the goals of CJR–X by maintaining a closer relationship between target prices and current regional episode spending while still smoothing spending experience across 3 baseline years.

We also note that CJR–X target prices are based on regional spending rather than hospital-specific spending. As a result, CJR–X participants are not competing only against their own historical performance, and an individual participant's efficiencies would not, by themselves, substantially determine that participant's future target prices. We believe that using a 3-year baseline constructed from regional spending across hospitals helps mitigate concerns that a participant would be directly penalized for its own prior success, while preserving an achievement-based methodology that rewards participants for delivering efficient, high-quality LEJR episode care relative to regional spending patterns.

We address commenters' broader recommendations regarding target price floors, administrative trend approaches, and other safeguards to address long-term target price sustainability in the discussion of trending prices in section X.C.2.f.(3)(f) of this final rule and related pricing safeguards in sections X.C.2.f.(3)(e) and X.C.2.f.(4) of this final rule. We will continue to consider monitoring data, evaluation findings,

operational experience, and stakeholder feedback in connection with the baseline methodology and related pricing policies.

After consideration of the public comments, we are finalizing without modification the proposals at § 512.605 to define ''baseline episode spending,'' ''baseline period,'' and ''baseline year'' and the proposals at § 512.640(b)(2) and (3) to use 3 years of baseline episode spending, rolled forward for each performance year, with more recent baseline years weighted more heavily, to calculate CJR–X target prices.

(b) Regional Target Prices

We proposed to provide target prices to CJR–X participants for each proposed MS–DRG/HCPCS episode type and region based on 100 percent regional data for all CJR–X participants prior to each PY. We stated in the proposed rule that this approach would be consistent with PYs 4 through 8 of the CJR Model and aligns with the approach implemented in TEAM (89 FR 69751). While CJR target prices used a blend of two-thirds hospital-specific data and one-third regional data for PYs 1 and 2, and one-third hospital-specific data and two-thirds regional data for PY 3, we stated our reasons in the 2015 CJR final rule for moving towards fully regional target pricing as participants gained more experience in the model (80 FR73347). We stated that target prices based on hospital-specific data would require a CJR–X participant to compete against its own previous performance and improve over that performance to receive a reconciliation payment. Conversely, target prices based on regional data would require a CJR–X participant to compete against its peers in that region, such that only a specific level of achievement, as opposed to improvement alone, would result in a reconciliation payment. For historically inefficient CJR–X participants, compared to their peers, hospital-specific target prices would be higher than regional target prices because hospital-specific baseline episode spending would be greater than average baseline episode spending for the region. We indicated that for CJR–X participants that are historically efficient compared to their peers, hospital-specific target prices would be lower than regional target prices because hospital-specific baseline episode spending would be lower than average baseline episode spending for the region. We noted in the 2015 CJR final rule that if we used 100 percent hospital-specific pricing in CJR, historically efficient hospitals could have fewer opportunities for achieving additional efficiencies under the model and would not be rewarded for maintaining high quality and efficiency, whereas less efficient hospitals would be rewarded for improvement even if they did not reach the same level of high quality and efficiency as the more historically efficient hospitals.

We sought comment on our proposal at § 512.640(b)(1) to provide regional target prices to all CJR–X participants for each PY.

The following is a summary of the public comments received on our proposal to construct regional target prices, and our responses to these comments:

Comment: A commenter supported CMS' proposal to use regional target prices, stating that regional benchmarking can help avoid requiring CJR–X participants to compete only against their own historical performance.

Response: We appreciate the commenter's support for the use of regional target prices. We proposed to use regional target prices because we believe regional pricing supports an achievement-based methodology and helps avoid requiring CJR–X participants to compete only against their own historical performance. Under a hospital-specific pricing methodology, a participant hospital's future target prices would be more directly affected by that hospital's own prior spending reductions, which could reduce the opportunity for historically efficient hospitals to earn reconciliation payments and could penalize hospitals for prior success. By contrast, regional target prices are based on broader regional spending experience, so CJR–X participants are evaluated relative to regional peers rather than solely against their own historical spending.

Comment: Many commenters raised concerns about the proposed use of 100 percent regional data to calculate target prices. Commenters stated that regional target prices may help mitigate some concerns associated with hospital-specific benchmarks, but that the proposed regional methodology may not sufficiently account for variation among hospitals and markets within the same region. Commenters stated that hospitals within a single region may face materially different labor costs, supply costs, implant costs, post-acute care availability, skilled nursing facility and inpatient rehabilitation facility capacity, rural or urban market conditions, Medicare Advantage penetration, patient complexity, referral patterns, and baseline resource levels. Commenters expressed concern that broad regional benchmarks could disadvantage hospitals in higher-cost local markets, hospitals with fewer post-acute care options, rural hospitals, safety net hospitals, Medicare-dependent, small rural hospitals, sole community hospitals, academic medical centers, or hospitals that have already achieved efficiencies relative to other hospitals in their region.

Some commenters stated that regional target prices could create volatility or unrealistic benchmarks if a region includes hospitals with substantially different cost structures, patient populations, or care delivery environments. Commenters also expressed concern that regional benchmarks may not adequately account for regional or local markets that have already achieved lower LEJR spending through prior participation in CJR, BPCI Advanced, TEAM, Medicare Advantage arrangements, or other value-based care initiatives. Commenters stated that, in these markets, regional target prices could reflect prior efficiency gains and leave limited opportunity for additional savings.

Commenters recommended that CMS modify the regional target price methodology or add safeguards to account for these concerns. Commenters suggested alternatives such as using more granular geographic areas, state-level benchmarks, urban and rural stratification, local market adjusters, post-acute care market adequacy adjustments, hospital-specific or hybrid hospital/regional benchmarks, peer groups based on hospital type or resource level, adjustments for historically efficient regions or hospitals, benchmark floors, hold-harmless protections, use of the higher of national or regional historical spending, additional transparency regarding regional benchmark construction, and ongoing monitoring of whether regional target prices create realistic opportunities for hospitals to achieve savings.

Response: We acknowledge commenters' concerns that hospitals within the same region may differ in ways that affect episode spending, including differences in local market conditions, patient populations, resource levels, prior efficiency, and post-acute care availability. We agree that these factors are important, but we do not believe they should be addressed primarily by replacing regional target prices with hospital-specific or more narrowly stratified benchmarks. Many of these concerns are addressed more directly through other aspects of the CJR–X pricing and payment methodology, including risk adjustment and normalization policies that account

for beneficiary and hospital-level factors, the high-cost outlier cap, and stop-loss protections. We address related comments regarding risk adjustment, safety net hospital status, rural hospitals, stop-loss protections, and post-acute care access in the applicable sections of this final rule.

We considered commenters' recommendations to use more granular geographic benchmarks, state-level benchmarks, urban and rural stratification, local market adjusters, peer-group-specific benchmarks, hospital-specific or hybrid hospital/regional benchmarks, benchmark floors, hold-harmless protections, or adjustments for historically efficient hospitals or regions. We do not believe that adopting these alternatives would be appropriate for CJR–X at this time. More granular or peer-group-specific benchmarks could reduce the number of episodes used to calculate benchmark prices, increasing volatility and reducing the stability and reliability of target prices. Hospital-specific or hybrid benchmarks could also reintroduce the concern that participants are competing against their own historical performance and could reduce the achievement-based incentives of the model.

We continue to believe that 100 percent regional target pricing better balances accuracy, stability, transparency, administrative feasibility, and model incentives for a nationally expanded model. Regional pricing helps reward hospitals that furnish efficient, high-quality LEJR episode care relative to broader regional spending patterns, rather than rewarding improvement alone without regard to whether the hospital's episode spending remains high relative to peers. We also believe it is important that target prices reflect current regional spending patterns and that CJR–X maintain incentives for hospitals to improve care coordination, reduce avoidable utilization, and maintain or improve quality.

We acknowledge commenters' requests for additional transparency regarding regional target price construction. We intend to provide CJR–X participants with information needed to understand model methodology, episode attribution, target prices, quality measures, reconciliation, and other operational requirements before the model begins. We will also continue to make model resources publicly available, including through the CJR–X Model-specific web page and other implementation materials.

We will continue to consider monitoring data, evaluation findings, operational experience, and stakeholder feedback to determine whether additional refinements to regional target pricing or related pricing policies may be warranted to support implementation, protect beneficiary access, preserve incentives for high-quality care, and maintain realistic opportunities for CJR–X participants to achieve savings.

Comment: Some commenters recommended that CMS revise the level of detail used to calculate CJR–X target prices. Commenters stated that target prices should better distinguish among different episode types, sites of service, and patient populations. Commenters recommended separate target prices for inpatient and outpatient LEJR episodes, separate target prices for hip replacements and other procedures, and different treatment for fracture-related episodes or other episodes expected to involve higher acuity or post-acute care needs.

Some commenters also raised concerns about site-of-care migration. Commenters stated that as lower-acuity LEJR procedures shift to outpatient or ASC settings, the remaining hospital-based episodes may reflect higher acuity, greater comorbidity burden, higher readmission risk, or greater post-acute care needs. Commenters recommended that CMS adjust target prices based on local ASC use or otherwise account for changes in hospital case mix caused by movement of healthier beneficiaries to outpatient or ASC settings.

A commenter recommended that CMS modify treatment of transfer episodes by excluding the amount paid to the initial admitting hospital when calculating target prices and actual episode spending. The commenter stated that this would avoid penalizing hospitals for clinically appropriate transfers.

Response: We acknowledge commenters' recommendations to use more granular target price categories or additional adjustments for site-of-care and episode-type differences. We agree that target prices should account for meaningful differences in expected episode spending. The proposed CJR–X methodology already calculates target prices at the MS–DRG/HCPCS episode type and region level, rather than using a single target price for all LEJR episodes. The methodology also applies beneficiary-level and hospital-level risk adjustment at reconciliation, including variables intended to account for clinical complexity, prior post-acute care use, social risk, and hospital-level characteristics.

We are not adopting additional separate target price tracks for inpatient and outpatient episodes, hip replacements and other procedures, fracture-related episodes within each MS–DRG/HCPCS episode type, or local ASC market share. Some of the differences identified by commenters are already reflected in the MS–DRG/HCPCS episode type structure, episode construction, or risk adjustment methodology. We also believe that creating additional separate pricing tracks for inpatient and outpatient episodes could undermine one of the goals of CJR–X, which is to support appropriate patient status and site-of-service decisions based on beneficiary clinical needs rather than model payment differences. Creating additional pricing cells could reduce episode volume within each cell, increase volatility, and make target prices less stable and less transparent for participants. We believe the proposed MS–DRG/HCPCS episode type-level methodology better balances payment accuracy, stability, transparency, appropriate site-of-service incentives, and administrative feasibility.

We recognize commenters' concerns that continued migration of lower-acuity LEJR procedures to outpatient or ASC settings could affect the mix of hospital-based episodes. We believe the proposed methodology is designed to account for changes in episode mix through MS–DRG/HCPCS episode type pricing, beneficiary-level risk adjustment, normalization, and trending policies. We are not adopting a local ASC-use adjustment because ASC market share may reflect many factors, including local practice patterns, beneficiary selection, payer mix, market capacity, and physician referral patterns, and we do not believe it would provide a reliable standalone basis for adjusting CJR–X target prices at model launch.

We also are not adopting the recommendation to exclude the amount paid to an initial admitting hospital when calculating target prices or actual episode spending for transfer episodes. The CJR–X episode payment methodology is intended to evaluate total episode spending for LEJR episodes, including spending that occurs across providers during the episode. Excluding payments to the initial admitting hospital could understate total episode spending and create inconsistency in how transfer and non-transfer episodes are measured. We believe concerns about higher-acuity transfer cases are better addressed through episode type, risk adjustment, high-cost outlier, and reconciliation policies rather than excluding a portion of episode spending from target price or actual spending calculations.

We will continue to assess whether CJR–X target prices appropriately reflect changes in site of care, episode mix, and patient complexity as care patterns evolve.

After consideration of the public comments, we are finalizing without modification the proposal at § 512.640(b)(1) to provide regional target prices to all CJR–X participants for each performance year.

(c) Services That Extend Beyond an Episode

We recognized that a CJR–X episode with a fixed 90-day post-discharge episode length, as discussed in section X.C.2.d.(3)(d) of this final rule, may result in some instances where a service included in the episode begins during the episode but concludes after the end of the episode and for which Medicare makes a single payment under an existing payment system. We noted in the proposed rule that an example would be a beneficiary in an episode who is admitted to a SNF for 30 days, beginning on day 65 post-discharge from the CJR–X anchor hospitalization or anchor procedure. The first 25 days of the SNF admission would fall within the episode, while the subsequent 5 days would fall outside of the episode. We proposed that, to the extent that a Medicare payment for included episode services spans a period of care that extends beyond the episode, these payments would be prorated so that only the portion attributable to care during the episode is attributed to the episode payment when calculating actual Medicare payment for the episode. For non-IPPS inpatient hospital (for example, CAH) and inpatient post-acute care (for example, SNF, IRF, LTCH, IPF) services, we proposed to prorate payments based on the percentage of actual length of stay (in days) that falls within the episode window. For HHA services that extend beyond the episode, we proposed that the payment proration be based on the percentage of days, starting with the first billable service date (''start of care date'') and through and including the last billable service date, that fall within the episode. We stated in the proposed rule that this policy would ensure that CJR–X participants are not held responsible for the cost of services that did not overlap with the episode period. For IPPS services that extend beyond the episode (for example, readmissions included in the episode definition), we proposed to separately prorate the IPPS claim amount from episode target price and actual episode payment calculations, called the normal MS–DRG payment amount for purposes of this final rule. We stated the normal MS–DRG payment amount would be pro-rated based on the geometric mean length of stay, comparable to the calculation under the IPPS post-acute care transfer policy at § 412.4(f) and as published on an annual basis in Table 5 of the IPPS/LTCH PPS final rules. As discussed in the proposed rule, consistent with the IPPS post-acute-care transfer policy, the first day for a subset of MS–DRGs (indicated in Table 5 of the IPPS/LTCH PPS final rules) would be doubly weighted to count as 2 days to account for likely higher hospital costs incurred at the beginning of an admission. If the actual length of stay that occurred during the episode is equal to or greater than the MS–DRG geometric mean, the normal MS–DRG payment would be fully allocated to the episode. If the actual length of stay that occurred during the episode is less than the geometric mean, the normal MS–DRG payment amount would be allocated to the episode based on the number of inpatient days that fall within the episode. If the full amount is not allocated to the episode, any remaining amount would be allocated to the 90-day post-episode payment calculation discussed in section X.A.3.(d)(5). of this final rule. We indicated in the proposed rule that this approach for prorating the normal MS–DRG payment amount is consistent with the IPPS transfer per diem methodology. We also noted that this methodology would be consistent with CJR and is described as applied to CJR in the 2015 CJR final rule (80 FR 73333).

We sought comment on our proposed methodology at § 512.655 for prorating services that extend beyond the episode.

We received no comments on our proposed methodology for prorating services that extend beyond the episode and are therefore finalizing without modification the proposal at § 512.655 for prorating services that extend beyond the episode.

(d) Episodes That Begin in One Performance Year and End in the Subsequent Performance Year

Given that we proposed episodes with a 90-day post-discharge period, we recognized that some episodes will begin during one performance year and end during the following performance year. We proposed that all episodes would receive the target price associated with the date of discharge from the anchor hospitalization or the anchor procedure, as applicable, regardless of the episode end date. We noted in the proposed rule that the assignment of target prices based on the date of discharge from the anchor hospitalization or the anchor procedure is different from the CJR model, where the target price was assigned based on the episode start date rather than the discharge date, but this proposed policy is consistent with BPCI Advanced. We stated that this slight modification of using the anchor hospitalization and anchor procedure date of discharge ensures the same approach is applied to target price assignment and reconciliation of episodes. As noted in section X.C.2.f.(5)(a). of this final rule, annual reconciliation is based on episodes with a date of discharge from the anchor hospitalization or a date of discharge from the anchor procedure during that performance year. We stated that if an episode starts in one performance year and has an anchor hospitalization discharge date that extends past the end of a performance year, that episode would factor into the next performance year's reconciliation, which is consistent with TEAM.

We sought comment on our proposal at § 512.640(a)(3) for applying target prices to an episode that begins in one performance year and ends in the subsequent performance year.

We received no comments on our proposal to apply target prices to episodes that begin in one performance year and end in the subsequent performance year and are therefore finalizing our proposal at § 512.640(a)(3) without modification.

(e) High-Cost Outlier Cap for Benchmarking

In the proposed rule we stated that given the broad proposed episode definition and 90-day proposed post-discharge period, we want to ensure that hospitals have some protection from the downside risk associated with especially high payment episodes, where the clinical scenarios for these cases each year may differ significantly and unpredictably. As we stated in the 2015 CJR final rule (80 FR 73335), we do not believe that the opportunity for a hospital's systematic care redesign of particular surgical episode has the significant potential to impact the clinical course of these extremely disparate high payment cases. In the 2015 CJR final rule (80 FR 73335), we finalized a policy to limit hospital responsibility for high episode payment cases by utilizing a high price payment ceiling at two standard deviations above the mean episode payment amount in calculating the target price and in comparing actual episode payments during the performance year to the target prices. We indicated in the proposed rule that this policy was designed to prevent participant

hospitals from being held responsible for catastrophic episode spending amounts that they could not reasonably have been expected to prevent. The policy, and the reasoning behind it, is described in detail at (80 FR 73335). However, as we described in 86 FR 23518, based on data from the first few years of the CJR model, we observed that the original 2 standard deviation methodology was insufficient to identify and cap high episode spending, as more episodes than expected exceeded the spending cap. We described in detail our reasoning for finalizing a change to the high episode spending cap in the 2021 CJR 3-Year Extension final rule (86 FR 23518). We finalized a change to the calculation of the high episode spending cap to derive the amount by setting the high episode spending cap at the 99th percentile of historical costs for each MS–DRG for each region. We stated the resulting methodology for the CJR Extension was similar to the BPCI Advanced methodology for capping high-cost episode spending at the 99th percentile for each MS–DRG. We proposed a similar high-cost outlier policy for CJR–X, which also aligns with TEAM. We proposed to cap both baseline episode spending and performance year episode spending at the 99th percentile of spending at the MS–DRG/HCPCS episode type, region and baseline year, referred to as the ''high-cost outlier cap'' and defined at proposed § 512.605. We proposed to determine the 99th percentile of spending at the MS–DRG/HCPCS episode type, region, and baseline year during the applicable time period, and then set spending amounts that exceed the high-cost outlier cap to the amount of the high-cost outlier cap. For instance, if the high-cost outlier cap was set at $30,000, an episode that had actual episode spending of $45,000 would have its spending amount, for purposes of the model, reduced by $15,000 when the cap was applied and therefore, the spending for that episode would be held at $30,000. We proposed to use capped episode spending when calculating benchmark prices in order to ensure that high-cost outlier episodes do not artificially inflate the benchmark. When calculating performance year episode spending at reconciliation, we proposed to use capped episode spending so that a CJR–X participant would not be held responsible for catastrophic episode spending amounts that they could not reasonably have been expected to prevent.

We sought comment on our proposal at § 512.605 to define ''high-cost outlier cap'' and our proposal at § 512.640(b)(4) for calculating and applying the high-cost outlier cap.

The following is a summary of the public comments received on our proposal to calculate and apply a high-cost outlier cap, and our responses to these comments:

Comment: Some commenters supported the intent of limiting the effect of unusually high-cost episodes but recommended that CMS revise the proposed high-cost outlier cap methodology. Commenters stated that capping episode spending only above the 99th percentile may not sufficiently limit the effect of unusually high-cost or clinically complex episodes on benchmark prices, target price accuracy, or reconciliation calculations.

Commenters recommended alternatives such as setting the high-cost outlier cap at the 90th percentile, using a 95th percentile cap, applying both low- and high-cost trims, using a threshold based on two standard deviations above the mean, or using different thresholds for hospitals with higher case mix or HCC burden. Commenters stated that these alternatives could reduce variability, improve target price accuracy, and limit the effect of extreme episode spending on model calculations.

Response: We acknowledge commenters' support for the intent of the high-cost outlier cap and their recommendations to use a different threshold or methodology. We proposed the high-cost outlier cap to limit the effect of unusually high-cost episodes in both benchmark price construction and performance-year episode spending. Under the proposal, spending above the 99th percentile would be capped at the MS–DRG/HCPCS episode type, region, and baseline year level, so extreme high-cost episodes would not artificially inflate benchmarks or disproportionately affect performance-year episode spending.

We are not adopting commenters' recommendations to lower the high-cost outlier cap to the 90th or 95th percentile, use a two-standard-deviation threshold, or apply both low- and high-cost trims. We recognize that these approaches would exclude or limit the effect of a larger number of episodes, but we believe doing so could reduce target price accuracy by treating more expected episode spending variation as outlier spending. The high-cost outlier cap is intended to limit the effect of extreme high-cost episodes, not to remove ordinary variation in LEJR episode spending that may reflect patient complexity, complications, post-acute care needs, or other factors that are part of the expected episode spending distribution.

We also are not adopting hospital-specific or participant-specific high-cost outlier thresholds based on tertiary referral status, case mix, HCC burden, or similar characteristics. The proposed cap is calculated at the MS–DRG/HCPCS episode type, region, and baseline year level, which maintains a consistent methodology across participants while still accounting for differences by episode type and region. We believe that using hospital-specific thresholds would add complexity, reduce comparability across participants, and make the cap less predictable. Concerns about patient and hospital-level differences are addressed more directly through the CJR–X risk adjustment methodology, while the high-cost outlier cap is designed to address extreme episode spending.

We previously used a two-standard-deviation methodology in the original CJR Model but later modified the high episode spending cap after experience showed that the original methodology was insufficient to identify and cap high episode spending. For the CJR Extension, we used a 99th percentile methodology similar to BPCI Advanced, and we proposed a similar high-cost outlier policy for CJR–X, which also aligns with TEAM. We continue to believe the 99th percentile methodology appropriately balances the goal of limiting the effect of extreme high-cost episodes with the need to preserve accurate benchmark and reconciliation calculations.

After consideration of the public comments, we are finalizing without modification the proposals at § 512.605 to define ''high-cost outlier cap'' and at § 512.640(b)(4) for calculating and applying the high-cost outlier cap.

(f) Trending Prices

In the proposed rule we stated that target prices are derived from a prediction based on previous Medicare spending patterns, but it is not possible to perfectly predict how Medicare spending patterns may change over the course of the performance year. We stated in the original BPCI model, prospective target prices were not provided to participants, so the trend factor was calculated retrospectively based on the observed spending during the performance period. Quarterly reconciliations in BPCI meant that participants could gain a sense of how their target prices tended to change over time and get relatively frequent feedback on their performance in the model. However, BPCI participants expressed concern with the uncertainty

of not knowing their target prices in advance.

As noted in the proposed rule, the initial CJR methodology and Model Years 1 through 3 of BPCI Advanced, CMS provided fully prospective target prices to participants. We stated that participants appreciated the certainty of prospective target prices, where we predict in advance how spending patterns might shift and hold those target prices firm even if we underpredicted or overpredicted spending. We noted this methodology included applying update factors to account for setting-specific payment system updates, allowing us to estimate how a given set of services performed during the baseline would be priced had those same services been subject to the fee schedules in effect during the performance period.

We stated in the proposed rule that in CJR, we originally overpredicted performance year spending, not accounting for the overall decline in spending on LEJR episodes nationwide that occurred outside of the model during its first few performance years. We also stated that in BPCI Advanced, we similarly overpredicted performance period spending for certain episodes because our methodology was unable to account for medical coding changes that occurred between the baseline and performance period, or during the performance period itself. For instance, in FY 2016, changes to medical coding guidance were made for Inpatient Congestive Heart Failure, such that certain patients who during the baseline would have been coded as the less expensive MS–DRG 292, were instead coded as the more expensive MS–DRG 291. We noted that this was done in spite of having the same clinical characteristics. This meant that many beneficiaries who received a target price associated with the more expensive MS–DRG 291, actually had the lower performance period costs previously associated with the less expensive MS–DRG 292. We indicated that the use of a fully prospective trend factor was unable to capture these changes in both practice patterns and coding guidelines.

Subsequently, we stated in the proposed rule that we modified both models' methodologies to include a retrospective trend adjustment. Starting in model year 4, we continued to provide BPCI Advanced participants with a prospective target price using an estimated trend factor, but we adjusted the target price at reconciliation based on the retrospective calculation of the trend factor using performance period data. We stated that initially, this policy included guardrails around the magnitude of the retrospective trend factor adjustment of +/−10 percent. In response to participant feedback, we lowered the maximum level of the retrospective trend factor adjustment to +/−5 percent starting in model year 6.

We noted in the proposed rule that in the CJR Extension, the retrospective trend was known as the market trend factor adjustment. It was fully retrospective and calculated at reconciliation, meaning that the unadjusted target price we posted on the CJR website prior to the performance year did not include a prospective trend factor. We stated that in response to participant requests, we provided estimates of the market trend factor on the CJR website based on the most recently available data to help participants estimate their potential target prices. The market trend factor was calculated separately for each MS–DRG/region combination. For the PY 8 reconciliation (corresponding to episodes that ended between January 1, 2024 and December 31, 2024), the highest market trend factor was 1.307 for MS–DRG 469 episodes in the Mountain region, while the lowest market trend factor was 0.998 for MS–DRG 470 episodes in the New England region.

As discussed in the proposed rule, in TEAM, we initially proposed a fully prospective trend factor adjustment based on the percentage difference between average regional MS–DRG/HCPCS episode type expenditures for baseline year 3 (the most recent baseline year) and baseline year 1 (the earliest baseline year) (89 FR 36430). Based on stakeholder feedback, we ultimately revised this approach to align more closely with the modified BPCI Advanced methodology. As described in the TEAM final rule (89 FR 69755), TEAM participants receive a preliminary target price that incorporates a prospective trend factor adjustment for each MS–DRG/HCPCS episode type and region, which reflects the average annual change in episode spending over the baseline period both regionally and nationally. We stated that at reconciliation, a retrospective trend factor adjustment is applied to preliminary target prices based on the average capped performance year episode spending vs. the average capped baseline episode spending. This retrospective adjustment is capped at +/−3 percent of the prospective trend adjustment in order to maintain predictability for participants. TEAM also further refined their prospective trend approach in the FY 2026 IPPS/LTCH PPS final rule (90 FR 37099) to incorporate a linear regression that includes all years in the baseline period to construct the trend, rather than a trend that only looked at the change from baseline year 1 to baseline year 3. TEAM also finalized the addition of two trend years to capture more years of data in the construction of the trend.

For CJR–X, we proposed to apply a ''prospective trend factor'', defined at proposed § 512.605, as the multiplier incorporated into the preliminary target price to estimate changes in spending patterns between the baseline period and the performance year. We also proposed to apply a +/−3 percent capped ''retrospective trend factor'', defined at proposed § 512.605, as the multiplier incorporated into the reconciliation target price to estimate realized changes in spending patterns during the performance year. We indicated in the proposed rule that this methodology would be similar to the approach used in TEAM. The key difference from TEAM is that CJR–X will not include the two trend years in the prospective trend factor, because we wanted to keep consistent the time frame of data we are sharing with CJR–X participants to the data used to construct target prices. For example, CJR–X would share three years of baseline data with CJR–X participants which would align with the baseline period used to construct the prospective trend, whereas TEAM shares 3 years of data that encompasses their baseline period but TEAM participants do not receive data associated with the two trend years. We believed using an approach similar with TEAM's, specifically applying a prospective trend with a +/−3 percent capped retrospective trend factor, will better account for significant spending changes that are not accounted for in the baseline while also ensuring that trends in regions where efficiency is improving over time do not overshoot what is feasible, leading to target prices that more accurately reflect spending patterns during the performance year.

Given our proposal to use a prospective trend factor to predict future spending for the purposes of pricing stability, we considered in the proposed rule but did not propose to include update factors that take into account Medicare payment system updates for each FY or CY and could improve pricing accuracy. Specifically, we considered a methodology similar to BPCI Advanced and Performance Years 1–5 of the CJR Model, where preliminary target prices were updated to reflect the most current FY and CY payment system rates using setting-specific update factors for payment system, including the IPPS, OPPS,

Physician Fee Schedule (PFS), Home Health Prospective Payment System (HH PPS), Medicare Economic Index (MEI), the IRF PPS, and the SNF PPS. However, we stated in the proposed rule that updating target prices using setting-specific update factors would result in CJR–X participants receiving more than one target price for an MS–DRG/HCPCS episode type in a performance year which can increase complexity. Further, we noted that while including update factors would generally increase target prices, it also decreases pricing stability since the preliminary target price would change due to the application of update factors. However, we are interested in capturing the most accurate episode spending in CJR–X that captures these payment system updates. We have included a policy in section X.C.2.f.(5)(d). of this final rule to account for this by updating the preliminary target price when constructing the reconciliation target price that avoids sharing update factors and having CJR–X participants manage multiple preliminary target prices within a given performance year.

We also considered in the proposed rule, but did not propose, alternative caps on the retrospective adjustment, including +/−5 percent and +/−10 percent of the prospective trend adjustment. Ultimately, we believed that a narrower adjustment range would improve stability and predictability for CJR–X participants. We stated that a lower cap on retrospective adjustments also mitigates the risk that target prices will be disproportionately impacted by performance year shifts in spending patterns that could not have been foreseen.

We sought comment on our proposal at § 512.640(b)(7) to apply a prospective trend factor to preliminary target prices and our proposal at § 512.645(f) to apply a retrospective trend factor with a +/−3 percent cap. We sought comment on our proposals at § 512.605 to define ''prospective trend factor'' and ''retrospective trend factor.''

We also requested comment on alternative ways to calculate the trend factor to both increase accuracy of prospective target prices and to mitigate the ratchet effect. We recognized in the proposed rule that spending on LEJR episodes has been decreasing over time and may reach a point where further decreases in spending could compromise quality and patient safety. The downward trend in LEJR episode spending we observed in the early years of CJR has stabilized in more recent years, suggesting that there may no longer be as much of an opportunity for participant savings as there was in the early years of CJR. In the case where spending has been decreasing but has since stabilized, trending the episode target price forward based on previous years' trends could result in target prices that are too low. In such a scenario, a retrospective trend adjustment might actually result in a higher target price than a fully prospective trend. We sought comment on ways to construct a trend factor that can result in a reasonable target price regardless of whether spending has been increasing, decreasing, or stabilizing.

For example, in the CY 2023 Physician Fee Schedule final rule, CMS finalized a policy to include a prospectively-determined component, the Accountable Care Prospective Trend (ACPT), in the factor used to update the benchmark to the performance year for ACO agreement periods starting on or after January 1, 2024 (see 87 FR 69881 to 69898). We stated in the proposed rule that this would help address the ratchet effect by insulating a portion of the update factor from the impact that ACO savings can have on retrospective national and regional spending trends. This type of trend is referred to as an administrative trend, because it is not directly linked to ongoing observed FFS spending. However, we recognize that there may be some concerns using administrative trends for episode-based payment models, as opposed to population-based payment models like ACOs, because administrative trends may not capture episode-specific trends, which could lead to higher or lower preliminary target prices when compared to actual performance year spending. We requested comment on this type of trending approach, or other potential ways to increase the accuracy of prospective target prices and mitigate the ratchet effect when we update CJR–X target prices.

The following is a summary of the public comments received on our proposals to apply a prospective trend factor to preliminary target prices and a capped retrospective trend factor to reconciliation target prices, and our responses to these comments:

Comment: A couple commenters supported CMS' proposed trending approach. These commenters supported the use of a prospective trend factor to update baseline episode spending to the performance year and supported the use of a capped retrospective trend factor to account for changes in episode spending during the performance year.

Response: We appreciate commenters' support for the proposed prospective trend factor and capped retrospective trend factor. We continue to believe that using both a prospective trend factor and a limited retrospective trend factor improves target price accuracy by accounting for changes in episode spending between the baseline period and the performance year.

Comment: Some commenters requested changes or clarification regarding the proposed prospective and retrospective trend methodology. Commenters expressed concern that the retrospective trend factor could make final target prices difficult for participants to predict during the performance year, increasing uncertainty about potential reconciliation payments or repayment responsibility. Commenters also requested additional information about how CMS would calculate the prospective and retrospective trend factors, including step-by-step methodology, the data used for each calculation, and how participants could independently estimate or model the trend factors.

Some commenters recommended that CMS provide additional trend information during the performance year, such as quarterly trend updates or other interim information to help participants understand whether episode spending is changing relative to baseline expectations. Commenters also requested that CMS account for Medicare FFS payment updates or other payment system changes between the baseline and performance year so that participants are not held financially responsible for changes outside their control. A commenter recommended that CMS align the CJR–X trend methodology more closely with TEAM to reduce operational differences across models.

Response: We acknowledge commenters' concerns that a retrospective trend factor may reduce certainty because final reconciliation target prices cannot be known with complete precision before the end of the performance year. We believe, however, that the limited retrospective trend factor is important because prospective trend factors may not fully capture actual changes in LEJR episode spending during the performance year. The proposed 3 percent cap on the retrospective trend factor is intended to balance these considerations by allowing reconciliation target prices to reflect actual spending changes while limiting the degree to which retrospective updates can increase or decrease target prices after the performance year.

We also acknowledge commenters' requests for additional detail and transparency regarding the trend methodology. We intend to provide

participants with information needed to understand the target price methodology, including how trend factors are calculated and applied. We will consider what additional operational materials, examples, or data can be shared to help participants estimate target prices and understand reconciliation calculations, while maintaining a methodology that can be administered consistently across all CJR–X participants.

We are not adopting a requirement to provide quarterly trend factor updates or to update target prices during the performance year based on interim trend calculations. We recognize that interim updates could provide additional visibility, but they could also create confusion if interim trends differ from the data ultimately used for reconciliation. We believe the proposed methodology better balances predictability and accuracy by providing prospective target prices before the performance year and applying a capped retrospective trend factor at reconciliation.

We also are not adopting a separate hold-harmless policy for Medicare FFS payment updates or other payment system changes between the baseline and performance year. The purpose of the trend methodology is to account for changes in episode spending over time, including changes that may result from payment policy, utilization, coding, or care delivery changes reflected in Medicare claims. We believe the proposed prospective and capped retrospective trend methodology provides an appropriate mechanism to account for these changes within the target price calculation.

We recognize the commenter's recommendation to align the CJR–X trend methodology more closely with TEAM. CJR–X and TEAM both use prospective and retrospective trend factors, but there are differences between the models, including the episode categories included, model structure, and pricing methodology. We believe the proposed CJR–X trend methodology is appropriate for LEJR episodes in CJR–X while maintaining substantial consistency with TEAM where appropriate. Although TEAM uses additional trend years in constructing its prospective trend, CJR–X is focused on a single episode category, and we believe that more recent LEJR spending patterns are likely to be the most relevant predictor of performance year spending rather than relying on earlier data that may be less predictive of future LEJR spending. We also believe it is important to align the data period used to construct target prices with the three years of baseline data shared with CJR–X participants because this alignment would improve transparency and make it easier for CJR–X participants to understand the data underlying their target prices.

Comment: Some commenters recommended that CMS adopt alternative trend approaches or additional monitoring related to the proposed trend methodology. Commenters recommended approaches such as regional trend factors, administrative or ACPT-like trend concepts, efficient-price benchmarks, or other methods intended to improve the accuracy and sustainability of the prospective and retrospective trend adjustments.

Some commenters recommended that CMS monitor whether LEJR episode spending trends have stabilized and assess whether the trend methodology continues to produce realistic target prices over time. Commenters stated that if regional or national LEJR spending trends have stabilized, continued downward updates through the pricing methodology could reduce opportunities for savings or create target prices that are difficult to achieve while maintaining quality and beneficiary access.

Some commenters recommended annual assessments, public reporting, or future refinements if the trend methodology produces unrealistic target prices, fails to reflect stabilized spending trends, or contributes to access, quality, or patient safety concerns.

Response: We acknowledge commenters' recommendations to use alternative trend approaches or additional monitoring if LEJR episode spending trends stabilize or if the proposed trend methodology produces target prices that are difficult to achieve while maintaining quality and beneficiary access. We agree that the trend methodology is an important component of target price accuracy because it affects how baseline episode spending is updated to the performance year and how final target prices reflect performance-year spending changes.

We are not adopting an administrative trend factor, ACPT-style benchmark, regional trend factor, efficient-price benchmark, or other alternative trend factor at this time. We believe the proposed prospective trend factor and capped retrospective trend factor are more directly tied to LEJR episode spending under CJR–X than an external administrative benchmark or a benchmark based on a separate model or population. The proposed methodology is designed to reflect changes in LEJR episode spending, payment policy, utilization, coding, and care delivery patterns over time, while the 3 percent cap on the retrospective trend factor limits the degree to which reconciliation target prices can change after the performance year.

We also are not adopting an automatic trend-based trigger or adjustment mechanism at this time. We recognize commenters' concerns that stabilized spending trends could reduce opportunities for additional savings if target prices continue to decline. However, an automatic trigger would require CMS to determine when spending has reached a sustainable level and how that determination should apply across regions, episode types, and performance years. We believe there is uncertainty about how to operationalize such a policy at model launch without reducing target price accuracy or weakening incentives for efficient, high-quality care.

We will assess whether the prospective and retrospective trend methodology continues to support accurate and sustainable target prices as CJR–X is implemented. This assessment may include consideration of LEJR episode spending trends, reconciliation results, quality performance, beneficiary access, site-of-care patterns, participant experience, and stakeholder feedback.

After consideration of the public comments, we are finalizing without modification the proposal at § 512.605 to define ''prospective trend factor'' and ''retrospective trend factor.'' We are also finalizing without modification the proposal at § 512.640(b)(7) to apply a prospective trend factor to preliminary target prices and at § 512.645(f) to apply a retrospective trend factor with a +/− 3 percent cap to reconciliation target prices.

(g) Discount Factor

In addition to the prospective trend factor, at proposed § 512.640(b)(8) we proposed to apply a discount factor, defined at proposed § 512.605, to the benchmark price when calculating preliminary target prices. Specifically, we proposed to apply a 2 percent discount factor to the benchmark price to serve as Medicare's portion of reduced expenditures from the episode. We stated in the proposed rule that this discount would be similar to the 2 percent discount factor applied to LEJR episode target prices in TEAM.

We noted in the proposed rule that in both the CJR Model and BPCI Advanced, we applied a 3 percent discount to benchmark prices when calculating preliminary target prices for LEJR episodes. However, based on

evidence and participant feedback from the final performance years of the CJR Extension, we believed that a 3 percent discount would not be sustainable for an expanded model and could result in more price ratcheting over a longer time horizon.

We also considered in the proposed rule but did not propose lower discount factors including 1.5 percent, 1 percent, or no discount factor. In addition, we considered linking the discount to variability in episode spending during the baseline, such that an episode with minimal variability in baseline spending might have a lower discount percentage, given that lower variability in baseline spending might indicate fewer opportunities for savings. We also considered in the proposed rule but did not propose to incrementally reduce the discount rate over a predetermined timeline and different ways to adjust the Medicare discount over time or based on differential savings opportunities for different episode types.

We sought comment on our proposal at § 512.605 to define ''discount factor'' and on our proposal at § 512.640(b)(8) to apply a 2 percent discount factor to preliminary episode target prices for CJR–X. We also sought comment on alternative discounts and discount adjustments.

The following is a summary of the public comments received on our proposal to apply a discount factor to preliminary target prices, and our responses to these comments:

Comment: Some commenters supported or expressed appreciation for CMS' proposal to apply a 2 percent discount factor rather than the 3 percent discount factor used for LEJR episodes in prior CJR and BPCI Advanced pricing. These commenters stated that the lower discount factor better recognized sustainability concerns in a mandatory national model, and some commenters stated that a 2 percent discount would be a meaningful and potentially achievable target.

Response: We appreciate commenters' support for the proposed 2 percent discount factor.

Comment: Many commenters opposed the proposed 2 percent discount factor or recommended that CMS reduce or eliminate the discount factor. Commenters stated that the 2 percent discount could be arbitrary, too aggressive, or difficult to achieve, particularly in a mandatory national model without a defined end date. Commenters expressed concern that the discount factor, when combined with annual rebasing, regional benchmarking, trend methodology, and prior efficiency gains, could further reduce opportunities for hospitals to earn reconciliation payments and could contribute to long-term price ratcheting.

Commenters stated that the proposed discount factor could be especially challenging for hospitals with narrow or negative margins, rural hospitals, safety net hospitals, hospitals with limited experience in bundled payment models, and hospitals that have already achieved efficiencies through prior participation in CJR, BPCI Advanced, TEAM, or other value-based care initiatives. Commenters expressed concern that the discount factor could reduce hospitals' ability to invest in care redesign, care coordination infrastructure, analytics, post-acute care relationships, quality improvement initiatives, or other activities needed to succeed under CJR–X. Commenters recommended that CMS eliminate the discount factor, reduce the discount factor to 1 percent or lower, apply no discount factor, or otherwise reduce the discount burden to better reflect realistic savings opportunities while preserving beneficiary access and quality of care.

Response: We acknowledge commenters' concerns that even a 2 percent discount factor may be difficult to achieve if target prices already reflect substantial prior efficiency or if LEJR spending in a region has stabilized. We considered these concerns in developing the proposed discount factor for CJR–X.

We proposed a 2 percent discount factor because CJR–X is an expansion of the tested CJR Model, which included a discount factor as part of the target price methodology. At the same time, we recognized that CJR–X is intended to operate over a longer time horizon than the original CJR Model test and that LEJR spending has declined since the CJR Model was first implemented. For those reasons, we proposed a lower discount factor than the 3 percent discount factor used for LEJR episodes in prior CJR and BPCI Advanced pricing.

We do not believe it would be appropriate to eliminate the discount factor or reduce it below 2 percent at this time. We have not tested a CJR-based LEJR episode payment model without a discount factor, and we do not have sufficient evidence to conclude that eliminating the discount factor would preserve the model's incentives, maintain the integrity of the tested CJR framework, and continue to satisfy the requirements for model expansion. We continue to believe that a 2 percent discount factor appropriately balances participant sustainability concerns with the need to maintain the CJR Model's tested episode-based accountability structure.

We also note that the 2 percent discount factor is the maximum discount factor that would apply before accounting for quality performance at reconciliation. CJR–X participants with higher composite quality scores may qualify for a reduced effective discount factor, as discussed in the quality-based reconciliation methodology section of this final rule. We believe this policy directly responds to concerns that the discount factor could create pressure to reduce spending without sufficient regard to quality, because it allows stronger quality performance to reduce the effective discount factor applied to reconciliation target prices.

We recognize commenters' concerns that hospitals or regions that have already achieved efficiencies may have fewer remaining opportunities to reduce episode spending. As discussed in the regional target price section of this final rule, we believe the use of regional target prices helps mitigate, though not eliminate, this concern by avoiding a methodology under which each participant is benchmarked only against its own historical performance. We also address broader concerns regarding target price sustainability, price ratcheting, annual rebasing, and trend methodology in the applicable pricing sections of this final rule.

We will continue to consider monitoring data, evaluation findings, operational experience, and stakeholder feedback to determine whether refinements to the discount factor or related pricing policies may be warranted to support implementation, protect beneficiary access, preserve incentives for high-quality care, and maintain realistic opportunities for CJR–X participants to achieve savings.

Comment: Many commenters recommended that CMS adopt an alternative discount factor formula or adjustment instead of applying a uniform 2 percent discount factor to all CJR–X participants. Commenters stated that a uniform discount factor may not account for differences in hospital readiness, prior efficiency, baseline spending, local market conditions, hospital resources, patient populations, quality performance, or remaining opportunities for savings.

Some commenters recommended that CMS phase in the discount factor, use a glide path with lower introductory discount factors during the initial years of CJR–X, or phase out the discount factor over time. Commenters stated that these approaches could help hospitals adapt to mandatory participation, build infrastructure for care redesign, avoid

excessive financial pressure during implementation, or account for evolving evidence about whether realistic savings opportunities remain over the longer term.

Commenters also recommended that CMS vary or adjust the discount factor based on hospital or episode characteristics. Commenters suggested lower or waived discounts for rural hospitals, safety net hospitals, sole community hospitals, Medicare-dependent, small rural hospitals, hospitals with limited experience in bundled payment models, or hospitals that have already achieved efficiencies through prior participation in CJR, BPCI Advanced, or other value-based care initiatives. Commenters also recommended discount factors based on a hospital's historical spending relative to regional target prices, baseline efficiency, episode-spending variation, episode type, or quality performance. A few commenters recommended replacing the discount factor with a first-dollar shared savings approach or another shared-savings methodology.

Response: We acknowledge commenters' recommendations to vary or adjust the proposed discount factor, including by using a phase-in or glide path, phasing out the discount factor over time, varying the discount factor by hospital or episode characteristics, or replacing the discount factor with another shared-savings approach.

We are not adopting a phase-in or glide path for the discount factor. We recognize that lower introductory discount factors could provide transition relief in the initial model years, but we believe the proposed 2 percent discount factor, together with the quality-based adjustment to the effective discount factor at reconciliation, provides a more straightforward and predictable structure for the start of CJR–X. We also note that the proposed 2 percent discount factor already reflects a reduction from the 3 percent discount factor used for LEJR episodes in prior CJR and BPCI Advanced pricing.

We are not adopting commenters' recommendations to vary the discount factor by hospital type, prior participation experience, baseline efficiency, historical spending relative to the region, local market characteristics, episode type, or baseline episode-spending variation at this time. We recognize that commenters raised these recommendations to address differences in hospital resources, market conditions, prior efficiency, and remaining savings opportunities. However, we believe many of these concerns are addressed more directly through policies designed for those specific issues, including regional target prices, risk adjustment and normalization, quality-based adjustments to the effective discount factor, and stop-loss protections for certain hospital categories. We are concerned that varying the discount factor across these dimensions could add complexity, reduce predictability and comparability across participants, and increase volatility without necessarily improving target price accuracy or model incentives.

We are also not adopting commenters' recommendation to replace the discount factor with a first-dollar shared savings approach or another shared-savings methodology. We believe retaining a discount factor is more consistent with the proposed CJR–X target price methodology and provides a simpler and more predictable structure for determining reconciliation payments.

We agree that the question of whether the discount factor should change over time is important for a longer-term expanded model. In particular, recommendations to phase out or otherwise reduce the discount factor in future years would depend on evidence about episode-spending trends, reconciliation results, quality performance, beneficiary access, participant experience, and whether realistic savings opportunities remain. We will consider monitoring data, evaluation findings, operational experience, and stakeholder feedback in assessing whether future refinements to the discount factor are warranted.

After consideration of the public comments, we are finalizing without modification the proposals at § 512.605 to define ''discount factor'' and at § 512.640(b)(8) to apply a 2 percent discount factor to preliminary episode target prices.

(h) Special Considerations for Low Volume Hospitals

In both the CJR Model and BPCI Advanced, we recognized in the proposed rule that hospitals that perform a number of episodes below a certain volume threshold would have insufficient volume to receive a target price based on their own baseline data. In the 2015 CJR final rule (80 FR 73285), we acknowledged that such hospitals might not find it in their financial interests to make systemic care redesigns or engage in an active way with the CJR model. At 80 FR 73292, we acknowledged commenter concerns about low volume providers, including but not limited to, observations that low volume providers could be less proficient in taking care of LEJR patients in an efficient and cost-effective manner, more financially vulnerable with fewer resources to respond to the financial incentives of the model, and disproportionately impacted by high-cost outlier cases. In spite of these potential challenges, we stated that the inclusion of low volume hospitals in the CJR Model was consistent with the goal of evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure, care redesign experience, market position, and other considerations and circumstances (80 FR 73292).

We stated in the proposed rule that in the CJR Model, we set the low volume threshold as fewer than 20 LEJR episodes across the 3-year baseline years of 2012 through 2014. Low volume hospitals received target prices based on 100 percent regional data, rather than a blended target price that incorporated their participant-specific data, because a target price based on limited data is less likely to be accurate and reliable. We indicated that these hospitals were also subject to the lower stop-loss limits that we offered to rural hospitals, in recognition of the fact that they might be less prepared to take on downside risk than hospitals with higher episode volume. In the CJR 2017 final rule that reduced the number of mandatory MSAs, low volume hospitals were among the types of hospitals that were required to opt in if they wanted to remain in the model (82 FR 57072). In the 2020 final rule, we removed the remaining low volume hospitals from the CJR Extension when we limited the ''participant hospital'' definition to those hospitals that had been mandatory participants throughout the model (86 FR 23497).

We noted in the proposed rule that in BPCI Advanced, our low volume threshold policy was to not provide a target price for a given clinical episode category if performed at a hospital that did not meet the 41 clinical episode minimum volume threshold during the 4-year baseline period. This meant that no BPCI Advanced episodes would be triggered for that particular clinical episode category during the applicable performance period at that hospital. However, participants could continue to trigger other clinical episode categories for which they had enrolled and for which there was sufficient baseline volume. Additionally, clinical episodes that occurred at the hospital during the performance period, though not triggering a BPCI Advanced episode, would count toward the low volume threshold when that year became part of the baseline. Therefore, as the baseline

shifted forward each year, bringing a more recent year into the baseline and dropping the oldest year, a hospital could potentially meet the volume threshold and receive a target price for the clinical episode category for a subsequent performance period.

We stated in the proposed rule that in TEAM, if a TEAM participant does not meet the minimum baseline threshold of at least 31 episodes in a given episode category during the baseline period, the hospital's episodes are included in reconciliation calculations, but the hospital will not be held financially accountable for spending that exceeds the target price for that episode category in that performance year. We stated this effectively waives downside financial risk for the hospital for any episode categories in which it did not meet the low-volume threshold, providing protection against undue financial exposure while still allowing the hospital to participate in the model and benefit from savings, if applicable. We believe this policy is appropriate for TEAM given the increased number of episode categories mandatorily tested compared to the original CJR model and its time-limited test compared to longer-term CMS initiatives.

For CJR–X, we proposed a low volume policy that aligns with the approach we tested in BPCI Advanced because low volume hospitals were voluntary and ultimately removed from participation at the time of CJR Extension. We indicated in the proposed rule that we do not believe removing or excluding low volume hospitals is a good long-term policy for CJR–X since we recognize episode volumes can change over time. Also, there also may be instances when a hospital is just starting out and may have low volumes but then ramp up operations and see a substantial number of beneficiaries for LEJR procedures. Thus, we noted in the proposed rule that we believe a better policy for CJR–X would be to have a low volume policy that is responsive to episode volume changes year over year and acknowledges hospitals with low volume may not have the ability to spread risk when there is an insufficient number of procedures being performed. We proposed at § 512.605 to define ''low-volume hospital'' as a hospital with fewer than 31 LEJR episodes performed during the applicable baseline period. We proposed at § 512.640(a)(4) that low-volume hospitals would be excluded from reconciliation for the performance year. We stated in the proposed rule that as in BPCI Advanced, hospitals that do not meet the minimum volume threshold for a given performance year would not trigger CJR–X episodes or receive a target price. We stated that any LEJR episodes performed at these hospitals during the performance year would be excluded from regional benchmark calculations, although they would count toward the low volume threshold when that year becomes part of the baseline. Therefore, as the baseline shifts forward each year, bringing a more recent year into the baseline and dropping the oldest year, a hospital could potentially meet the volume threshold and trigger CJR–X episodes for a subsequent performance year.

We considered in the proposed rule implementing minimum episode volume thresholds during the performance year. Specifically, we considered excluding CJR–X participants from reconciliation if they initiate fewer than 10 or 15 LEJR episodes during that performance year. However, we were concerned that including minimum episode volume thresholds during the performance year may introduce program integrity issues where CJR–X participants steer CJR–X beneficiaries to other providers to be below the threshold and not be accountable for episodes in CJR–X.

We sought comment on our proposal at § 512.605 to define ''low-volume hospital'' and our proposal at § 512.640(a)(4) for setting and applying the low volume threshold at reconciliation.

The following is a summary of the public comments received on our proposal to exclude low-volume hospitals from reconciliation, and our responses to these comments:

Comment: A couple of commenters supported the proposal to exclude low-volume hospitals from reconciliation for a performance year. These commenters generally agreed that low-volume hospitals may have insufficient episode volume to support reliable target prices or meaningful reconciliation results.

Response: We thank the commenters for their feedback and support.

Comment: Many commenters stated that the proposed low-volume threshold of fewer than 31 LEJR episodes during the applicable baseline period was too low to support reliable benchmarking or meaningful performance assessment. Commenters stated that this threshold averaged roughly 10 episodes per year and would leave hospitals exposed to financial results driven by random variation, case mix differences, or a small number of complex or high-cost outlier cases. Some commenters stated that low-volume hospitals may lack sufficient episode volume to justify investments in care coordination staff, data infrastructure, analytics, post-acute relationships, or gainsharing arrangements. Commenters recommended that CMS substantially increase the threshold, determine the threshold empirically, consult actuarial or program evaluation experts, or adopt alternative thresholds such as 50, 75, or 100 LEJR episodes. Other commenters recommended that CMS apply the threshold annually, by episode category, during each baseline year, through a rolling average, through regional-specific standards, or through minimum performance-year volume criteria to improve predictability and reduce year-to-year volatility.

Response: We acknowledge commenters' concerns that low episode volume can increase the effect of random variation, case mix differences, and outlier cases on financial performance. We recognized these concerns in the proposed rule and proposed the low-volume policy because hospitals that perform a number of episodes below a certain volume threshold may have insufficient volume to receive a reliable target price based on their own baseline data and may not be able to spread risk when too few procedures are performed. We also recognized that low-volume hospitals may have fewer resources to respond to financial incentives and may be disproportionately affected by high-cost outlier cases, which is why we proposed to exclude low-volume hospitals from reconciliation for the performance year.

We considered the commenters' recommendations to increase the threshold or apply a different methodology. We note that in the CJR Extension, low volume hospitals were removed from the model based on a volume threshold from a static baseline prior to the start of the model. This meant that some hospitals that became low volume over time were not designated as such for purposes of CJR, and vice versa. The proposed CJR–X policy was designed to align with the approach tested in BPCI Advanced, under which a hospital that did not meet the applicable baseline volume threshold for an episode category would not trigger episodes or receive a target price for that category during the applicable performance period. We proposed this approach for CJR–X because it is responsive to changes in episode volume over time: episodes performed during a performance year would count toward the low-volume threshold when that year becomes part of the baseline, allowing a hospital that increases its LEJR volume to trigger CJR–X episodes in a later performance year. We also proposed this approach

because removing low-volume hospitals permanently from CJR–X would not be a good long-term policy where episode volumes may change over time.

We also considered commenters' recommendations to use annual, per-category, rolling-average, or performance-year thresholds. We considered minimum episode volume thresholds during the performance year, including excluding participants from reconciliation if they initiated fewer than 10 or 15 LEJR episodes during that performance year. However, we believe a baseline-period threshold is appropriate because it provides a prospective basis for determining whether a hospital will trigger CJR–X episodes and receive target prices for the performance year, while still allowing the threshold to update as the baseline shifts forward.

After consideration of the public comments, we are finalizing without modification the proposals at § 512.605 to define ''low-volume hospital'' and at § 512.640(a)(4) for setting and applying the low volume threshold at reconciliation.

(i) Preliminary Target Prices

We proposed to define ''preliminary target price'' as the target price provided to the CJR–X participant prior to the start of the performance year, which is subject to adjustment at reconciliation. We proposed at § 512.640(b)(9) that CMS would provide preliminary target prices to CJR–X participants, in a form and manner specified by CMS, prior to the start of each performance year. For instance, since the earliest episodes for a given performance year would end on January 1, and most of these episodes would have been initiated by an anchor hospitalization or anchor procedure that occurred near the end of November or the beginning of December of the previous calendar year, we proposed to provide preliminary target prices to the CJR–X participant by the end of November prior to each performance year. We proposed that preliminary target prices would be based on regional episode spending during the baseline period. We stated in the proposed rule that CJR–X participants would receive the preliminary target prices for each MS–DRG/HCPCS episode type that corresponded to their region. We proposed that these preliminary target prices would incorporate a prospective trend factor (as described in section X.C.2.f.(3)(f). of this final rule) and a discount factor (as described in section X.C.2.f.(3)(g). of this proposed rule), as well as a prospective normalization factor (as described in section X.C.2.f.(4). of this final rule).

We sought comment on our proposal at § 512.640(b)(9) to provide preliminary target prices to CJR–X participants prior to the start of each performance year.

The following is a summary of the public comments received on our proposal to provide preliminary target prices to CJR–X participants prior to the start of each performance year, and our responses to these comments:

Comment: Some commenters recommended that CMS provide preliminary target prices, target price methodologies, or related baseline data earlier or with more operational detail. Commenters stated that participants need timely target price information before the performance year to evaluate financial risk, plan budgets, educate care teams, enter into operational or contractual arrangements, and develop care redesign strategies.

Some commenters expressed concern that providing preliminary target prices by the end of November would not give participants sufficient time to prepare if CJR–X performance years began on October 1. These commenters recommended that CMS provide preliminary target prices before the beginning of the performance year, including no later than the end of August for an October 1 performance year start. A commenter recommended that CMS issue target prices in January, stating that doing so would better align with hospital operational realities and avoid competing fall reporting and regulatory deadlines.

Some commenters recommended that CMS provide target price update factors or other updated pricing information during the performance year as soon as they become available so that participants can better forecast financial performance before reconciliation. Commenters also requested that CMS publish target price methodologies with sufficient detail for participants to model performance prospectively and publish hospital-level baseline data before model launch so that participants can assess their starting position and operational risk.

Response: We agree with commenters that participants should have access to preliminary target prices and sufficient methodological information before they are held accountable for performance under CJR–X. We proposed at § 512.640(b)(9) to provide preliminary target prices to CJR–X participants prior to the start of each performance year, in a form and manner specified by CMS. We continue to believe that providing preliminary target prices before the start of each performance year is necessary to support participant planning, budgeting, care redesign, and operational readiness.

We acknowledge commenters' concerns that an end-of-November target price release would not precede an October 1 performance year start. As discussed in section X.C.2.a of this final rule, we are finalizing a January 1, 2028 start date for the first CJR–X performance year and aligning CJR–X performance years with the calendar year. Under that final policy, providing preliminary target prices by the end of November will give participants access to preliminary target prices before the start of each performance year. We are not adopting a January release timeline because participants should receive preliminary target prices before, rather than after, the start of the performance year.

We also acknowledge commenters' requests for target price update factors and updated pricing information during the performance year. We intend to provide participants with information needed to understand preliminary target prices, target price methodology, episode attribution, applicable adjustment factors, and reconciliation calculations. However, we are not adopting a requirement to update preliminary target prices during the performance year each time additional information or update factors become available. Preliminary target prices are, by definition, subject to adjustment at reconciliation, and piecemeal updates during the performance year could create confusion if interim information differs from the data ultimately used for reconciliation.

We acknowledge commenters' requests for target price methodology, baseline data, and other information that would allow participants to model performance prospectively and assess operational risk. We intend to provide implementation materials, data files, and methodological information, as appropriate, to help participants understand the CJR–X pricing methodology and prepare for participation. Any data shared with participants would be provided in a form and manner specified by CMS and would be subject to applicable privacy, security, operational, and data-use requirements.

After consideration of the public comments, we are finalizing without modification the proposals at § 512.640(b)(9) to provide preliminary target prices to CJR–X participants prior to the start of each performance year

(4) Risk Adjustment and Normalization

We stated in the proposed rule that in the original CJR Model methodology, we

first proposed that risk adjustment be limited to providing separate target prices for episodes initiated by MS–DRG 469 versus MS–DRG 470, because MS–DRGs under the IPPS are designed to account for some of the clinical and resource variations that exist and that impact hospitals' costs of providing care (80 FR 73338). In response to comments requesting further risk adjustment, in the 2015 CJR final rule we finalized a policy to risk-adjust target prices based on the presence of a hip fracture diagnosis code in order to capture a significant amount of patient-driven episode expenditure variation (80 FR 73339). As a result, we provided four separate target prices to participant hospitals based on MS–DRG 469 versus MS–DRG 470, and presence versus absence of a primary hip fracture. We stated that the impact of hip fractures on inpatient costs associated with a hip replacement was subsequently acknowledged by CMS' decision to create two new MS–DRGs (521 and 522) for hip replacements in the presence of a primary hip fracture (85 FR 58432). We incorporated these new MS–DRGs into the CJR Model episode definition as of October 1, 2020 via the November 2020 Interim Final Rule with Comment (IFC) (85 FR 71170).

We stated in the proposed rule that in the 2021 CJR 3-Year Extension final rule, we acknowledged the need for further risk adjustment to account for beneficiary-level factors that tend to impact spending in a way that is beyond the control of the provider. We introduced age bracket (less than 65 years, 65 to 74 years, 75 to 84 years, and 85 years or more), CJR HCC count (zero, one, two, three, and four or more), and dual eligibility (receiving both full Medicare and Medicaid benefits) as beneficiary-level risk adjustment factors that would be applied to each episode at reconciliation. The definition of these risk adjustment variables, and our reasoning for incorporating them into the risk adjustment methodology, is described in detail at 86 FR 23523.

We indicated in the proposed rule that the coefficients for the risk adjustment variables in the CJR Extension were calculated prospectively, prior to the beginning of each performance year, using a linear regression model. As we stated at 86 FR 23524, this regression model approach would allow us to estimate the impact of each risk adjustment variable on the episode cost of an average beneficiary, based on typical spending patterns for a nationwide sample of beneficiaries with a given number of CMS–HCC conditions, within a given age bracket, and with dual eligibility or non-dual eligibility status. We used an exponential model to account for the fact that LEJR episode costs are not normally distributed. A detailed description of the regression model begins at 86 FR 23524.

We explained in the proposed rule that at reconciliation, after applying the high-cost episode cap to remove outliers, the risk adjustment coefficients for the three risk adjustment variables were applied to the episode-level target price based on the applicable episode region and MS–DRG. However, since age, CJR HCC count, and dual eligibility status are inherently included in the regional target price, since regions with beneficiaries who are older, more medically complex, and socioeconomically disadvantaged tend to have higher average episode costs, we applied a normalization factor to remove the overall impact of adjusting for age, CJR HCC count, and dual eligibility on the national average target price, as described at 86 FR 23527.

By contrast, BPCI Advanced used a more complex risk adjustment model that included many more risk adjustment coefficients, including both patient and provider characteristics. Categories of patient characteristics included (but were not limited to): HCCs (individual flags, interactions, and counts), recent resource use, and demographics. We stated that provider characteristics, which were used to group hospitals into peer groups, included bed size, rural vs. urban, safety net vs. non-safety net, and whether or not the participant was a major teaching hospital. We noted that the first stage of the BPCI Advanced risk adjustment methodology used a compound log-normal model in order to account for the substantial right skew of the distribution of episode costs. This meant that it combined two log-normal distributions in order to capture costs associated with both low-cost episodes (which were the majority of episodes) and very high-cost episodes (which were fewer in number but exerted a strong influence on spending averages). However, participants found this risk adjustment model difficult to interpret, particularly since it was not widely used in other research or healthcare models.

We stated in section X.C.2.f.(4) the proposed rule (91 FR 19697) and reiterated in this section of the final rule that for TEAM, in an effort to simplify the risk adjustment methodology and allow participants to more easily calculate an episode-level estimated target price, we based our methodology on the CJR Extension methodology, with a few key differences. We indicated that rather than calculating one national set of risk adjusters across all MS–DRGs for a given episode category, we calculate risk adjustment coefficients at the MS–DRG/HCPCS episode type level. We considered calculating risk adjustment at the MS–DRG/HCPCS episode type/region level, but we believed that, when further subdivided into regions, the low volume of episodes for certain MS–DRG/HCPCS episode types would be insufficient to create accurate and reliable risk adjustment multipliers.

We stated that in the TEAM proposed rule, we initially proposed to use three beneficiary-level risk adjustment variables that were similar to the CJR Extension methodology, with two key differences. First, instead of using the annual HCC file to calculate the HCC count variable, we proposed to conduct a 90-day lookback of FFS Medicare claims for each beneficiary, beginning with the day prior to the anchor hospitalization or anchor procedure, and count the number of HCC flags assigned. We subsequently revised this to a 180-day lookback in the final rule (90 FR 37105). Second, instead of a dual-eligibility risk adjustment variable, we proposed a more comprehensive approach which accounted for dual eligibility status, as well as Low Income Part D Subsidy qualification and area-level socioeconomic deprivation. As discussed in the TEAM final rule (90 FR 37103), this beneficiary economic risk adjustment functions as a binary (yes=1, no=0) variable, with a value of 1 being assigned to episodes where the beneficiary meets at least one of the following three criteria as of the first day of the episode: (1) resides in an area that exceeds the 80th percentile threshold for National Community Deprivation Index; (2) eligible for Medicare Part D Low Income Subsidy; and (3) eligible for full Medicaid benefits.

We noted in the proposed rule that in addition to the three initially proposed risk adjustment variables, several additional beneficiary and participant-level risk adjustments were added to the TEAM target price methodology in response to public comments. This included hospital-level adjustments for bed size (250 beds or fewer, 251–500 beds, 501–850 beds, or 851+ beds) and safety net status, as defined in 42 CFR 512.505. Additionally, TEAM applied several episode category-specific beneficiary risk adjustment factors to target prices that were not used in the CJR Extension. These episode category-specific risk adjustment factors reflected the presence or absence of certain conditions or services during the 180-day lookback period. For the LEJR

episode category, this included binary risk adjustments (yes=1, no=0) for prior post-acute care use, disability as the original reason for Medicare enrollment, LEJR procedure, and 21 HCC flags, as detailed in 42 CFR 512.545(a)(6)(ii), including, but not limited to, morbid obesity [HCC 48] and diabetes with severe acute [HCC 36] or chronic [HCC 37] complications. The decision to risk adjust based on individual HCCs, in addition to the aggregate HCC count adjustment, was intended to reflect the differential effects that individual chronic conditions like diabetes or chronic kidney disease can have on total episode spending, allowing us to provide more accurate and nuanced target prices.

We also stated in the proposed rule that another key difference between the TEAM and CJR Extension risk adjustment methodologies is that, in TEAM, we provide a prospective normalization factor with preliminary target prices. We stated this prospective normalization factor is subject to a limited adjustment at reconciliation based on the observed case mix, up to +/−5 percent. We indicated that this allows participants to better estimate their target prices, as it incorporates the normalization factor prospectively, rather than only introducing the normalization factor at reconciliation. We noted in the proposed rule that we believe that this approach strikes a balance between predictability and protecting TEAM participants and CMS from significant shifts in patient case mix between the final baseline year and the performance year.

For CJR–X, we proposed at § 512.645 to use the same risk adjustment methodology and variables, as defined at proposed § 512.605, that are used in TEAM. Specifically, we proposed the following:

- To risk adjust target prices at the hospital level using a hospital bed size risk adjustment factor and a safety net risk adjustment factor.
- To risk adjust target prices at the beneficiary level using a 180-day lookback period to construct a ''CJR–X HCC count risk adjustment factor'', an ''age bracket risk adjustment factor'', a ''beneficiary economic risk adjustment factor'', and based on certain conditions or HCCs in the 180-day lookback period including—

++ Ankle procedure or reattachment, partial hip procedure, partial knee arthroplasty, total hip arthroplasty or hip resurfacing procedure, and total knee arthroplasty;
++ Disability as the original reason for Medicare enrollment;
++ Prior post-acute care use;
++ HCC 17: Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic;
++ HCC 36: Diabetes with Severe Acute Complications;
++ HCC 37: Diabetes with Chronic Complications;
++ HCC 48: Morbid Obesity;
++ HCC 125: Dementia, Severe;
++ HCC 126: Dementia, Moderate;
++ HCC 127: Dementia, Mild or Unspecified;
++ HCC 151: Schizophrenia;
++ HCC 155: Major Depression, Moderate or Severe, without Psychosis;
++ HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia;
++ HCC 224: Acute on Chronic Heart Failure;
++ HCC 225: Acute Heart Failure (Excludes Acute on Chronic);
++ HCC 226: Heart Failure, Except End-Stage and Acute;
++ HCC 238: Specified Heart Arrhythmias;
++ HCC 253: Hemiplegia/Hemiparesis[
++ HCC 267: Deep Vein Thrombosis and Pulmonary Embolism
++ HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders
++ HCC 326: Chronic Kidney Disease, Stage 5
++ HCC 327: Chronic Kidney Disease, Severe (Stage 4)
++ HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle
++ HCC402: Hip Fracture/Dislocation

- Include a ''prospective normalization factor'' that would be subject to a limited adjustment at reconciliation based on the observed case mix, up to +/−5 percent to construct the ''final normalization factor''. This is inclusive of TEAM's proposal to include the full baseline period in the construction of the prospective normalization factor, as discussed in section X.A.2.c.(3) of this final rule.

As described in section X.C.2.f.(1)(c) of this final rule, TEAM was designed to blend and improve upon policies from both BPCI Advanced and the CJR Model based on the cumulative evidence from both model tests. For CJR–X, we propose a risk adjustment methodology that builds upon lessons learned from both the CJR Model and BCPI Advanced. While the original CJR approach was straightforward, we recognized it did not fully account for key patient and provider complexities. The BPCI Advanced model offered greater precision but proved too complex for participants to interpret. For CJR–X, we sought to balance these considerations by integrating more precise adjustments for specific conditions and socioeconomic factors—thus improving upon CJR's simplicity—without sacrificing the transparency that was lost in BPCI Advanced. We believe this balanced approach will ensure that target prices are both equitable and actionable without fundamentally altering the model design or structure that was tested in the Phase I CJR Model.

We considered in the proposed rule, but did not propose, a more nuanced approach to the safety net hospital risk adjustment that segmented hospitals into 3 or more groups based on the share of FFS inpatient episodes provided to dual-eligible beneficiaries. We recognized that a binary risk adjustment for safety net hospitals may not accurately reflect the financial challenges for participants with a high percentage of dual-eligible episodes that do not meet the threshold for being classified as a safety net hospital, as defined in § 512.605. For example, the financial challenges faced by hospitals that fall just below the threshold are likely similar to those for hospitals that fall just above it. Furthermore, we recognized in the proposed rule that for participants on the margin, their status as a safety net hospital may change from year to year due to random variance and that this may not reflect the more persistent nature of the underlying challenges that the risk adjustment is attempting to address. However, we were concerned that the further segmentation of hospitals into smaller groups may result in sample size and accuracy problems. We proposed that a safety net hospital in CJR–X is a hospital in the top 25th percentile in their region for percentage of FFS LEJR inpatient episodes provided to dually eligible beneficiaries during the applicable baseline period. We sought comment on the proposal § 512.605 to use a binary safety net hospital risk adjustment.

To summarize, for CJR–X we proposed a risk adjustment methodology based on the CJR Extension methodology, but with refinements similar to those applied to the TEAM methodology. We believe these refinements will improve the accuracy of target price calculations without fundamentally altering the model design or structure that was tested in the Phase I CJR Model. As in both TEAM and the CJR Extension, we proposed to use baseline data to calculate risk adjustment multipliers

and hold them constant at reconciliation. We proposed that participants would be provided with these risk adjustment multipliers prior to the start of the performance year and would be able to use them to estimate their episode-level target prices. We proposed that, as in TEAM, these risk adjustment multipliers would be calculated at the MS–DRG level, resulting in a separate set of risk adjustment multipliers for each MS–DRG episode type. We also proposed to incorporate a prospective normalization factor into preliminary target prices, which would be subject to a limited adjustment at reconciliation.

We sought comment on our proposals at § 512.645(a) through (d) for risk adjusting episodes and at § 512.605 for the definitions of ''age bracket risk adjustment factor'', ''beneficiary economic risk adjustment factor'', ''CJR–X HCC count risk adjustment factor'', ''final normalization factor'', ''prospective normalization factor'', and ''safety net hospital''.

The following is a summary of the public comments received on our proposal to risk adjust and normalize target prices, and our responses to these comments:

Comment: Some commenters supported CMS' proposal to expand risk adjustment in CJR–X compared with the original CJR Model, including the use of additional beneficiary-level, social-risk, and hospital-level factors intended to better account for patient acuity, clinical complexity, social risk, and differences across participant hospitals.

Response: We thank the commenters for their support.

Comment: Some commenters requested clarification or modifications to the lookback period used to construct beneficiary-level risk adjustment factors. Commenters expressed concern that the proposed 180-day lookback period may be too short to capture chronic conditions, underlying comorbidities, and other risk factors that materially affect LEJR episode spending, particularly for beneficiaries with limited claims history or beneficiaries with non-elective episodes.

Commenters recommended that CMS use a longer lookback period, such as 12 months or 365 days. Some commenters also recommended that CMS include the anchor hospitalization or procedure in the lookback period or otherwise account for diagnoses and clinical information identified close to the start of the episode.

Response: We acknowledge commenters' concerns about the proposed 180-day lookback period. We proposed a claims-based lookback period so that beneficiary-level risk adjustment factors would be based on information available before the episode, rather than conditions, complications, coding, or utilization patterns that may arise during the episode itself. We believe this approach helps preserve episode-based accountability while still accounting for important beneficiary-level differences that are observable before the anchor hospitalization or procedure.

We are not adopting commenters' recommendations to use a 12-month or 365-day lookback period or to include the anchor hospitalization or procedure in the lookback period. A longer lookback period could capture additional historical diagnoses, but it may also place more weight on conditions that are less closely related to expected LEJR episode spending. Including the anchor hospitalization or procedure in the lookback period could create circularity by using information from the episode itself to adjust the episode target price. We believe the proposed 180-day lookback period appropriately balances the goal of capturing relevant pre-episode clinical information with the need to maintain a clear and administrable risk adjustment methodology.

We also note that CJR–X beneficiary eligibility criteria are designed to ensure that Medicare has complete and consistent claims data for included episodes. As proposed, beneficiaries must be enrolled in Medicare Part A and Part B, have Medicare as the primary payer, not be enrolled in a managed care plan, and meet the other beneficiary inclusion criteria for the model. These criteria help support the reliability of the claims data used for episode construction, spending calculations, and risk adjustment. We also note that a longer lookback period reduces episode volume because beneficiary eligibility must similarly extend back as far. Sufficient episode volume is important to spread financial risk and identify opportunities for savings and efficiency.

Comment: A couple commenters requested additional transparency regarding the beneficiary-level data used for risk adjustment. Commenters stated that participants should be able to understand, validate, and audit the beneficiary-level risk adjustment inputs used to calculate reconciliation target prices.

Commenters requested additional operational guidance on episode construction, beneficiary eligibility, claims history, incomplete data during the lookback period, and the data that would be made available to participants for risk-adjustment validation.

Response: We acknowledge commenters' requests for additional transparency regarding the beneficiary-level data used for risk adjustment. We intend to provide participants with information needed to understand the risk adjustment methodology, beneficiary-level risk adjustment factors, episode attribution, target price construction, and reconciliation calculations.

We also expect to provide operational guidance and implementation materials before the model begins, including information to help participants understand the data used in model calculations. Any beneficiary-level data shared with participants for model operations or validation would be subject to applicable privacy, security, and data-use requirements.

Comment: Many commenters recommended that CMS further expand or refine beneficiary-level risk adjustment to account for additional information related to medical history, clinical complexity, and episode-specific complexity. Commenters stated that the proposed methodology may not fully capture factors such as surgical complexity, revision history, fracture or non-fracture status, emergent or elective status, inpatient or outpatient episode initiation, frailty, functional limitations, cognitive impairment, behavioral health conditions, medically complex patients, prior post-acute care use, and conditions identified close to the start of the episode. Commenters stated that incomplete adjustment for these factors could result in target prices that are too low for hospitals treating higher-acuity beneficiaries or could create incentives to avoid beneficiaries who may require more intensive resources during or after LEJR episodes.

Many commenters also recommended that CMS further refine beneficiary-level risk adjustment to account for social risk factors and circumstances that may affect post-acute care use, recovery, and episode spending. Commenters cited factors such as dual eligibility, disability, housing instability, food insecurity, transportation barriers, caregiver availability, home environment, access to outpatient or post-acute care, community resource availability, and beneficiary choice of post-acute care provider. Commenters expressed concern that hospitals treating beneficiaries with greater social needs or barriers to recovery could be disadvantaged if target prices do not adequately account for these factors.

Some commenters recommended separate target prices or protections for dual-eligible beneficiaries, peer grouping, or other safeguards to ensure

that hospitals are not penalized for treating clinically or socially complex patients. A few commenters also recommended that CMS publish information on the performance of the risk adjustment model, including whether the methodology adequately accounts for patient complexity and social risk.

Response: We acknowledge commenters' recommendations to add beneficiary-level risk adjustment factors for additional medical history, clinical complexity, and episode-specific characteristics. We agree that these factors may affect episode spending and recovery after an LEJR procedure. We also note that the proposed CJR–X risk adjustment methodology already includes several variables intended to capture clinical complexity and episode-specific differences, including age group, CJR–X HCC count, prior post-acute care use, disability status as the reason for initial Medicare enrollment, recent medical history based on the 180-day lookback period, and risk adjustment multipliers calculated at the MS–DRG/HCPCS episode type level. In addition, certain differences identified by commenters are already reflected in episode construction or pricing. For example, fracture-related hip replacement episodes are reflected in the MS–DRG structure, and inpatient and outpatient episodes are priced at the applicable MS–DRG/HCPCS episode type level.

We are not adopting additional medical history, clinical complexity, or episode-specific risk adjustment variables at this time. Some recommended factors may already be captured in whole or in part through the proposed variables, episode type, or MS–DRG/HCPCS structure, while others may not be consistently available or reliably measured in standardized Medicare claims data across all CJR–X participants. We also believe that adding factors based on information identified during the episode, or on care decisions made during the episode, could reduce episode-based accountability or create incentives related to coding, documentation, or utilization rather than underlying beneficiary risk. We believe the proposed methodology substantially expands beneficiary-level risk adjustment compared with the original CJR Model while maintaining a clear and administrable approach for a national model.

We also acknowledge commenters' recommendations to add or refine risk adjustment for social risk factors and circumstances that may affect post-acute recovery. We agree that social risk, caregiver support, home environment, transportation barriers, access to post-acute care, and community resources may influence recovery and episode spending. The proposed beneficiary economic risk adjustment factor is intended to account for social risk in a standardized way by identifying beneficiaries who meet at least one of several criteria, including residence in an area with high community deprivation, eligibility for the Part D Low-Income Subsidy, or full Medicaid eligibility. The proposed methodology also includes disability status and prior post-acute care use, which may help capture differences in beneficiary needs and expected resource use.

We are not adopting separate target prices or episode tracks for dual-eligible beneficiaries or other beneficiary subgroups. Dual eligibility is already one component of the proposed beneficiary economic risk adjustment factor, and we believe that incorporating social risk through a standardized beneficiary-level factor is preferable to creating separate target price tracks for specific subgroups. Separate tracks or peer groups could reduce episode volume within pricing cells, increase volatility, and make target prices less stable. We address related comments regarding the safety net hospital definition and safety net hospital adjustment in the applicable sections of this final rule.

We acknowledge commenters' requests that CMS publish information on risk-adjustment model performance. We intend to monitor the performance of the CJR–X risk adjustment methodology as the model is implemented, including whether the methodology adequately accounts for clinical complexity, social risk, episode type, patient mix, and shifts in site of care. We will consider what information can be shared publicly or through model materials in a manner that supports transparency while protecting beneficiary privacy, data security, and the integrity of model operations.

Comment: Some commenters recommended that CMS incorporate additional hospital-level or participant-level risk adjustment factors into the CJR–X pricing methodology. Commenters stated that facility characteristics such as sole community hospital status, Medicare-dependent, small rural hospital status, rurality, teaching hospital status, indirect medical education intensity, academic medical center or tertiary referral center status, trauma-driven or non-elective referral patterns, hospital resources, and prior efficiency may affect LEJR episode spending and financial risk.

Commenters expressed concern that the proposed methodology may not fully account for structural differences among hospitals or the role of hospitals that treat more complex patients, accept referrals from other hospitals, serve as regional tertiary centers, or operate in rural or resource-constrained markets. Commenters stated that, without additional hospital-level adjustment, target prices could be too low for these hospitals, reconciliation results could reflect differences in hospital mission or referral patterns rather than episode performance, and the model could create disincentives to accept complex transfers or higher-risk patients.

Some commenters recommended that CMS add specific participant-level adjusters, such as teaching hospital status, indirect medical education intensity, sole community hospital status, Medicare-dependent, small rural hospital status, or academic medical center status. Some commenters also recommended regional-efficiency or shared-savings adjustments to recognize hospitals or regions that have already achieved lower spending. A couple commenters requested that CMS publish additional information on risk-adjustment coefficients or analyses comparing episode cost distributions across hospital categories, including teaching and non-teaching hospitals.

Response: We acknowledge commenters' recommendations to add hospital-level risk adjustment factors for additional provider characteristics. We agree that hospital characteristics, referral patterns, resource levels, and institutional roles may affect episode performance and financial risk. The proposed CJR–X risk adjustment methodology already includes hospital-level risk adjustment factors for bed size and safety net hospital status, in addition to beneficiary-level and episode-specific factors that account for differences in patient acuity and expected episode spending. We believe these proposed factors substantially expand the risk adjustment methodology compared with the original CJR Model while maintaining a methodology that participants can understand and apply to estimate target prices.

We are not adopting additional participant-level risk adjustment factors for teaching hospital status, indirect medical education intensity, academic medical center or tertiary referral center status, sole community hospital status, Medicare-dependent, small rural hospital status, or rurality at this time. Some of the concerns raised by commenters are more directly addressed through other CJR–X policies. For

example, beneficiary-level risk adjustment and MS–DRG/HCPCS episode type pricing are designed to account for patient and episode complexity, the safety net hospital risk adjustment factor is designed to account for a specific hospital-level social-risk measure, and reduced stop-loss limits provide additional financial protection for certain hospital categories. We address comments on the safety net hospital definition, safety net adjustment, and special designation hospital protections in the applicable sections of this final rule.

We are also concerned that adding multiple additional hospital-level designations to risk adjustment could reduce transparency, increase complexity, and make target prices less comparable across participants. Hospital designations such as teaching status, tertiary referral status, SCH status, or MDH status may reflect important institutional roles, but they do not necessarily provide a more precise or episode-specific measure of expected LEJR episode spending after accounting for beneficiary case mix, episode type, bed size, and safety net status. We believe the proposed methodology better balances payment accuracy, transparency, and administrative feasibility for a nationally expanded model.

We also acknowledge commenters' recommendations for regional-efficiency or shared-savings adjustments for historically efficient hospitals or regions. We address broader concerns about prior efficiency, price ratcheting, and regional benchmarking in the applicable pricing sections of this final rule. We do not believe those recommendations should be addressed by adding a hospital-level risk adjustment factor because they relate to target price sustainability and benchmark design rather than differences in expected episode spending attributable to hospital characteristics.

We acknowledge commenters' requests for additional information on risk-adjustment coefficients and model performance across hospital categories. As proposed, we intend to provide participants with risk adjustment multipliers before the start of the performance year so that participants can estimate episode-level target prices. We will also consider what additional methodological information can be shared through model materials in a way that supports transparency while protecting beneficiary privacy, data security, and the integrity of model operations.

Comment: Many commenters recommended that CMS revise or broaden the proposed definition of ''safety net hospital'' for CJR–X. Commenters stated that defining safety net hospitals based on whether a hospital is in the top quartile in its region for the percentage of FFS LEJR inpatient episodes furnished to dually eligible beneficiaries would be too narrow, unstable, or inconsistent with other CMS approaches. Commenters expressed concern that the proposed definition could fail to identify hospitals that serve large numbers of low-income, Medicaid, uninsured, or otherwise underserved patients across their broader patient population, but that do not have a high proportion of FFS inpatient LEJR episodes furnished to dually eligible beneficiaries.

Commenters raised concerns about several elements of the proposed definition. Some commenters stated that a service line-specific LEJR measure may not reflect a hospital's overall safety net role, and that an inpatient-only measure may not reflect shifts in LEJR procedures to outpatient settings. Some commenters stated that a FFS-only measure may understate safety net status in markets with high Medicare Advantage or integrated dual-eligible enrollment. Commenters also stated that a dual-eligibility-only measure may be affected by state Medicaid eligibility rules or may not capture other indicators of low-income status or social risk.

Commenters recommended alternative criteria. Some commenters recommended Medicare-specific alternatives, including alignment with the TEAM safety net hospital definition, use of all Medicare beneficiaries or all Medicare service lines, Part D Low-Income Subsidy status, or a national rather than regional threshold. Other commenters recommended broader hospital-wide, all-payer, or community-based measures, including DSH patient percentage, Medicaid volume, uncompensated care, all-payer low-income metrics, Area Deprivation Index or other community deprivation measures, state-level low-income care criteria, or other measures intended to capture hospitals that serve low-income, uninsured, Medicaid, or medically underserved populations.

Some commenters stated that hospitals should retain safety net hospital status once they qualify, even if they later fall below the proposed threshold. These commenters stated that retaining safety net status would reduce instability and provide greater predictability for hospitals near the threshold.

Response: We acknowledge commenters' concerns that the proposed CJR–X safety net hospital definition may not identify every hospital that serves a broader safety net role. We also recognize that hospitals may serve low-income, uninsured, Medicaid, Medicare Advantage, or otherwise underserved populations in ways that are not fully reflected by the share of FFS inpatient LEJR episodes furnished to dually eligible beneficiaries.

We are not adopting a broader safety net hospital definition for the initial CJR–X design at this time. We continue to believe that the proposed definition is appropriate for CJR–X because it is directly connected to the population and episode category used in the CJR–X risk adjustment and target price methodology. CJR–X is a LEJR episode model that includes only Medicare FFS episodes for beneficiaries meeting the model's inclusion criteria. For that reason, we believe a definition based on FFS LEJR inpatient episodes furnished to dually eligible beneficiaries is more directly related to expected episode spending under CJR–X than broader hospital-wide or all-payer measures.

We also are not adopting commenters' recommendation to align the CJR–X safety net hospital definition with the TEAM definition at this time. TEAM includes multiple episode categories and uses a broader multi-episode design, while CJR–X includes only LEJR episodes. Although alignment across models can reduce operational differences, we believe the CJR–X definition should be tailored to the CJR–X episode population and pricing methodology. We also believe that using a regional comparison is appropriate because CJR–X target prices are based on regional spending, and the safety net hospital risk adjustment factor is part of that regional pricing framework. In addition, using a regional comparison provides a more nuanced approach than a national threshold because it helps account for regional differences, including differences influenced by state Medicaid eligibility rules and dual-eligibility patterns.

We considered commenters' recommendations to use Medicare-specific alternatives, such as broader Medicare populations, Part D Low-Income Subsidy status, or a national threshold. We also considered recommendations to use broader hospital-wide, all-payer, or community-based measures, such as DSH patient percentage, Medicaid volume, uncompensated care, all-payer low-income metrics, or community deprivation measures. We are not adopting those alternatives at this time

because they would identify safety net status based on measures that may be less directly connected to the LEJR episodes included in CJR–X or to expected CJR–X episode spending. Some of those measures may also introduce additional variation unrelated to CJR–X episode spending, including variation based on payer mix, hospital service mix, uncompensated care policy, and state Medicaid policy.

We recognize commenters' concerns that a binary threshold may create cliff effects or year-to-year changes in safety net hospital status for hospitals near the threshold. We considered more nuanced approaches in the proposed rule, including segmenting hospitals into additional groups based on the share of FFS inpatient LEJR episodes furnished to dually eligible beneficiaries. However, further segmentation would reduce the number of episodes in each group and could create sample size and accuracy concerns.

We are not adopting a policy under which hospitals would retain safety net status for the duration of CJR–X once they qualify. We recognize that such a policy could increase predictability for hospitals near the threshold, but tying safety net status to the applicable baseline period aligns the designation with the data used for CJR–X pricing and risk adjustment and allows the designation to reflect changes in the episode population over time.

We will continue to assess whether the safety net hospital definition appropriately identifies hospitals that face higher expected LEJR episode spending due to the patient populations they serve. We will consider monitoring data, evaluation findings, operational experience, and stakeholder feedback in determining whether future refinements to the safety net hospital definition are warranted.

Comment: Many commenters recommended that CMS revise the proposed safety net hospital risk adjustment policy or adopt additional protections for safety net and other vulnerable hospitals. Commenters stated that a binary safety net hospital adjustment may not adequately reflect the range of financial and operational challenges faced by hospitals that serve high shares of low-income or socially vulnerable beneficiaries. Commenters expressed concern that hospitals just below the proposed safety net threshold may face challenges similar to hospitals just above the threshold, but would not receive the same adjustment.

Commenters recommended that CMS adopt a graduated, tiered, continuous, or non-linear safety net adjustment instead of a binary adjustment. Commenters suggested that the adjustment could increase as the share of low-income, dual-eligible, or socially vulnerable beneficiaries increases, or that CMS could use peer groups based on the share of dual-eligible or low-income beneficiaries. Commenters stated that a graduated approach could reduce cliff effects, better account for hospitals with different levels of social-risk burden, and provide more appropriate support for hospitals that serve vulnerable populations.

Some commenters recommended additional protections for safety net hospitals, near-safety-net hospitals, rural hospitals, sole community hospitals, Medicare-dependent, small rural hospitals, or other resource-constrained hospitals. Commenters suggested policies such as greater risk adjustment, additional monitoring, recalibration of the safety net adjustment, or other safeguards if vulnerable hospitals experience disproportionate repayments, access concerns, or financial instability under CJR–X.

Response: We acknowledge commenters' concerns that a binary safety net hospital risk adjustment may not capture every difference in financial risk or resource constraints among hospitals that serve vulnerable populations. We recognized this concern in the proposed rule and considered a more nuanced approach that would segment hospitals into additional groups based on the share of FFS inpatient LEJR episodes furnished to dually eligible beneficiaries. We also recognized that hospitals just below the proposed threshold may face challenges similar to hospitals just above it.

We are not adopting a graduated, tiered, continuous, or non-linear safety net hospital risk adjustment at this time. We remain concerned that further segmenting hospitals into smaller groups could reduce the number of episodes used to calculate risk adjustment multipliers and could create sample size and accuracy concerns. A more granular safety net adjustment could also increase volatility for hospitals near multiple thresholds and make it more difficult for participants to understand and estimate target prices. We believe the proposed binary safety net hospital risk adjustment provides a clearer and more administrable approach for the initial CJR–X methodology while still adding a hospital-level adjustment that was not part of the original CJR Model methodology.

We recognize commenters' concerns that hospitals near the safety net threshold or hospitals serving vulnerable populations may still face financial and operational challenges under CJR–X. The safety net hospital risk adjustment factor is intended to improve target price accuracy by accounting for a specific hospital-level social-risk measure in the pricing methodology. Other forms of financial protection, including limits on repayment responsibility, are addressed through the reconciliation methodology rather than through the risk adjustment methodology.

We agree that the performance of safety net hospitals and other vulnerable hospitals will be an important issue to evaluate as CJR–X is implemented. We will monitor whether the safety net hospital risk adjustment factor is appropriately accounting for differences in expected episode spending, including whether hospitals near the safety net threshold experience disproportionate repayments or access, quality, or operational concerns. We will consider monitoring data, evaluation findings, operational experience, and stakeholder feedback in determining whether refinements to the safety net hospital risk adjustment methodology are warranted.

Comment: A couple commenters recommended that CMS revise the proposed cap on the final normalization factor adjustment. Commenters stated that retrospective normalization adjustments can materially affect reconciliation target prices and reduce participants' ability to predict performance before reconciliation.

A commenter expressed concern that the normalization factor could offset or exceed the effect of risk adjustment and recommended that CMS cap the normalization factor so that it does not exceed the risk adjustment. Another commenter recommended reducing the proposed limit on the normalization factor adjustment from 5 percent to 3 percent to align with the proposed limit on the retrospective trend factor adjustment.

Response: We acknowledge commenters' concerns about the effect of the final normalization factor on reconciliation target prices and participant predictability. The normalization factor and risk adjustment multipliers work together, but they serve different functions. Risk adjustment multipliers account for differences in beneficiary and hospital-level characteristics that affect expected episode spending, while normalization is intended to ensure that risk adjustment does not increase or decrease target prices overall solely because of the application of the risk adjustment methodology.

We are not adopting a policy to cap the normalization factor so that it does not exceed the risk adjustment. We do not believe that comparison would provide an appropriate limit because normalization is calculated to address the aggregate effect of risk adjustment and case-mix changes, while individual risk adjustment multipliers operate at the episode level. Limiting normalization based on the magnitude of risk adjustment could prevent the methodology from appropriately accounting for differences between the case mix reflected in preliminary target prices and the case mix observed during the performance year.

We are also not reducing the proposed final normalization factor adjustment cap from 5 percent to 3 percent. We recognize that the retrospective trend factor adjustment is capped at 3 percent, but the trend factor and normalization factor serve different purposes. The retrospective trend factor accounts for changes in spending patterns between the baseline and performance year, while the final normalization factor accounts for changes in observed case mix. We continue to believe that a 5 percent cap on the final normalization factor adjustment appropriately balances predictability with the need to account for meaningful case-mix changes during the performance year.

We also note that this approach is consistent with the TEAM methodology, which uses a 5 percent cap on the normalization factor adjustment and a 3 percent cap on the retrospective trend factor adjustment. Maintaining the same caps in CJR–X supports consistency across episode-based payment methodologies while preserving the different functions of the two adjustments.

Comment: A commenter requested that CMS reduce the limit on the normalization factor adjustment to 3% to align with the limit on the trend factor adjustment.

Response: We appreciate the commenter's suggestion to align the limit on the normalization factor adjustment with the limit on the trend adjustment. We note that the normalization factor and trend factor serve different purposes, with the normalization factor accounting for changes in patient case mix between the baseline and performance year and the trend factor accounting for changes in spending patterns between the baseline and performance year. Our goal for capping each adjustment is to strike a balance between predictability of target prices and protecting both CJR–X participants and CMS from significant shifts in patient case mix and spending patterns. We note that in the CJR Extension there was no cap on the retrospective adjustment to either the normalization factor adjustment or the trend factor adjustment. In TEAM, we finalized a 5% limit on the normalization factor. We finalized the 3% limit on the trend factor adjustment to be responsive to comments and consistent with the pattern of BPCI Advanced, which decreased its trend factor adjustment cap in later years of the model. We continue to believe that these caps represent the best way to balance predictability and protection from changes between the baseline and performance years. We also believe that maintaining the same caps in CJR–X as we do in TEAM will minimize unnecessary confusion.

After consideration of the public comments, we are finalizing without modification the proposals at § 512.605 for the definitions of ''age bracket risk adjustment factor'', ''beneficiary economic risk adjustment factor'', ''CJR–X HCC count risk adjustment factor'', ''final normalization factor'', ''prospective normalization factor'', and ''safety net hospital''. We are also finalizing without modification the proposals at § 512.645(a–d) for risk adjusting episodes.

(5) Process for Reconciliation

In the CJR Model, we performed an annual reconciliation calculation to compare CJR Model PY spending for a CJR participant to a reconciliation target price in order to determine if CMS owed the CJR participant a reconciliation payment, or if the CJR participant owed CMS a repayment. This section reviews our proposals for conducting an annual reconciliation process in CJR–X. As was the case in the CJR Model, we proposed to incorporate the participant's quality performance into the reconciliation calculation by adjusting the reconciliation target price for quality based on the CJR–X participant's CQS, which would be constructed from their performance on the proposed quality measures discussed in section X.C.2.e. of this final rule. The proposed quality adjustment is discussed in more detail in section X.C.2.f.(5)(f). of this final rule. We proposed to update the trend factor as discussed in section X.C.2.f.(3)(f). of this final rule and apply episode-level risk adjustment and update the normalization factor as discussed in X.C.2.f.(4). of this final rule. We proposed to calculate the difference between the participant's aggregated reconciliation target price across all episodes and their episode spending to create the raw NPRA. We proposed to apply stop-loss/stop-gain limits to the raw NPRA to determine the CJR–X participant's NPRA. Finally, we proposed to subtract the post-episode spending amount from the NPRA, when applicable, to determine the reconciliation payment or repayment amount.

We refer readers to section X.C.2.d.(3). of this final rule for our definition of related services for our episodes, to section X.C.2.a of this final rule for our definition of performance years, and to section X.C.2.f.(3) of this final rule for our approach to establish preliminary target prices.

(a) Annual Reconciliation

As we did in the CJR Model, we proposed to conduct an annual reconciliation calculation that would compare performance year spending on episodes with a date of discharge from the anchor hospitalization or a date of discharge from the anchor procedure during that PY with reconciliation target prices for those episodes to calculate a reconciliation amount for each CJR–X participant. We would reconcile, on an annual basis, all episodes attributed to a CJR–X participant that end in a given calendar year. We note that we proposed that performance years would be aligned with fiscal years but are finalizing a policy to align performance years with calendar years, as discussed in section X.C.2.a. of this final rule. As we stated in the 2015 CJR final rule that finalized the CJR Model (80 FR 73385) and reiterated in the FY 2025 IPPS/LTCH PPS final rule that finalized TEAM (89 FR 69773), we believe that one annual reconciliation accommodates the need for regular performance feedback while minimizing the administrative burden of more frequent reconciliations.

We sought comment on this proposal at § 512.650 to conduct one reconciliation for each performance year. The following is a summary of the public comments received.

Comment: A commenter recommended that CMS provide quarterly preliminary reconciliation estimates during the performance year while retaining annual reconciliation as the formal payment process. The commenter stated that quarterly visibility would improve cash-flow predictability and help hospitals manage downstream provider relationships. The commenter also stated that interim estimates would support gainsharing arrangements by allowing participants to maintain care coordination incentives throughout the year. The commenter stated their belief that preliminary reconciliation estimates would help hospitals identify

and address performance issues before year-end reconciliation.

Response: We appreciate the commenter's support for an annual reconciliation process and recommendation for quarterly preliminary reconciliation estimates. We recognize the importance of maximizing visibility into participants' performance throughout the year. However, we are concerned that quarterly preliminary reconciliation estimates could not be produced with sufficient claims runout and reliability to provide additional meaningful information to hospitals beyond what we will include in their monthly claims data feeds. We note that the monthly data feed will include both line-level claims data and summary data. Additionally, we anticipate providing quarterly estimates of the trend, normalization, and payment system update factors to help participants better estimate their reconciliation target prices. Given the potential for volatility between preliminary reconciliation estimates and final reconciliation results, we do not plan to provide preliminary reconciliation estimates at this time. However, we believe that the monthly data feeds, in conjunction with the preliminary target prices and quarterly trend, normalization, and update factor estimates, will give participants sufficient, actionable information regarding their performance in the model.

After consideration of the public comment we received, we are finalizing without modification the proposal at § 512.650 to conduct one reconciliation for each performance year.

(b) Timing

We proposed to conduct the annual reconciliation of each CJR–X participant's actual episode payments against the target price(s) roughly 6 months after the end of the performance year, consistent with the 6 months of claims runout we allowed for the reconciliation in the CJR Extension for CJR Model PYs 6 through 8. As we stated in the 2021 CJR 3-Year Extension final rule that finalized the CJR Extension (85 FR 23519) and reiterated in the FY 2025 IPPS final rule that finalized TEAM (89 FR 69773), we believe that 6 months is sufficient time for claims runout given that an internal review of Medicare claims data found that 98.71 percent of IP claims had been received, and 89.96 percent were considered final, by 6 months after the date of service.[605] For HOPD claims, those rates were 98.10 percent and 95.78 percent, respectively. Similar rates were found for all other types of claims, including Carrier, SNF, HH, and DME, indicating that we would have a nearly complete picture of performance year spending by 6 months after the end of the performance year. In the proposed rule, we proposed that CJR–X performance years would align with the fiscal year (October to September) rather than the calendar year, so we proposed to capture claims submitted by April 1st following the end of the performance year and carry out the NPRA calculation as described previously to make a reconciliation payment or hold CJR–X participants responsible for repayment. However, as discussed in section X.C.2.a of this final rule, in response to comments we are finalizing a policy at § 512.630(a) to begin the first performance year of CJR–X on January 1, 2028 and align CJR–X performance years with the calendar year instead of the fiscal year. This change will allow additional time for participants to prepare for the first performance year and will align performance years with TEAM. This shift to a calendar year means that we will capture claims submitted by July 1st following the end of a performance year in order to carry out the NPRA calculation.

Comment: A commenter stated their concern that the CJR–X Model continues to be built on the FFS framework, with providers largely continuing to bill Medicare on a fee-for-service basis followed by an annual retrospective reconciliation some months after the conclusion of the performance year. They noted that this structure creates significant lags between when care is delivered and when performance is recognized.

Response: We acknowledge the commenter's concern that the annual retrospective reconciliation creates a lag between when care is delivered and when reconciliation reports and potential reconciliation payments are received. Although we recognize that the time lag may be a challenging aspect of the model, we note that we will provide monthly claims data feeds that provide timely feedback that can be used by participants to identify cost drivers, identify opportunities for greater care coordination, and gauge their performance in the model.

Comment: A commenter stated their concern that the annual reconciliation timeline could cause charges to be erroneously included in the episode in cases where claims may need to be rebilled after the reconciliation window closes. They expressed particular concern about episodes that occur near the end of the calendar year, when many patients seek to schedule procedures before their annual deductible resets.

Response: We appreciate the commenter's concerns about charges being erroneously included in an episode due to a billing error that was not remediated within the annual reconciliation window. We reiterate our belief that a 6-month window for claims run-out after the end of the performance year strikes the appropriate balance between allowing time for claims to be adjudicated, and corrected as needed, and providing finalized reconciliation results within a reasonable timeframe. We note that 6 months is the minimum amount of claims runout, applying to episodes that end at the end of the performance year. Episodes that end earlier in the performance year will have additional months of claims runout. We also note that, since we are finalizing a policy to align CJR–X episodes with the calendar year rather than the fiscal year as proposed, 90-day episodes that are initiated near the end of a given calendar year will end in the early months of the following performance year, allowing for considerably more than 6 months of claims runout to adjudicate any errors.

After consideration of the public comments received, we are finalizing without modification our proposal at § 512.560(b) to perform reconciliation 6 months after the end of the performance year.

(c) Participants That Experience a Reorganization Event

In the CJR Model, we recognized that there could be CJR participants that experience a reorganization event during a given performance year. We proposed to align CJR–X policies for reorganization events with those of the CJR Model. At proposed § 512.605, we proposed to define a ''reorganization event'' as a merger, consolidation, spin-off or other restructuring that results in a new hospital entity under a given CCN. As a result of such an event, the CJR–X participant may begin billing under a different CCN, or an additional entity could be incorporated into the CJR–X participant's existing CCN, resulting in a new hospital entity. For instance, CJR–X participant A may merge with, or be purchased by, CJR–X participant B and begin billing under CJR–X participant B's CCN. In this case, we proposed to perform separate reconciliation calculations for CJR–X participant A and CJR–X participant B

[605] Chronic Conditions Data Warehouse: Medicare Claims Maturity White Paper *https://www2.ccwdata.org/documents/10280/19002256/medicare-claims-maturity.pdf.*

for those episodes where the anchor hospitalization admission or the anchor procedure occurred before the effective date of the merger or purchase. We proposed to reconcile episodes where the anchor hospitalization admission or the anchor procedure occurred on or after the effective date of the merger or purchase under the new or surviving CCN that applies to the blended entity. We proposed this policy in recognition that the blended entity may have different spending patterns, or a different overall patient case mix, than the two separate entities prior to the merger. In a different instance, if a CJR–X participant merges into or is purchased by a hospital that is excluded from CJR–X participation as specified in proposed § 512.610(b) and begins billing under the CCN of the non-CJR–X participant, we proposed to reconcile episodes for the CJR–X participant where the anchor hospitalization admission or the anchor procedure occurred before the effective date of the merger or purchase. This policy would allow for the CJR–X participant to earn a reconciliation payment or owe a repayment for the episodes that occurred during the portion of the performance year that they were in the model. However, once the CJR–X participant begins to bill under the non-CJR–X participant's CCN, the blended entity would not be considered a CJR–X participant and we would not reconcile episodes where the anchor hospitalization admission or the anchor procedure occurred on or after the effective date of the merger or purchase under the new or surviving CCN that applies to the blended entity.

We sought comment on our proposal at § 512.650(b)(2) for conducting reconciliations for CJR–X participants that experience a reorganization event during a given performance year. We received no comments on this proposal and therefore are finalizing this provision without modification.

(d) Updating Preliminary Target Prices To Create Reconciliation Target Prices

As discussed in sections X.C.2.f.(3)(f). and X.C.2.f.(4). of this final rule, we proposed to apply beneficiary-level risk adjustment and a limited adjustment to the prospective trend factor and normalization factor, as applicable, to increase the accuracy of our reconciliation calculations. At the time of reconciliation, we would apply these adjustments, if applicable, to the preliminary target prices we calculated and communicated to CJR–X participants prior to the applicable performance year, as described in Section X.C.2.f.(5)(d). of this final rule. Additionally, preliminary target prices would be adjusted for geographic wage factor updates, similar to the CJR Model, to convert target prices, which were previously expressed in standardized dollars, into ''real'' or unstandardized amounts. Application of these adjustments to the preliminary target price, in addition to the Composite Quality Score adjustment described in section X.C.2.f.(5)(e). of this final rule, will result in the reconciliation target price. We note that in some cases, the final target price applied to an episode in a given performance year at reconciliation will not change. In addition, in some cases the reconciliation target price will increase from the preliminary target price provided prior to the performance year, potentially benefiting CJR–X participants. For instance, if the prospective trend was 0.98 and the prospective normalization factor were calculated as 0.85, but the realized spending trends and beneficiary case mix during the performance year differed from the values constructed for preliminary target prices, such that the capped retrospective trend adjustment factor was 1.10 and the capped final normalization factor were calculated as 0.87, the reconciliation target price would incorporate these updated factors and therefore be higher than the preliminary target price.

Furthermore, we recognize that due to the availability of data and the timing of when preliminary target prices would be shared with CJR–X participants, the most up-to-date payment data from CMS payment rules, including the Calendar Year OPPS/ASC rule and the Fiscal Year IPPS/LTCH PPS rule would not be captured in the prices. Typically, CMS proposes and finalizes coding or rate changes, as applicable, through established annual payment rules. While we recognize the retrospective trend factor adjustment will take into account realized spending trends during the performance year, given the proposed 3 percent cap, we are concerned the retrospective trend factor adjustment may not capture payment rate changes or other changes, such as ambulatory payment classification (APC) or MS–DRG changes that arise from these payment rules. Therefore, we proposed at § 512.645(g) during reconciliation target price construction to update the preliminary target price to account for updated payment rule changes to reflect episode spending during the performance year. We recognize that accounting for payment rule changes during reconciliation target price construction rather than sharing updated preliminary target prices during the performance year may result in CJR–X participants not having the most updated information during the performance year. We note this methodology differs from TEAM's proposal in section X.A.2.c.(2). of this final rule. We believe this approach is appropriate for CJR–X given the single episode category tested in CJR–X and anticipate fewer coding changes affecting the LEJR episode. We considered but did not propose to update and deliver preliminary target prices to CJR–X participants for each calendar and fiscal year final rule. We believe managing three different preliminary target prices in a given performance year will increase participant burden and pricing methodology complexity. Lastly, we also considered but did not propose removing the 3 percent capping of the retrospective trend factor adjustment. Applying a full retrospective trend factor to reconciliation target prices, rather than capping at 3 percent would account for actual performance year spending and would incorporate payment rule changes not captured in preliminary target prices. However, we recognize that removing the 3 percent cap may introduce target price instability making it more difficult for CJR–X participants to predict reconciliation target prices and assess spending performance in the model.

We sought comment on our proposal at § 512.645(g) to account for payment system changes during the construction of reconciliation target prices.

Comment: A couple of commenters recommended that CMS provide APC, MS–DRG, or other payment-rule update factors during the performance year rather than waiting until reconciliation. The commenters stated that earlier visibility into update factors would improve transparency and financial planning. The commenters stated their belief that hospitals should be able to anticipate how annual payment rule changes will affect target prices while the performance year is underway. The commenters suggested that more actionable information would support care redesign and internal accountability. The commenters requested that CMS align the timing of information sharing with hospitals' operational need to manage performance prospectively.

Response: We appreciate the recommendation to provide additional visibility into payment-rule update factors during the performance year. We recognize that additional information during the performance year could improve participant planning and

understanding of reconciliation target prices. We anticipate providing preliminary update factors, along with quarterly estimates of the trend and normalization factors.

After consideration of the public comments we received, we are finalizing without modification our proposal at § 512.645(g) to account for payment system changes during the construction of reconciliation target prices.

(e) Applying Composite Quality Score to Reconciliation Target Prices

(i) Overview

Similar to the CJR Model, we discuss in section X.C.2.f.(3)(g). of this final rule to include a discount factor for all CJR–X participants that would be incorporated into preliminary target prices. While the CJR Model included a 3.0 percent discount factor (80 FR 73353), we proposed a 2.0 percent discount factor for CJR–X that takes into consideration the opportunity for CJR–X participants to find savings and acknowledges the reductions in LEJR spending since the CJR Model was implemented. We stated in the proposed rule that CJR–X participants that provide high-quality episode care would have the opportunity to reduce the effective discount factor used to calculate their reconciliation target price. As in the CJR Model, we proposed to adjust the discount factor based on the CJR–X participant's composite quality score by categorizing them into one of four categories, specifically ''Excellent,'' ''Good,'' ''Acceptable,'' and ''Below Acceptable,'' for each performance year. Based on where the CJR–X participant is categorized, then they may receive a reduction to their discount factor, no reduction to their discount factor, or no reduction and ineligibility to receive a reconciliation payment.

(ii) Adjusting the Discount Factor

We proposed to incorporate the composite quality score, as described in section X.C.2.e.(6) in this final rule, in the CJR–X pricing methodology by (1) requiring a minimum composite quality score for reconciliation payment eligibility if the CJR–X participant's actual episode payments are less than the reconciliation target price and (2) determining the effective discount factor included in the reconciliation target price experienced by the CJR–X participant in the reconciliation process.

Under this methodology, we proposed CJR–X participants must achieve a minimum composite quality score of >=6.1 to be eligible for a reconciliation payment if actual episode spending were less than the reconciliation target price based on the 2.0 percent maximum discount factor. We proposed at § 512.645(h)(4) that CJR–X participants with ''below acceptable'' quality performance reflected in a composite quality score less than or equal to 6.0 would not be eligible for discount factor reduction nor would they be eligible for a reconciliation payment if actual episode spending were less than the reconciliation target price. We noted in the proposed rule that a level of quality performance that is below acceptable would not affect CJR–X participants' repayment responsibility if actual episode spending exceeded the reconciliation target price. We believed that excessive reductions in utilization that lead to low actual episode spending and that could result from the financial incentives of the model would be limited by a requirement that this minimum level of quality be achieved for reconciliation payments to be made. We noted this policy would encourage CJR–X participants to focus on appropriate reductions or changes in utilization to achieve high quality care in a more efficient manner. Therefore, we stated these CJR–X participants would be ineligible to receive a reconciliation payment if actual episode spending were less than the reconciliation target price.

We proposed at § 512.645(h)(3) that CJR–X participants with an ''acceptable'' composite quality score of greater than or equal to 6.1 and less than or equal to 12.0 would be eligible for a reconciliation payment if actual episode spending were less than the reconciliation target price but would not be eligible for a discount factor reduction. Therefore, acceptable performance would be based on a 2.0 percent discount factor because their quality performance was at the acceptable level established for the model. We stated that these CJR–X participants would be eligible to receive a reconciliation payment if actual episode spending were less than the reconciliation target price.

We proposed at § 512.645(h)(2) that CJR–X participants with a ''good'' composite quality score of greater than or equal to 12.1 and less than or equal to 17.0 would be eligible for a reconciliation payment if actual episode spending were less than the reconciliation target price and would be eligible for a 1.0 percent discount factor that reflects their good quality performance. Thus, we noted that participants achieving this level of quality would either have less repayment responsibility (that is, the reduced discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise if the 2.0 discount factor were maintained.

Finally, we proposed at § 512.645(h)(1) CJR–X participants with an ''excellent'' composite score quality score of greater than or equal to 17.1 would be eligible to receive a reconciliation payment if actual episode spending was less than the reconciliation target price and would be eligible for a 0.0 percent discount factor that reflects their excellent performance. Thus, we stated that participants achieving this level of quality would either have less repayment responsibility (that is, the reduced discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise if the 2.0 discount factor were maintained.

Under this methodology, the stop-loss and stop-gain limits discussed in section X.C.2.f.(5)(g) of this final rule would not change. We stated in the proposed rule that we believe this approach to quality incentive payments based on the composite quality score could have the effect of increasing the alignment of the financial and quality performance incentives under CJR–X to the potential benefit of CJR–X participants and their collaborators as well as CMS and would be consistent with the original CJR model methodology linking quality and payment.

The CJR–X composite quality score ranges are display in Table X.C–06.

TABLE X.C.-06: RELATIONSHIP OF COMPOSITE QUALITY SCORE ON RECONCILIATION PAYMENT ELIGIBILTY AND DISCOUNT FACTOR

Composite quality score (CQS)	Composite Quality Score Category	Eligible for Reconciliation Payment	Discount Factor
CQS <=6.0	Below acceptable	No	2.0
CQS >=6.1 and <12.0	Acceptable	Yes	2.0
CQS >=12.1 and <=17.0	Good	Yes	1.0
CQS >=17.1	Excellent	Yes	0.0

We sought comment on our proposal at § 512.650(g) to link quality to payment by adjusting the discount factor for reconciliation target prices.

The following is a summary of the public comments received on our proposal to adjust the discount factor based on quality performance, and our responses to these comments:

Comment: A commenter stated that CMS should align CJR–X more closely with the design principles reflected in the Transforming Episode Accountability Model (TEAM) and other recent Innovation Center models, particularly with respect to quality incentives.

Response: We recognize the importance of designing payment methodologies that appropriately encourage high-quality care and acknowledge that TEAM incorporates quality adjustments through a methodology that differs from the approach proposed for CJR–X. However, we note that CJR–X is as an expansion of the CJR Model under section 1115A(c) of the Act. As discussed in section X.C.1.c of this final rule, the Secretary determined that the CJR Model met the statutory requirements for expansion based on evidence that the model reduced Medicare spending while maintaining quality of care, and the CMS Chief Actuary certified that expansion would reduce or not increase net program spending. We believe it is important that CJR–X maintain the core features of the model that were tested and evaluated through the CJR Model and that formed the basis for the Secretary's determination and the Chief Actuary's certification. Adopting a substantially different quality incentive structure that more closely mirrors TEAM could represent a significant departure from the model design that was tested and demonstrated to achieve savings while maintaining quality.

We also believe that adjusting the discount factor based on quality performance is an appropriate and effective mechanism for incorporating quality incentives into CJR–X. This approach directly links a participant's opportunity to earn reconciliation payments to its quality performance while preserving the fundamental retrospective bundled payment methodology that was tested under the CJR Model. By adjusting the discount factor applied to episode spending based on quality performance, the model rewards participants that achieve higher quality outcomes while maintaining a clear relationship between quality performance, financial accountability, and Medicare savings. We believe this approach balances the goals of encouraging high-quality care, maintaining consistency with the tested CJR methodology, preserving operational simplicity for participants, and supporting the continuation of a model design that demonstrated the ability to reduce spending while maintaining quality of care.

Comment: A commenter believed that the CQS should not be used to modify the discount factor, but rather, the CQS should only set a performance threshold that should be achieved to be eligible for payment for a positive net payment reconciliation amount.

Response: We agree that quality performance should be an important consideration in determining whether participants are eligible to receive reconciliation payments under CJR–X. In fact, under the CQS methodology, a CJR–X participant must achieve at least an acceptable CQS in order to be eligible to receive a reconciliation payment. Therefore, the model already incorporates a quality threshold below which CJR–X participants are not eligible to receive reconciliation payments.

However, we continue to believe that adjusting the discount factor based on quality performance, in addition to the quality threshold for receiving a reconciliation payment, is the more appropriate approach for the model. While the quality threshold ensures that participants must achieve a minimum level of quality performance before receiving a reconciliation payment, using the CQS solely as a threshold would create a largely binary quality incentive structure in which CJR–X participants either qualify for a reconciliation payment or do not. Under such an approach, once a CJR–X participant achieved the minimum acceptable quality threshold, there would be limited additional financial incentive to further improve quality performance. In contrast, the proposed methodology creates a more continuous relationship between quality performance and financial outcomes by providing greater financial rewards for higher levels of quality achievement above the minimum threshold. We believe this approach better encourages ongoing quality improvement across the full range of CJR–X participant performance rather than focusing incentives only on attainment of a minimum standard.

In addition, we believe adjusting the discount factor appropriately balances the model's dual goals of improving quality and reducing Medicare spending. By linking the effective discount factor to quality performance, CJR–X participants that achieve stronger quality outcomes retain a greater opportunity to earn reconciliation payments, while CJR–X participants with lower quality performance receive a smaller financial benefit even when spending is below the target price. We believe this approach more directly aligns quality and financial accountability and encourages CJR–X participants to pursue both quality improvement and efficient episode management.

Finally, this methodology is consistent with the quality incentive structure tested and evaluated under the CJR Model, which demonstrated the ability to reduce Medicare spending while maintaining quality of care. We believe preserving this relationship between quality performance and reconciliation outcomes supports continuity with the tested model design that forms the basis for the proposed expansion of CJR–X.

After consideration of the public comments, we are finalizing without modification the proposal at § 512.650(g) to link quality to payment by adjusting the discount factor for reconciliation target prices.

(f) Calculating the Raw Net Payment Reconciliation Amount (NPRA)

Consistent with the original CJR model, after the completion of a performance year, we proposed to retrospectively calculate a CJR–X participant's actual episode performance based on the episode definition. We note that episode spending would be subject to proration for services that extend beyond the episode (as described in section X.C.2.f.(3)(c). of this final rule). We proposed to cap performance year spending at the high-cost outlier cap as described in section X.C.2.f.(3)(e). of this final rule. We proposed to apply the high-cost outlier cap to episodes in the performance year similarly to how we proposed to apply it to baseline episodes, using the 99th percentile for each MS–DRG/HCPCS episode type and region as the maximum. Any performance year episode spending amount above the high-cost outlier cap would be set to the amount of the high-cost outlier cap. Similar to the CJR Model, we would apply geographic wage factors to total capped episode spending to convert the amount from standardized dollars into ''real'' or unstandardized amounts. We then proposed to compare each CJR–X participant's performance year spending to its reconciliation target prices, calculated as discussed in X.C.2.f.(5)(d). of this final rule. We note that, as discussed in section X.C.2.f.(3)(i). of this final rule, a CJR–X participant would have multiple target prices for episodes ending in a given performance year, based on the MS–DRG/HCPCS episode type and the performance year when the episode was initiated. We proposed to determine the applicable reconciliation target price for each episode using the aforementioned criteria, and then determine the raw NPRA by calculating the difference between each CJR–X participant's aggregated performance year spending and its aggregated reconciliation target price for all episodes in the performance year.

We sought comment on our proposal at § 512.650(c)(1) through (c)(5) for calculating the raw NPRA.

Comment: A commenter recommended an alternative method to determining a reconciliation payment or repayment and suggested that CMS implement a risk corridor, with only spending outside the corridor resulting in a reconciliation payment or repayment amount.

Response: We thank the commenter for their recommendation. We recognize the commenter's concern that hospitals operating on tight budgets may experience financial disruption from relatively small reconciliation amounts and that, for hospitals with average episode spending close to the target price, year-to-year variation may not reflect meaningful differences in performance. Given that this deviates from the design of the CJR Model and what we have proposed for CJR–X, we do not believe it would be possible to implement such a policy without assessing its merits. As discussed in section X.C.1. of the proposed rule (91 FR 19671) and reiterated in section X.C.1. of this final rule, the CJR–X payment methodology is designed around comparing episode spending to target prices, subject to quality performance and other payment methodology rules, and the proposed model expansion relies on evaluation findings and actuarial certification that expansion is expected to reduce Medicare spending while maintaining quality. Accordingly, while we acknowledge there may be potential value of a risk corridor as a way to address random variation and reduce administrative burden, we would need to analyze its effects on model incentives and projected Medicare spending before considering whether to propose such a policy through future notice-and-comment rulemaking.

After consideration of the public comment we received, we are finalizing without modification our proposal at § 512.650(c)(1) through (c)(5) for calculating the raw NPRA.

(g) Limitations on NPRA

As we did in the CJR Model, we proposed to include both stop-loss and stop-gain limits on the total amount that a CJR–X participant could owe to CMS as a repayment or receive from CMS as a reconciliation payment. As we stated in the 2015 CJR final rule (80 FR 73398), we acknowledge that CJR–X participants vary with respect to their readiness to function under an episode payment model with regard to their organizational and systems capacity and structure, as well as their beneficiary population served. Conversely, we also note that CJR–X participants may be incentivized to excessively reduce or shift utilization outside of the CJR–X episode, even with the proposed quality requirements discussed in section X.C.2.e. of this final rule. In order to ensure that CJR–X participants would neither be subject to an unmanageable level of risk nor be incentivized to stint on care to achieve savings, we proposed limiting a CJR–X participant's NPRA through the application of symmetrical stop-loss and stop-gain limits, calculated as a percentage of the hospital's aggregate reconciliation target price. We note that the stop-loss limit would not apply to any post-episode spending amount as discussed in section X.C.2.f.(5)(h). of this final rule.

Consistent with the CJR Model, we proposed a stop-loss and stop-gain limit of 20 percent for most CJR–X participants. We believe maintaining consistency with the CJR Model's 20 percent stop-loss and stop-gain limits for most CJR–X participants provides an appropriate balance of financial risk and reward to promote spending reductions with reasonable risk thresholds. However, we also acknowledge that certain groups of CJR–X participants may have lower risk tolerance and less infrastructure and support to achieve efficiencies for high-cost episodes, as we stated in the 2015 CJR final rule (80 FR 73403). Therefore, we proposed to provide additional safeguards to certain categories of CJR–X participants, largely consistent with the CJR Model. We proposed to apply a 5 percent stop-loss for CJR–X participants that are rural hospitals as defined at proposed § 512.605, Medicare-dependent, small rural hospitals (MDH), and sole community hospitals (SCH). We also proposed to apply a 5 percent stop-loss for CJR–X participants that meet the proposed definition of safety net hospitals, as defined at proposed § 512.605. Although we did not apply this additional stop-loss protection to safety net hospitals in the CJR Model, evaluation results indicated that this category of hospital was disproportionately likely to owe repayments to Medicare, as we discuss in section X.C.2.f.(4). of this final rule.

We sought comment on our proposal at § 512.650(c)(6)(i) and (ii) to apply 20 percent stop-loss and stop-gain limits to most CJR–X participants, and our proposal at § 512.650(c)(6)(iii) to apply a 5 percent stop-loss limit to certain categories of CJR–X participants. The following is a summary of the public comments received.

Comment: A commenter supported the continuation of the 20 percent stop-loss and stop-gain methodology from the CJR Extension as the appropriate baseline for participants not otherwise excluded from CJR–X. The commenter stated that, although they believed that rural hospitals, Medicare-dependent, small rural hospitals, sole community hospitals, and safety-net hospitals should be excluded from mandatory participation in CJR–X, the proposed 5 percent stop-loss limit was the appropriate floor of protection for these categories of hospital if they are mandated to participate. A couple of commenters also expressed support for

the proposed 5 percent stop-loss limit for these types of hospitals. A commenter described the lower stop-loss limit as a necessary safeguard for vulnerable provider categories. Another commenter stated their belief that the lower stop-loss limit would provide additional protection beyond risk adjustment for providers who often serve patient populations with higher needs and operate on thin margins.

Response: We appreciate the commenters' support for the proposed stop-loss and stop-gain framework. We continue to believe that this framework, which includes symmetric 20 percent limits for most participants and a lower stop-loss limit for certain categories of hospital, balances financial accountability, protection from excessive losses, and the need to preserve incentives for efficiency.

Comment: Some commenters stated that the proposed 20 percent stop-loss limit for most participants was too high and should be reduced. Commenters stated their belief that the limit could create substantial aggregate financial volatility, especially for hospitals with high case-mix variability, medically complex patients, or patients facing social and access-related barriers. A commenter stated that the proposed 20 percent stop-loss limit was excessively high and could compound target-price concerns related to the rolling annual benchmark and lack of a target price floor. Another commenter questioned whether the proposed stop-loss protections would sufficiently mitigate the financial exposure associated with high-cost, medically complex episodes. A commenter stated their concern that the 20 percent stop-loss level could encourage risk avoidance rather than care redesign.

Response: CMS acknowledges commenters' concerns that a 20 percent stop-loss limit may be too high and could expose some participants to substantial repayment responsibility. CMS understands that downside risk may be especially concerning for hospitals with limited margins, lower episode volume, or less experience managing post-acute care and other episode spending. However, CMS believes that lowering the stop-loss limit for all CJR–X participants could materially reduce the strength of the model's incentives. CJR–X is designed to test whether hospitals can improve coordination across the full lower-extremity joint replacement episode, including discharge planning, post-acute care use, readmissions, complications, and recovery. A broadly lower stop-loss limit would reduce the amount of episode spending for which participants are accountable and could lessen the incentive to make operational investments in care redesign, data analytics, discharge planning, collaboration with post-acute care providers, and monitoring of episode performance.

CMS also believes that the proposed 20 percent limit should be considered in the context of the broader CJR–X payment methodology, which includes not only the aggregate stop-loss policy, but also other design features intended to improve predictability and protect participants from excessive risk, including risk adjustment, low-volume protections, and a high-cost outlier cap. As we stated in the proposed rule, the high-cost outlier cap would prevent participants from being held responsible for catastrophic episode spending amounts that they could not reasonably have been expected to prevent.

Finally, we note that the 20 percent stop-loss limit is an integral part of the CJR Model methodology that was certified by the CMS Chief Actuary to qualify for expansion on the basis that it would not increase Medicare spending. When CMS temporarily waived downside risk for the CJR Model during the PHE, it resulted in significant losses to Medicare due to increased spending on reconciliation payments to participants that was not mitigated by repayments from other participants. Lowering the stop-loss limit for most hospitals (other than those vulnerable hospital categories that receive the 5 percent stop-loss limit) would risk increasing Medicare spending. Although we proposed and are finalizing other, minor modifications to the CJR Model payment methodology (such as additional risk adjustment and caps on both the trend and normalization factors), we note that these factors were determined by the CMS Chief Actuary to be unlikely to increase Medicare spending over time. By contrast, a change to the stop-loss limits would risk increasing Medicare spending over time and we would not be able to maintain certification for expansion.

Comment: Many commenters requested that stop-loss limits be phased in over time, with limits gradually increasing as organizations gain experience with the model. A few commenters requested an option for upside risk only at the beginning of the model. A commenter stated that a phased approach would better support financial stability and align more closely with the gradual downside risk transition used in TEAM. Another commenter requested that CMS use the same multiple risk transition tracks as TEAM. Multiple commenters suggested that CMS implement a lower stop-loss limit such as 5 percent to 10 percent for the first year. A couple of commenters requested that the 5 percent stop-loss limit proposed for special category hospitals be extended to all hospitals during the first year of the model, noting that many hospitals have no prior experience with models such as the Medicare Shared Savings Program, Bundled Payments for Care Improvement Advanced, or the CJR Model. A couple of commenters requested that the phased approach should occur over a period of at least five years, leading to a maximum stop-loss of 10% for most CJR–X participants and 2.5% for special designation hospitals.

Response: We appreciate commenters' concerns regarding the financial risk associated with CJR–X participation and their recommendation that CMS provide a phase-in period before participants are subject to downside risk with a 20 percent stop-loss limit. We recognize that CJR–X participants may vary in their readiness to operate under an episode-based payment model, including differences in organizational capacity, systems, staffing, and experience with care redesign. However, we believe that two-sided financial accountability is an important component of CJR–X because it creates incentives for participants to coordinate care, manage post-acute utilization, and reduce unnecessary spending while maintaining or improving quality of care.

We note that the January 1, 2028 start date, which we are finalizing at § 512.630(a) in response to commenters' requests, would provide more than one year for participants to prepare for CJR–X. We also note that many hospitals are expected to have prior experience with LEJR episodes given that the Innovation Center has tested episode-based payment models for over a decade and many other payers have also adopted the use of episode-based payment arrangements for certain types of care. We also reiterate our concern that providing a phase-in period of lowered or no downside risk would potentially lead to increased Medicare spending during the early years of CJR–X and would not conform to the payment methodology that has been certified for expansion by the CMS Chief Actuary.

Comment: Some commenters recommended stronger financial protections for rural hospitals, safety-net hospitals, hospitals serving dual-eligible beneficiaries, hospitals serving a high number of low-income and uninsured patients, Medicare-dependent, small rural hospitals, and sole community

hospitals. Commenters stated that these hospitals often operate with lower margins, lower volume, fewer capital resources, and treat populations with greater patient complexity. A few commenters stated that these hospitals have less control over post-acute care patterns and community resources, resulting in fewer opportunities to generate savings in an episode-based payment model. A commenter stated that the proposed 5 percent stop-loss for safety net hospitals was insufficient due to documented disparities in post-acute outcomes for dual-eligible beneficiaries. Commenters questioned whether the proposed stop-loss protections would sufficiently mitigate exposure from high-cost or medically complex episodes. Some commenters stated that even a 5 percent repayment obligation could be material for financially vulnerable hospitals. A commenter stated their belief that participation in CJR–X with downside risk in addition to proposed DSH adjustments and a proposed 0.8 percent productivity adjustment to payment rates would represent three separate, significant financial drains on safety net and rural hospitals that already operate on thin or negative margins. Many commenters requested additional safeguards or reduced exposure for special hospital categories.

A commenter expressed concern that the 5 percent stop-loss for rural hospitals would not adequately address the financial accountability consequences for rural CJR–X participants who send their patients to CAH swing beds because there are no qualified SNFs available locally. They note that CAH swing bed stays can cost two to three times more than a standard SNF stay, and they state their belief that rural hospitals in regions dominated by urban peers would face structurally disadvantaged target prices that would not be offset by the lower stop-loss limit. The commenter requested a clear commitment that CMS would monitor CAH swing bed utilization and its associated episode costs for rural CJR–X participants and propose adjustments through notice and comment rulemaking if monitoring reveals that rural participants face systematically unachievable target prices due to post-acute care market structure rather than care delivery choices.

Another commenter similarly requested that CMS closely monitor financial impacts during the initial performance years of the model for safety net and other vulnerable hospitals and establish clear mechanisms for mid-course corrections should unintended consequences arise. They stated their belief that such safeguards would be essential to ensure that participation in the model does not destabilize hospital finances or reduce access to care for Medicare beneficiaries.

A commenter stated that, if SCHs and MDHs are mandated to participate in CJR–X, they should be exempt from downside risk until CMS has collected sufficient data through CJR–X and TEAM to evaluate the impacts of episode-based payments for LEJRs on patient access and quality of care for counties located outside of metropolitan statistical areas and to evaluate the performance of SCHs and MDHs under these models. The commenter noted that very few SCHs or MDHs participated in CJR during its early performance years, and no SCHs or MDHs participated in the CJR Extension. This commenter stated that given the lack of historical experience in CJR for SCHs and MDHs, the closest proxy were likely to be safety net hospitals, which performed worse than non-safety net hospitals on average and tended to have higher rates of patients with fractures, major comorbidities, and unmet non-medical needs.

Response: We appreciate commenters' concerns about the financial exposure of rural hospitals, safety-net hospitals, Medicare-dependent, small rural hospitals, sole community hospitals, and hospitals serving medically or socially complex beneficiaries. We recognize that commenters believe additional protections may be needed for hospitals with limited resources, lower volume, or higher patient complexity. Regarding the concern about the use of CAH swing beds creating a structural disadvantage for rural hospitals, we note that CMS would use standardized payment amounts to calculate target prices and episode spending in CJR–X.

CMS will monitor the spending patterns for these special categories of hospital to determine whether their performance in the model is disproportionately impacted by features of their local market or patient population that lead to costs they could not reasonably be expected to control. While our goal is to account for these factors through risk adjustment, our low volume policy, and protective stop-loss limits, we recognize that we may need to make adjustments to our methodology in the future as we observe how different types of participants are able to perform in the model. Through evaluating the CJR Model, we identified the need for additional protections for safety net hospitals and implemented those protections in TEAM, as well as proposing and finalizing them in the CJR–X Model. We acknowledge that SCHs and MDHs in particular have had limited experience in the CJR Model. We intend to monitor the performance of SCHs and MDHs, along with rural hospitals and safety net hospitals, in CJR–X. As we stated in response to a previous comment, we may also consider the potential viability of a short glide path for new participants to CJR–X and hospitals in special categories including SCHs and MDHs. If we believe such refinements are warranted, we may consider proposing them through notice-and-comment rulemaking.

Comment: Many commenters requested that eligibility for the 5 percent stop-loss protections be expanded to additional types of hospitals. A commenter recommended that CMS expand eligibility for the 5 percent stop-loss to include a broader safety-net definition aligned with TEAM. The commenter stated their belief that the proposed categories may not capture all hospitals that need additional financial protection. A commenter stated their belief that defining safety net hospital status based solely on the share of FFS LEJR inpatient episodes provided to dually eligible beneficiaries is an overly narrow definition that would exclude many hospitals that serve large proportions of low-income and uninsured patients across their full case mix but would not qualify as safety net hospitals under this LEJR-specific definition. The commenter suggested using a definition that incorporates DSH patient percentages or overall dual eligibility across all service lines, rather than a single procedure category volume measure.

Some commenters recommended that CMS add academic medical centers to the categories eligible for special stop-loss protection. Commenters stated that academic medical centers incur mission-based costs related to resident and fellow training, management of transfer-in patients and downstream complications, delivery of highly specialized orthopedic care, and coordination for patients who travel long distances to access tertiary expertise. A commenter stated their belief that these responsibilities are essential to sustaining the national orthopedic workforce and preserving access to complex joint replacement care, but their costs are not adequately reflected in the stop-loss protections. A commenter recommended using teaching hospital designation or the IME adjustment ratio as eligibility criteria for designation as an academic medical center. Commenters requested a stop-

loss threshold at least comparable to the 5 percent protection proposed for rural and safety-net hospitals.

A couple of commenters recommended that CMS apply the rural hospital definition used in the CJR Model for purposes of eligibility for the 5 percent stop-loss limit. They noted that in the CJR Model, rural policies applied to all hospitals that were treated as rural for Medicare payment purposes, while CMS has proposed to limit rural protections for CJR–X participants to those hospitals physically located in rural areas. A commenter stated that rural hospitals often operate with low volume, limited post-acute care infrastructure, workforce shortages, and fewer opportunities to redesign care in ways that produce measurable savings under the model. They stated their belief that these structural constraints make rural hospitals less able to succeed and more vulnerable to losses. They stated their belief that CMS should therefore apply rural protections—specifically protections from downside risk—to all rural hospitals including those treated as rural for Medicare payment purposes, to avoid penalizing providers that simply do not have the scale or market conditions needed to generate savings.

A commenter requested that the reduction in downside financial risk also apply to hospitals with low surgical volume. The commenter noted that for community hospitals with a low volume of joint replacement surgeries, a small number of complex or outlier cases can result in significant financial losses. They requested protections for low volume hospitals to mitigate the impact of case variability.

Response: We appreciate the recommendation to broaden eligibility for the 5 percent stop-loss to additional hospitals, including academic medical centers, more broadly defined safety-net and rural hospitals, and low volume hospitals. We acknowledge commenters' concerns that these hospitals may face financial pressures, serve complex patient populations, or have higher episode spending risk and variability.

While we acknowledge the specific challenges facing academic medical centers, CMS does not believe it would be appropriate to extend the 5 percent stop-loss limit to academic medical centers as a class. Although some academic medical centers may treat clinically complex patients or serve important regional roles, academic medical center status alone does not necessarily indicate the type of financial vulnerability, limited infrastructure, rural access constraints, or disproportionate repayment risk that the 5 percent stop-loss policy is intended to address. Many academic medical centers also have substantial episode volume, specialized clinical resources, established referral networks, and analytic or care management infrastructure that may support their ability to achieve savings in CJR–X. CMS therefore does not believe that academic medical center status is an appropriate categorical proxy for the additional stop-loss protection proposed for more financially vulnerable hospital categories.

In response to commenters who requested we apply the broader safety net hospital definition used in TEAM to apply the 5 percent stop loss protections for safety net hospitals in CJR–X, we refer commenters to sections X.C.2.f.(4) for a more detailed discussion and justification for our proposed safety net hospital definition in the context of risk adjustment. We believe it is appropriate to use a consistent definition of safety net hospital for both risk adjustment and stop-loss protections. Given that CJR–X includes only one episode, as opposed to the 5 episodes in TEAM, the safety net definition based on FFS LEJR inpatient episodes is more directly connected to the population whose episode spending is being risk adjusted. The regional, as opposed to national, comparison in the CJR–X definition is also aligned with the broader CJR–X target pricing methodology, which is based on regional spending. While TEAM's definition serves TEAM's broader multi-episode and track-based design, we continue to believe a more targeted safety net hospital definition is more appropriate for risk adjustment and stop-loss purposes in CJR–X.

In response to commenters who requested that we apply the 5% stop-loss limit to all hospitals that qualify as rural for Medicare payment purposes, we note that this would include hospitals that were reclassified as a rural hospital under § 412.103 or this chapter or is designated a rural referral center (RRC) under § 412.96 of this chapter. CMS recognizes that rural status for Medicare payment purposes may differ from geographic rurality. However, CMS does not believe that hospitals treated as rural only through Medicare payment reclassification should automatically receive the 5 percent stop-loss limit, because the proposed safeguard is intended to address geographic rural access, infrastructure, and market constraints rather than every circumstance in which a hospital may receive rural treatment under another Medicare payment provision. In the final rule finalizing TEAM (89 FR 69796) we stated that, in the context of a mandatory model, we believed that a narrower rural definition based strictly on geographic area could prevent creating an incentive for a hospital to seek rural reclassification given the flexibilities offered to rural hospitals under the model. We believe that the same rural definition is appropriate for CJR–X.

In response to the request for reduced stop-loss for low-volume hospitals that do not meet the proposed criteria for additional stop-loss protections, we note that we proposed and are finalizing a policy of excluding low-volume hospitals from reconciliation for a given performance year if they do not meet a minimum volume threshold during the applicable baseline. We believe that our low-volume policy, discussed in section X.2.f.(3).(h). of this final rule, combined with our high-cost outlier cap, discussed in section X.2.f.(3).(e) of this final rule, provide sufficient protection against case variability for low-volume hospitals that do not meet the criteria for the reduced stop-loss limit.

Comment: A commenter requested that, if CMS is unwilling to provide safety net hospitals an upside-only glide path for performance years 1 through 3, CMS should extend the 5 percent stop-loss for safety net hospitals through performance year 3 and commit, in the final rule, to maintaining it for any hospital whose safety net status lapses solely due to year-to-year variance in the classification test.

Response: We appreciate the commenter's concern about safety net hospitals in CJR–X. We do not believe an upside-only glide path for safety net hospitals is necessary, as discussed in the comment responses in section X.C.1.c. of this final rule. We note that the 5 percent stop-loss protection for safety net hospitals is intended to be an ongoing feature of the model, so it will already extend beyond performance year 3. We acknowledge the commenter's concern that safety net hospital status could change from year to year for hospitals near the threshold, potentially resulting in different stop-loss protections despite similar underlying financial challenges. We recognized this concern in the proposed rule and we refer the commenter to our responses to comments on the proposed binary safety net hospital risk adjustment in section X.C.2.f.(4) of this final rule. As we note in that section, we considered more nuanced approaches but we were concerned that further segmenting hospitals into smaller groups could create sample size and accuracy problems. We also believe that fixing safety net status over multiple years of the model could create different

accuracy concerns by continuing enhanced protection for hospitals whose episode mix no longer meets the proposed safety net definition, while excluding hospitals whose dual-eligible episode share increases in later applicable baseline periods. The proposed approach ties safety net status to the applicable baseline period, aligns the designation with the data used for CJR–X pricing and risk adjustment, and preserves a clear, administrable method for identifying hospitals with the highest relative share of FFS LEJR inpatient episodes furnished to dually eligible beneficiaries in their region.

Comment: A commenter requested that CMS clarify whether special designation hospitals are subject to the same 20 percent stop-gain limit that applies to CJR–X hospitals without a special designation. The commenter noted that the proposed rule did not specifically address stop-gain limits for these hospitals. The commenter supported application of the same 20 percent stop-gain limit for special designation hospitals.

Response: We appreciate the request for clarification regarding stop-gain limits for special designation hospitals. We note that special designation hospitals would be subject to the 20 percent stop-gain limit even though their stop-loss limit would be reduced to 5 percent.

After consideration of the public comments we received, we are finalizing without modification the proposal at § 512.650(c)(6)(i) and (ii) to apply 20 percent stop-loss and stop-gain limits to most CJR–X participants, and our proposal at § 512.650(c)(6)(iii) to apply a 5 percent stop-loss limit to certain categories of CJR–X participants.

(h) CJR–X Participant Responsibility for Increased Post-Episode Payments

As we noted in the 2015 CJR final rule that finalized the post-episode spending policy for the CJR Model (80 FR 73398), while the CJR episode extended 90-days post-discharge from the anchor hospitalization, some hospitals may have had an incentive to withhold or delay medically necessary care until after an episode ended to reduce their actual episode payments. We did not believe this would be likely in the CJR Model, especially given the relatively long episode duration, and we continue to believe that this will not be likely in CJR–X. However, in order to identify and address such inappropriate shifting of care, we proposed to maintain the CJR Model post-episode spending policy in CJR–X. Specifically, we proposed to calculate the total Medicare Parts A and B expenditures in the 30-day period following completion of each episode for all services covered under Medicare Parts A and B for each performance year, regardless of whether the services are included in the episode definition proposed in this final rule (as discussed in section X.C.2.d.(2). and (3). of this final rule). Because we based the episode definition on exclusions, identified by MS–DRGs for readmissions and ICD–10–CM diagnosis codes for Part B services as discussed in section X.C.2.d.(3)(c). of this final rule, and Medicare beneficiaries may typically receive a wide variety of related (and unrelated) services during episodes, there is some potential for CJR–X participants to inappropriately withhold or delay a variety of types of services until the episode concludes regardless of whether the service is included in the episode definition, especially for Part B services where diagnosis coding on claims may be less reliable. This inappropriate shifting could include both those services that are related to the episode (for which the CJR–X participant would bear financial responsibility as they would be included in the actual episode spending calculation) and those that are unrelated (which would not be included in the actual episode spending calculation), because a CJR–X participant engaged in shifting of medically necessary services outside the episode for potential financial benefit may be unlikely to clearly distinguish whether the services were related to the episode or not.

This calculation would include prorated payments for services that extend beyond the episode as discussed in section X.C.2.f.(3)(c). of this final rule. Specifically, we would identify whether the average 30-day post-episode spending for a CJR–X participant in any given performance year is greater than three standard deviations above the regional average 30-day post-episode spending, based on the 30-day post-episode spending for episodes attributed to all CJR–X participants in the same region. Similar to the CJR Model, post-episode spending would be adjusted for geographic wage factors to express spending in ''real'' or unstandardized amounts. We proposed that if the CJR–X participant's average post-episode spending exceeds this threshold, the CJR–X participant would repay Medicare for the amount that exceeds such threshold. Consistent with the CJR Model, this amount would not be subject to the proposed stop-loss limits discussed in section X.C.2.f.5.(g). of this final rule.

We sought comment on our proposal at § 512.650(c)(7) to make CJR–X participants responsible for making repayments to Medicare based on high spending in the 30 days after the end of the episode and for our proposed methodology to calculate the threshold for high post-episode spend. The following is a summary of the public comments received.

Comment: A few commenters stated that they agreed with the intent of the post-episode spending policy to ensure that services are not withheld or delayed until after an episode ends, but they requested that CMS apply the same stop-loss limits used for 90-day episode reconciliation to post-episode spending recoupments. A commenter stated their concern that the policy creates unlimited financial liability without stop-loss protection. Another commenter stated their concern that certain complex cases requiring substantial post-acute care may exceed the proposed threshold, resulting in penalties for care that is clinically appropriate. A commenter referred to the finding in the evaluation contractor's report on safety net hospital experiences in CJR that safety net hospitals faced post-episode spending recoupments at twice the rate of non-safety net hospitals during the CJR Extension. The commenter stated their belief that the disparate impact on safety net hospitals reflects the underlying difficulty hospitals have controlling spending that occurs after the 90-day episode window. In addition to applying stop-loss limits, the commenter also requested that CMS provide operational guidance on how to identify and manage post-episode spending risks before recoupment occurs.

Response: We appreciate commenters' concerns about post-episode spending recoupment and their recommendation to apply stop-loss limits. We acknowledge their concern that CJR–X participants should have predictable limits on financial exposure under the model. However, we do not believe it would be appropriate to apply the episode stop-loss limits to the separate 30-day post-episode spending amount in most cases. The post-episode spending policy serves a different purpose than the stop-loss limit applied to reconciliation of the 90-day episode. Specifically, the post-episode spending calculation is intended to protect beneficiaries and the Medicare Trust Fund by discouraging participants from delaying medically necessary care until after the episode ends. We believe that applying the stop-loss limit to this separate repayment could weaken the policy's effectiveness as a safeguard against stinting on care, inappropriate service delays, or shifting of costs

outside the episode window. We believe the proposed threshold—based on average 30-day post-episode spending that exceeds three standard deviations above the regional average—appropriately limits repayment to unusually high post-episode spending, rather than ordinary variation in post-episode care use.

However, we agree that the potential disparate impact of post-episode spending recoupments on safety net hospitals is of particular concern. Although we proposed and are finalizing a number of changes to the CJR–X pricing and payment methodology to add protections for safety net hospitals, we did not propose to apply stop-loss protections to post-episode recoupments for any group of hospitals. We may consider the possibility of applying stop-loss protections to post-episode spending recoupments for safety net hospitals, and potentially other categories of hospitals such as rural, SCHs, and MDHs, in the future if we see that they are being disproportionately impacted by post-episode spending recoupments in CJR–X.

Regarding the request that CMS provide operational guidance on how to identify and manage post-episode spending risks before recoupment occurs, CMS intends to provide educational materials before the start of CJR–X to support participant readiness and refer participants to prior CJR materials and reports describing successful care transformation strategies, most notably the CJR Drivers of Care Transformation Report (*https://www.cms.gov/priorities/innovation/data-and-reports/2024/cjr-py6-ar-drivers-transformation*). CMS will also be providing monthly claims data feeds to help participants monitor utilization and spending patterns. We believe that participants remain best positioned to determine how to use available CMS data, internal clinical and operational data, care management processes, and relationships with post-acute care providers to monitor beneficiaries and manage episode performance. Approaches used to manage risk during the episode may also help participants identify potential post-episode risks, such as readmissions, post-acute care use, complications, and follow-up needs. CMS will consider whether additional participant education or technical assistance would be useful, while maintaining CJR–X requirements related to beneficiary protections, freedom of choice, privacy, and access to medically necessary care.

After consideration of the public comments we received, we are finalizing without modification our proposal at § 512.650(c)(7) to make CJR–X participants responsible for making repayments to Medicare based on high spending in the 30 days after the end of the episode and our proposed methodology to calculate the threshold for high post-episode spend.

(i) Reconciliation Payments and Repayments

Consistent with the CJR Model, we proposed that after subtracting a CJR–X participant's post-episode spending amount from their NPRA as applicable, as described previously in this section, if the resulting amount is positive, the CJR–X participant for the applicable performance year would receive the amount as a one-time lump sum reconciliation payment from Medicare. If the amount is negative, Medicare would hold the CJR–X participant for the applicable performance year responsible for a one-time lump sum repayment. CMS would collect the one-time lump sum repayment in a manner that is consistent with all relevant federal debt collection laws and regulations.

We sought comment on our proposal at § 512.650(d) to make reconciliation payments to, and collect repayment amounts from CJR–X participants as a one-time, lump sum payment.

Comment: A commenter recommended an alternative method to determining a reconciliation payment or repayment and suggested that CMS implement a risk corridor and only spending outside the corridor would result in reconciliation payment or repayment amount.

Response: We thank the commenter for their recommendation. We recognize the commenter's concern that hospitals operating on tight budgets may experience financial disruption from relatively small reconciliation amounts and that, for hospitals with average episode spending close to the target price, year-to-year variation may not reflect meaningful differences in performance. Given this deviates from the design of the CJR model and what we have proposed for CJR–X, we do not believe it would be possible to implement such a policy without assessing its merits. As discussed in the proposed rule, the CJR–X payment methodology is designed around comparing episode spending to target prices, subject to quality performance and other payment methodology rules, and the proposed model expansion relies on evaluation findings and actuarial certification that expansion is expected to reduce Medicare spending while maintaining quality. Accordingly, while we acknowledge there may be potential value of a risk corridor as a way to address random variation and reduce administrative burden, we would need to analyze its effects on model incentives and projected Medicare spending.

After consideration of the public comments we received, we are finalizing without modification our proposal at § 512.650(d) to make reconciliation payments to, and collect repayment amounts from, CJR–X participants as a one-time, lump sum payment.

g. Appeals Process

(1) Notice of Calculation Error and Reconsideration Request

We believe that it is necessary to have a process by which CJR–X participants may appeal the reconciliation report. Therefore, we proposed at § 512.660(a) to permit CJR–X participants to submit a notice of calculation error regarding the calculations contained within the CJR–X reconciliation report if the CJR–X participant believes an error occurred in calculations due to data quality or other issues, or if the CJR–X participant believes an error occurred in calculations due to misapplication of methodology. We note that the CJR–X participant would still be subject to the same limitations on review as stipulated at § 512.170. We also proposed at § 512.660(b)(1) that if a CJR–X participant believes the CJR–X reconciliation report contains a calculation error, then the CJR–X participant would be required to submit a timely error notice in writing documenting the suspected calculation error within 30 calendar days of issuance of the CJR–X performance report. We also proposed that CMS may specify different requirements for the form, manner, or deadline for submission of the error notice. If the CJR–X participant does not provide such timely error notice in accordance with the timelines and processes specified by CMS, then we proposed at § 512.660(b)(2) that the CJR–X reconciliation report would be deemed final and the CJR–X participant would be precluded from later contesting those elements of the CJR–X reconciliation report for that performance year. Additionally, we proposed that only a CJR–X participant may submit a timely error notice according to the provisions at proposed § 512.660(b)(3).

The proposed 30-day window to review and appeal CMS calculations aligns with the length of time we have finalized for submitting appeals in other mandatory Innovation Center models,

such as TEAM, the Ambulatory Specialty Model, and the Increasing Organ Transplant Access Model.

We proposed at § 512.660(c) that if CMS receives a timely notice of a calculation error, we would issue an initial determination in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct. We note that CMS would reserve the right to an extension of the time for providing its initial determination upon written notice to the CJR–X participant.

If a CJR–X participant disagrees with and wishes to dispute the results of the initial determination, under § 512.660(d), the CJR–X participant or CMS may request a reconsideration of the initial determination by following the reconsideration review process described in the standard provisions at § 512.190.

We sought comment on our proposed appeals process for CJR–X at § 512.660.

We received no comments on this proposal and therefore are finalizing this provision without modification.

h. Concurrent Participation in Other CMS Models and Initiatives

(1) Background

We stated in the proposed rule that when determining the best strategy for addressing concurrent participation in multiple CMS models or initiatives, we recognize we need to consider how to promote meaningful collaboration between providers and CJR–X participants as the model expands. Historically, the overlap policies of Innovation Center models, including the original CJR (80 FR 73274), were intended to avoid duplicative incentive payments or giving precedence to a single accountable entity. However, what resulted were confusing methodologies or misaligned incentives which were difficult to navigate. Participants from prior models have also cited confusion with identifying all of the model(s) to which a beneficiary may be aligned or attributed.

We noted in the proposed rule that earlier episode-based payment models, such as the original CJR Model (80 FR 73274) in certain circumstances, and BPCI, are examples of this well-meaning but potentially confusing overlap policy. In these models, CMS addressed overlap by implementing a complex calculation and recouping a portion of the pricing discount for providers also participating in certain ACO initiatives. The recoupment was intended to prevent duplicate incentive payments for the same beneficiary's care; however, some participants perceived the resulting recoupment as a financial loss, discouraging providers from participating in both initiatives. We believed it was important to learn from previous episode-based payment model policies, as discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69786), so that CJR–X can implement a sustainable long-term policy to account for interactions with other CMS models and initiatives.

(2) Beneficiary Participation in Multiple CMS Models or Initiatives

We proposed that a beneficiary could be in an episode in CJR–X, as described in section X.C.2.d. of this final rule, by undergoing a procedure at an acute care hospital participating in CJR–X, and be attributed to a provider participating in a total cost of care or shared savings model or program. For example, a beneficiary may be attributed to a provider participating in the Shared Savings Program for an entire performance year, as well as having initiated an episode in CJR–X during the ACO's performance year. We indicated in the proposed rule that each model or program incorporates a reconciliation process, where total included spending during the performance period or episode are calculated, as well as any potential savings achieved by the model or program. We proposed to allow any savings generated on an episode in CJR–X and any contribution to savings in the total cost of care model be retained by each respective participant. We indicated that this would mean the episode spending in CJR–X would be accounted for in the total cost of care model's total expenditures, but CJR–X's reconciliation payment amount or repayment amount would not be included in the total cost of care model's total expenditures. Likewise, the total cost of care model's savings payments or losses would not be included in the episode spending in CJR–X.

We noted in the proposed rule that this approach deviates slightly from the latter years of the CJR Model, where concurrent participation in total cost of care models was permitted, except for the ENHANCED track of the Medicare Shared Savings Program because the ENHANCED track offered greater financial accountability as compared to the BASIC track or predecessor tracks. As we discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69787), by allowing a beneficiary aligned to a total cost of care model participant, such as the Medicare Shared Savings Program or other ACO initiatives, to also initiate a CJR–X episode, we would be eliminating complexities experienced in prior models where it was difficult for participants to know when a beneficiary would trigger an episode and when the episode would be excluded. Furthermore, we noted that this would match the procedure used in newer models such as TEAM, increasing policy design similarity between models. We indicated in the proposed rule that we hope that this uniform decision will increase simplicity. We also believed that allowing concurrent participation for beneficiaries aligned to a total cost of care model who also initiate an episode in CJR–X and allowing both participants to retain savings will have a positive impact on beneficiaries by fostering a cooperative relationship between accountable care and CJR–X participants where all parties have interest in providing coordinated, longitudinal care.

In addition, we stated in the proposed rule that there are other potential benefits to allowing overlap between a beneficiary who is aligned to a total cost of care model and who initiates an episode in CJR–X, such as strengthening the volume of episodes a CJR–X participant is responsible for. We indicated that we know from prior experience that low episode volume creates challenges for participants to generate meaningful savings and manage outlier cases with unusually high episode expenditures. We stated in the proposed rule that allowing CJR–X episodes to trigger despite the beneficiary being aligned to a total cost of care model will increase CJR–X episode volume to mitigate these low volume challenges.

We also acknowledged in the proposed rule that certain ACOs may prefer that their aligned beneficiary population not be included in CJR–X. We stated that since ACOs are accountable for total cost of care, they may prefer to manage their beneficiaries and have full control over all expenditures and beneficiary care instead of sharing that responsibility with a CJR–X participant. However, we believed the benefits of episode-based payment models in combination with ACO models will ultimately improve Medicare beneficiary care, and episode-based payment models will not be disruptive to ACO practices.

However, we proposed that CJR–X would not allow for concurrent participation with TEAM. We discuss in section X.C.2.b.(2)(i). of this final rule not to allow TEAM participants to be CJR–X participants because TEAM and CJR–X both test bundled payments for LEJRs and are running concurrently. If an LEJR episode occurs at an acute care hospital participating in TEAM, we

discussed in section X.C.2.b.(i). of this final rule, that TEAM participants would be excluded from CJR–X participation which means that TEAM supersedes the CJR–X Model and those LEJR procedures will trigger a TEAM episode rather than a CJR–X episode. Further, we proposed at § 512.630(e) that if a beneficiary in a TEAM episode has a LEJR procedure performed at a CJR–X hospital during TEAM's 30-day post-discharge period, then the LEJR procedure will not initiate a CJR–X LEJR episode and the spending from the LEJR procedure will be included in the TEAM episode. We noted in the proposed rule that while this instance would result in the CJR–X participant not being attributed the episode, the episode that would have been triggered in CJR–X in the absence of the overlapping TEAM episode would still remain in the national set of episodes used in the calculation of various CJR–X target price components. We indicated that this is because the national set of LEJR episodes in CJR–X includes all MS–DRG/HCPCS region combinations and therefore all LEJR episodes would need to be retained in the national set. As stated in the proposed rule, we anticipate this occurrence to be rare given TEAM's shorter post-discharge period and the reduced likelihood that a beneficiary would have another procedure performed within such a short time period if not clinically appropriate. Additionally, in section X.A.2.a.(3). of this final rule, we proposed that if a beneficiary in a CJR–X episode has a procedure performed at a TEAM hospital that would initiate a TEAM episode during the CJR–X 90-day post-discharge period, then that procedure would not initiate a TEAM episode and the spending from that procedure would be included in the CJR–X episode. We considered in the proposed rule giving TEAM precedence in this situation and dropping the CJR–X episode to initiate a TEAM episode to support episode volume in TEAM, but we believed it was important to hold the anchoring provider of the initial procedure accountable for spending and care coordination, especially given the investments that hospitals employ to manage a beneficiary's care. We believed this policy would avoid duplicative calculations for the same procedure in a model that is similar in overall design. We also considered in the proposed rule allowing a CJR–X and a non-LEJR TEAM episode to run concurrently. For example, if a beneficiary in a CJR–X episode has a procedure performed at a TEAM hospital during the CJR–X 90-day post-discharge period, then that procedure would initiate a TEAM episode. While we believed this situation would be very rare, we were concerned there could be double payment of savings and may make it difficult to determine which model and hospital were the driver to any realized savings or losses. We were also concerned this situation could make it challenging for the beneficiary to have two accountable episode-based entities potentially providing different guidance on who is managing their care.

We acknowledged in the proposed rule that there may be new models or programs that could have overlap with CJR–X. We stated this could occur because a beneficiary may trigger an episode in CJR–X while being aligned to a new CMS model or program or because a CJR–X participant also participates in another CMS model or program. We indicated that we would plan to assess each new model to determine if the structure of payment and savings calculation would need any additional overlap requirements to account for the new model and would propose a policy in future notice and comment rulemaking, as necessary.

The following is a summary of the public comments received on our proposal to allow concurrent participation in total cost of care models but not allow overlap in TEAM, and our responses to these comments:

Comment: A few commenters supported the CJR–X overlap policy with other models, and with the approach to not allow overlap with TEAM.

Response: We thank the commenters for their support.

Comment: A commenter indicated that CJR–X does not have a primary care referral requirement like TEAM and should consider adopting safeguards to ensure that patients who are already aligned to a provider be ''tucked back in'' to that provider.

Response: We appreciate the commenter's recommendation that CJR–X include additional safeguards to help ensure that beneficiaries who are already aligned with a primary care provider or accountable care relationship are returned to that provider following the LEJR episode.

We acknowledge that CJR–X does not include a primary care referral requirement like the policy included in TEAM. We agree that effective transitions back to a beneficiary's longitudinal care providers, including primary care providers and ACO-affiliated clinicians where applicable, can support continuity of care, reduce fragmentation, and help align episode-based care with broader population health management. We do not believe it is necessary to add a primary care referral requirement to CJR–X at this time given this policy was not included in the CJR Model. However, we will assess TEAM's primary care referral policy as TEAM is implemented, including whether the policy strengthens beneficiary connections to longitudinal care providers or creates unanticipated burden. Based on the data and experience from TEAM and other relevant model monitoring, we may consider whether a similar policy would be appropriate for future rulemaking.

Comment: Many commenters requested clearer and more aligned model overlap rules particularly between CJR–X and TEAM. Some commenters indicated that participation across multiple concurrent models may create operational complexity, duplicative reporting requirements, and the potential for misaligned financial incentives,—particularly for health systems with hospitals participating in different models, such as CJR–X and TEAM. A few commenters supported the alignment of policies shared between CJR–X and TEAM. Several commenters noted that many providers participate in multiple payment models and the varying flexibilities across these models, coupled with the complexity of understanding and tracking their distinctions, may discourage providers from utilizing those flexibilities. A commenter requested CMS provide guidance relative to attribution dispute resolution in connection with CJR–X and reconciliation. Another commenter stated that CMS should align key design elements between CJR–X and TEAM where appropriate to reduce operational burden and facilitate private sector adoption.

Response: We agree that clear overlap rules are important for participant operations and model integrity. For that reason, we proposed specific rules governing how CJR–X interacts with other models, including TEAM. Because CJR–X and TEAM both involve lower extremity joint replacement episodes and test episode-based accountability for similar services, we believe it is important to avoid concurrent participation in both models for the same hospital in a way that could create duplicative episode accountability, overlapping financial incentives, or confusion about which model's payment and quality rules apply. For example, a beneficiary in a CJR–X episode may not initiate a TEAM episode during the CJR–X 90-day post-discharge period. Likewise, a beneficiary in a TEAM episode may not

initiate a CJR–X episode during the TEAM 30-day post-discharge period.

At the same time, we recognize that many providers participate in multiple value-based care initiatives, and we support alignment where feasible. This is why between CJR–X and TEAM we tried to align policies so reduce confusion, especially for health systems that have hospitals that participate in both models. For example, both CJR–X and TEAM rely on existing CMS quality reporting programs to collect quality measure performance rather than have hospitals separately report their measures for each model. Additionally, the CJR–X and TEAM target price methodologies are broadly similar and also follow a similar reconciliation process and timeline. We understand there are also some key differences, namely episode length and how quality performance is assessed, that make each model distinct. There also may be differences in care redesign flexibilities, such as differences between the Medicare payment policies waivers available to each participant. To help participants of each model and the public understand the differences, we anticipate creating resources that will have highlight the similarities and differences between the models. We anticipate these resources could help health systems identify efficiencies that could be employed across their hospitals, agnostic of the specific model participation. We will also be creating public-facing specification documents, in particular, episode and reconciliation specifications, that will address how episodes are constructed, attributed and reconciled to avoid overlap with TEAM. We also anticipate including variables in the monthly data shared with CJR–X participants that would identify whether a potential CJR–X beneficiary may be in a TEAM episode to reduce attribution confusion.

We also believe the CJR–X overlap policy supports private sector adoption by establishing simple, administrable rules for how episode-based payment can operate alongside other models or total-cost-of-care initiatives. Rather than creating complex exclusions or recoupment methodologies when a beneficiary is aligned to another accountable care model, the approach allows CJR–X and population-based models to operate concurrently, with each model applying its own payment methodology.

This approach may make episode-based payment models more attractive and easier to replicate because it reflects how many hospitals, ACOs, and health systems operate in practice: under multiple value-based payment arrangements at the same time. By reducing uncertainty about overlapping accountability and avoiding unnecessary disruption to existing model participation, CJR–X can help providers focus on care redesign, coordination, and episode management rather than on navigating conflicting model rules.

We will continue to consider ways to make overlap policies, beneficiary attribution rules, payment reconciliation rules, reporting expectations, and model flexibilities clear and administrable for participants. We will also monitor participant experience with CJR–X overlap rules and may consider future guidance or notice and comment rulemaking.

Comment: A few commenters requested guidance on how CJR–X collaborator and financial arrangement requirements compare and align with shared savings models, because they believed differences between CJR–X and shared savings models may constrain their ability to deploy consistent strategies across models. A commenter requested clarification on whether CMS will apply any reconciliation limits across models, in particular with the Medicare Shared Savings Program, and clarification on whether unified reporting or data support will be available. Another commenter requested that CMS provide detailed, actionable guidance as promptly as possible, specifically clarifying how CJR–X episodes will interact with the Long-term Enhanced ACO Design (LEAD) Model attribution and financial reconciliation.

Response: We believe the CJR–X overlap policy will support more administrable interaction between CJR–X and other models, including shared savings and total-cost-of-care arrangements, while preserving the distinct payment methodology, participation requirements, and evaluation integrity of each model. CJR–X is an episode-based payment model focused on lower extremity joint replacement episodes, while shared savings and total-cost-of-care models generally assess broader accountability for beneficiary spending and quality over time. For that reason, we believe it is appropriate for CJR–X to maintain model-specific collaborator, gainsharing, beneficiary incentive, reconciliation, and compliance requirements, even as CMS seeks to reduce unnecessary complexity where feasible. We note that CJR–X includes certain requirements for CJR–X participants to include in their financial arrangements but there is no requirement to use a CJR–X specific financial arrangements template when setting up sharing arrangements with CJR–X collaborators. There are no CJR–X requirements that preclude the CJR–X participant from creating financial arrangement template that satisfies both models as long as the template meets all the financial arrangements requirements, as discussed in section X.C.2.i of this final rule. We believe giving the CJR–X participant the flexibility to set up the structure of the financial arrangement may help create operational efficiency if participating in multiple models.

With respect to reconciliation across models, we are not imposing any reconciliation limits, other than the stop-gain and stop-loss limits for CJR–X participants, as described in section X.C.2.f of this final rule. For models that overlap with CJR–X, all included Medicare Parts A and B spending, as discussed in section X.C.2.d.(3)(b) of this final rule, will be included in CJR–X reconciliation but model performance payments will not be included. For example, if a CJR–X beneficiary is also assigned to the Medicare Shared Savings Program, then all the included Medicare Parts A and B spending during the episode will be included in CJR–X, regardless of whether the spending was a result of the CJR–X participant or a provider in the Medicare Shared Savings Program. The CJR–X reconciliation will not include any shared savings or losses that occurred from the Shared Savings Program. A similar process would be used for CJR–X beneficiaries that are aligned with the LEAD model. In that CJR–X would include all included Medicare Parts A & B spending but would not include any payments resulting from a LEAD ACO's shared savings or losses. Likewise, due to timing of when CJR–X performs reconciliation, a CJR–X participant's reconciliation payments or repayment amounts would not be included in the Medicare Shared Savings Program's or LEAD performance year spending calculations. We believe this approach is more transparent and administrable than complex across-model recoupment methodologies, while still allowing CMS to monitor for unintended financial effects and interactions that could affect model integrity.

We also appreciate the request for unified reporting, data support, and detailed operational guidance. We will also be creating public-facing specification documents, in particular, episode and reconciliation specifications, that will address how episodes are constructed, attributed and reconciled. We also anticipate including variables in the monthly data shared

with CJR–X participants that would identify whether a potential CJR–X beneficiary may also be aligned to a shared savings model. We will consider other opportunities to provide greater insight into beneficiary overlap that will support collaboration between CJR–X participants and participants in other models.

Comment: A commenter requested that CMS explicitly address in the final rule how CJR–X episode reconciliation payments and repayments amounts will be treated within ACO REACH's total cost of care calculations. Another commenter stated excluding CJR–X episodes from the ACO REACH total cost of care denominator for aligned ACO participants, or establish a symmetric offset mechanism that prevents dual penalization for the same spending event.

Response: The ACO REACH Model is scheduled to end on December 31, 2026 while the CJR–X Model is scheduled to begin on January 1, 2028. Given there is no overlap between ACO REACH and CJR–X, CJR–X's reconciliation payments and repayment amounts will not affect ACO REACH's total cost of care calculations.

Comment: Many commenters expressed concern about the cumulative impact of overlapping Medicare value-based care initiatives. Commenters stated that simultaneous mandatory models, including TEAM and CJR–X, could create significant operational and clinical confusion, require parallel clinical workflows, and create substantial operational, administrative, and financial burden for hospitals. Some commenters recommended CMS to avoid requiring national, integrated health systems to simultaneously operate multiple episode-based models. A commenter indicated that the operational complexity is compounded for hospitals operating in regions where TEAM is also being implemented.

Response: We thank the commenters for raising concerns about the cumulative impact of overlapping Medicare value-based care initiatives, but we disagree that simultaneous participation in these models is creating compounded administrative, clinical, and financial burden for hospitals, particularly for national or integrated health systems with hospitals participating in different models. Nor do we believe that health systems with hospitals participating in multiple CMS models or initiatives should be exempt from CJR–X participation solely on that basis. Many hospitals and health systems already operate in multiple value-based payment arrangements.

We believe these concerns are mitigated in part because CJR–X and TEAM share many operational and clinical similarities. Both models involve episode-based accountability for lower extremity joint replacement episodes, and the anchor hospitalization or anchor procedure period is generally the same. As a result, health systems with hospitals participating in both models should be able to identify clinical efficiencies that can be used for both models during the anchor hospitalization or anchor procedure phase of care, including patient identification, discharge planning, care coordination, beneficiary engagement, and post-acute care planning. The principal differences between the models relate to the applicable model rules and the time periods after the beneficiary is discharged or the procedure is completed, rather than requiring entirely separate clinical approaches during the anchor hospitalization or anchor procedure period.

We also believe that health systems currently participating in TEAM may be able to leverage the infrastructure they have already developed and replicate many of the same operational processes for their CJR–X hospitals. For example, systems may be able to use similar workflows for episode tracking, care redesign, provider education, beneficiary communication, post-acute coordination, internal monitoring, and compliance oversight. Because CJR–X and TEAM share many features common to episode-based payment models, we do not believe administrative burden should necessarily be compounded in direct proportion to the number of participating hospitals. Rather, many processes may be interchangeable or adaptable across both models.

At the same time, we acknowledge that operating across multiple models requires careful attention to model-specific rules, episode timeframes, payment methodologies, quality requirements, and participant obligations. We will continue to monitor operational experience for hospitals participating in CJR–X, TEAM, and other value-based care initiatives. We may consider this further in future rulemaking.

Comment: Some commenters stated that hospitals already participating in shared savings models or other APMs may already assume substantial accountability for the total cost and quality of care and that concurrent CJR–X participation could create overlapping financial accountability structures, duplicative reporting burdens, conflicting incentives, or require significant staffing and resources. Some commenters recommended extending an exception, like what is offered to TEAM participants, to other APM participants. Other commenters recommended excluding ACO-attributed beneficiaries or allowing voluntary opt-in for hospitals also participating in ACO models.

Response: We appreciate commenters' concerns about potential overlap between CJR–X and other shared savings, accountable care, or alternative payment models. However, we disagree that hospitals participating in ACOs, shared savings models, or other APMs should be categorically excluded from CJR–X, that ACO-attributed beneficiaries should be excluded from CJR–X episodes, or that such hospitals should participate only through a voluntary opt-in. CJR–X is a nationwide expansion of the CJR Model, for which the model has met the statutory criteria for expansion, including certification from the CMS Chief Actuary that nationwide expansion would not result in any increase in net program spending. Excluding broad categories of APM-participating hospitals or ACO-attributed beneficiaries would reduce the reach of the expanded model and would be inconsistent with CMS' desire to hold all eligible acute care hospitals accountable for LEJR episodes nationwide, subject only to the specific exceptions.

We recognize that overlap policies in prior episode-based models created operational complexity, including confusion about when a beneficiary would trigger an episode and whether a payment recoupment would apply. For that reason, we believe the CJR–X overlap policy is a more sustainable overlap approach for CJR–X as LEJR episodes become standard practice across hospitals. Episode spending would be accounted for in the total cost of care model's expenditures, but CJR–X reconciliation payments or repayment amounts would not be included in the total cost of care model's expenditures, and total cost of care model savings or losses would not be included in CJR–X episode spending. We believe this approach reduces the complexity of prior exclusion or recoupment policies while preserving clear accountability under each model.

We also disagree that the TEAM exclusion should be extended to all APM participants. The TEAM exception is based on specific model-design concerns that are unique to TEAM given both models test LEJR episodes. Excluding TEAM participants allows for comparison of the effects of 30-day and

90-day LEJR episodes and avoids subjecting the same hospital to TEAM rules for some TEAM episodes and CJR–X rules for LEJR episodes. Those same concerns do not apply in the same manner to ACOs or other shared savings models, which use a broader total cost of care framework rather than a separate LEJR episode payment methodology.

We further believe that excluding ACO-attributed beneficiaries would undermine CJR–X's care coordination goals. CJR–X is designed to hold the hospital accountable for the LEJR episode because the hospital furnishes the anchor procedure, manages discharge planning, and is well positioned to coordinate care during the 90-day post-discharge period. We also believe that allowing overlap between CJR–X and ACO models creates important synergies rather than conflicting incentives. CJR–X focuses accountability on the acute procedural event, discharge planning, post-acute care, and recovery during the 90-day LEJR episode. ACOs, by contrast, focus on broader population health, longitudinal care management, and total cost of care across a beneficiary's care experience. Allowing both models to operate concurrently, while allowing each model to retain the savings it generates, encourages hospitals, physicians, post-acute care providers, and ACOs to collaborate around shared goals: reducing avoidable spending, improving care coordination, and maintaining or improving quality. For example, a CJR–X participant may choose to partner with an ACO to share care coordination infrastructure, such as care navigators, discharge planning support, or beneficiary follow-up processes. These kinds of arrangements could help reduce duplicative efforts, align communication across providers, and allow each model participant to focus on its comparative role: episode providers on the discrete surgical episode and ACO providers on broader population-level and longitudinal care needs.

Accordingly, we do not agree that a broader APM exception, ACO-attributed beneficiary exclusion, or voluntary opt-in for ACO-participating hospitals would better serve the goals of CJR–X. We believe the overlap policy better balances model simplicity, beneficiary access to coordinated episode care, accountability for LEJR episode spending and quality, and alignment with broader value-based care initiatives.

Comment: A couple of commenters requested CMS to consider removing CJR–X episodes from the Hospital Value-Based Purchasing (HVPB) Program's Medicare Spending Per Beneficiary (MSPB) measure. A commenter believed the implementation of CJR–X has the potential to be a double penalty when combined with HVBP MSPB measure.

Response: We appreciate the commenter's concern regarding CJR–X participation and the HVBP Program's MSBP measure. However, we disagree that CJR–X hospitals should be excluded from the HVBP Program or that CJR–X procedures should be removed from the MSPB measure used in the HVBP Program.

CJR–X and the HVBP Program serve related but distinct purposes. CJR–X is an episode-based payment model focused on improving care coordination, quality, and spending for LEJR episodes that begin with an anchor hospitalization or anchor procedure and continue through the 90-day post-discharge period. The HVBP Program, including the MSPB measure, is a broader hospital quality and efficiency program that evaluates hospital performance under its own statutory and programmatic framework. Removing CJR–X procedures from the MSPB measure would create a special carve-out for one category of hospital care that remains clinically and financially relevant to hospital efficiency and quality performance.

We also do not believe that the interaction between CJR–X and the MSPB measure constitutes an inappropriate double penalty. The fact that the same care episode may be relevant to more than one Medicare payment or quality program does not, by itself, mean that the programs are duplicative or unfair. Hospitals are already accountable across multiple Medicare programs for different dimensions of care, including quality, efficiency, patient outcomes, and episode spending. CJR–X would provide a model-specific reconciliation methodology for LEJR episodes, while the Hospital VBP Program's MSPB measure would continue to assess hospital resource use under the Hospital VBP framework. These are separate methodologies with separate purposes, not duplicate penalties for the same calculation.

We also believe that excluding CJR–X procedures from the MSPB measure could weaken the alignment between CJR–X and broader Medicare value-based purchasing goals. LEJR episodes are high-volume, high-cost procedures with meaningful opportunities to improve discharge planning, post-acute care use, readmissions, complications, and care transitions. These are the same types of efficiency and quality concerns that Medicare value-based purchasing policies are intended to encourage hospitals to address. Removing CJR–X procedures from the MSPB measure could reduce incentives for hospitals to broadly improve efficiency for a clinically important service line. We anticipate that CJR–X will spur hospital improvements, such as increase coordination of care and improve quality, and those improvements may also support hospitals' performance under other Medicare quality and value-based purchasing programs. For example, a hospital that reduces avoidable readmissions, improves discharge planning, and supports clinically appropriate post-acute care during CJR–X episodes may also improve the efficiency of care captured under broader hospital performance measures. We continue to believe that maintaining alignment across CMS programs and initiatives supports a consistent Medicare policy objective: encouraging hospitals to deliver high-quality, coordinated, and efficient care.

Comment: MedPAC indicated that it will be important for the agency to monitor the financial effects of the model's overlap policy, which would result in two different Advanced APMs (CJR–X plus some other Advanced APM, such as an ACO model) holding two sets of providers accountable for spending for a single beneficiary during a single, shared period of time (that is, a 90-day episode in CJR–X, which could also end up being included in the 12-month performance period of another A–APM). They noted in their June 2022 report that when implementing new model overlap policies, performance payments for providers should not be so large that they increase total Medicare spending. If the CJR–X overlap policy results in net increases in Medicare spending, CMS should consider changing the policy.

Response: We thank MedPAC for their recommendation. We agree that monitoring model overlap is important to ensure that concurrent participation supports care coordination and value-based care goals without increasing total Medicare spending. We do not believe overlap between CJR–X and another Advanced APM warrants excluding overlapping beneficiaries or changing the overlap policy at this time. We do not currently have an indication that allowing model overlap for the same beneficiary during the same period of time would result in material losses to Medicare.

We also note that ACOs and CJR–X participants are accountable for different, complementary aspects of care. ACOs retain broader accountability

for population health, longitudinal care management, and upstream clinical decision-making, including care management and referral patterns that may affect whether surgery is recommended as the appropriate course of treatment. CJR–X, by contrast, focuses on the acute procedural episode and the 90-day post-discharge recovery period after the episode is triggered. Maintaining overlap therefore preserves accountability for both the upstream population-based incentives addressed by ACO models and the episode-based care coordination incentives addressed by CJR–X.

At the same time, we recognize MedPAC's concern that performance payments across overlapping models should not be so large that they increase total Medicare spending. We will monitor the financial effects of the CJR–X overlap policy, including whether overlapping model participation results in unexpected increases in Medicare spending or payment interactions that are inconsistent with the goals of CJR–X.

Comment: A commenter requested for CMS to ensure that hospitals will have data available to them that will identify patients who are excluded from initiating TEAM or CJR–X episodes to ensure that this policy can be best understood and implemented by hospitals participating in both models.

Response: We appreciate the commenter's request that CMS make data available to hospitals to help them understand and operationalize the overlap policy between TEAM and CJR–X. We agree that clear and timely data will be important for hospitals that may be affected by a beneficiary that has received care from both a CJR–X and TEAM hospital. We anticipate including in the monthly data provided to hospitals a variable that identifies whether a beneficiary may be excluded from CJR–X due to overlap with TEAM. We believe providing this information will help CJR–X hospitals understand which beneficiaries or episodes are subject to the TEAM exclusion and support hospital implementation, internal tracking, care coordination, and reconciliation review. We will continue to consider whether additional guidance or data elements are needed to support accurate implementation of the CJR–X/TEAM overlap policy.

Comment: A commenter requested that when TEAM concludes CMS must provide a formal, dedicated transition period for hospitals to participate in CJR–X to allow organizations to safely adjust their operations to the distinct regulatory and structural differences between the two models.

Response: We agree that hospitals should have sufficient notice and operational clarity before transitioning from TEAM to CJR–X. It is our intent to include TEAM participants in CJR–X seamlessly after TEAM concludes, provided they meet the CJR–X participant definition, as defined at § 512.605. We do not believe a separate delay or holding period is necessary to accomplish that goal. Rather, we believe that a seamless transition would better support continuity in LEJR episode-based care redesign for hospitals already managing LEJR episodes under TEAM.

We recognize that TEAM and CJR–X are distinct models and that hospitals transitioning from TEAM to CJR–X will need to account for differences in model design, including differences in episode duration, payment methodology, quality requirements, beneficiary notification requirements, and other operational policies. We anticipate providing sufficient notice before TEAM hospitals begin participation in CJR–X and expect to provide guidance or develop resources to help hospitals understand key differences between TEAM and CJR–X. Such guidance or resources may highlight operational issues hospitals should consider as they prepare for CJR–X participation after TEAM concludes.

Comment: A commenter requested that CMS convene a stakeholder working group prior to the final rule to develop a durable policy framework for the interaction of episode-based and population-based payment programs.

Response: We appreciate the commenter's recommendation and we are committed to continued stakeholder engagement on model overlap policies. However, we are generally limited in our ability to convene a stakeholder working group for the purpose of developing or revising final CJR–X policies while the final rule is pending. The Administrative Procedure Act establishes the notice-and-comment process as the mechanism for public input on proposed rulemaking, and CMS must consider comments submitted through that process before issuing a final rule. For that reason, CMS is not convening a pre-final-rule stakeholder working group to develop CJR–X final rule policies outside the public comment process. We believe that notice and comment rulemaking is a valuable and important tool for engaging the public and receiving stakeholder feedback on proposed model policies. We considered comments submitted during this rulemaking cycle, including comments on model overlap, to inform final CJR–X policies. In addition, stakeholder feedback received through this rulemaking helps inform our consideration of future overlap policies between episode-based and population-based models.

Nevertheless, we value stakeholder input and remain committed to engaging stakeholders after publication of the final rule to support implementation and to better understand how overlap policies operate in practice. We believe that ongoing engagement can help ensure that policies governing overlap between episode-based and population-based models are meaningful, operationally clear, and responsive to participant experience. We will also use monitoring, evaluation, and operational experience to assess whether CJR–X overlap policies are functioning as intended.

After consideration of the public comments, we are finalizing without modification the policy at § 512.630(e) that if a beneficiary in a TEAM episode has a LEJR procedure performed at a CJR–X hospital during TEAM's 30-day post-discharge period, then the LEJR procedure will not initiate a CJR–X LEJR episode and the spending from the LEJR procedure will be included in the TEAM episode.

i. Financial Arrangements

(1) Background

We believe certain financial and beneficiary incentives could help a CJR–X participant reach their quality and efficiency goals under the model and benefit both beneficiaries and the Medicare Trust Fund by reducing hospital readmissions, complications, days in acute care, and mortality. We also believe there is value in offering flexibilities to CJR–X participants that could support their performance in CJR–X and enable them to meet beneficiaries' needs. The flexibilities outlined in this section include allowing CJR–X participants to share all or some of their reconciliation payment amount or repayment amount with non-model participants and offering beneficiary incentives to encourage engagement and adherence to recommended treatment throughout recovery.

(2) Overview of CJR–X Financial Arrangements

CJR–X participants may wish to enter into financial arrangements with certain providers and suppliers that support CJR–X activities to share their reconciliation payment amount or repayment amount resulting from participation in CJR–X. We believe that allowing such arrangements to align

financial incentives would support high-quality care, improve health outcomes, and reduce Medicare spending by improving beneficiary care transitions and reducing fragmentation following surgery. We expect that CJR–X participants would identify key providers and suppliers caring for beneficiaries in the surrounding communities with whom to establish partnerships to promote accountability for the quality, cost, and overall care for beneficiaries, including managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigning care processes for high quality and efficient service delivery; and carrying out other obligations or duties under CJR–X.

These providers and suppliers may invest substantial time and other resources in these activities, yet they would not be the direct recipients of any reconciliation payment amounts or responsible for repayment amounts to CMS, as they are not the risk bearing entity and do not directly participate in CJR–X. Therefore, we believe it is possible that a CJR–X participant who may receive a reconciliation payment amount or be responsible for a repayment amount to CMS, may want to enter into financial arrangements with other providers or suppliers to share this reconciliation payment amount or repayment amount with the CJR–X participant. As discussed in section X.C.2.i.(9) of this final rule, CMS has made the determination that the anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)) is available to protect certain remuneration in the form of the sharing arrangement's gainsharing payments and alignment payments and the distribution arrangement's distribution payments in compliance with the requirements established in this final rule and the conditions of the safe harbor for CMS-sponsored model arrangements established at 42 CFR 1001.952(ii).

CMS recognizes that CJR–X participants may seek to enter into relationships with organizations other than those described in the financial arrangements under the CJR–X regulations. For example, CJR–X participants may look to engage organizations that are not providers or suppliers to assist with data analysis, local provider and supplier engagement, care redesign planning and implementation, beneficiary outreach, care coordination and management, monitoring compliance with model terms and conditions, or other model-related activities.

(3) CJR–X Collaborators

As finalized, CJR–X is a two-sided financial risk model, and the CJR–X participant would bear sole financial risk for any repayment amount to CMS in the absence of financial arrangements. However, given the incentive to reduce episode spending to earn a reconciliation payment amount, as described in section X.C.2.f.(5) of this final rule, a CJR–X participant may want to engage in financial arrangements with providers and suppliers or participants in Medicare ACO initiatives who are making contributions to the CJR–X participant's performance in the model. Such arrangements would allow the CJR–X participant to share reconciliation payment amounts or repayment amounts with individuals and entities that have a role in the CJR–X participant's performance in the model. In this final rule, we use the term ''CJR–X collaborator'' to refer to these individuals and entities.

Because CJR–X participants would be accountable for spending and quality during the anchor hospitalization or anchor procedure and the 90-day post-discharge period, as described in section X.C.2.d.(3)(b) of this final rule, providers and suppliers other than the CJR–X participant may furnish services to the beneficiary during the model. As such, for purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)), we proposed at § 512.605 to define ''CJR–X collaborator'' as any of the following types of providers and suppliers that are Medicare-enrolled and eligible to participate in Medicare or entities that are participating in a Medicare ACO initiative, may be CJR–X collaborators:

- SNF.
- HHA.
- LTCH.
- IRF.
- Physician.
- Nonphysician practitioner.
- Therapist in a private practice.
- Comprehensive Outpatient Rehabilitation Facility (CORF).
- Provider or supplier of outpatient therapy services.
- Physician Group Practice (PGP).
- Hospital.
- Critical Access Hospital (CAH).
- Non-physician provider group practice (NPPGP).
- Therapy group practice (TGP).
- Medicare ACO.

We sought comment on the proposed definition of ''CJR–X collaborator'' and any additional Medicare-enrolled providers or suppliers that should be included in this definition. For example, we considered Rural Emergency Hospitals (REHs), rural clinics, and Federally Qualified Health Centers (FQHCs) because CJR–X would hold CJR–X participants accountable for cost and quality of care during a 90-day episode, including rural beneficiaries who may receive a LEJR procedure. We anticipate that rural beneficiaries would receive pre- and post-operative care locally through these sites, and allowing these providers to participate in financial arrangements would align incentives across all entities influencing episode outcomes and would encourage better care transitions and follow-up.

The following is a summary of the public comments received on this proposal and our responses.

Comment: Multiple commenters supported CMS' proposed definition of a CJR–X collaborator as a provider or supplier, or a participant in a Medicare ACO initiative, that contributes to a CJR–X participant's performance under the model. Commenters stated that the proposed definition appropriately recognizes the range of clinicians, provider organizations, and post-acute care entities that may contribute to care coordination, episode management, and hospital performance in CJR–X.

Commenters specifically appreciated CMS's proposal to include nonphysician practitioners, such as Certified Registered Nursing Assistants (CRNAs), and nonphysician provider group practices, including CRNA group practices, as eligible CJR–X collaborators. Commenters stated that including CRNAs and CRNA group practices would allow these clinicians and practices to participate more fully in CJR–X activities, enter into financial arrangements with participating hospitals, and engage in gainsharing payments permitted under the model.

Commenters also supported the inclusion of physician group practices (PGPs) as CJR–X collaborators. They stated that PGPs' participation would allow hospitals and physicians to enter into financial arrangements that support CJR–X activities and align incentives among clinicians involved in lower-extremity joint replacement episodes.

In addition, commenters supported CMS' inclusion of other provider and supplier types, such as skilled nursing facilities, home health agencies, and inpatient rehabilitation facilities. Commenters stated that these entities may contribute to a CJR–X participant's performance by supporting care transitions, post-acute care coordination, beneficiary recovery, and episode management.

A commenter also stated that including CRNAs and CRNA group

practices could expand opportunities to participate in a Qualifying Alternative Payment Model (APM). Overall, commenters viewed the proposed collaborator definition as appropriately broad and supportive of gainsharing, care coordination, and shared accountability under CJR–X.

Response: We thank the commenters for their support for the proposed definition of a CJR–X collaborator. CMS agrees that CJR–X participants may need to work with a range of providers, suppliers, and Medicare ACOs to support care coordination, care transitions, post-acute care management, physician alignment, and episode performance under the model. Under the CJR–X collaborator definition, a CJR–X collaborator may include the following Medicare-enrolled providers and suppliers eligible to participate in Medicare, as well as entities participating in a Medicare ACO initiative:

1. Skilled nursing facility;
2. Home health agency;
3. Long-term care hospital;
4. Inpatient rehabilitation facility;
5. Physician;
6. Nonphysician practitioner;
7. Therapist in private practice;
8. Comprehensive outpatient rehabilitation facility;
9. Provider or supplier of outpatient therapy services;
10. Physician group practice;
11. Hospital;
12. Critical access hospital;
13. Nonphysician provider group practice;
14. Therapy group practice; and
15. Medicare Accountable Care Organization.

We believe this definition appropriately includes the types of providers, suppliers, group practices, and Medicare ACO entities that may contribute to a CJR–X participant's performance under the model. These entities may support CJR–X activities, including managing and coordinating care, encouraging investment in infrastructure and redesigned care processes, supporting efficient service delivery, and fulfilling other obligations or duties under the model. We believe the finalized collaborator framework supports financial arrangements that align incentives among CJR–X participants and collaborators while maintaining model safeguards, documentation requirements, and compliance with applicable laws and regulations.

Comment: A commenter supported CMS' inclusion of Medicare ACOs in the CJR–X collaborator list and requested additional guidance on overlapping participation. The commenter specifically asked CMS to clarify whether and how the same physician group may participate both as a CJR–X collaborator and as a participating provider in a Medicare ACO.

Response: We appreciate the commenter's support for including Medicare ACOs in the proposed CJR–X collaborator definition. We recognize the potential for confusion when various Innovation Center models overlap, in this case, the CJR–X Model and the Medicare Share Savings Programs under which an ACO might be enrolled, as well as the financial arrangements available to providers and suppliers. This final rule allows CJR–X participants to enter into financial arrangements with providers, suppliers, and participants in Medicare ACO initiatives that contribute to the CJR–X participant's performance under the definition of CJR–X collaborators.

With respect to the commenter's request for clarification, we clarify that within the CJR–X financial arrangements structure, an ACO can be a CJR–X collaborator but cannot serve as a ''collaboration agent'' or ''downstream collaboration agent.'' The key distinction is that a collaboration agent is defined more narrowly as an individual or entity that is not a CJR–X collaborator and that is a PGP, NPPGP, or TGP member in a distribution arrangement with the same PGP, NPPGP, or TGP. A downstream collaboration agent is defined as an individual who is not a CJR–X collaborator or collaboration agent and who is a PGP, NPPGP, or TGP member in a downstream distribution arrangement.

Comment: Several commenters recommended that CMS expand the proposed definition of a CJR–X collaborator to include additional entities that could support episode management and beneficiary recovery. A commenter requested that CMS include implant manufacturers on the list of eligible collaborators so they can share both upside and downside risk for a CJR–X 90-day episode. Another commenter recommended that CMS expand the proposed definition of ''CJR–X collaborator'' to include providers that furnish functional support services, such as assistance with mobility and custodial care. That commenter stated that these services are important for safe recovery after lower-extremity joint replacement surgery and may help reduce avoidable institutional post-acute care use and overall episode spending in bundled payment models. A third commenter recommended that CMS expand the proposed definition of ''CJR–X collaborator'' to include Rural Emergency Hospitals, Federally Qualified Health Centers, and Rural Health Clinics.

Response: We thank the commenters for their recommendations to expand the types of entities allowed as CJR–X collaborators to include implant manufacturers, providers that furnish functional support services, and Rural Emergency Hospitals, Federally Qualified Health Centers, and Rural Health Clinics. We also note their suggestions to allow greater latitude for new financial arrangements.

We recognize that functional support for patients with limited mobility after surgery may help beneficiaries recover safely and reduce avoidable use of institutional post-acute care and episode spending.

We appreciate the commenter's recommendation to include Rural Emergency Hospitals, federally qualified health centers, and rural health clinics as additional types of organizations that may be CJR–X collaborators. We recognize that these organizations may support access, care coordination, and beneficiary recovery, particularly for beneficiaries in rural or underserved areas.

In future rulemaking, we may consider the commenter's recommendations when determining whether to include additional categories of Medicare-enrolled providers or suppliers in the CJR–X collaborator definition. Any expansion of the CJR–X collaborator definition would need to be consistent with the goals of supporting care coordination and financial alignment while maintaining beneficiary protections, program integrity safeguards, and clear accountability for CJR–X episode performance.

We are finalizing the definition of a CJR–X collaborator as proposed. The CJR–X Model will only allow providers or suppliers certified as Medicare providers or suppliers as defined in 42 CFR 512.605, to be a CJR–X collaborator.

(4) Sharing Arrangements

(a) General

Similar to the original CJR Model (42 CFR 510.500), we are finalizing that certain financial arrangements between a CJR–X participant and a CJR–X collaborator be termed ''sharing arrangements.'' For purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)), we proposed that a sharing arrangement would be to share reconciliation payment amounts or

repayment amounts. In this final rule, we define ''sharing arrangement'' as a financial arrangement between a CJR–X participant and a CJR–X collaborator for the sole purpose of making gainsharing payments or alignment payments under CJR–X. Where a payment from a CJR–X participant to a CJR–X collaborator is made pursuant to a sharing arrangement, we define it such that payment is known as a ''gainsharing payment,'' which is discussed in section X.C.2.i.(4)(c) of this final rule. Where a payment from a CJR–X collaborator to a CJR–X participant is made pursuant to a sharing arrangement, we define that payment as an ''alignment payment,'' which is discussed in section X.C.2.i.(4)(c) of this final rule. A CJR–X participant must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement. In this final rule, we establish that a sharing arrangement must comply with the provisions of section X.C.2.i.(4)(b) of this final rule and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements. In this rule, we are finalizing that the CJR–X participant and CJR–X collaborator must document this agreement in writing and, per monitoring and compliance guidelines (§ 512.670(b)), the written agreement must be made available to CMS upon request.

This final rule finalizes our proposal that the CJR–X participant must develop, maintain, and use a set of written policies for selecting individuals and entities to be CJR–X collaborators. Moreover, the selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between, or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, or any individual affiliated with a CJR–X participant, CJR–X collaborator, or collaboration agent. In addition to including quality of care in their selection criteria, CJR–X participants must also consider the selection of CJR–X collaborators based on criteria that include the anticipated contribution to the performance of the CJR–X participant in the model by the potential CJR–X collaborator to ensure that the selection of CJR–X collaborators takes into consideration the likelihood of their future performance.

Finally, we are finalizing that if a CJR–X participant enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the model. Requiring oversight of sharing arrangements to be included in the compliance program provides a safeguard for program integrity. We note that CMS will monitor CJR–X participants for compliance, as permitted under § 512.150, especially if we believe the requirement is not being met as indicated through monitoring activities such as documentation requests, interviews, and site visits.

We sought comment on the proposed ''sharing arrangement'' definition at § 512.605, the sharing arrangement proposals at § 512.670(a), and whether additional or different safeguards are needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

The following is a summary of the public comments received on this proposal and our responses to those comments.

Comment: Some commenters supported the proposed gainsharing and financial arrangement policies for CJR–X participants. Commenters stated that these policies would provide participant hospitals with additional tools to align incentives with physicians, physician group practices, post-acute care providers, and other care partners involved in lower-extremity joint replacement episodes. They viewed the gainsharing framework as an important mechanism for encouraging collaboration, care redesign, shared accountability, and coordinated episode management.

Commenters appreciated CMS' proposal to allow CJR–X participants to share all or part of reconciliation payments and repayment responsibility with eligible collaborators. Commenters noted that sharing both potential savings and losses could help align hospitals and downstream providers with quality, cost, and care coordination goals. A commenter stated that the gainsharing provisions could offer hospitals additional ways, beyond existing pay-for-performance programs such as the Medicare Shared Savings Program, to encourage physician groups and other partners to participate in collaborative arrangements. Commenters also supported CMS' proposed safeguards for these financial arrangements. Other commenters requested additional guidance regarding compliance of sharing arrangements with applicable fraud and abuse laws and sought clarification as to whether a CJR–X participant may charge a CJR–X collaborator a fee for inclusion on a preferred provider or supplier list.

Response: We thank the commenters for their support of the proposed framework and safeguards for CJR–X financial arrangements. We recognize we did not propose a policy that prohibits a CJR–X participant from charging a CJR–X collaborator a fee for inclusion on their preferred provider or supplier list. However, we may take this policy into consideration in future rulemaking.

We reiterate that CJR–X participants may not limit beneficiary freedom of choice. Beneficiaries retain the right to obtain care from any Medicare-participating provider or supplier, subject to applicable Medicare requirements. CJR–X participants may identify or recommend preferred providers or suppliers only in a manner consistent with applicable law and Medicare beneficiary protections.

Comment: Several commenters supported CMS' proposal to continue the original CJR Model's policy of no physician gainsharing cap. Commenters noted that the original CJR Model eliminated the 50 percent cap on gainsharing payments in later years and applauded CMS for continuing this policy under the new CJR–X Model. Commenters stated that maintaining flexibility in physician gainsharing would support meaningful physician engagement and allow hospitals to structure arrangements that reflect the contributions of physicians and other collaborators to model performance.

Response: We thank commenters for their support for the gainsharing and financial arrangement policies available under CJR–X. We agree that appropriately structured sharing arrangements can help align incentives among CJR–X participants, CJR–X collaborators, collaboration agents, and downstream collaboration agents to support care coordination, physician engagement, post-acute care management, quality improvement, and episode performance.

In this final rule, we are finalizing policies that allow CJR–X participants to enter into sharing arrangements with eligible CJR–X collaborators, as discussed in section X.C.2.i.(3) of this final rule, and to share reconciliation payment amounts through gainsharing payments, as well as to share repayment responsibility through alignment payments, as discussed in section X.C.2.i.(4)(c) of this final rule. We are also finalizing related distribution and downstream distribution arrangements, where applicable, to allow certain CJR–X collaborators to share gainsharing payments with eligible individuals or entities that contribute to CJR–X activities, as discussed in sections X.C.2.i.(5) and X.C.2.i.(6) of this final rule. We believe these arrangements provide important operational flexibility while maintaining safeguards to ensure

that payments are tied solely to quality of care and to activities that support CJR–X beneficiaries and model performance.

We note that CJR–X participants remain accountable for repayment amounts owed to CMS. To ensure that CJR–X participants retain meaningful financial responsibility under the model, we finalized limits on the amount of repayment responsibility that may be shifted to CJR–X collaborators. For a performance year, the aggregate amount of alignment payments a CJR–X participant receives from all CJR–X collaborators may not exceed 50 percent of the CJR–X participant's repayment amount. In addition, the aggregate amount of alignment payments from any CJR–X collaborator that is not a Medicare ACO may not exceed 25 percent of the CJR–X participant's repayment amount, while the aggregate amount from a CJR–X collaborator that is a Medicare ACO may not exceed 50 percent of the CJR–X participant's repayment amount.

To use the gainsharing framework, entities must comply with the CJR–X financial arrangement requirements. Among other requirements, the sharing arrangement must be documented in writing and must identify the purpose and scope of the arrangement, the parties and their obligations, the CJR–X activities to be performed, the financial or economic terms of the arrangement, and the methodology and accounting formula for determining gainsharing and alignment payments. The methodology for gainsharing payments must be based solely on quality of care and the provision of CJR–X activities.

We also finalized safeguards to protect beneficiaries and program integrity. Sharing arrangements may not induce the CJR–X participant, CJR–X collaborator, or their employees, contractors, or subcontractors to reduce or limit medically necessary services. The arrangement also may not restrict a collaborator's ability to make decisions in the best interests of CJR–X beneficiaries, including decisions regarding devices, supplies, and treatments.

CJR–X participants must maintain oversight and documentation of these arrangements. The board or other governing body of the CJR–X participant is responsible for overseeing the participant's model participation, arrangements with CJR–X collaborators, gainsharing and alignment payments, and the use of beneficiary incentives. CJR–X participants must also maintain accurate current and historical collaborator lists, document payments and recoupments, track internal cost savings, track reconciliation payments and repayment amounts, and retain and provide access to required records in accordance with CJR–X requirements and 42 CFR 1001.952(ii).

We have determined that the anti-kickback statute safe harbor for CMS-sponsored models at 42 CFR 1001.952(ii) is available to protect specified remuneration exchanged under CJR–X financial arrangements, including gainsharing payments, alignment payments, distribution payments, and downstream distribution payments, when the arrangements comply with the final CJR–X requirements, applicable model documentation, and all conditions of the safe harbor. Anyone engaging in CJR–X financial arrangements must continue to comply with all applicable laws and regulations, including applicable fraud and abuse laws.

We believe these policies balance commenters' interest in flexibility with the need for accountability, transparency, and beneficiary protections. The gainsharing framework enables CJR–X participants and collaborators to align incentives for quality and care coordination, while repayment caps, written agreement requirements, payment methodology rules, documentation obligations, and safe harbor conditions help ensure that financial arrangements remain tied to CJR–X activities and model goals.

Comment: Some commenters criticized CMS' proposed gainsharing and financial arrangement policies as insufficiently flexible, specific, or comprehensive to support effective collaboration among hospitals participating in the CJR–X Model and other providers and/or suppliers serving Original Medicare beneficiaries. Commenters generally agreed that gainsharing can be useful but stated that the proposed framework may not adequately align hospitals, physicians, post-acute care providers, and other entities that influence episode costs, quality, and beneficiary outcomes.

Some commenters stated that the proposed gainsharing mechanisms would not be strong enough to meaningfully influence independent physician referral patterns, post-acute care decisions, or care standardization across the full 90-day episode. These commenters recommended that CMS enhance the mechanisms hospitals may use to collaborate with independent physicians to support consistent care pathways, referral coordination, and shared accountability for episode performance.

Several commenters raised concerns about the clinical basis for gainsharing payments. They stated that gainsharing should advance patient outcomes, not merely reward the use of lower-cost products or services. They specifically urged CMS to prohibit gainsharing arrangements tied exclusively to the use of lower-cost or less clinically appropriate implantable medical devices. Commenters stated that such arrangements could undermine patient care and increase Medicare spending if they result in higher rates of revisions, reoperations, infections, complications, or other adverse outcomes. At the same time, commenters supported gainsharing arrangements that reward improvements in meaningful clinical outcomes, such as reduced readmissions, complications, infections, revisions, and avoidable spending.

Other commenters focused on post-acute care alignment. They stated that post-acute care providers play a critical role in determining CJR–X episode costs and quality outcomes because their management of beneficiaries' medical needs after discharge affects length of stay, readmissions, functional recovery, utilization patterns, and care coordination. Commenters expressed concern that hospitals would remain financially accountable for total episode performance even though key drivers of that performance may be controlled or influenced by post-acute care providers who do not share in downside risk. They stated that this could limit hospitals' ability to manage episode variation and constrain care redesign efforts. Commenters recommended that CMS consider expanded collaboration models, shared accountability structures, or additional flexibility for hospitals to partner with high-performing post-acute care providers.

A commenter stated that academic medical centers may face particular challenges under the proposed gainsharing framework because they often serve as regional referral hubs for complex patients. The commenter noted that after providing specialized surgical care, academic medical centers frequently return patients to local community providers for recovery, allowing beneficiaries to remain near family, caregivers, and their usual medical teams. Because academic medical centers may not have contractual relationships with all downstream providers in the many communities they serve, the commenter stated that holding these hospitals financially accountable for a 90-day episode would be unfair.

Commenters also stated that the proposed rule lacked sufficient specificity regarding participation by certain clinicians and entities in

gainsharing arrangements. A commenter recommended that CMS define minimum expectations for anesthesiologist participation in gainsharing agreements, governance structures, and performance feedback mechanisms, noting that non-surgeon specialists may play an important role in episode care. Other commenters stated that the proposal appeared primarily focused on direct hospital-physician relationships and did not clearly address whether reconciliation payments could flow through a clinically integrated network to independent physician participants.

Commenters specifically asked CMS to clarify whether clinically integrated networks may serve as intermediaries for distributing reconciliation payments to independent physicians, the conditions under which post-acute care providers may receive distribution payments, and the documentation and oversight requirements that would apply to arrangements mediated by clinically integrated networks.

Several commenters requested additional guidance on permissible gainsharing structures. A commenter recommended that CMS issue this guidance before the model begins, rather than leaving these questions for later comment-and-response cycles.

A commenter recommended that CMS require participating acute care hospitals to enter into mandated shared-savings agreements with the applicable surgeon. The commenter stated that surgeons are central to the episode of care and should not be excluded from performance-based financial incentives. The commenter also stated that requiring surgeon participation in shared-savings arrangements could improve physician engagement and generate greater savings under CJR–X.

Response: We thank commenters for their recommendations on the CJR–X gainsharing framework. We recognize that commenters supported broader or more prescriptive policies on financial arrangements, including expanded mechanisms to influence independent physician and post-acute care decision-making, required shared-savings agreements with surgeons, additional specificity for anesthesiologists and clinically integrated networks, and restrictions on gainsharing tied to the use of lower-cost implantable devices.

We are not modifying the gainsharing framework as requested. We believe the finalized framework appropriately balances flexibility, participant accountability, beneficiary protections, quality safeguards, and program integrity. Under the model, CJR–X participants are accountable for episode spending and quality performance, and the gainsharing policies are intended to give participants flexibility to enter into arrangements with eligible collaborators that contribute to CJR–X activities and model performance. We do not believe it would be appropriate to require all participant hospitals to adopt specific gainsharing structures, to require shared savings arrangements with specific clinician types, or to prescribe a uniform approach to financial alignment across all episodes and markets.

We also believe that participating hospitals are best positioned to determine which collaborators are necessary to support their CJR–X activities, subject to the model's requirements. Hospitals may vary significantly in their clinical staffing models, referral patterns, post-acute care networks, geographic service areas, and existing relationships with physicians and other providers. A mandatory or highly prescriptive gainsharing structure could limit hospitals' ability to design arrangements that fit local care delivery circumstances and could create an operational burden for entities that do not need or cannot support those arrangements.

We agree that gainsharing should support quality and beneficiary care, not inappropriate cost reduction. For that reason, we finalized safeguards that require gainsharing payment methodologies to be tied to quality of care and the provision of CJR–X activities. The framework also prohibits arrangements that induce reductions or limitations in medically necessary services or that restrict a collaborator's ability to make decisions in the best interests of CJR–X beneficiaries, including decisions about devices, supplies, and treatments. These requirements address concerns that gainsharing could be used to reward the use of lower-cost products regardless of their clinical appropriateness.

We also do not require CJR–X participants to enter into shared savings agreements with specific surgeons, anesthesiologists, post-acute care providers, clinically integrated networks, or other entities. Although these providers may play important roles in CJR–X episodes, requiring participation by particular entities could interfere with a participant hospital's ability to structure arrangements based on actual contributions to CJR–X activities and performance. It could also create disputes over eligibility, payment allocation, and participation rights that are better addressed through voluntary written arrangements that satisfy CJR–X requirements and applicable law.

We recognize that post-acute care providers and community-based clinicians may influence episode outcomes, particularly length of stay, readmissions, functional recovery, and care transitions. The CJR–X financial arrangement framework permits participant hospitals to enter into arrangements with eligible collaborators, including certain post-acute care providers, when those entities contribute to model performance. However, we are not expanding the framework to require shared downside risk or shared savings for all such entities. CJR–X participants remain ultimately accountable to CMS for performance under the model, and the finalized repayment caps ensure that hospitals retain meaningful financial responsibility rather than transferring excessive downside risk to collaborators.

We also decline to create separate gainsharing rules for academic medical centers or regional referral centers. We understand that these hospitals may care for complex beneficiaries and discharge patients back to community providers across a broad service area. The model's gainsharing policies are designed to apply consistently nationwide as a mandatory model, while allowing CJR–X participants to establish voluntary arrangements with eligible collaborators. We believe this approach provides flexibility for hospitals with different care delivery patterns without creating special rules that could increase model complexity or lead to inconsistent accountability.

CMS acknowledges the commenter's request that it expressly address the use of clinically integrated networks as intermediaries for distributing reconciliation payments to independent physicians, the circumstances under which post-acute care providers may receive distribution payments, and the oversight obligations and documentation applicable to such arrangements.

After considering the public comments we received, we are finalizing our proposal at § 512.605 on the ''sharing arrangement'' definition and our proposal at § 512.670(a) on general sharing arrangement policies without modification.

(b) Requirements

We are finalizing several requirements for sharing arrangements to help ensure that their sole purpose is to create financial alignment between CJR–X participants and CJR–X collaborators toward the goals of the model while maintaining adequate program integrity safeguards. This final rule establishes

that the sharing arrangement must be in writing, signed by the parties, and entered into before care is furnished to CJR–X beneficiaries. In addition, participation in a sharing arrangement must be voluntary and without penalty for nonparticipation. It is important that providers and suppliers that render items and services to beneficiaries during the episode have the freedom to provide medically necessary items and services to beneficiaries without any requirement to participate in a sharing arrangement to safeguard beneficiary freedom of choice, access to care, and quality of care. The sharing arrangement must set out the mutually agreeable terms for the financial arrangement between the parties to guide and reward model care redesign for future performance toward model goals, rather than reflect the results of model performance years that have already occurred and where the financial outcome of the sharing arrangement terms would be known before signing.

We are finalizing the sharing arrangement to require the CJR–X collaborator and its employees, contractors, and subcontractors to comply with certain requirements that are important for program integrity under the arrangement. We note that the terms contractors and subcontractors include collaboration agents as defined in § 512.670(b)(3). The sharing arrangement must require all of the individuals and entities party to the arrangement to comply with provisions related to access to records and record retention and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees, in accordance with the standard provisions for Innovation Center models at § 512.135, because these individuals and entities all would play a role in model care redesign and be part of financial arrangements under the model as finalized. The sharing arrangement must also require all individuals and entities party to the arrangement who are providers or suppliers to comply with the applicable Medicare provider enrollment requirement at § 424.500, including having a valid and active TIN or NPI, during the term of the sharing arrangement. This requirement is in place to ensure that the individuals and entities have the required enrollment relationship with CMS under the Medicare program, although we note that they are not responsible for complying with requirements that do not apply to them. Finally, the sharing arrangement must require individuals and entities to comply with all other applicable laws and regulations. The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care so that financial relationships between CJR–X participants and CJR–X collaborators do not negatively impact beneficiary protections under the model. The sharing arrangement as finalized in this rule must require the CJR–X collaborator to have a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the model, just as we require CJR–X participants to have a compliance program that covers oversight of the sharing arrangement for this purpose as a program integrity safeguard. We sought comment on the anticipated effect of the proposed compliance program requirement for CJR–X collaborators, particularly with regard to individual physicians and nonphysician practitioners, small PGPs, NPPGPs, and TGPs and whether alternative compliance program requirements for all or a subset of CJR–X collaborators should be adopted to mitigate any effect of the proposal that could make participation as a CJR–X collaborator infeasible for any provider, supplier, or other entity on the finalized list of types of CJR–X collaborators.

It is necessary that CJR–X participants have adequate oversight over sharing arrangements to ensure that all arrangements meet the requirements of this section and provide program integrity protections. Therefore, this final rule establishes that the board or other governing body of the CJR–X participant has the responsibility for overseeing the hospital participation in the model, its arrangements with CJR–X collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the model. Additionally, we are requiring that the CJR–X participant and CJR–X collaborator must document this agreement in writing and, as part of the model's monitoring and compliance activities, which must be provided if CMS requests it, as is spelled out in section § 512.670(b)(7) of this final rule.

For purposes of sharing arrangements under the model, we proposed at § 512.605 that the definition of ''CJR–X activities'' refer to activities related to promoting accountability for the quality, cost, and overall care for CJR–X beneficiaries and performance in the model, including managing and coordinating care; encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; or carrying out any other obligation or duty under the model. In addition to the quality of care provided during episodes, we believe the activities that would fall under this definition encompass the totality of activities upon which it would be appropriate for sharing arrangements under the model to be based in order to value the contributions of providers, suppliers, and other entities toward meeting the performance goals of the model. We sought comment on the proposed definition of ''CJR–X activities'' as an inclusive and comprehensive framework for capturing direct care and care redesign that contribute to performance toward model goals.

We are finalizing in this final rule that the written agreement memorializing a sharing arrangement must specify the following parameters of the arrangement:

- The purpose and scope of the sharing arrangement.
- The identities and obligations of the parties, including specified CJR–X activities and other services to be performed by the parties under the sharing arrangement.
- The date of the sharing arrangement.
- Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out CJR–X activities.
- The financial or economic terms for payment, including the following:

++ Eligibility criteria for a gainsharing payment.

++ Eligibility criteria for an alignment payment.

++ Frequency of gainsharing or alignment payment.

++ Methodology and accounting formula for determining the amount of a gainsharing payment that is solely based on the quality of care and the provision of CJR–X activities.

++ Methodology and accounting formula for determining the amount of an alignment payment.

Finally, we are requiring that the terms of the sharing arrangement must not induce the CJR–X participant, CJR–X collaborator, or any employees, contractors, or subcontractors of the CJR–X participant or CJR–X collaborator to reduce or limit medically necessary services to any beneficiary or restrict the ability of a CJR–X collaborator to make decisions in the best interests of CJR–X beneficiaries, including the selection of devices, supplies, and treatments. These requirements are intended to ensure that the quality of care for beneficiaries is not negatively affected by sharing arrangements under the model.

We sought comment on the ''CJR activities'' definition and the sharing arrangement requirements at § 512.670.

The following is a summary of the public comments received on this proposal and our responses to those comments.

Comment: A commenter requested further clarification on CMS' proposed treatment of upside and downside risk-sharing under CJR–X financial arrangements. The commenter stated that CMS appears to permit collaborating entities to receive up to 100 percent of reconciliation payments and internal cost savings, while limiting the amount of shared losses they may assume through the proposed cap on alignment payments.

The commenter did not oppose broader flexibility for upside gainsharing but recommended parity between gainsharing and loss-sharing. The commenter stated that participant hospitals and collaborators should be allowed to negotiate arrangements that treat upside and downside risks equally, based on what makes financial and clinical sense for their local markets and patient populations.

The commenter also stated that hospitals may achieve internal cost savings through activities such as bulk purchasing of equipment and materials, but they also incur significant implementation costs under CJR–X. These costs may include investments in advanced data analytics, internal change management, new or revised vendor and supplier agreements, and personnel changes.

The commenter recommended that CMS allow hospitals and collaborators to negotiate more flexible arrangements that share both upside gains and downside losses on an equal basis.

Response: We thank the commenter for requesting clarification on the relationship between upside gainsharing and downside risk-sharing under CJR–X financial arrangements. We recognize the commenter's view that CJR–X participants and CJR–X collaborators should have the flexibility to negotiate arrangements that allocate reconciliation payments, internal cost savings, and repayment responsibilities in ways that reflect local market conditions, patient populations, and the operational investments required to succeed under the model.

We agree that CJR–X participants may need flexibility to share potential upside payments with collaborators who contribute to CJR–X activities and to model performance. Accordingly, we are finalizing policies that permit gainsharing payments, distribution payments, and downstream distribution payments when the applicable CJR–X requirements are met. These policies allow participant hospitals and eligible collaborators to structure voluntary arrangements that support care coordination, quality improvement, episode management, and efficient service delivery.

We are not modifying the cap on alignment payments to allow collaborators to assume 100 percent of a participant hospital's repayment responsibility. We believe it is important for CJR–X participants to retain meaningful financial accountability for performance under the model. Participant hospitals are directly accountable to CMS for CJR–X episode spending, quality performance, reconciliation payments, and repayment amounts. Allowing a participant hospital to transfer all downside risk to collaborators could weaken the hospital's accountability for model performance and reduce the incentive for the hospital to invest in care redesign, internal operations, data analytics, discharge planning, and care coordination.

In this final rule, we are finalizing the alignment payment caps to preserve accountability while still allowing participants and collaborators to share downside risk. For each performance year, the aggregate amount of alignment payments a CJR–X participant receives from all CJR–X collaborators may not exceed 50 percent of the participant's repayment amount. In addition, the aggregate amount of alignment payments from any one CJR–X collaborator that is not a Medicare ACO may not exceed 25 percent of the participant's repayment amount. For a CJR–X collaborator that is a Medicare ACO, the aggregate amount may not exceed 50 percent of the participant's repayment amount.

We believe this approach appropriately balances flexibility and accountability. The finalized policy permits participant hospitals to negotiate voluntary arrangements that share upside and downside risk, while ensuring that hospitals remain responsible for at least a meaningful portion of any repayment owed to CMS. We also believe the cap helps protect collaborators from excessive downside exposure, particularly when a collaborator may influence only part of the episode and may not control all factors that affect total episode spending.

We recognize that CJR–X participants may incur implementation costs under CJR–X, including investments in data analytics, care coordination infrastructure, internal change management, staffing, and vendor or supplier arrangements. The gainsharing framework allows hospitals to account for these investments when structuring financial arrangements, provided those arrangements comply with CJR–X requirements, applicable model documentation, and all applicable laws and regulations. However, we do not believe these implementation costs justify allowing CJR–X participants to shift all repayment responsibility to CJR–X collaborators.

We also note that upside and downside arrangements are not identical from the perspective of program integrity and model accountability. Sharing earned reconciliation payments or internal cost-savings rewards compensates collaborators for their contributions to CJR–X activities and performance. By contrast, transferring repayment responsibility determines how losses owed to CMS are allocated among the participant hospital and its collaborators. Because the participant hospital remains accountable to CMS under the model, we believe it is appropriate to maintain limits on the amount of repayment responsibility that may be shifted through alignment payments.

We believe the finalized gainsharing and alignment payment policies provide sufficient flexibility for participant hospitals and collaborators to negotiate arrangements that reflect local needs while preserving the core CJR–X accountability structure. Participant hospitals may enter into voluntary arrangements with eligible collaborators, but those arrangements must meet the final CJR–X financial arrangement requirements, documentation obligations, program integrity safeguards, and applicable safe harbor conditions.

After considering the public comments we received, we are finalizing the proposal at § 512.670 on the ''CJR activities'' definition and the sharing arrangement requirements without modification.

(c) Gainsharing Payment and Alignment Payment Conditions and Limitations

We are finalizing several conditions and limitations on gainsharing payments and alignment payments, as program integrity protections for payments to and from CJR–X collaborators. We require that gainsharing payments be derived solely from a CJR–X participant's reconciliation payment amounts, internal costs savings, or both; that they be distributed on an annual basis, not more than once per calendar year; that

they not be a loan, advance payment, or payment for referrals or other business; and that they be clearly identified as a gainsharing payment at the time they are paid.

We believe that gainsharing payment eligibility for collaborators should be conditioned on two requirements—(1) quality of care criteria; and (2) the provision of CJR–X activities. With respect to the first requirement, we have determined that to be eligible to receive a gainsharing payment, the collaborator must meet quality of care criteria during the performance year for which the participant earned a reconciliation payment amount that comprises the gainsharing payment. We are finalizing that the quality of care criteria be included in the sharing arrangement and mutually agreed upon by the CJR–X participant and CJR–X collaborator. With regard to the second requirement, to be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a collaborator other than a PGP, NPPGP, or TGP must have directly furnished a billable item or service to a beneficiary during the same performance year for which the participant earned a reconciliation payment amount or repayment amount. For purposes of this requirement, we consider a hospital, CAH, or post-acute care provider to have ''directly furnished'' a billable service if one of these entities billed for an item or service for a CJR–X beneficiary in the performance year for which the CJR–X participant earned a reconciliation payment amount or repayment amount. The phrase ''episode'' refers to all Part A and B items and services described in section X.C.2.d.(3)(b) of this final rule (excluding the items and services described in section X.C.2.d.(3)(c)) of this final rule that are furnished to a beneficiary described in section X.C.2.c of this final rule. During the time period that begins with the beneficiary's admission to an anchor hospitalization or the date of the anchor procedure, as applicable, and ends on the 90th day of either the date of discharge from the anchor hospitalization or the date of service for the anchor procedure. These requirements ensure that there is a required relationship between eligibility for a gainsharing payment and the direct care for CJR–X beneficiaries during an episode for these CJR–X collaborators. We believe the provision of direct care is essential to the implementation of effective care redesign, and the requirement provides a safeguard against payments to CJR–X collaborators other than a PGP, NPPGP, or TGP that are unrelated to direct care for CJR–X beneficiaries during the model's performance year.

We are finalizing similar requirements for PGPs, NPPGPs, and TGPs even though these entities themselves do not directly furnish billable services. To be eligible to receive a gainsharing payment or required to make an alignment payment for a given performance year, a PGP, NPPGP or TGP must have billed for an item or service that was rendered by one or more members of the PGP, NPPGP or TGP to a CJR–X beneficiary during the episode that is attributed to the same performance year for which the CJR–X participant earned a reconciliation payment amount or repayment amount. Like the proposal for CJR–X collaborators that are not PGPs, these proposals also require a link between the CJR–X collaborator, that is the PGP, NPPGP or TGP, and the provision of items and services to beneficiaries during the episode by PGP, NPPGP or TGP members.

Moreover, this final rule establishes that because PGPs, NPPGPs and TGPs might not directly furnish items and services to beneficiaries, in order to be eligible to receive a gainsharing payment or be required to make an alignment payment, for a given performance year the PGP, NPPGP or TGP must have contributed to CJR–X activities and been clinically involved in the care of beneficiaries during an episode that is attributed to the same performance year for which the CJR–X participant earned a reconciliation payment amount or repayment amount that comprises the gainsharing payment.

This final rule establishes that the amount of any gainsharing payments must be determined in accordance with a methodology that is solely based on the quality of care and the provision of CJR–X activities. We considered whether this methodology could substantially, rather than solely, be based on quality of care and the provision of CJR–X activities but ultimately determined that basing the methodology solely on these two elements creates a model safeguard where gainsharing aligns directly with the model goal of quality of care and with CJR–X activities. The gainsharing methodology may consider the amount of such CJR–X activities provided by a CJR–X collaborator relative to other CJR–X collaborators. While we emphasize that financial arrangements may not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among CJR–X participants, any CJR–X collaborator, any collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, or collaboration agent so that their sole purpose is to align the financial incentives of the CJR–X participant and CJR–X collaborators toward the model, we believe that accounting for the relative amount of CJR–X activities by CJR–X collaborators in the determination of gainsharing payments does not undermine this objective. Rather, this requirement allows flexibility in determining gainsharing payments where the amount of a CJR–X collaborator's provision of CJR–X activities (including direct care) to CJR–X beneficiaries during a performance year may contribute to the CJR–X participant's reconciliation payment amount that may be available for a gainsharing payment. Greater contributions of CJR–X activities by one CJR–X collaborator versus another CJR–X collaborator that result in greater differences in the funds available for gainsharing payments may be appropriately valued in the methodology used to make gainsharing payments to those CJR–X collaborators in order to reflect these differences in CJR–X activities among CJR–X collaborators.

However, we do not believe it would be appropriate to allow the selection of CJR–X collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment to take into account the amount of CJR–X activities provided by a potential or actual CJR–X collaborator relative to other potential or actual CJR–X collaborators because these financial relationships are not to be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, or collaboration agent. Specifically, with respect to the selection of CJR–X collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment, we do not believe that the amount of model activities provided by a potential or actual CJR–X collaborator relative to other potential or actual CJR–X collaborators could be taken into consideration by the CJR–X participant without a significant risk that the financial arrangement in those instances could be based directly or indirectly on the volume or value of referrals or business generated by, between or among the parties. Similarly, if the methodology for determining alignment payments was allowed to take

into account the amount of CJR–X activities provided by a CJR–X collaborator relative to other CJR–X collaborators there would be a significant risk that the financial arrangement could directly account for the volume or value of referrals or business generated by, between or among the parties and, therefore, we are finalizing that the methodology for determining alignment payments may not directly take into account the volume or value of referrals or business generated by, between or among the parties.

We also considered whether the methodology for gainsharing payments should be based substantially on quality of care and the provision of CJR–X activities, rather than solely on these two elements, and whether the methodology could take into account the amount of CJR–X activities provided by a CJR–X collaborator relative to other CJR–X collaborators. We were particularly interested in whether this standard would provide sufficient additional flexibility in the gainsharing payment methodology to allow the financial reward for CJR–X collaborators to be commensurate with their level of effort in achieving the model goals. Ultimately, we have determined to follow the CJR Model and TEAM gainsharing methodologies.

We have established that for each performance year, the aggregate amount of all gainsharing payments derived from a reconciliation payment by the CJR–X participant must not exceed the amount of the reconciliation payment. In accordance with the prior discussion, no entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments on the volume or value of referrals or business otherwise generated by, between or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, or collaboration agent. This final rule states that a CJR–X participant must not make a gainsharing payment to a CJR–X collaborator that is subject to any action for noncompliance by CMS or any other Federal or state entity or subject to noncompliance with any other Federal or state laws or regulations, or for the provision of substandard care to beneficiaries or other integrity problems. Finally, the sharing arrangement must require the CJR–X participant to recover any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation payment amount or was based on the submission of false or fraudulent data. These requirements provide safeguards for program integrity under gainsharing arrangements.

With respect to alignment payments, we finalized that alignment payments from a CJR–X collaborator to a CJR–X participant may be made at any interval agreed upon by both parties. Alignment payments must not be issued, distributed, or paid prior to the calculation by CMS of the repayment amount, and cannot be assessed in the absence of a repayment amount. The CJR–X participant must not receive any amounts under a sharing arrangement from a CJR–X collaborator that are not alignment payments.

We are also establishing certain limitations on alignment payments that are consistent with the CJR Model. For a performance year, the aggregate amount of all alignment payments received by the CJR–X participant from all of the CJR–X participants' CJR–X collaborators must not exceed 50 percent of the repayment amount. Given that the CJR–X participant would be responsible for developing and coordinating care redesign strategies in response to its participation in CJR–X, we believe it is important that the CJR–X participant retain a significant share of its repayment responsibility. In addition, the aggregate amount of all alignment payments from a CJR–X collaborator to the CJR–X participant for a CJR–X collaborator other than an ACO may not exceed 25 percent of the CJR–X participant's repayment amount. The aggregate amount of all alignment payments from a CJR–X collaborator to the CJR–X participant for a CJR–X collaborator that is an ACO may not exceed 50 percent of the CJR–X participant's repayment amount. In this final rule, we are finalizing that all gainsharing payments and any alignment payments must be administered by the CJR–X participant in accordance with GAAP and Government Auditing Standards (The Yellow Book). Additionally, we are finalizing that all gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction. We made this proposal to mitigate the administrative burden that the electronic fund transfer (EFT) requirement would place on the financial arrangements between certain CJR–X participants and CJR–X collaborators, especially individual physicians, and nonphysician practitioners and small PGPs, NPPGPs or TGPs, which could discourage participation of those suppliers as CJR–X collaborators.

We sought comment on our proposals at § 512.670(c) on the conditions and restrictions on gainsharing payments, alignment payments, and internal cost savings under the model.

The following is a summary of the public comments received on this proposal and our responses to those comments.

Comment: Multiple commenters recommended that CMS create additional, more consistent opportunities for gainsharing and incentive alignment among clinicians and providers involved in CJR–X episodes. Commenters generally stated that although the proposed collaborator framework allows hospitals to enter into financial arrangements with certain providers and suppliers, it relies too heavily on hospital discretion and may not ensure that the clinicians and post-acute care providers most responsible for episode outcomes are meaningfully included.

Several commenters focused on orthopedic surgeons. Commenters stated that orthopedic surgeons are central to the care team for lower-extremity joint replacement episodes and make many of the clinical decisions that influence both quality and cost. They cited decisions on implant selection, length of stay, post-acute discharge planning, follow-up cadence, and overall episode management. Commenters stated that because surgeons have substantial influence over these clinical and operational factors, they should be able to share in the savings generated by participants in the CJR–X Model.

Some commenters recommended that CMS require participating acute care hospitals to enter into shared savings agreements with the applicable surgeon. They stated that CJR–X savings could be higher if physicians were uniformly included in the hospital's financial arrangements. These commenters also expressed concern that, without such a requirement, hospitals could exclude the providers most directly involved in the episode of care from performance-based financial incentives.

Other commenters recommended that CMS provide stronger incentives for CJR–X participating hospitals to use the collaborator policies to engage individual surgeons and physician group practices. Commenters stated that surgeons and physician group practices should have consistent opportunities to participate in gainsharing arrangements and to help manage the CJR–X episode, rather than relying on variable hospital-specific decisions about whether and how to share savings.

Commenters also recommend expanding gainsharing opportunities beyond surgeons. Some commenters stated that CMS should require written agreements that set minimum expectations for including specialists in gainsharing arrangements. They recommended transparent methodologies and clear distribution rules for shared savings, so clinicians who contribute to episode performance understand how they may participate and how payments will be calculated.

Several commenters identified anesthesiologists and other non-surgeon specialists as clinicians who should be included in CJR–X governance and incentive structures. Commenters stated that these clinicians contribute to perioperative care coordination, patient optimization, complication prevention, pain management, and care redesign. They recommended that hospital governing bodies ensure a minimum level of representation for anesthesiologists and other non-surgeon specialists to enable meaningful participation in model implementation and decision-making.

Commenters also raised broader concerns about accountability and misaligned incentives. They noted that CJR–X holds hospitals financially accountable for episode performance, yet many episode outcomes depend on clinicians and providers outside the hospital's direct control. Commenters recommended that CMS align model incentives across all clinicians who contribute to episode performance and reduce reliance on variable, institution-specific arrangements.

A commenter raised concerns about post-acute care providers and beneficiary access. The commenter stated that hospitals may choose to collaborate only with selected preferred post-acute care providers and exclude others, including long-term care hospitals, inpatient rehabilitation facilities, and outpatient rehabilitation providers. The commenter stated that this could reduce access to appropriate post-acute care and interfere with Medicare beneficiaries' freedom to choose their providers. The commenter recommended that CMS clarify that CJR–X participants may not limit beneficiary access to specific post-acute care providers or restrict beneficiaries' ability to choose any Medicare-participating provider.

Response: We thank the commenters for their recommendations on additional opportunities to advance gainsharing and align incentives among providers involved in CJR–X episodes. We recognize that orthopedic surgeons, physician group practices, anesthesiologists, other non-surgeon specialists, and post-acute care providers may each contribute to episode quality, care coordination, beneficiary recovery, and total episode spending.

We agree that appropriately structured financial arrangements can support collaboration across the episode. Accordingly, we are finalizing policies that permit CJR–X participants to enter into financial arrangements with eligible CJR–X collaborators, make gainsharing payments, and share repayment responsibility through alignment payments, provided all CJR–X requirements set forth in this final rule are met. These policies provide participant hospitals with flexibility to engage clinicians and other providers who contribute to CJR–X activities and to model performance.

We do not require CJR–X participants to enter into gainsharing agreements with specific provider types, such as orthopedic surgeons, anesthesiologists, non-surgeon specialists, physician group practices, or post-acute care providers. We believe that CJR–X participants are best positioned to determine which collaborators are needed to support their CJR–X activities, given local care delivery patterns, staffing models, referral relationships, patient populations, and existing care coordination infrastructure. Requiring uniform gainsharing agreements for specific provider types could limit participants' flexibility and create operational complexity in markets where such arrangements may not reflect actual contributions to CJR–X performance.

We also decline to require minimum representation of specific clinician types on hospital governing bodies. While we recognize the important role of anesthesiologists and other specialists in perioperative care coordination and care redesign, hospital governance structures and clinical operations vary. We believe CJR–X participants should retain flexibility to determine the best way to engage clinicians in CJR–X implementation, subject to the model's oversight, documentation, and compliance requirements.

We reiterate that gainsharing payment methodologies must be based solely on quality of care and the provision of CJR–X activities. Arrangements may not induce reductions or limitations in medically necessary services or restrict a collaborator's ability to make decisions in the best interests of CJR–X beneficiaries. Sharing arrangements must be in writing and must identify the parties and their obligations, describe the CJR–X activities to be performed, set forth the financial or economic terms, and specify the methodology for determining gainsharing and alignment payments.

We also acknowledge concerns about access to post-acute care and beneficiaries' freedom of choice. The CJR–X collaborator framework does not permit a participant hospital to limit a beneficiary's choice of Medicare-participating providers or suppliers. CJR–X participants may identify preferred providers or enter into collaborator arrangements, but they must comply with beneficiary protections, including freedom of choice, access to medically necessary care, and applicable Medicare requirements.

We believe the finalized framework balances commenters' requests for broader incentive alignment with the need for flexibility, beneficiary protection, and program integrity. The model allows participants to engage eligible clinicians and providers through voluntary financial arrangements, preserves hospital accountability for CJR–X performance, and avoids a one-size-fits-all gainsharing requirement across all provider types.

Comment: A commenter recommended that CMS limit the maximum repayment amount a CJR–X participating hospital may require an individual CJR–X collaborator to contribute, ensuring that the amount is proportional to the collaborator's potential upside payment under the distribution arrangement. The commenter supported CMS limiting the share of repayments that hospitals may require from physician collaborators but stated that any downside repayment responsibility should correspond to the collaborator's share of savings.

Response: We thank the commenter for the recommendation to limit repayment responsibility for individual CJR–X collaborators. We understand the commenter's concern that a collaborator's downside repayment responsibility should be proportional to the amount of upside revenue the collaborator is eligible to receive under a sharing or distribution arrangement.

We agree that CJR–X participants should not be permitted to transfer unlimited repayment responsibility to collaborators. Accordingly, in this final rule, we are finalizing caps on alignment payments. For each performance year, the aggregate amount of alignment payments a CJR–X participant receives from all CJR–X collaborators may not exceed 50 percent of the participant's repayment amount. In addition, the aggregate amount of

alignment payments from any one CJR–X collaborator that is not a Medicare ACO may not exceed 25 percent of the participant's repayment amount. For a CJR–X collaborator that is a Medicare ACO, the aggregate amount may not exceed 50 percent of the participant's repayment amount.

We believe these caps appropriately ensure that participant hospitals retain meaningful accountability for repayment amounts owed to CMS while allowing collaborators to share downside responsibility when they voluntarily enter into CJR–X financial arrangements. We are not modifying the policy to require that each collaborator's repayment responsibility be capped at the same percentage as the collaborator's potential upside payment. We believe CJR–X participants and CJR–X collaborators should retain the flexibility to negotiate the specific terms of voluntary arrangements, including the allocation of potential gainsharing and alignment payments, provided the arrangements comply with CJR–X requirements, applicable model documentation, and all applicable laws and regulations.

We also note that CJR–X financial arrangements must be set forth in writing and must describe the financial or economic terms of the arrangement, including the methodologies for determining gainsharing and alignment payments. These requirements are intended to ensure transparency and accountability between the participant hospital and the collaborator. A collaborator may choose whether to enter into such an arrangement based on the terms offered, including the relationship between potential upside payments and downside repayment responsibility.

We believe the finalized caps on alignment payments, written agreement requirements, documentation obligations, and program integrity safeguards appropriately balance flexibility with protection against excessive risk transfer. Participant hospitals remain accountable to CMS for repayment amounts owed under the model, and any sharing of repayment responsibility with collaborators must comply with the final CJR–X financial arrangement requirements.

Comment: A commenter requested guidance on how CJR–X gainsharing payments would interact with Medicare ACO savings distributions when the same beneficiary is attributed to or otherwise involved in both arrangements.

Response: We thank the commenter for requesting guidance on how CJR–X gainsharing payments interact with Medicare ACOs' shared savings distributions for the same beneficiary. CMS recognizes that some providers and suppliers may participate in both CJR–X financial arrangements and Medicare ACO initiatives and that participants may seek clarity on overlapping incentive arrangements.

In this final rule, we finalize the CJR–X financial arrangement policies to permit CJR–X participants to enter into financial arrangements with eligible CJR–X collaborators, including certain Medicare ACO providers, when those entities contribute to the CJR–X participant's performance under the model, and all CJR–X requirements are met. Any gainsharing payment under CJR–X must be made pursuant to a compliant CJR–X sharing arrangement and be based solely on quality of care and the provision of CJR–X activities.

We note that CJR–X gainsharing payments and Medicare ACO shared savings distributions arise under separate payment models and are governed by their respective requirements. Participation in a CJR–X financial arrangement does not relieve any organization of its obligation to comply with Medicare ACO rules, applicable participation agreements, distribution requirements, fraud and abuse laws, and safe harbor conditions.

We have determined that the CMS-sponsored model arrangements safe harbor is available for specified CJR–X financial arrangements, including gainsharing payments, alignment payments, distribution payments, and downstream distribution payments, when all applicable requirements are met. We believe the finalized gainsharing framework provides a clear and flexible pathway for participants and collaborators to align incentives for CJR–X activities while maintaining safeguards against inappropriate reductions in care, excessive risk transfer, and remuneration unrelated to the model. Therefore, we are finalizing the sharing arrangements without the modifications requested by commenters.

After considering the public comments we received, we are finalizing our proposal at § 512.670(c) on the conditions and restrictions on gainsharing payments, alignment payments, and internal cost savings under the model without modification.

(d) Documentation Requirements

To ensure the integrity of the sharing arrangements, we are finalizing in this final rule the documentation requirements that CJR–X participants must meet to engage in financial arrangements. Specifically, the CJR–X participant must—

- Document the sharing arrangement contemporaneously with the establishment of the arrangement;
- Maintain accurate current and historical lists of all CJR–X collaborators, including CJR–X collaborator names and addresses; update such lists on at least a quarterly basis; and publicly report the current and historical lists of CJR–X collaborators on the CJR–X participant's website; and
- Maintain and require each CJR–X collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum the—

++ Nature of the payment (gainsharing payment or alignment payment);

++ Identity of the parties making and receiving the payment;

++ Date of the payment;

++ Amount of the payment;

++ Date and amount of any recoupment of all or a portion of a CJR–X collaborator's gainsharing payment; and

++ Explanation for each recoupment, such as whether the CJR–X collaborator received a gainsharing payment that contained funds derived from a CMS overpayment of a reconciliation payment amount, or was based on the submission of false or fraudulent data.

In addition, we are finalizing the requirement that the CJR–X participant must keep records for all of the following:

- A process for determining and verifying potential and current CJR–X collaborators' eligibility to participate in Medicare if the CJR–X collaborator is a Medicare-enrolled provider or supplier.
- A plan to track internal cost savings.
- Information on the accounting systems used to track internal cost savings.
- A description of current health information technology, including systems to track reconciliation payment amounts, repayment amounts, and internal cost savings.
- A plan to track gainsharing payments and alignment payments.

Finally, this final rule establishes that the CJR–X participant must retain and provide access to, and must require each CJR–X collaborator to retain and provide access to, the required documentation in accordance with § 512.135 and 42 CFR 1001.952(ii).

We sought comment on our proposals on the documentation requirements for sharing arrangements at § 512.670(d). We sought comment about all of the

requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

The following is a summary of the public comments received on this proposal and our responses to those comments.

Comment: A commenter recommended that CJR–X participants be permitted to enter into financial arrangements with collaborators and requested that CMS provide a gainsharing template outlining key compliance considerations under applicable laws and regulations. The commenter stated that such a template could help participants structure compliant arrangements.

Response: We thank the commenter for the recommendation regarding financial arrangements with CJR–X collaborators and the request for a gainsharing template. We agree that financial arrangements can support CJR–X objectives when they are structured to align incentives around care coordination, quality improvement, episode management, and efficient service delivery.

We finalized policies that permit CJR–X participants to enter into financial arrangements with eligible CJR–X collaborators, including physician group practices, when the arrangements satisfy the final CJR–X requirements. These arrangements may allow the sharing of reconciliation payment amounts through gainsharing payments and the sharing of repayment responsibility through alignment payments, subject to the model's limits, documentation requirements, beneficiary protections, program integrity safeguards, applicable model documentation, and all applicable laws and regulations.

We do not intend to provide a gainsharing methodology or a financial arrangements template to CJR–X participants. Because CJR–X participants and CJR–X collaborators may differ in organizational structure, clinical operations, local market conditions, legal relationships, and the specific CJR–X activities they perform, a single template may not capture all relevant facts or compliance obligations.

We believe the finalized financial arrangement requirements provide the necessary framework for compliant arrangements while preserving flexibility for participants and collaborators to structure arrangements that reflect their roles in CJR–X activities and in model performance.

After consideration of the public comments, we are finalizing our proposal at § 512.670(d) on the documentation requirements for sharing arrangements without modifications.

(5) Distribution Arrangements

(a) General

Similar to the CJR Model (80 FR 73541), we are finalizing that certain financial arrangements between CJR–X collaborators and other individuals or entities called ''collaboration agents'' be termed ''distribution arrangements.'' In the January 2017 CJR final rule (82 FR 180), we finalized a full replacement of the prior CJR Model regulations to allow for—(1) participant hospitals to enter into sharing arrangements with additional categories of CJR collaborators, including certain ACOs, hospitals, CAHs, NPPGPs and therapy group practices (TGPs); (2) ACOs, PGPs, NPPCGs and TGPs that are CJR collaborators to enter into distribution arrangements with certain entities and individuals; and (3) PGPs, NPPGPs and TGPs that received distribution payments from ACOs to enter into downstream distribution arrangements to share distribution payments with certain of their members. Similarly in CJR–X, a ''collaboration agent'' would be defined as an individual or entity that is not a CJR–X collaborator and that is a PGP, NPPGP, or TGP member that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP, in which he or she is an owner or employee. For purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)), we have established that a ''distribution arrangement'' would be defined as a financial arrangement between a CJR–X collaborator that is a PGP, NPPGP, or TGP and a collaboration agent for the sole purpose of sharing a gainsharing payment received by the PGP, NPPGP or TGP. Where a payment from a CJR–X collaborator to a collaboration agent is made pursuant to a CJR–X distribution arrangement, we define that payment as a ''distribution payment.'' A CJR–X collaborator may make a distribution payment only in accordance with a distribution arrangement that complies with the provisions of this model, as finalized, and all other applicable laws and regulations, including fraud and abuse laws.

Just as we finalized the requirements for gainsharing payments, the amount of any distribution arrangements must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR–X activities. We considered whether this methodology could substantially, rather than solely, be based on quality of care and the provision of CJR–X activities, but ultimately determined that basing the methodology solely on these two elements creates a model safeguard in which gainsharing aligns directly with the model goal of quality of care and with CJR–X activities.

We sought comment on our definitions for ''collaboration agent,'' ''distribution arrangements,'' and ''distribution payment'' at § 512.605. We also sought comment on our distribution arrangements proposals at § 512.675(a).

The following is a summary of the public comments received on this proposal and our responses to those comments.

Comment: Some commenters recommended that CMS require, rather than merely permit, distribution arrangements between CJR–X participant hospitals and the surgeons and other physicians who perform procedures that trigger CJR–X episodes. The commenters stated that mandatory physician distribution arrangements should be a standard feature of CJR–X because surgeons and other procedural physicians play a central role in episode performance, care coordination, and cost and quality outcomes.

The commenters also expressed concern that optional distribution arrangements could contribute to forced market consolidation by giving hospitals greater leverage over independent physicians. They suggested that requiring participant hospitals to share financial arrangements with procedural physicians could help support physician alignment without encouraging consolidation that could lead to higher patient prices.

Response: We appreciate the commenters' recommendation that CJR–X require rather than allow distribution arrangements between participant hospitals and the surgeons and other physicians who perform procedures that trigger CJR–X episodes. We recognize the commenters' view that physicians who furnish the episode-triggering procedures play an important role in care coordination, quality, and episode spending, and that financial alignment with those physicians may support model goals.

Under the CJR–X financial arrangement policies, CJR–X participants may enter into sharing arrangements with CJR–X collaborators and certain downstream distribution arrangements, subject to applicable safeguards. These safeguards include written agreements, documentation requirements, limits on gainsharing and alignment payments, compliance with

applicable law, and protections to ensure that financial arrangements are not conditioned on the volume or value of referrals and do not reduce medically necessary care or restrict beneficiary choice.

Mandatory financial arrangements between CJR–X participants and physicians would require consideration of operational feasibility, participant accountability, program integrity, beneficiary protections, and the varied relationships between participant hospitals and physicians across markets. Any CJR–X financial arrangement involving surgeons or other physicians would need to comply with applicable CJR–X financial arrangement requirements, including those for sharing arrangements, distribution arrangements, payment methodologies, documentation, and program integrity safeguards. We may consider the commenters' recommendation in future rulemaking.

Comment: A commenter requested guidance on whether a provider's or entity's participation in an ACO would affect the calculation of internal cost savings available for distribution under CJR–X sharing arrangements. The comment raises an operational clarification issue about whether savings or performance associated with an ACO relationship would change how CJR–X participants calculate and distribute internal cost savings to CJR–X collaborators.

Response: We appreciate the commenter's request for clarification on whether a financial arrangement between a CJR–X participant hospital and an ACO affects the calculation of internal cost savings available for distribution under CJR–X sharing arrangements. Under the CJR–X financial arrangement framework, a sharing arrangement with an ACO would not, by itself, change the participant hospital's calculation of internal cost savings. The CJR–X participant would remain responsible for tracking internal cost savings under the applicable CJR–X methodology and for maintaining documentation of the accounting systems and processes used to track those savings.

Where the ACO relationship matters is not in the basic calculation of internal cost savings, but in the limits and safeguards governing how those savings may be shared. Any gainsharing payment to an ACO would still need to be based solely on quality of care and the provision of CJR–X activities, to comply with the written sharing arrangement, and to avoid duplicate payments or double-counting the same contribution to CJR–X activities. This final rule also includes ACO-specific limits for alignment payments: for a CJR–X collaborator that is an ACO, aggregate alignment payments from that ACO to the participant may not exceed 50 percent of the participant's repayment amount. By comparison, non-ACO collaborators are subject to a lower 25 percent collaborator-specific limit on alignment payments.

Thus, while the ACO arrangement would not independently alter the calculation of internal cost savings, it would affect how any resulting gainsharing or alignment payments may be structured, documented, limited, and distributed under the finalized financial arrangement requirements for CJR–X.

After consideration of the public comments we received, we are finalizing without modification our proposal at § 512.605 on our definitions for ''collaboration agent,'' ''distribution arrangements,'' and ''distribution payment.'' We are also finalizing, without modification, our proposals at § 512.675(a) regarding distribution arrangements policies.

(b) Requirements

We have established several requirements to help ensure that the sole purpose of distribution arrangements is to create financial and CJR–X performance alignment between CJR–X collaborators and collaboration agents. These requirements are spelled out in section X.C.2.i.(4)(b) of this final rule for sharing arrangements and gainsharing payments. We are finalizing that all distribution arrangements must be in writing, signed by the parties, contain the effective date of the agreement, and be entered into before care is furnished to CJR–X beneficiaries under the distribution arrangement. Furthermore, we finalized in this rule that participation must be voluntary and without penalty for nonparticipation, and the distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

In this final rule, we are finalizing that any distribution payments must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR–X activities. We finalized that the opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between, or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, or collaboration agent. We have established more flexible standards for the determination of the amount of distribution payments from PGPs, NPPGPs, and TGPs, allowing CJR–X collaborators and collaboration agents to create tailored distribution payments that align with the specific structure of their arrangements.

We note that for distribution payments made by a PGP to PGP members, by NPPGPs to NPPGP members, or TGPs to TGP members, the requirement that the amount of any distribution payments must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR–X activities may be more limiting in how a PGP, NPPGP or TGP pays its members than is allowed under existing law. However, we believe quality of care is an important facet of episode-based payment models, and making this a requirement for distribution payments supports a greater emphasis on quality of care improvement in CJR–X. Further, this is consistent with the BPCI Advanced model's financial arrangements requirements, which stipulated that NPRA Shared Payments and Partner Distribution Payments must meet quality performance targets in order to receive these payments.

We sought comment on this proposal and specifically whether there are additional safeguards or a different standard is needed to allow for greater flexibility in calculating the amount of distribution payments that would avoid program integrity risks and whether additional or different safeguards are reasonable, necessary, or appropriate for the amount of distribution payments from a PGP to its members, a NPPGP to its members or a TGP to its members.

Similar to the requirements for sharing arrangements for CJR–X collaborators that furnish or bill for items and services, we are finalizing that a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to a beneficiary during an episode that occurred during the same performance year for which the CJR–X participant accrued the internal cost savings or earned a reconciliation payment amount that comprises the gainsharing payment being distributed. We note that all individuals and entities that fall within our definition of collaboration agent may either directly furnish or bill for items and services rendered to beneficiaries. This ensures that the same required relationship exists between direct care for CJR–X beneficiaries during a performance year and distribution payment eligibility that we

require for gainsharing payment eligibility. We believe this requirement provides a safeguard against payments to collaboration agents that are unrelated to direct care for CJR–X beneficiaries during the performance year.

We further finalized in this final rule that with respect to the distribution of any gainsharing payment received by an ACO, PGP, NPPGP, or TGP, the total amount of all distribution payments in a performance year must not exceed the amount of the gainsharing payment received by the CJR–X collaborator from the CJR–X participant for that performance year. As with gainsharing and alignment payments, we are finalizing the requirement that all distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. The collaboration agent must retain the ability to make decisions in the best interests of the CJR–X beneficiary, including the selection of devices, supplies, and treatments. Finally, the distribution arrangement must not induce the collaboration agent to reduce or limit medically necessary items and services for any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

In this final rule, we are finalizing that the CJR–X collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.675(b), including—

- The relevant written agreements;
- The date and amount of any distribution payment(s);
- The identity of each collaboration agent that received a distribution payment; and
- A description of the methodology and accounting formula for determining the amount of any distribution payment.

We are finalizing that the CJR–X collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same CJR–X participant, which is a continuation of the CJR Model policy in the 2015 final rule (80 FR 73427). This framework establishes separate limitations on the total amount of gainsharing payment and distribution payment to PGPs, NPPGPs, TGPs, physicians, and nonphysician practitioners that are solely based on quality of care and the provision of CJR–X activities are not exceeded in absolute dollars by a PGP, NPPGP, TGP, physician, or nonphysician practitioner's participation in both a sharing arrangement and distribution arrangement for the care of the same CJR–X beneficiaries during the performance year. Allowing both types of arrangements for the same individual or entity for care of the same beneficiary during the performance year could also allow for duplicate counting of the individual or entity's same contribution toward model goals and provision of CJR–X activities in the methodologies for both gainsharing and distribution payments, leading to financial gain for the individual or entity that is disproportionate to the contribution toward model goals and provision of CJR–X activities by that individual or entity. However, we recognize there could be instances where an individual or entity could have distribution arrangements with multiple CJR–X collaborators. For example, a physician may practice with and have reassigned their Medicare billing rights to multiple PGPs, and those PGPs may each be CJR–X collaborators. We sought comment on whether an individual or entity should have distribution arrangements with multiple CJR–X collaborators, and whether additional program integrity safeguards should be established in those scenarios. Finally, in this final rule, we establish that the CJR–X collaborator must retain and provide access to the required documentation for monitoring and compliance purposes.

We sought comment on the requirements for distribution arrangements under CJR–X at § 512.675(b).

We received no comments on this proposal and therefore are finalizing this provision without modification.

(6) Downstream Distribution Arrangements

(a) General

In this final rule, we are finalizing that CJR–X allows for certain financial arrangements within an ACO between a PGP and its members. Specifically, we establish that certain financial arrangements between a collaboration agent that is both a PGP, NPPGP, or TGP and an ACO participant, and another individual termed ''downstream collaboration agent'' be termed a ''downstream distribution arrangement.'' We define a ''downstream distribution arrangement'' as a financial arrangement between a collaboration agent that is both a PGP, NPPGP, or TGP, and an ACO participant and a downstream collaboration agent for the sole purpose of sharing a distribution payment received by the PGP, NPPGP, or TGP. We are finalizing the definition of a ''downstream collaboration agent'' as an individual who is not a CJR–X collaborator or a collaboration agent and who is a PGP member, a NPPGP member, or a TGP member that has entered into a downstream distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is a collaboration agent. Where a payment from a collaboration agent to a downstream collaboration agent is made pursuant to a downstream distribution arrangement, we define that payment as a ''downstream distribution payment.'' A collaboration agent may only make a downstream distribution payment in accordance with a downstream distribution arrangement that complies with the requirements of this section and all other applicable laws and regulations, including the fraud and abuse laws.

We sought comment on the definitions at § 512.605 for ''downstream collaboration agent,'' ''downstream distribution arrangement,'' and ''downstream distribution payment.''

We received no comments on this proposal and therefore are finalizing this provision without modifications.

(b) Requirements

To help ensure that the sole purpose of downstream distribution arrangements is to create financial alignment between collaboration agents that are PGPs, NPPGPs, or TGPs which are also ACO participants and downstream collaboration agents and to meet the quality and efficiency goals of CJR–X, in this final rule we are finalizing that all downstream distribution arrangements must be in writing and signed by the parties, contain the effective date of the agreement, and entered into before care is furnished to CJR–X beneficiaries under the downstream distribution arrangement. Furthermore, in this final rule we establish that participation must be voluntary and without penalty for nonparticipation, and the downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

Just like with gainsharing and distribution payments, we are finalizing that the opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with

a CJR–X participant, CJR–X collaborator, collaboration agent, or downstream collaboration agent. We have established that the amount of any downstream distribution payments from an NPPGP to an NPPGP member or from a TGP to a TGP member must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR–X activities and that may take into account the amount of such CJR–X activities provided by a downstream collaboration agent relative to other downstream collaboration agents. We believe that the amount of a downstream collaboration agent's provision of CJR–X activities (including direct care) to CJR–X beneficiaries during episodes may contribute to the CJR–X participant's internal cost savings and reconciliation payment amount that may be available for making a gainsharing payment to the CJR–X collaborator that is then shared through a distribution payment to the collaboration agent with which the downstream collaboration agent has a downstream distribution arrangement. Greater contributions of CJR–X activities by one downstream collaboration agent versus another downstream collaboration agent that result in different contributions to the distribution payment made to the collaboration agent with which the downstream collaboration agents both have a downstream distribution arrangement may be appropriately valued in the methodology used to make downstream distribution payments to those downstream collaboration agents.

Similar to the finalized requirements for distribution arrangements for those CJR–X collaborators that are PGPs, we are finalizing that a downstream collaboration agent is eligible to receive a downstream distribution payment only if the PGP billed for an item or service furnished by the downstream collaboration agent to a CJR–X beneficiary during an episode that was attributed to the same performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment amount that comprise the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant. This requirement ensures that the same required relationship exists between direct care for CJR–X beneficiaries during episodes and downstream distribution payment eligibility as we require for gainsharing and distribution payment eligibility. We believe this requirement provides a safeguard against payments to downstream collaboration agents that are unrelated to direct care for CJR–X beneficiaries during episodes.

Furthermore, we are finalizing that the total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the distribution payment received by the collaboration agent (that is, the PGP, NPPGP, or TGP that is an ACO participant) from the ACO that is a CJR–X collaborator. Like gainsharing, alignment, and distribution payments, we have established that all downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. The downstream collaboration agent must retain the ability to make decisions in the patient's best interest, including the selection of devices, supplies, and treatments. The distribution arrangement must not induce a downstream collaboration agent to reduce or limit medically necessary items and services for any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

This final rule establishes that the PGP, NPPGP, or TGP engaging in financial arrangements must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 512.680(b)(12), including all of the following:

- The relevant written agreements.
- The date and amount of any downstream distribution payment(s).
- The identity of each downstream collaboration agent that received a downstream distribution payment.
- A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

In this final rule, we are finalizing that the PGP, NPPGP, or TGP may not enter into a downstream distribution arrangement with any PGP, NPPGP, or TGP member who has a sharing arrangement with a CJR–X participant or distribution arrangement with the ACO that the PGP, NPPGP, or TGP is a participant in. This requirement ensures that the separate limitations on the total amount of gainsharing payment, distribution payment, and downstream distribution payment to PGP, NPPGP, or TGP members that are solely based on quality of care and the provision of CJR–X activities are not exceeded in absolute dollars by a PGP, NPPGP, or TGP member's participation in more than one type of arrangement for the care of the same CJR–X beneficiaries during episodes. Allowing more than one arrangement for the same PGP, NPPGP, or TGP member to care for the same CJR–X beneficiaries during episodes could also lead to duplicate counting of the PGP, NPPGP, or TGP member's effort in CJR–X activities across methodologies for different payments. Finally, this rule establishes that the PGP, NPPGP, or TGP must retain and provide access to, and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 512.680(b)(14). We sought comment on the requirements for downstream distribution arrangements at § 512.680.

We received no comments on this proposal and therefore are finalizing this provision without modifications.

(7) Beneficiary Incentives

We believe it is necessary and appropriate to provide additional flexibilities to CJR–X participants to increase access to tools that could improve the quality of care for CJR–X beneficiaries and meet other goals of the model. CJR–X participants may choose to provide in-kind patient engagement incentives to CJR–X beneficiaries in an episode, which may include, but would not be limited to, items of technology, subject to the conditions discussed below, which are broadly consistent with those that appeared in the CJR Model at 42 CFR 510.515.

As discussed in section X.C.2.i.(9) of this final rule, we have made a determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)) is available to protect the beneficiary incentives when the incentives are offered in compliance with the requirements established in the final rule and the conditions for use of the anti-kickback statute safe harbor set out at 42 CFR 1001.952(ii).

As stated previously, CJR–X participants may choose to provide in-kind engagement incentives, which may include but are not limited to items of technology, to CJR–X beneficiaries in an episode, subject to the conditions stipulated in this final rule. The incentive must be provided directly by the CJR–X participant or by an agent of the CJR–X participant, under the participant's direction and control, to the CJR–X beneficiary during an episode. Additionally, the item or service provided must be reasonably connected to the CJR–X beneficiary's medical care, and be a preventive care item or service or an item of service that advances a clinical goal, as described in section X.C.2.i.(7)(b) of this final rule, by engaging the CJR–X beneficiary in better managing their own health.

We sought comment on the proposed conditions for CJR–X beneficiary incentives, as outlined in § 512.685. Specifically, we sought comment on whether these proposed conditions are reasonable, and whether additional conditions are appropriate to further engage CJR–X beneficiaries in their own healthcare management while preventing fraud or abuse.

The following is a summary of the public comments received on this proposal and our responses to those comments.

Comment: A commenter responded to CMS's request for comments on proposed requirements for beneficiary engagement incentives involving technology by outlining safeguards the commenter believed should apply to recovery-at-home or home-based post-acute care arrangements. The commenter stated that participating hospitals would already be licensed and subject to the Original Medicare conditions of participation and should be required to apply for and obtain CMS approval before operating under any waivers.

The commenter stated that recovery-at-home requires rigorous documentation comparable to that of traditional facility-based care, including documentation of patient eligibility, daily in-person or telehealth evaluations, and home safety assessments. The commenter asserted that these requirements would create verification trails and support regulatory compliance and high-quality care.

The commenter recommended that organizations offering beneficiary incentives submit monthly data to CMS and remain subject to Medicare payment, billing, quality, and cost-reporting requirements comparable to those for traditional skilled nursing facilities. The commenter also recommended that CMS require programs to track functional and recovery outcomes, including mobility gains, falls, escalations, therapy completion, and return-to-community outcomes.

Response: We appreciate the commenters' recommendations on beneficiary engagement incentives and broader suggestions for safeguards related to recovery-at-home services after lower-extremity joint replacement. We recognize the commenter's view that home-based recovery arrangements may require clear documentation, patient eligibility standards, home safety assessments, outcome tracking, and oversight to ensure high-quality care and regulatory compliance.

The requirements applicable to beneficiary engagement incentives in CJR–X are intended to ensure that beneficiary engagement incentives are connected to medical care, advance a clinical goal, and are not used to induce beneficiaries to receive medically unnecessary services or to restrict beneficiary choice.

CMS may consider the commenter's recommendations on documentation, data submission, and outcome measurement as it evaluates the requirements for technology-related beneficiary engagement incentives and related beneficiary protections in future rulemaking.

Comment: A commenter supported CMS's proposed policies for beneficiary incentives intended to promote beneficiary engagement and adherence. The commenter requested that CMS provide additional guidance explaining how these beneficiary incentive flexibilities would operate under CJR–X and how they may differ from similar flexibilities available in other alternative payment models.

Response: We appreciate the commenter's support for the proposed CJR–X beneficiary engagement incentive policies. We also acknowledge the commenter's request for additional guidance on how these flexibilities would apply under CJR–X and how they may differ from beneficiary engagement incentives available in other Innovation Center models.

Beneficiary engagement incentives are set on a model-by-model basis and may vary by the model's statutory authority, tested care delivery approach, beneficiary population, participant type, payment methodology, overlap rules, and program integrity risks.

After consideration of the public comments we received, we are finalizing our proposal at § 512.685 on the requirements for CJR–X beneficiary incentives without modifications.

(a) Technology Provided to a CJR–X Beneficiary

In some cases, items or services involving technology may be useful as beneficiary engagement incentives to advance a clinical goal of CJR–X by engaging a CJR–X beneficiary in managing their health during the 90 days following discharge from the anchor hospitalization or anchor procedure. However, we believe specific enhanced safeguards are necessary for these items and services to prevent abuse, and our proposals are consistent with the CJR Model policies (80 FR 73437). Specifically, we are finalizing the requirement that items or services involving technology provided to a beneficiary may not exceed $1,000 in retail value for any CJR–X beneficiary in any episode (per episode), and that items or services involving technology provided to a CJR–X beneficiary must be the minimum necessary to advance a clinical goal as discussed in this section for a CJR–X beneficiary in an episode. CMS considers these additional requirements for items of technology exceeding $75 in retail value an additional safeguard against misuse of these items as beneficiary engagement incentives. Specifically, items of technology exceeding $75 in retail value remain the property of the CJR–X participant and must be retrieved from the CJR–X beneficiary at the end of the episode. The CJR–X participant must document all retrieval attempts, including the ultimate date of retrieval. We understand that CJR–X participants may not always be able to retrieve these items after the episode ends, such as when a CJR–X beneficiary dies or moves to another geographic area. Therefore, in cases when the item of technology cannot be retrieved, the CJR–X participant must determine why the item was not retrievable and, if it was determined that the item was used inappropriately (for example, if it was sold), prevent future beneficiary incentives for that particular CJR–X beneficiary. Following this process, documentation of diligent, good faith attempts to retrieve the technology will satisfy the retrieval requirement. We recognize this requirement may increase CJR–X participant burden to document attempts at retrieval and sought comment on whether the value threshold should be raised or if there are other ways to demonstrate attempts at retrieval that may be less burdensome for the CJR–X participant.

We sought comment on our proposed CJR–X requirements at § 512.685 regarding beneficiary engagement incentives that involve technology. We welcomed comment on additional or alternative program integrity safeguards for this type of beneficiary engagement incentive, including whether the financial thresholds proposed in this section are reasonable, necessary, and appropriate.

The following is a summary of the public comments received on this proposal and our responses to those comments.

Comment: A commenter supported CMS' proposal to allow beneficiary engagement incentives of up to $1,000 in in-kind items or services involving technology for any one CJR–X beneficiary during any one episode. The commenter stated this would provide CJR–X participants with the operational flexibility needed to manage episodes effectively across the care continuum.

The commenter viewed the incentives as supportive of care coordination and episode management under the model.

Response: We appreciate the commenter's view that the proposed beneficiary engagement incentives, including the ability to offer up to $1,000 in in-kind items or services involving technology, will provide CJR–X participants with operational flexibility to manage episodes effectively across the care continuum.

After consideration of the public comments we received, we are finalizing our proposal at § 512.685 for beneficiary engagement incentives that involve technology in CJR–X, without modifications.

(b) Clinical Goals of CJR–X

As discussed in section X.C.2.d. of this final rule, the ''episodes'' are broadly defined to include most Part A and Part B items and services furnished during episodes of care that extend 90 days following discharge from the anchor hospitalization or anchor procedure that begins the episode. Therefore, we believe that in-kind beneficiary engagement incentives may appropriately be provided to manage acute conditions arising from episodes, as well as chronic conditions if the condition is likely to have been affected by care during the episode or when substantial services are likely to be provided for the chronic condition during the episode. We are finalizing the flexibility that allows CJR–X participants to offer in-kind beneficiary engagement incentives, where such incentives must be closely related to the provision of high-quality care and advance a clinical goal for a CJR–X beneficiary and should not serve as inducements for CJR–X beneficiaries to seek care from the CJR–X participants or other specific suppliers and providers. This outline is similar to the beneficiary incentive guidelines outlined previously in the CJR Model (80 FR 73553). This final rule is finalizing the requirements that beneficiary incentives must advance one of the following clinical goals of CJR–X:

- Beneficiary adherence to drug regimens.
- Beneficiary adherence to a care plan.
- Reduction of readmissions and complications resulting from treatment during the episode.
- Management of chronic diseases and conditions that may be affected by treatment for the CJR–X clinical condition.

We sought comments on our proposals regarding clinical goals when offering beneficiary engagement incentives at § 512.685.

We received no comments and therefore are finalizing this provision without any modifications.

(c) Documentation of Beneficiary Engagement Incentives

As a safeguard against misuse of beneficiary engagement incentives under CJR–X, we are finalizing the requirements that CJR–X participants must maintain documentation of items and services furnished as beneficiary engagement incentives that exceed $25 in retail value, including items of technology, and to require that the documentation established contemporaneously with the provision of the items and services must include at least the following:

- The date the incentive is provided.
- The incentive and estimated value of the item or service.
- The identity of the beneficiary to whom the item or service was provided.

In this final rule, we are finalizing that when a CJR–X participant or one of its collaborators provides items of technology exceeding $75 in retail value, they are required to retrieve it from the beneficiary at the end of an episode and document all attempts to retrieve the technology item received by the beneficiary. In instances where the item of technology is not able to be retrieved, the CJR–X participant must determine why it is not retrievable, and if the item was misappropriated (if it was sold, for example), then further steps must be taken to ensure that that particular CJR–X beneficiary does not receive further beneficiary incentives. Following this process of documented, diligent, good faith attempts to retrieve items of technology will be deemed by CMS to meet the retrieval requirement. This outline is similar to the beneficiary incentive guidelines previously set forth in the CJR Model (80 FR 73553).

Finally, we are finalizing the requirement that the CJR–X participant must retain and provide access to the required documentation related to beneficiary incentives in accordance with § 512.135.

We sought comment on our proposed documentation requirements for beneficiary engagement incentives under CJR–X at § 512.685(d).

We received no comments on this proposal and therefore are finalizing this provision without modification.

(8) Enforcement Authority

OIG authority is not limited or restricted by the provisions of the model, including the authority to audit, evaluate, investigate, or inspect the CJR–X participant, CJR–X collaborators, collaboration agents, downstream collaboration agents, or any other person or entity or their records, data, or information, without limitations. Additionally, no model provisions limit or restrict the authority of any other Government Agency to do the same.

The enforcement authority for CJR–X, as finalized in this final rule, is in accordance with the standard provisions applicable to all Innovation Center models at § 512.160.

(9) Fraud and Abuse Waiver and OIG Safe Harbor Authority

Under section 1115A(d)(1) of the Act, the Secretary may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii) of the Act, and certain provisions of section 1934 of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act.

In the CJR 2015 final rule (80 FR 73325), the model was delayed by 3 months to allow for adequate time to prepare for hospital participation. Under the authority described in the previous paragraph, HHS Office of Inspector General (OIG) and CMS jointly issued Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Comprehensive Care for Joint Replacement Model on November 16, 2015. On December 5, 2017, the OIG and CMS jointly issued new waivers that superseded the original waivers issued in 2015 for certain arrangements permitted under the CJR Model (hereinafter ''CJR 2017 notice''), effective January 1, 2018.[606] The CJR 2017 notice set forth the specific conditions that must be met by CJR Model participants to qualify for a waiver. The waivers in the CJR 2017 notice protected specific financial arrangements that were entered into pursuant only to the CJR Model and described in the regulations governing the CJR Model at 42 CFR part 510, as amended from time to time.[607] The waivers in the CJR 2017 notice did not apply to other arrangements that may be entered into by participant hospitals and other entities or individuals and were not applicable outside of the CJR Model. These notices waived section 1128A(a)(5) of the Act (relating to the beneficiary inducements civil monetary

[606] The CJR 2017 Notice is available at: *https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/downloads/2017-cjr-model-waivers.pdf.*

[607] *See* 80 FR 73274 (November 24, 2015), as amended by 82 FR180 (January 3, 2017) and 82 FR 57066 (December 1, 2017).

penalty (CMP) law), sections 1128B(b)(l) and (2) of the Act (relating to the Federal anti-kickback statute), and section 1877(a) of the Act (relating to the Federal physician self-referral law) under section 1115A(d)(1) of the Act with respect to specified arrangements permitted under the CJR Model.

For this model and consistent with the authority under section 1115A(d)(1) of the Act, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act. No fraud or abuse waivers are being issued in this final rule; fraud and abuse waivers, if any, would be set forth in separately issued documentation. Any such waiver would apply solely to CJR–X and could differ in scope or design from waivers granted for other programs or models. Thus, notwithstanding any provision of this final rule, CJR–X participants, CJR–X collaborators, collaboration agents, and downstream collaboration agents must comply with all applicable laws and regulations, except as explicitly provided in any such separately documented waiver issued pursuant to section 1115A(d)(1) of the Act specifically for CJR–X.

At § 512.690(a), we proposed to make the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements available to protect remuneration furnished in CJR–X in the form of the sharing arrangement's gainsharing payments and alignment payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and proposed § 512.670, in the form of the distribution arrangement's distribution payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and proposed § 512.675, and in the form of the downstream distribution arrangement's distribution payments provided that all of the financial arrangements associated with such payment meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and proposed § 512.680. Additionally, at § 512.690(b), we proposed to make the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) available to protect CJR–X beneficiary incentives that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and 512.685. We sought comments on our proposals at § 512.690 that the Federal anti-kickback safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)(1)) and CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) be made available to CJR–X participants and CJR–X collaborators, collaboration agents, and downstream collaboration agents.

Independent of any potential waivers of the fraud and abuse provisions described previously, in this final rule, CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(1) and 42 CFR 1001.952(ii)(2)) are available to protect remuneration exchanged pursuant to certain financial arrangements and patient incentives that may be permitted under this final rule. Specifically, in this final rule, CMS has determined that the CMS-sponsored model safe harbor is available in CJR–X to protect the following financial arrangements and incentives: the sharing arrangement's gainsharing payments and alignment payments, the distribution arrangement's distribution payments, the downstream distribution arrangement's downstream distribution payments, and CJR–X beneficiary incentives.

The following is a summary of the public comments received on this proposal and our responses to those comments.

Comment: Some commenters urged CMS to provide stronger legal and operational support for gainsharing and other financial arrangements under CJR–X. Commenters stated that meaningful collaboration among participant hospitals, physician group practices, post-acute care providers, and other CJR–X collaborators would depend on the ability to enter into financial arrangements that align incentives, support care coordination, and promote continuity of care throughout the episode.

Commenters expressed concern that the proposed rule may potentially implicate fraud and abuse laws but CMS did not state that it would issue waivers of laws such as the physician self-referral law, the Federal anti-kickback statute, and the beneficiary inducements CMP Law. Commenters stated that waivers similar to those issued under the original CJR Model would provide participants and collaborators with greater certainty and flexibility in implementing gainsharing arrangements.

Some commenters also raised concerns that CMS's expected reliance on the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements and patient incentives may be insufficient, as there is no parallel exception under the physician self-referral law. They stated that the absence of clear fraud and abuse waivers could create uncertainty for hospitals, collaborators, and physician group practices and limit their ability to participate meaningfully in CJR–X financial arrangements.

Commenters further stated that waivers would be necessary to support beneficiary incentives and to avoid confusion about whether incentives offered as part of CJR–X could implicate the beneficiary inducements CMP law. A commenter questioned whether the proposal may result in confusion about the legality of beneficiary incentives.

Commenters recommended that CMS issue applicable fraud and abuse waivers in separate documentation or otherwise provide clear protection for financial arrangements and patient incentives under CJR–X. They stated that these protections would be important for aligning physicians, supporting participation by physician group practices, enabling collaboration with post-acute care providers, and achieving the model's goals of coordinated care and reduced spending. A commenter requested that CMS make significant changes to the model expansion's design features or provide sufficient infrastructure and technical support with respect to the financial arrangements and patient incentives.

Response: We thank commenters for raising concerns about protections for CJR–X financial arrangements and beneficiary incentives relating to fraud and abuse laws. We recognize the desire for CJR–X participants, CJR–X collaborators, collaboration agents, and downstream collaboration agents to obtain additional assurances and guidance with regard to financial arrangements that support care coordination, physician alignment, post-acute care collaboration, and episode management under CJR–X.

As discussed above and in the proposed rule (91 FR 19713), we acknowledge that the CJR Model included fraud and abuse waivers issued by CMS and the OIG under section 1115A(d)(1) of the Act. Those waivers preceded regulatory changes later made by OIG and CMS in 2020, and protected specified arrangements permitted under the CJR Model regulations, including certain arrangements involving gainsharing payments, alignment payments, and beneficiary incentives, provided all waiver conditions were met. In December 2020, CMS and OIG issued final rules in conjunction with two broad federal initiatives: the CMS Patients over Paperwork initiative and the Department of Health and Human Services' Regulatory Sprint to Coordinated Care. These final rules resulted in two significant regulatory

actions. First, the CMS final rule established exceptions to the physician self-referral law for certain compensation arrangements between or among physicians, providers, and suppliers that facilitate value-based health care delivery and payment. Second, the OIG final rule amended the safe harbors to the Federal anti-kickback statute to accommodate certain value-based arrangements and issued the CMS-sponsored model arrangements and CMS-sponsored model patient incentives safe harbor.

Given the 2020 regulatory changes, we are finalizing an approach to the specified financial arrangements and beneficiary incentives in CJR–X that is different but comparable to the CJR 2017 notice. We have determined that the CMS-sponsored model safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives safe harbor at 42 CFR 1001.952(ii) is available to protect remuneration exchanged pursuant to CJR–X financial arrangements and beneficiary incentives, provided that all applicable safe harbor conditions and CJR–X Model requirements are met. Under the finalized CJR–X policies, the CMS-sponsored model safe harbor applies to specified remuneration exchanged under CJR–X sharing arrangements, distribution arrangements, and downstream distribution arrangements, including gainsharing payments, alignment payments, distribution payments, and downstream distribution payments, when the arrangement complies with the CJR–X regulations, the CMS-sponsored model safe harbor, and any applicable model documentation. The CMS-sponsored model patient incentives safe harbor also applies to CJR–X beneficiary incentives that satisfy the finalized CJR–X requirements and the safe harbor conditions.

In contrast, the exceptions to the physician self-referral law, including the exceptions in § 411.357(aa) for value-based arrangements, do not require CMS to make a determination that they are available to parties that are participating in a particular model. We remind parties that, in order to avoid the physician self-referral law's referral and billing prohibitions, all requirements of an applicable exception must be satisfied.

We believe the availability of the of the CMS-sponsored model safe harbor and the physician self-referral law's exceptions for compensation arrangements that facilitate value-based health care delivery and payment (as well as any other exceptions to the physician self-referral law that may be applicable to a particular financial arrangement), provides CJR–X participants and collaborators with the same core operational protections as the fraud and abuse waivers in the CJR Model. Accordingly, we do not believe that separate fraud and abuse waivers are necessary for CJR–X.

Comment: A couple of commenters supported CMS' proposed protections for financial arrangements under CJR–X. Commenters stated that these protections would provide CJR–X participants with the operational flexibility needed to manage episodes across the care continuum expected that many arrangements between participants and downstream care providers would fall within the OIG safe harbor for CMS-sponsored model arrangements.

Response: We thank the commenters for their support for the protections available to CJR–X participants entering into financial arrangements as part of their implementation of the model.

Comment: A commenter stated that the proposed CJR–X collaborator framework would create substantial compliance and operational complexity. The commenter recommended that CMS provide additional guidance and model documentation to support consistent implementation and reduce uncertainty for participants and collaborators.

Response: We thank the commenter for sharing their concerns about compliance and operational complexity under the CJR–X collaborator framework. As discussed above, we value commenters' recommendations and we intend to provide learning and implementation support for CJR–X participants before the model begins. We anticipate engaging CJR–X participants before the model start date and sharing resources to help participants prepare for implementation. We will continue to make updated model resources publicly available, including the CJR–X Model-specific web page, frequently asked questions, fact sheets, and other implementation materials.

Comment: A commenter recommended that CMS consider engaging with OIG to expand the scope of the CMS-sponsored model arrangements safe harbor to include financial arrangements between hospitals and downstream care providers serving non-Medicare populations. The commenter stated that broader safe harbor protection would strengthen incentives for downstream providers to participate in collaborative care relationships with CJR–X hospitals, particularly when Medicare patients represent a small share of a downstream provider's patient population.

Response: We thank the commenter for raising the possibility of broader safe harbor protection for financial arrangements involving downstream care providers and non-Medicare populations. We recognize that downstream providers may serve mixed patient populations and that broader multi-payer alignment could, in some circumstances, support consistent care redesign across a provider's patient panel. However, the commenter's recommendation to expand safe harbor protections to financial arrangements across non-Medicare populations falls outside of the scope of this rulemaking.

After consideration of the public comments we received, we are finalizing without modifications our proposal at § 512.690 that the Federal anti-kickback safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)(1)) and CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) be made available to CJR–X participants and CJR–X collaborators, collaboration agents, and downstream collaboration agents.

j. Waivers of Medicare Program Requirements

(1) Overview

We believe it is necessary and appropriate to provide flexibilities to hospitals participating in CJR–X, as well as other providers and suppliers that provide services to beneficiaries in episodes. The purpose of such flexibilities is to support better, more coordinated care for beneficiaries and improved financial efficiencies for Medicare, providers, suppliers, and beneficiaries. The CJR Model eased the rules around the 3-Day SNF Rule and telehealth to allow for easier discharge to less intensive settings and avoid drops in quality of care via unplanned readmissions. For CJR–X, similar flexibilities will use the CMS waiver authority under section 1115A of the Act, which affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A of the Act. affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A of the Act.

As stated in section X.C.1.c. of this final rule, our previous and current efforts in testing episode-based-payment models have led us to believe that the greatest improvements in episode quality and efficiency are incentivized

when entities bear financial responsibility for total Medicare episode spending. We believe that holding CJR–X participants financially accountable for excess episode spending above the reconciliation target price increases incentives to coordinate care throughout the episode and reduce over-utilization of services. We also recognize that waivers of certain program rules may be appropriate to offer flexibility to Medicare providers and suppliers furnishing services to CJR–X beneficiaries. For example, Medicare requires a prior 3-day inpatient hospital stay to cover a skilled nursing facility (SNF) stay. By waiving this requirement, beneficiaries can be discharged to a SNF or swing bed after a shorter inpatient hospital stay, when clinically appropriate. This type of waiver has been implemented in many previous and existing CMS initiatives, including the CJR Model and TEAM. We believe adopting these waivers for CJR–X is appropriate.

Specific program rules for waivers that will be available to CJR–X participants are included in the sections that follow. These waivers, as finalized in this final rule, will apply to services furnished to a CJR–X beneficiary during an episode, even if the episode is later canceled as described in section X.C.2.d.(3)(e) of this final rule. We also are finalizing that if a service is found to have been billed and paid by Medicare under a CJR–X program rule waiver for a beneficiary not in CJR–X at the time the service was furnished, CMS would recover payment for that service from the provider or supplier and require the provider or supplier to repay the beneficiary for any coinsurance previously collected.

We welcomed comments on additional waivers that should be considered under section 1115A of the Act beyond those specifically discussed in this final rule. We were especially interested in comments explaining how such waivers would increase quality of care and reduce unnecessary episode spending in the context of CJR–X.

Comment: Some commenters requested broader waiver flexibility to support care delivery during CJR–X episodes. The commenters stated that CMS should provide robust waiver pathways for circumstances such as post-acute care capacity limits, SNF closures, severe weather, public health events, payer behavior, or beneficiary preference. They recommended that CMS give providers maximum flexibility to place beneficiaries in the clinical setting that best serves short- and long-term recovery goals. The commenters framed these requests as necessary to support efficient episode management and beneficiary-centered discharge planning.

Response: We appreciate the commenters' recommendations for broader waiver flexibility under CJR–X. We recognize the importance of flexibility during disruptions and local post-acute capacity constraints. However, we must evaluate each potential waiver for statutory authority, operational feasibility, Medicare coverage and payment implications, program integrity, and beneficiary protections. While these flexibilities were not included in the proposed rule, these comments may inform CMS' considerations going forward, including in potential future rulemaking.

Comment: Some commenters recommended that CMS waive certain inpatient rehabilitation facility requirements for CJR–X beneficiaries. The commenters referenced the IRF 60 percent rule, the three-hour rule, and the preponderance requirement for therapy. They stated that some post-surgical LEJR patients may clinically warrant IRF-level care but may not tolerate the required therapy intensity immediately after surgery or may not count toward the IRF compliance threshold. They believed that waiver flexibility would allow participants to place beneficiaries in the most clinically appropriate post-acute setting while maintaining accountability for quality and episode spending.

Response: We appreciate the commenters' concerns about access to clinically appropriate post-acute settings during CJR–X episodes. However, CMS did not propose waivers of the IRF 60 percent rule, three-hour rule, or preponderance requirement in the proposed rule. While these flexibilities were not included in the proposed rule, these comments will inform CMS' considerations going forward, including in potential future rulemaking.

Comment: A commenter requested that CMS allow existing surgical or discharge documentation of a beneficiary's post-operative home health needs to satisfy the Medicare home health face-to-face encounter requirement for post-surgical joint replacement patients. The commenter stated that requiring a separate qualifying encounter could create an unnecessary administrative step when the surgeon or attending physician has already documented the beneficiary's need for home health services.

Response: CMS appreciates the commenter's suggestion that CMS allow surgeon or attending physician documentation of post-operative care needs to satisfy the home health face-to-face encounter requirement for post-surgical joint replacement patients. CMS is not adopting this suggestion because this waiver was not proposed in the proposed rule and the face-to-face encounter requirement helps support medical necessity, beneficiary eligibility, documentation integrity, and program integrity before Medicare payment for home health services. Accordingly, CMS is not extending the SNF three-day waiver concept under CJR–X to waive or replace the home health face-to-face encounter requirement.

Comment: Some commenters requested that CMS waive or clarify waiver of the homebound requirement for home health services under CJR–X. The commenters stated that waiving the homebound requirement could provide hospitals with certainty when billing CJR–X home visit codes and could reduce episode spending by helping non-homebound beneficiaries avoid readmissions. They believed flexibility to determine whether home health is appropriate for beneficiaries near homebound status may be consistent with the purpose of model waivers. The commenters viewed this flexibility as a way to support post-acute care decisions and recovery in the home.

Response: We appreciate the commenters' recommendation that CMS waive or clarify waiver of the Medicare homebound requirement under CJR–X. However, we are not adopting this recommendation at this time because we did not introduce such a waiver in the proposed rule and the homebound requirement remains an important eligibility criterion for Medicare-covered home health services. A broader waiver of this requirement could raise coverage, payment, utilization, and program integrity concerns that are beyond the scope of the waivers that were proposed for CJR–X.

Comment: A commenter requested that CMS waive or modify hospital discharge planning requirements to provide hospitals with greater flexibility to guide beneficiaries to appropriate post-acute care options under CJR–X. The commenter stated that existing discharge planning requirements may limit hospitals' ability to coordinate post-hospital services effectively, particularly in connection with the SNF three-day rule waiver. The commenter suggested that additional discharge planning flexibility could support care coordination and appropriate post-acute placement during CJR–X episodes.

Response: We appreciate the commenter's recommendation that we waive certain hospital discharge

planning requirements to allow hospitals greater flexibility in directing beneficiaries to post-acute care options under CJR–X. We are not adopting this recommendation because we did not introduce such a waiver in the proposed rule, and discharge planning requirements help protect beneficiary freedom of choice, access to information, and informed decision-making when beneficiaries select post-hospital services. Accordingly, we are not adopting a waiver that could allow hospitals to restrict beneficiary freedom of choice or introduce concerns around steering.

Comment: A commenter recommended that CMS waive home health initiation-of-care rules so therapy staff could initiate care when both therapy and nursing are ordered. The commenter stated that current requirements can result in rejected referrals and delays when nursing is unavailable, even where therapy could begin timely care. The commenter believed delays in therapy may last days or weeks and could undermine functional recovery after joint replacement. The commenter requested a waiver allowing therapists to initiate episodes of care when an order includes some therapy, not only therapy.

Response: We appreciate the commenter's concern regarding timely access to therapy after discharge. We are not adopting a waiver of home health initiation-of-care requirements because we did not propose such a waiver in the proposed rule, and these requirements help ensure that home health care begins with the appropriate assessment, care planning, discipline involvement, and quality safeguards based on the beneficiary's ordered services and clinical needs. Allowing therapy staff to initiate care when both nursing and therapy are ordered would require broader review of Medicare home health conditions of participation, coverage rules, patient assessment requirements, and program integrity considerations beyond the scope of the waivers proposed for CJR–X.

Comment: A commenter requested that CMS confirm CJR–X waivers are available to any providers treating a beneficiary during an episode, rather than only selected providers in formal relationships with participant hospitals. The commenter referenced preferred providers and CJR–X collaborators as examples of formal relationships. The commenter appeared concerned that limiting waiver availability could reduce care coordination flexibility for downstream providers. The request focused on implementation scope and provider eligibility for waiver use.

Response: We appreciate the request for clarity regarding which providers and suppliers may use CJR–X waivers. In this final rule, we are finalizing program rule waivers that will apply to the care of CJR–X beneficiaries who are in episodes at the time the service is furnished under the waiver, subject to the specific requirements and billing conditions of each waiver. CJR–X collaborator status, preferred-provider relationships, or other formal arrangements with participant hospitals do not, by themselves, determine the scope of every waiver. We intend to provide implementation guidance, as appropriate, regarding which providers and suppliers may furnish or bill services under each waiver and what documentation, billing, and beneficiary protection requirements apply.

Comment: A commenter recommended that CMS waive the multiple procedure payment reduction for therapy services under CJR–X. The commenter stated that MPPR reduces payment for clinically distinct same-day therapy interventions that may be important to recovery after joint replacement. The commenter believed MPPR can disincentivize comprehensive treatment plans, contribute to delayed or fragmented care, and threaten therapy practice sustainability. The commenter framed the waiver as consistent with CJR–X goals of timely intervention, functional recovery, and reduced total episode costs.

Response: We appreciate the commenter's concerns regarding therapy payment policy and beneficiary recovery during CJR–X episodes. We are not adopting a waiver of the multiple procedure payment reduction for therapy services because we did not propose such a waiver in the proposed rule, and such a waiver would raise broader Medicare payment policy, utilization, budgetary, and operational considerations beyond the scope of the waivers proposed for CJR–X. We will consider the commenter's recommendation in future rulemaking as we consider whether additional therapy-related waivers should be addressed under the model.

Comment: A commenter requested that CMS consider a waiver related to home health consolidated billing rules. The commenter connected the request to CMS' proposal to allow separate reporting of certain post-discharge home visits during surgical global periods. The commenter appeared concerned that home health consolidated billing rules could limit access to separately furnished therapy or post-discharge services during a CJR–X episode. The request sought additional billing flexibility for care furnished during the episode.

Response: We appreciate the request to consider home health consolidated billing flexibility. CMS proposed to waive global surgery billing rules to allow separate reporting of certain CJR–X post-discharge home visits during the surgical global period because those visits are intended to support broader episode care coordination rather than duplicate routine post-operative surgical care. CMS did not propose a waiver of home health consolidated billing rules. Such a waiver would require review of Medicare home health payment rules, billing systems, duplicate payment risk, beneficiary protections, and whether the waiver is necessary for the model test.

Comment: A commenter requested CMS to include additional policy waivers to prevent delays in physical therapy during CJR–X episodes. The commenter stated that delays may result from provider availability, referral complexity, administrative burden, prior authorization, payment policies, or physician signature requirements. The commenter believed that delayed physical therapy can impair functional recovery, reduce the benefits of timely treatment, and increase costs for Medicare, patients, and providers. The commenter requested that CMS use waiver authority to ensure therapy is not delayed during transitions after joint replacement.

Response: We appreciate the commenter's emphasis on timely therapy access as part of recovery from LEJR procedures. We proposed CJR–X waivers intended to support care coordination, access, and post-discharge management, including home visits and telehealth flexibilities. However, we did not propose a broad waiver of therapy referral, signature, prior authorization, or payment requirements under CJR–X. We will consider the commenter's recommendation in future rulemaking as we consider whether additional therapy-related waivers should be addressed under the model.

Comment: A commenter recommended that CMS create a home-based swing-bed or ''swing-beds-without-walls'' pathway under CJR–X. The commenter stated that hospitals could furnish skilled-level post-acute recovery services in a beneficiary's home when clinically appropriate, particularly in areas with limited SNF capacity or inpatient bed shortages. The commenter suggested waiving certain hospital swing bed requirements so that nursing visits, therapy, medication management, remote monitoring, telehealth check-ins, virtual physician

supervision, and escalation protocols could be delivered in the home. The commenter believed the hospital would remain financially and clinically accountable for the full CJR–X episode while supporting safe recovery outside a facility.

Response: We appreciate the commenter's interest in expanding home-based post-acute care options, particularly where facility capacity is limited. We are not considering a separate ''swing-beds-without-walls'' pathway because it would go beyond the targeted CJR–X flexibilities initially proposed in this rule and would require separate review of how such care would be paid for and monitored for beneficiary protection. We proposed several waivers to support care coordination and access during CJR–X episodes, including home-based and post-acute care flexibilities, and invited comment on whether additional waivers could support the model test. We will consider the commenter's recommendation in future rulemaking as we consider whether additional therapy-related waivers should be addressed under the model.

After consideration of the public comments, we are not finalizing any additional waivers under section 1115A of the Act beyond those specifically discussed in this final rule.

(2) Post-Discharge Home Visits

The CJR Model permitted certain post-discharge home visits to encourage CJR participants to select the most appropriate post-acute care settings for beneficiaries. This allowed providers to consider beneficiary choice and location of beneficiary home or place of residence when selecting clinically appropriate lower acuity settings. Consistent with the CJR Model, we believe continuing such regulatory flexibilities for home-based care would support effective episode management.

Early post-discharge periods represent a time of heightened clinical vulnerability for beneficiaries undergoing joint replacement. Complications such as infection, medication-related issues, and mobility limitations frequently arise within the first weeks following discharge and may result in avoidable emergency department visits, readmissions, or use of institutional post-acute care services. We believe that timely, in-person home visits furnished by qualified clinicians may help identify emerging complications, reinforce discharge instructions, support medication reconciliation, and facilitate adherence to rehabilitation plans in the beneficiary's home environment.

We also anticipate that permitting targeted post-discharge home visits would promote safe discharge to home when clinically appropriate, potentially reducing reliance on higher-cost institutional post-acute care settings. Post-acute care spending represents a significant portion of episode spending, so enabling home-based clinical monitoring and care coordination, may lower total episode expenditures.

In the BPCI Advanced and CJR Models (80 FR 73444), we provided a waiver of the ''incident to'' rule. This allowed a physician or nonphysician practitioner participating in care redesign under a participating provider to bill for services furnished to a beneficiary who did not qualify for Medicare coverage of home health services, as set forth under § 409.42, after discharge from an acute care hospital. The ''incident to'' rules set forth in § 410.26(b) require that services and supplies furnished incident to the service of a supervising physician (or other practitioner) must be provided under ''direct supervision,'' as defined at § 410.26(a. Direct supervision denotes the physical or virtual presence of the supervising physician (or other practitioner).

In the BPCI Advanced and CJR Models, the waiver allowed for services that were furnished by licensed clinical staff under ''general supervision'' as defined at § 410.26(a)(3). That is, the service was furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence was not required during the performance of the service. The licensed clinician must have been allowed by law, regulation, and facility policy to perform or assist in the performance of the specific professional service, but did not individually report that professional service. In addition, the services furnished by the licensed clinical staff must have been billed by the supervising physician (or other practitioner) or model participant that the supervising physician had reassigned their billing rights (in accordance with CMS instructions using a Healthcare Common Procedures Coding System (HCPCS) G-code created for the BPCI Advanced and CJR Models). In the case of the ''incident to'' waiver under BPCI Advanced, the waiver allowed physician and nonphysician practitioners to furnish the services up to 13 home visits during each 90-day clinical episode. In the case of the ''incident to'' waiver under the original CJR Model, the waiver allowed physician and nonphysician practitioners to furnish the services up to 9 home visits during each 90-day clinical episode. This waiver was later modified to apply to anchor procedures in the CJR Extension (86 FR 23552). All other Medicare coverage and payment criteria had to be met for both BPCI Advanced and CJR Models.

We recognize TEAM did not waive the ''incident to'' rule set forth in § 410.26(b)(5) given the low waiver utilization in other CMS models and initiatives. However, we have determined to keep continuity between CJR–X and the CJR Extension to preserve the policies tested as it pertains to model waivers. However, we can monitor utilization and reassess the necessity of this waiver at a later date. We believe this will ensure the integrity of CJR model policies within CJR–X as it expands nationally. Therefore, we proposed to waive the ''incident to'' rule set forth in § 410.26(b)(5), to allow a CJR–X beneficiary who does not qualify for home health services to receive post-discharge visits in his or her home or place of residence any time during the episode. The waiver will not apply to beneficiaries who would qualify for home health services under the Medicare program, as set forth under § 409.42. Therefore, these visits will not be billed for such beneficiaries. Under the finalized waiver, we will allow licensed clinical staff, who may or may not be employed by the hospital, to furnish the service under the general supervision of a physician, who may be either an employee or a contractor of the hospital. We will allow services furnished under the waiver to be billed under the physician fees schedule by the physician or nonphysician practitioner or by the hospital the supervising physician has reassigned his or her benefits. In the latter scenario, we note that the post-discharge home visit services will not be ''hospital services,'' even when furnished by clinical staff of the hospital. We will monitor patterns of utilization of home health services using this waiver under CJR–X to monitor for overutilization or reductions in medically necessary care. Through this monitoring, we can evaluate effectiveness and redetermine the necessity of this waiver.

Under the CJR Model, we allowed up to 9 post-discharge home visits to be billed and paid during each 90-day post-anchor hospitalization or anchor procedure. This limit on the number of visits is based on the average post-acute care LOS of approximately 30 to 45 days for original CJR episodes and the incentives under original CJR to improve efficiency, which may shorten post-acute care stays. Thus, 9 visits represent a home visit on average of

once per week for two-thirds of the 90-day episode duration, the period of time when the typical beneficiary may have concluded post-acute care in an efficient episode. We proposed to adopt the same number of post-discharge home visits in CJR–X. Specifically, we proposed to allow up to 9 post-discharge home visits to be billed and paid during each 90-day post-anchor hospitalization or anchor procedure. We also proposed that the service be billed with a HCPCS code G-code. The G-code would be created before the start of CJR–X and would be specific to CJR–X to allow for a home visit for patient assessment performed by clinical staff for an individual not considered homebound. This G-code would include, but not be limited to patient assessment of clinical status, safety/fall prevention, functional status/ambulation, medication reconciliation/management, compliance with orders/plan of care, performance of activities of daily living, and ensuring CJR–X beneficiary connections to community and other services; for use only in CJR–X. Notably this code may not be billed for a 30-day period covered by a transitional care management code. We proposed the G-code would be paid at approximately $50 under the physician fee schedule. The standard physician fee schedule rate setting methodologies establish relative value units (RVUs) based on the resources required to furnish the typical service. In addition, we proposed to update the values each year to correspond to final values established under the physician fee schedule.

The waiver will not apply with respect to a CJR–X beneficiary who has qualified, or would qualify, for home health services when the visit was furnished. The visits by licensed clinical staff could include patient assessment, monitoring, assessment of functional status and fall risk, review of medications, assessment of adherence with treatment recommendations, patient education, communication and coordination with other treating clinicians, care management to improve beneficiary connections to community and other services, etc. These post-discharge home visits will remove barriers to follow-up care outside of the home with providers and suppliers and allow the CJR–X beneficiary to be treated in his or her home environment or place of residence, where potential safety concerns, such as tripping hazards, could quickly be identified and remediated. Given these occasions for further patient assessment and intervention, we believe that where such post-discharge home visits are furnished, there are opportunities to increase patient-centered care coordination and decrease episode spending, potentially resulting in higher-quality care for beneficiaries and increased episode efficiency which may benefit the beneficiaries, the Medicare Trust Fund, and CJR–X participants.

We also proposed to waive current Medicare billing rules in order to allow the separate reporting of these post-discharge home visits during surgical global periods. The physician fee schedule payment for the surgical procedure includes 90 days of post-operative care furnished by the surgeon. Post-operative follow-up care is not separately billable by the surgeon or, unless there is a transfer of care, by another practitioner. The current construction of the global packages included in physician fee schedule payments reflects a narrow view of surgical follow-up care that does not encompass broader, more comprehensive models of post-operative care, such as an episode payment model CJR–X. We do not believe that the CJR–X post-discharge home visits, which can include nursing assessments for chronic conditions for which care may be affected by the surgery, will replace or substantially duplicate the kind of post-operative visits involved in furnishing post-operative follow-up care for the global surgery procedure under the physician fee schedule. Instead, we anticipate that the work of these post-discharge visits will be similar to the work furnished by the physician coordinating the patient's overall episode care. Therefore, we proposed to waive the global surgery billing rules to allow the surgeon or other practitioners to furnish and bill for the post-discharge home visits during surgical global periods.

We sought comments at § 512.695(c) on the proposed waiver of the ''incident to'' rule to pay for a maximum number of nine post-discharge home visits to beneficiaries who do not qualify for home health services by licensed clinical staff under the general supervision of a physician.

Comment: Some commenters supported the proposed post-discharge home visit waiver and broader home-based recovery flexibilities under CJR–X. The commenters stated that the waiver related to the ''incident to'' requirement could allow nonphysician practitioners, advanced practice providers, and other licensed clinical staff to furnish home visits under more flexible care team models. They believed these flexibilities would improve care coordination, expand access to services in the home, support patient recovery, and help manage episodes more efficiently. Some commenters stated that home-based post-acute care could help address limited post-acute care capacity and allow older adults to recover safely at home when clinically appropriate. A commenter emphasized that modern care teams can use remote monitoring, structured protocols, and real-time physician supervision while maintaining or improving quality. A commenter also supported CMS' proposal to allow separate reporting of certain post-discharge home visits during surgical global periods, especially when the care is part of broader episode management rather than routine post-operative care. Overall, commenters supported the proposed waivers as important to CJR–X success and to protecting beneficiary access to care.

Response: We appreciate the commenters' support for the proposed post-discharge home visit waiver and related home-based recovery flexibilities.

Comment: Some commenters recommended expanding the role of rehabilitation therapists in the home health setting under CJR–X. Specifically, commenters recommended that occupational therapy be treated as a qualifying service for Medicare home health eligibility and that rehabilitation therapists, including occupational therapists, physical therapists, and speech-language pathologists, be permitted to perform home health assessments when both therapy and nursing services are ordered. Commenters stated that these clinicians are well positioned to assess functional, behavioral, and safety needs and would help achieve the goals of CJR–X by improving quality and reducing episode spending.

Response: We acknowledge the commenters' requests to authorize additional provider types, including rehabilitation therapists such as occupational therapists, physical therapists, and speech-language pathologists, to perform certain home health services and assessments under CJR–X. We appreciate the important role these clinicians play in supporting functional recovery and successful transitions to the home setting. However, we did not propose policies to modify Medicare home health qualifying service requirements or home health assessment requirements under CJR–X. Home health eligibility, qualifying service rules, and assessment requirements are separate Medicare coverage and program requirements.

These comments may inform potential future rulemaking.

Comment: A commenter recommended that CMS consider targeted investments or waivers to support interoperability infrastructure. The comment suggested that data exchange and infrastructure support may be important for successful coordination and implementation capacity under CJR–X.

Response: We appreciate the commenter's recommendation regarding interoperability infrastructure. The commenter did not identify a specific Medicare coverage or payment requirement that should be waived for interoperability purposes, so CMS would need additional detail to assess the legal authority, operational feasibility, and relationship to CJR–X Model testing.

Comment: A commenter recommended that integrated at-home post-discharge care become a standard discharge option for appropriate CJR–X beneficiaries. The commenter stated that the right patient population should be selected based on moderate functional impairment, stable medical status, minimal skilled nursing needs, and caregiver availability. The commenter suggested CMS consider using the Activity Measure for Post-Acute Care 6-Clicks basic mobility short form and qualitative assessment by physical therapists, occupational therapists, or case managers. The commenter stated that case managers, admission care coordinators, and the medical team should work together to determine whether a beneficiary is appropriate for post-acute rehabilitation at home.

Response: We appreciate the commenter's recommendation regarding standardized assessment for home-based post-discharge options. We proposed beneficiary notification, discharge planning notice recordkeeping, post-discharge home visit flexibilities, and telehealth flexibilities intended to support beneficiary understanding, care coordination, and appropriate care transitions. However, the proposed rule did not prescribe a specific functional assessment tool or require hospitals to make a particular home-based option a standard discharge pathway. Furthermore, we do not wish to restrict the post-acute care setting that makes the most sense for beneficiaries and their provider teams by creating a standardized discharge option for participants.

After consideration of the public comments we received, we are finalizing § 512.695(c) on the proposed waiver of the ''incident to'' rule to pay for a maximum number of nine post-discharge home visits to beneficiaries who do not qualify for home health services by licensed clinical staff under the general supervision of a physician.

(3) Telehealth

The CJR Model waived certain telehealth service requirements to allow providers and suppliers furnishing services to model beneficiaries to utilize telemedicine for beneficiaries that are not classified as rural and allowed the greatest degree of efficiency and communication between providers and suppliers and beneficiaries by allowing beneficiaries to receive telehealth services at their home or place of residence. We believe similar telehealth waivers will be essential to maximize the opportunity to improve the quality of care and efficiency for episodes of care in CJR–X.

Under section 1834(m) of the Act, Medicare pays for telehealth services furnished by a physician or practitioner under certain conditions even though the physician or practitioner is not in the same location as the beneficiary. The telehealth services must be furnished to a beneficiary located in one of the ten types of originating sites specified in section 1834(m)(4)(C)(ii) of the Act and the site must satisfy at least one of the requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. Generally, for Medicare payment to be made for telehealth services under the Medicare Physician Fee Schedule several conditions must be met, as set forth under § 410.78(b). Specifically, the service must be on the Medicare list of telehealth services and meet all of the following other requirements for payment:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the services must be in an eligible originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and provides separate payment to the distant site practitioner for the service. Section 1834(m)(4)(F)(i) of the Act defines ''Medicare telehealth services'' to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. For the list of approved Medicare telehealth services, see the CMS website at *https://www.cms.gov/medicare/coverage/telehealth/list-services.* Under section 1834(m)(4)(F)(ii) of the Act, CMS has an annual process to consider additions to and deletions from the list of telehealth services. We do not include any services as telehealth services when Medicare does not otherwise make a separate payment for them.

In the CJR Model (80 FR 73274) as well as the national COVID–19 public health emergency (PHE) telehealth waiver,[608] and in the most recent Consolidated Appropriations Act, 2026, hospitals were permitted to use telehealth waivers that applied to two provisions:

- CMS waived the geographic site requirements under 1834(m)(4)(C)(i)(I) through (III) of the Act which allowed telehealth services to be furnished to eligible telehealth individuals when they are located at one of the eight originating sites at the time the service is furnished via a telecommunications system but without regard to the site meeting one of the geographic site requirements.
- CMS waived the originating site requirements under section 1834(m)(4)(C)(ii)(I) through (X) of the Act which allowed the eligible telehealth individual to not be in an originating site when the otherwise eligible individual is receiving telehealth services in their home or place of residence.

Specifically, like the telehealth waivers in the CJR Model (80 FR 73448), we proposed to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. Waiver of this requirement will allow beneficiaries located in any region to receive services related to the episode to be furnished via telehealth, as long as all other Medicare requirements for telehealth services are met. Any service on the list of Medicare approved telehealth services and reported on a claim that is not excluded from the proposed episode definition (see section X.C.2.d.(3). of this proposed rule) could be furnished to a CJR–X beneficiary, regardless of the CJR–X beneficiary's geographic location. Under CJR–X, this waiver will support care coordination and increasing timely access to high quality care for all CJR–X beneficiaries, regardless of geography. Additionally, we proposed for CJR–X waiving the originating site

[608] Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Public Law 116–123 § 101 (Mar. 6, 2020 *https://www.govinfo.gov/content/pkg/BILLS-116hr748enr/pdf/BILLS-116hr748enr.pdf.*

requirements of section 1834(m)(4)(C)(ii)(I) through (X) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system. Specifically, we proposed to waive the requirement only when telehealth services are being furnished in the CJR–X beneficiary's home or place of residence during the episode. Any service on the list of Medicare approved telehealth services that is not excluded from the proposed episode definition (see section X.C.2.d.(3)(b). of this proposed rule) could be furnished to a CJR–X beneficiary in their home or place of residence, unless the service's HCPCS code descriptor precludes delivering the service in the home or place of residence. For example, subsequent hospital care services could not be furnished to beneficiaries in their home since those beneficiaries will not be inpatients of the hospital. Though these activities are allowed via broad Medicare telehealth waivers, as recently extended under the Consolidated Appropriations Act, 2026, these waivers are not permanent and have been subject to reconsiderations and extensions by Congress. This CJR–X telehealth waiver will guarantee that the telehealth services mentioned in this waiver will continue for CJR–X participants even if the broad Medicare telehealth waivers expire.

The existing set of codes used to report evaluation and management (E/M) visits are extensively categorized and defined by the setting of the service, and the codes describe the services furnished when both the patient and the practitioner are located in that setting. Section 1834(m) of the Act provides for particular conditions under which Medicare can make payment for office visits when a patient is located in a health care setting (the originating sites authorized by statute) and the eligible practitioner is located elsewhere. However, we do not believe that the kinds of E/M services furnished to patients outside of health care settings via real-time, interactive communication technology are accurately described by any existing E/M codes. This will include circumstances when the patient is located in his or her home and the location of the practitioner is unspecified. In order to create a mechanism to report E/M services accurately, the BPCI Advanced and CJR Models (80 FR 73450) created specific sets of HCPCS G-codes to describe the E/M services furnished to the model beneficiaries in their homes via telehealth. Similarly, for CJR–X, we proposed to create a specific set of 4 HCPCS G-codes to describe the E/M services furnished to CJR–X beneficiaries in their homes via telehealth. CMS will specify the precise G-code created for CJR–X and share them to CJR–X participants prior to the first performance year.

Among the existing E/M visit services, we envision these services will be most similar to those described by the office and other outpatient E/M codes. Therefore, we proposed to structure the new codes similarly to the office/outpatient E/M codes but adjusted to reflect the location as the CJR–X beneficiary's residence and the virtual presence of the practitioner. Specifically, we proposed to create a parallel structure and set of descriptors currently used to report office or other outpatient E/M services, see Table X.C–07, for CPT codes CPT codes 99212 through 99215 for established patient visits. For example, the proposed G-code for a level 3 E/M visit for an established patient will be a telehealth visit for the evaluation and management of an established patient in the patient's home, which requires at least 2 of the following 3 key components:

- An expanded problem focused history;
- An expanded problem focused examination;
- Medical decision making of low complexity.

Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the patient's or family's needs or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent with the patient or family or both via real-time, audio and video intercommunications technology.

TABLE X.C-07: PROPOSED CJR-X TELEHEALTH WAIVER G-CODE CROSSWALK

CJR-X G-Code (Used for illustrative purposes. Specific G-codes will be created if CJR-X is finalized.)	Short Descriptor	Corresponding Office/Outpatient E/M CPT Code
GXX12	Remote E/M est. pt 10mins	99212
GXX13	Remote E/M est. pt 20mins	99213
GXX14	Remote E/M est. pt 30mins	99214
GXX15	Remote E/M est. pt 40mins	99215

We note that we did not propose a G-code to parallel the level 1 office/outpatient visit for an established patient, since that service does not require the presence of the physician or other qualified health professional.

We proposed to develop payment rates for these new telehealth G-codes for E/M services in the patient's home that are similar to the payment rates for the office/outpatient E/M services, since the codes will describe the work involved in furnishing similar services. Therefore, we proposed to include the resource costs typically incurred when services are furnished via telehealth. In terms of the relative resource costs involved in furnishing these services, we believe that the efficiencies of virtual presentation generally limit resource costs other than those related to the professional time, intensity, and malpractice risk to marginal levels. Therefore, we proposed to adopt work and malpractice (MP) RVUs associated with the corresponding level of office/outpatient codes as the typical service because the practitioner's time and intensity and malpractice liabilities when conducting a visit via telehealth are comparable to the office visit. We would include final RVUs under the CY 2027 Medicare Physician Fee Schedule for PY 1. Additionally, we proposed to update these values each performance year to correspond to final values established under the Medicare Physician Fee Schedule.

We considered whether each level of visit typically would warrant support by auxiliary licensed clinical staff within the context of CJR–X. The cost of such staff and any associated supplies, for example, would be incorporated in the practice expense (PE) RVUs under the

PFS. For the lower level visits, levels 2 and 3 for established visits, we did not believe that the visit would necessarily require auxiliary medical staff to be available in the patient's home. We anticipate these lower level visits would be the most commonly furnished and would serve as a mechanism for the patient to consult quickly with a practitioner for concerns that can be easily described and explained by the patient. We did not propose to include PE RVUs for these services, since we do not believe that virtual visits envisioned for this model typically incur the kinds of costs included in the PE RVUs under the Medicare Physician Fee Schedule. For higher level visits, we typically would anticipate some amount of support from auxiliary clinical staff. For example, wound examination and minor wound debridement would be considered included in an E/M visit and would require licensed clinical staff to be present in the CJR–X beneficiary's home during the telehealth visit in order for the complete service to be furnished. We believe it would be rare for a practitioner to conduct as complex and detailed a service as a level 4 or 5 E/M home visit via telehealth for CJR–X beneficiaries in episodes without licensed clinical staff support in the home.

We have considered support by auxiliary clinical staff to be typical for level 4 or 5 E/M visits furnished to CJR–X beneficiaries in the home via telehealth, however, we did not propose to incorporate these costs through PE RVUs. Given the anticipated complexity of these visits, we would expect to observe level 4 and 5 E/M visits to be reported on the same claim with the same date of service as a home visit or during a period of authorized home health care. If neither of these occurs, we proposed to require the physician to document in the medical record that auxiliary licensed clinical staff were available on site in the patient's home during the visit and if they were not, to document the reason that such a high-level visit would not require such personnel.

We note that because the services described by the proposed G-codes, by definition, are furnished remotely using telecommunications technology, they therefore are paid under the same conditions as in-person physicians' services and they do not require a waiver to the requirements of section 1834(m) of the Act. We also note that because these home telehealth services are E/M services, all other coverage and payment rules regarding E/M services will continue to apply.

Under CJR–X, this proposal to waive the originating site requirements and create new home visit telehealth HCPCS codes will support the greatest efficiency and timely communication between providers and beneficiaries by allowing beneficiaries to receive telehealth services at their places of residence.

With respect to home health services paid under the home health prospective payment system (HH PPS), we emphasize that telehealth visits under this model cannot substitute for in-person home health visits per section 1895(e)(1)(A) of the Act. Furthermore, telehealth services by social workers cannot be furnished for CJR–X beneficiaries who are in a home health episode because medical social services are included as home health services per section 1861(m) of the Act and paid for under the Medicare HH PPS. However, telehealth services permitted under section 1834 of the Act and furnished by physicians or other practitioners, specifically physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, nurse anesthetists, psychologists, and dieticians, can be furnished for CJR–X beneficiaries who are in a home health episode. Finally, sections 1835(a) and 1814(a) of the Act require that the patient has a face-to-face encounter with the certifying physician or an allowed nonphysician practitioner (NPP) working in collaboration with or under the supervision of the certifying physician before the certifying physician certifies that the patient is eligible for home health services. Under § 424.22(a)(1)(v), the face-to-face encounter can be performed up to 90 days prior to the start of home health care or within 30 days after the start of home health care. Section § 424.22(a)(1)(v)(A) also allows a physician, with privileges, who cared for the patient in an acute or post-acute-care setting (from which the patient was directly admitted to home health) or an allowed NPP working in collaboration with or under the supervision of the acute or post-acute care physician to conduct the face-to-face encounter.

Although sections 1835(a) and 1814(a) of the Act allow the face-to-face encounter to be performed via telehealth, we did not propose that the waiver of the telehealth geographic site requirement for telehealth services and the originating site requirement for telehealth services furnished in the CJR–X beneficiary's home or place of residence would apply to the face-to-face encounter required as part of the home health certification when that encounter is furnished via telehealth. In other words, when a face-to-face encounter furnished via telehealth is used to meet the requirement for home health certification, the usual Medicare telehealth rules apply with respect to geography and eligibility of the originating site. We expect that this policy would not limit CJR–X beneficiaries' access to medically necessary home health services because beneficiaries receiving home health services during an episode will have had a face-to- face encounter with either the physician or an allowed NPP during their anchor hospitalization or a physician or allowed NPP during a post-acute facility stay prior to discharge directly to home health services.

Under the finalized waiver of the geographic site requirement and originating site requirement, all telehealth services will be required to be furnished in accordance with all Medicare coverage and payment criteria, and no additional payment would be made to cover set-up costs, technology purchases, training and education, or other related costs. The facility fee paid by Medicare to an originating site for a telehealth service will be waived if there is no facility as an originating site (that is, the service originated in the CJR–X beneficiary's home). Finally, providers and suppliers furnishing a telehealth service to a CJR–X beneficiary in his or her home or place of residence during the episode will not be permitted to bill for telehealth services that were not fully furnished when an inability to provide the intended telehealth service is due to technical issues with telecommunications equipment required for that service. CJR–X beneficiaries will be able to receive services furnished pursuant to the telehealth waivers only during the episode.

We plan to monitor patterns of utilization of telehealth services under CJR–X to monitor for overutilization or reductions in medically necessary care, and significant reductions in face-to-face visits with physicians and NPPs. Though this waiver existed in the CJR Model, the broader Medicare telehealth waivers also covered much of the CJR Model. By including a telehealth waiver specific to CJR–X now and monitoring use, we could gauge effectiveness and guarantee its access even if the broad Medicare telehealth waiver, that were recently extended under the Consolidated Appropriations Act, 2026, expires. We plan to specifically monitor the distribution of new telehealth home visits that we proposed, as we anticipate greater use of lower level visits. Given our concern that auxiliary licensed clinical staff be present for level 4 and

5 visits, we will monitor our proposed requirement that these visits be billed on the same claim with the same date of service as a home nursing visit, during a period authorized home health care, or that the physician document the presence of auxiliary licensed clinical staff in the home or an explanation as to the specific circumstances precluding the need for auxiliary staff for the specific visit.

We sought comment on the proposed waivers with respect to telehealth services and the proposed creation of the home visit telehealth codes at § 512.695(a).

Comment: Many commenters supported including telehealth waivers in CJR–X. The commenters stated that telehealth flexibilities can improve care coordination, support access to services in the home, reduce administrative burden, and help clinicians address issues early in the rehabilitative process. Several commenters noted that similar flexibilities were useful in the CJR Model, other Innovation Center models, and Medicare Shared Savings Program. Some commenters emphasized that telehealth and remote care are now integrated into health care delivery and can help bring appropriate care to beneficiaries in familiar home environments.

Response: We appreciate the commenters' support for CJR–X telehealth flexibilities.

Comment: Some commenters recommended that CMS use existing CPT or E/M telehealth coding practices rather than create new CJR–X-specific G-codes. The commenters stated that the proposed G-codes did not appear clinically different from existing E/M codes on the Medicare telehealth services list. They suggested that existing place-of-service coding and professional telehealth billing guidance could identify telehealth visits furnished in the home. The commenters believed using existing codes would reduce administrative complexity and avoid unnecessary new billing requirements.

Response: We appreciate the recommendation to rely on existing telehealth coding where feasible. CMS proposed CJR–X-specific home visit telehealth G-codes, rather than existing E/M codes, to identify services furnished to CJR–X beneficiaries to allow CMS to monitor utilization under the model and approve the waiver flexibilities. The proposed rule explains that these services would be paid under the same conditions as in-person physician services and that other E/M coverage and payment rules would continue to apply. We recognize the commenters' concern that new codes may create burden and may take them under consideration in future rulemaking.

Comment: A commenter recommended expanding in-home telehealth G-codes to include geriatric assessment and 4Ms-aligned services. The commenter noted the older age profile of the CJR–X population. The commenter appeared to view geriatric assessment as relevant to safe recovery, function, medication management, and home-based care after joint replacement.

Response: We appreciate the recommendation to expand in-home telehealth G-codes include geriatric assessment and services aligned with the 4Ms framework. We recognize that beneficiaries receiving lower extremity joint replacement services may have complex clinical, functional, medication, and home-based care needs during recovery. However, the proposed CJR–X telehealth waiver would allow for E/M telehealth services such as assessments of geriatric aged patients to be furnished to CJR–X beneficiaries in their home or place of residence during an episode.

After consideration of the public comments we received, we are finalizing without modification the proposed waivers with respect to telehealth services and the proposed creation of the home visit telehealth codes at § 512.695(a).

(4) 3-Day SNF Rule

Pursuant to section 1861(i) of the Act, a beneficiary must have a prior inpatient hospital stay of no fewer than 3 consecutive days to be eligible for Medicare coverage of inpatient SNF care. We refer to this as the SNF 3-day rule. We note that the SNF 3-day rule has been waived for Medicare SNF coverage under many Innovation Center initiatives, including the BPCI Advanced and CJR Models (80 FR 73460) and the Medicare Shared Savings Program. Model and program participants that elect to use the waiver can discharge model beneficiaries in fewer than 3 days from an anchor hospital stay or anchor procedure (in the case of the CJR Model) to a SNF, or swing bed where services are covered under Medicare Part A if all other coverage requirements for such services are satisfied.

Because of the potential benefits we see for CJR–X participants, their provider partners, and beneficiaries, we proposed to waive the SNF 3-day rule for coverage of a SNF stay following the anchor hospitalization or anchor procedure under CJR–X. We proposed to use our authority under section 1115A of the Act with respect to certain SNFs that furnish Medicare Part A post-hospital extended care services to beneficiaries included in an episode in CJR–X. All other Medicare rules for coverage and payment of Part A-covered SNF services will continue to apply to CJR–X beneficiaries in all performance years of the model. Further, to ensure protection to CJR–X beneficiary safety and optimize health outcomes, we proposed to require that CJR–X participants may only discharge a CJR–X beneficiary under this proposed waiver of the SNF 3-day rule to a SNF rated an overall of three stars or better by CMS based on information publicly available at the time of hospital discharge from an anchor hospital stay or anchor procedure. However, providers furnishing SNF services under swing bed agreements will not be subject to the star ratings requirement as described later in this section. CMS created a Five-Star Quality Rating System for SNFs to allow SNFs to be compared more easily and to help identify areas of concerning SNF performance. The Nursing Home Compare website gives each SNF an overall rating of between 1 and 5 stars.[609] Those SNFs with 5 stars are considered to have much above average quality, and SNFs with 1 star are considered to have quality much below average. Published SNF ratings include distinct ratings of health inspection, staffing, and quality measures, with ratings for each of the three sources combined to calculate an overall rating. These areas of assessment are all relevant to the quality of SNF care following discharge from the anchor hospitalization or anchor procedure initiating an episode, especially if that discharge occurs after fewer than 3 days in the hospital. Because of the potential greater risks following early inpatient hospital discharge, we believe it is appropriate that all CJR–X beneficiaries discharged from the CJR–X participant to a SNF, or swing bed, in fewer than 3 days be admitted to a SNF that has demonstrated that it can provide quality care to patients with significant unresolved post-surgical symptoms and problems. We believe such a SNF will need to provide care of at least average overall quality, which will be represented by an overall SNF 3-star or better rating.

Thus, the CJR–X participant must discharge the CJR–X beneficiary to a SNF that is qualified under the SNF 3-

[609] Find & Compare Providers near you. Medicare.gov. *https://www.medicare.gov/care-compare/?redirect=true&providerType=NursingHome.*

day rule waiver. We proposed that to be qualified under the SNF 3-day rule waiver a SNF must be included in the most recent calendar year quarter Five-Star Quality Rating System listing for SNFs on the Nursing Home Compare website for the date of the CJR–X beneficiary's admission to the SNF. The qualified SNF must be rated an overall 3 stars or better for at least 7 of the 12 months based on a review of the most recent rolling 12 months of overall star ratings, unless providers furnishing SNF services are doing so under swing bed agreements We proposed to post on the CMS website the list of qualified SNFs in advance of the calendar quarter.

We recognize that there may be instances where a CJR–X participant would like to use the 3-day SNF rule waiver, but the CJR–X beneficiary receives inpatient post-acute care through swing bed arrangements in a hospital or Critical Access Hospital (CAH), as designated in § 485.606 of this chapter, which is not subject to the Five-Star Quality Rating System. For example, a CJR–X beneficiary located in a rural area may wish to receive post-acute care closer to their home but there are no qualified SNFs in their area. The CJR Model (80 FR 73459) did not allow for exceptions to the star-rating requirements in the 3-day SNF waiver out of a concern for balancing the needs of participant flexibilities and beneficiary protections. However, in TEAM we finalized a policy allowing hospitals with swing beds arrangements to make use of the 3-day SNF waiver (90 FR 37130). Similar to TEAM, we proposed allowing CJR–X participants to use the 3-day SNF rule waiver for hospitals and CAHs operating under swing bed agreements to support CJR–X beneficiary freedom of choice and provide greater flexibility to increase access and capacity. We also proposed that, for purposes of the SNF 3-day rule waiver, providers furnishing SNF services under swing bed arrangements will be treated as SNFs. However, the requirement to maintain a minimum 3-star rating for at least 7 of the previous 12 months will apply only to providers eligible for inclusion in the CMS Five-Star Quality Rating System. Accordingly, hospitals and Critical Access Hospitals (CAHs) furnishing SNF services under swing bed arrangements will not be subject to the 3-star requirement because they are not included in the Five-Star system. This approach is consistent with the Shared Savings Program's SNF 3-day rule waiver, which similarly permits use of the waiver for hospitals and CAHs furnishing SNF services under swing bed arrangements.

CMS will continue to monitor and audit use of the SNF 3-day rule waiver, including by providers furnishing SNF services under swing bed arrangements, to ensure beneficiary protections are maintained. CMS reserves the right to take remedial action if it identifies concerns related to waiver use or beneficiary outcomes. We also plan to monitor patterns of SNF utilization under the CJR–X, particularly with respect to hospital discharge in fewer than 3 days to a SNF, to ensure that CJR–X beneficiaries are not being discharged prematurely to SNFs and that they are able to exercise their freedom of choice without patient steering.

We sought comment on our proposal at § 512.695(b)(1) through (4) to waive the SNF 3-day stay rule following discharge from the anchor hospitalization or anchor procedures for episodes in CJR–X.

Comment: Some commenters supported the proposed SNF three-day rule waiver for CJR–X. The commenters stated that the waiver would provide meaningful flexibility, support care coordination, reduce administrative burden, and help beneficiaries receive skilled nursing or rehabilitation services without an unnecessary inpatient stay. Some commenters believed the waiver would improve episode management, support recovery, preserve hospital capacity for higher-acuity patients, and lower Medicare costs by allowing care in lower-cost settings when clinically appropriate. The commenters generally viewed the waiver as necessary for the success of CJR–X and for protecting patient access to care.

Response: We appreciate the commenters' support for the proposed SNF three-day rule waiver.

Comment: A commenter recommended that CMS consider waivers to support skilled-level post-acute recovery services in the home, including SNF-at-home approaches and virtual physician involvement in SNF-related care. The commenter referenced a study stating that SNF-at-home models may improve outcomes, reduce rehospitalizations, lower costs, and support clinically appropriate home recovery for beneficiaries who need more than traditional home health but may not require institutional placement. The commenter recommended waiving or modifying requirements such as 24/7 onsite nursing, facility life safety code standards, and certain SNF physician visit or supervision requirements so that remote monitoring, home visits, and virtual physician supervision could support home-based, post-acute care.

Response: We acknowledge the recommendation to explore SNF-at-home approaches for CJR–X beneficiaries. We share the commenter's interest in post-acute capacity, safe home-based recovery, and avoiding unnecessary institutional utilization. Therefore, we are finalizing waivers which support home-based flexibilities, including post-discharge home visits and telehealth waivers. However, the creation of new at-home benefits are a legislative matter and beyond the scope of CJR–X. Additionally, these changes would require program-wide implementation prior to adoption. Should such changes to Medicare coverage be implemented at the program level, we would consider further appropriate action.

Comment: A commenter supported the SNF three-day rule waiver but stated that SNFs may be reluctant to accept beneficiaries who have not had a three-day inpatient stay. The commenter stated that SNFs may not understand the logistics of the waiver, may view billing as complex, and may worry that the waiver will not be honored if the beneficiary's status changes. The commenter recommended additional education and guidance for SNFs regarding use and allowability of the waiver. The commenter also requested that CMS automatically approve a beneficiary's three-day stay waiver without requiring the SNF to submit different billing information.

Response: We appreciate the commenter's concerns regarding SNF understanding of waiver eligibility, billing, and documentation requirements. We recognize the importance of clear operational guidance to support implementation of the waiver and will consider whether additional subregulatory guidance or educational materials may be appropriate. We thank the commenter for this suggestion.

Comment: A commenter strongly supported inclusion of the SNF three-day rule waiver and urged CMS to confirm it as an automatic, universal provision for all CJR–X participants. The commenter mentioned that patients undergoing outpatient joint replacement currently cannot access SNF-level care under Medicare due to not having an inpatient stay. For this reason, the commenter stated that the waiver should not be a discretionary flexibility that may or may not be implemented.

Response: We appreciate the commenter's support for inclusion of the SNF 3-day rule waiver and the comment regarding beneficiaries

undergoing outpatient joint replacement procedures. We note that extending the SNF 3-day rule waiver to beneficiaries receiving outpatient procedures was not proposed and therefore is beyond the scope of this rulemaking. We further note that we do not believe it is necessary or appropriate to automatically apply the SNF 3-day rule waiver to all beneficiaries who may trigger an episode in CJR–X. We continue to believe that episode-based payment models can mitigate incentives to overuse SNF services, while allowing participants flexibility to coordinate post-acute care when warranted. Accordingly, we are finalizing the SNF 3-day rule waiver as proposed. We thank the commenter for this suggestion and may consider it in future rulemaking.

Comment: A commenter expressed concern that the proposed SNF Five Star rating requirement for the three-day rule waiver could create unequal access to flexible post-acute care. The commenter stated that beneficiaries in markets with an adequate supply of three-star SNFs may have more patient-centered options than beneficiaries in markets with limited three-star SNF capacity. The commenter also questioned the star rating methodology, citing variation in how survey standards and guidance are applied across states and surveyors. The commenter believed the proposed structure could disadvantage beneficiaries and hospitals in markets where the rating threshold limits available SNF options.

Response: We appreciate the commenter's concerns about the proposed qualified SNF criteria. We proposed the three-star overall rating requirement as a beneficiary protection to identify SNFs that have demonstrated at least average overall quality based on health inspection, staffing, and quality measure domains. We believe that implementing the three-star overall rating requirement does not limit patient care options as patients are still able to be admitted to a SNF not meeting the three-star requirement after meeting the three-day inpatient stay requirement. Additionally, we believe it is necessary to establish benchmarks for quality to protect beneficiaries from being discharged to low-quality providers under a model where participant hospitals may have financial incentives to limit post-acute care spending. The 3-star standard ensures that financial considerations do not supersede clinical appropriateness. Additionally, we recognize that a SNF's star rating may fluctuate from month to month. However, by requiring that a SNF maintain an overall rating of 3 stars or better for at least 7 of the most recent rolling 12 months, we account for normal variations while still ensuring a baseline of sustained quality over time.

Comment: Some commenters supported allowing use of the SNF three-day rule waiver for swing bed arrangements, particularly in rural communities where no qualified SNF may be available locally. The commenters stated that swing beds can be critical to managing post-acute transitions and preserving access close to a beneficiary's home. They recommended that CMS treat swing bed facilities equitably within the waiver framework and avoid eligibility standards that favor traditional SNFs over rural swing bed capacity. They also requested additional operational clarity on how qualified swing bed facilities would be identified, monitored, and supported under CJR–X.

Response: We appreciate the commenters' support for recognizing swing bed arrangements under the proposed SNF three-day rule waiver. We proposed the waiver for discharges to hospitals and Critical Access Hospitals operating under swing bed agreements to provide greater flexibility in post-acute care in rural areas without qualified local SNF availability. We also proposed that providers furnishing SNF services under swing bed arrangements will be considered SNFs for purposes of the waiver. However, the minimum 3-star quality rating requirement will apply only to providers that are eligible for the CMS Five-Star Quality Rating System. As a result, swing bed hospitals, which are not rated under the Five-Star system, will not be subject to the minimum star-rating requirement. We recognize the commenters' request for operational clarity and anticipate implementation materials, participant guidance, and monitoring activities to help participants understand how the waiver applies.

Comment: Some commenters supported the proposed swing bed flexibility but stated that the proposal did not address any financial accountability concerns for rural participants that use CAH swing beds. The commenters stated that CAH swing beds are reimbursed on a cost basis and can be substantially more expensive than traditional SNF stays. They believed regional target prices may not adequately reflect rural post-acute care market structure when rural hospitals are compared with urban peers that have access to lower-cost SNFs. They recommended that CMS acknowledge the cost differential, monitor CAH swing bed utilization and episode costs, and propose adjustments through notice-and-comment rulemaking if rural participants face systematically unachievable target prices.

Response: We appreciate the commenters' support for the proposed swing bed flexibility and recognize their concern that CAH swing bed use may have different spending implications for rural CJR–X participants than traditional SNF care. We proposed to waive the SNF 3-day rule for CJR–X beneficiaries, including for hospitals and CAHs with swing bed agreements, to support beneficiary choice and care coordination. However, CJR–X participants will remain accountable for episode spending under the proposed pricing and reconciliation methodology. We will monitor SNF utilization patterns, including shorter inpatient stays and potential patient steering, and will consider the commenters' concerns regarding CAH swing bed utilization, rural episode spending, and target price implications as we evaluate the proposed waiver and related monitoring policies.

After consideration of the public comments we received, we are finalizing with modification to our proposal at § 512.695(b)(1) through (4) to waive the SNF 3-day stay rule within 30 days following discharge from the anchor hospitalization or anchor procedures for episodes in CJR–X. The modification of 30 days is to maintain a continuation of the existing waiver policy established by the CJR Model.

(a) Additional Beneficiary Protections Under the SNF 3-Day Stay Rule Waiver

We believed that it was necessary to propose beneficiary protections against financial liability in addition to the beneficiary protections discussed elsewhere in this proposed rule. Specifically, we believed it is important to discern whether a waiver applies to SNF services furnished to a particular beneficiary to ensure compliance with the conditions of the waiver and improve our ability to monitor waivers for misuse.

In considering additional beneficiary protections that may be necessary to ensure proper use of SNF 3-day rule waiver under the CJR–X, we note that there are existing, well-established payment and coverage policies for SNF services based on sections 1861(i), 1862(a)(1), and 1879 of the Act that include protections for beneficiaries from liability for certain non-covered SNF charges. These existing payment and coverage policies for SNF services continue to apply under the CJR–X, including SNF services furnished pursuant to the SNF 3-day waiver. (For example, see section 70 in the Medicare

Claims Processing Manual, Chapter 30—Financial Liability Protections on the CMS website at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c30.pdf;* and Medicare Coverage of Skilled Nursing Facility Care *https://www.medicare.gov/coverage/skilled-nursing-facility-snf-care;* Medicare Benefit Policy Manual, Chapter 8—Coverage of Extended Care (SNF) Services Under Hospital Insurance at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c08pdf.pdf*). In general, CMS requires that the SNF inform a beneficiary in writing about services and fees before the beneficiary is discharged to the SNF (§ 483.10(b)(6)–); the beneficiary cannot be charged by the SNF for items or services that were not requested (§ 483.10.(c)(8)(iii)(A)); a beneficiary cannot be required to request extra services as a condition of continued stay (§ 483.10.(c)(8)(iii)(B)); and the SNF must inform a beneficiary that requests an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be (§ 483.10.(c)(8)(iii)(C)). (See also section 6 of Medicare Coverage of Skilled Nursing Facility Care at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c06.pdf.*)

As we discussed in the 2015 CJR final rule (80 FR 73454 through 73460), commenters expressed concern regarding the lag between a CJR beneficiary's Medicare coverage or eligibility status change and a CJR–X participant's awareness of that change. There may be cases in which a SNF waiver is used by a CJR–X participant because the CJR–X participant believes that the beneficiary meets the inclusion criteria, based on the information available to the hospital and SNF at the time of the beneficiary's admission to the SNF, but in fact the beneficiary's Medicare coverage has changed and the hospital was unaware of it based on available information. We recognize that despite good faith efforts by CJR–X participants and SNFs to determine a beneficiary's Medicare status for the model, it may occur that a beneficiary is not eligible to be included in the CJR–X at the time the SNF waiver is used. In these cases, we will cover services furnished under the waiver when the information available to the provider at the time the services under the waiver were furnished indicated that the beneficiary was included in the model.

Based on our experience with SNF 3-day rule waiver, including in the CJR Model, we believe there are situations where it would be appropriate to require additional beneficiary financial protections under the SNF 3-day waiver for the CJR–X. Specifically, we are concerned about potential beneficiary financial liability for non-covered Part A SNF services that might be directly related to use of the SNF 3-day waiver under the CJR–X. We are concerned that there could be scenarios where a CJR–X beneficiary could be charged for non-covered SNF services that were a result of a CJR–X participant's inappropriate use of the SNF waiver. Specifically, we are concerned that a CJR–X beneficiary could be charged for non-covered SNF services if a CJR–X participant discharges a CJR–X beneficiary to a SNF that does not meet the quality requirement (3 stars or higher in 7 of the last 12 months), and payment for SNF services is denied for lack of a qualifying inpatient hospital stay. We recognize that requiring a discharge planning notice would help mitigate concerns about CJR–X beneficiaries' potential financial liability for non-covered services. Nevertheless, we are concerned that in this scenario, once the claim is rejected, the CJR–X beneficiary may not be protected from financial liability under existing Medicare rules because the waiver would not be available, and the CJR–X beneficiary would not have had a qualifying inpatient hospital stay. Thus, the CJR–X beneficiary could be charged by the SNF for non-covered SNF services that were a result of an inappropriate attempt to use the waiver. In this scenario, Medicare would deny payment of the SNF claim, and the CJR–X beneficiary could potentially be charged by the SNF for these non-covered SNF services, potentially subjecting such CJR–X beneficiaries to significant financial liability. In this circumstance, we assume the CJR–X participant's intent was to rely upon the SNF 3-day waiver, but the waiver requirements were not met. We believe that in this scenario, the rejection of the claim could easily have been avoided if the hospital had confirmed that the requirements for use of the SNF 3-day waiver were satisfied or if the CJR–X beneficiary had been provided the discharge planning notice and elected to go to a SNF that met the quality requirement.

The CJR Model modifications in the 2016 EPM rule (82 FR 180) addressed beneficiary liability financial concerns for non-covered SNF services related to the waiver by generally placing the risk on the participant hospital and we believe it is appropriate to propose a similar policy for CJR–X. Original CJR participant hospitals were generally held financially responsible for misusing the waiver in situations where waiver requirements are not met, because participant hospitals were required to be aware of the 3-day waiver requirements. Participant hospitals were the entities financially responsible for episode spending under the model and made the decision as to whether it is appropriate to discharge a beneficiary without a 3-day stay. In addition, the requirements for use of the SNF waiver were clearly laid out in the 2015 CJR Final Rule (80 FR 73460). CMS posted on the public website a list of qualifying SNFs (those with a 3-star or higher rating for 7 of the last 12 months). Original CJR participant hospitals were required to consult the published list of SNFs prior to utilizing the SNF 3-day rule waiver.

For participant hospitals that provide a beneficiary with the discharge planning notice, the hospital would not have financial liability for non-covered SNF services that result from inapplicability of the waiver. In other words, when the participant hospital has discharged a beneficiary to a SNF that does not qualify under the conditions of the waiver, and has not provided the required discharge planning notice so that the beneficiary is aware that he or she is accepting financial liability for non-covered SNF services as a result of not having a qualifying inpatient stay, the ultimate responsibility and financial liability for the non-covered SNF stay rests with the participant hospital. For this reason, we proposed to align with the CJR Model policy and require CJR–X participants to keep a record of discharge planning notice distribution to CJR–X beneficiaries. We will monitor CJR–X participants' use of discharge planning notices to assess the potential for their misuse.

To protect CJR–X beneficiaries from being charged for non-covered SNF charges in instances when the waiver was used inappropriately, and similar to the CJR Model (82 FR 558), we proposed to add certain beneficiary protection requirements that would apply for SNF services that would otherwise have been covered except for lack of a qualifying hospital stay. Specifically, we proposed that if a CJR–X participant discharges a CJR–X beneficiary without a qualifying 3-day inpatient stay to a SNF that is not on the published list of SNFs that meet the CJR–X SNF 3-Day Rule waiver quality requirements as of the date of admission to the SNF, the CJR–X participant will be financially liable for the SNF stay if no discharge planning notice is provided to the CJR–X

beneficiary, alerting them of potential financial liability. If the CJR–X participant provides a discharge planning notice then the CJR–X participant will not be financially liable for the cost of the SNF stay and the normal Medicare FFS rules for coverage of SNF services will apply. In cases where the CJR–X participant provides a discharge planning notice and the CJR–X beneficiary chooses to obtain care from a non-qualified SNF without a qualifying inpatient stay, the CJR–X beneficiary assumes financial liability for services furnished (except those that are covered by Medicare Part B during a non-covered inpatient SNF stay).

In the event a CJR–X beneficiary is discharged to a SNF without a qualifying 3-day inpatient stay, but the SNF is not on the qualified list as of the date of admission to the SNF, and the CJR–X participant has failed to provide a discharge planning notice, we proposed that CMS apply the following rules:

- CMS does not make payment to the SNF for such services.
- The SNF must not charge the CJR–X beneficiary for the expenses incurred for such services; and the SNF must return to the CJR–X beneficiary any monies collected for such services.
- The hospital must be responsible for the cost of the uncovered SNF stay.

We sought comment on these proposals at § 512.695(b)(5) to hold the CJR–X participant financially responsible when the waiver of the SNF 3-day rule is used inappropriately. We received no comments on this proposal and therefore are finalizing this provision without modification.

k. Data Sharing

(1) Overview

In the proposed rule, we aimed to incentivize CJR–X participants to engage in care redesign efforts to improve quality of care and reduce Medicare FFS spending for beneficiaries included in the model during the anchor hospitalization or anchor procedure and the 90 days post-discharge from the hospital or hospital outpatient department. We stated these care redesign efforts would require CJR–X participants to work with and coordinate care with other health care providers and suppliers to improve the quality and efficiency of care for Medicare beneficiaries.

We noted in the proposed rule that we have experience with a range of efforts designed to improve care coordination for Medicare beneficiaries, including the BPCI Advanced and CJR Models (80 FR 73274), both of which make certain Medicare data available to participants to better enable them to achieve their goals. For example, both the BPCI Advanced and CJR Model (80 FR 73515) participants were eligible to request to receive beneficiary-identifiable claims data and financial performance data from the baseline period and throughout their tenure in the model to help them better understand the FFS beneficiaries that are receiving services from their providers and help them improve quality of care and conduct care coordination and other care redesign activities to improve patient outcomes or reduce health care for beneficiaries that could have initiated an episode in the model.

Based on our experience with these efforts, as set forth later in this section, we proposed to make certain beneficiary-identifiable claims data and regional aggregate data available to participants in CJR–X regarding Medicare FFS beneficiaries who may initiate an episode and be attributed to them in the model. However, we also expected that CJR–X participants are able to, or will work toward, independently identifying and producing their own data, through electronic health records, health information exchanges, or other means that they believe are necessary to best evaluate the health needs of their patients, improve health outcomes, and produce efficiencies in the provision and use of services.

(2) Beneficiary-Identifiable Claims Data

(a) Legal Authority To Share Beneficiary-Identifiable Data

In the proposed rule we stated that we believe that CJR–X participants may need access to certain Medicare beneficiary-identifiable data for the purposes of evaluating their performance, conducting quality assessment and improvement activities, conducting population-based activities relating to improving health or reducing health care costs, or conducting other health care operations listed in the first or second paragraph of the definition of ''health care operations'' under the HIPAA Privacy Rule, 45 CFR 164.501. We recognized that there are issues and sensitivities surrounding the disclosure of beneficiary-identifiable health information, and that several laws place constraints on sharing individually identifiable health information. For example, section 1106 of the Act generally bars the disclosure of information collected under the Act without consent unless a law (statute or regulation) permits the disclosure. We state that here, the HIPAA Privacy Rule would allow for the proposed disclosure of beneficiary-identifiable health information by CMS because it permits the use and disclosure of such data to carry out treatment, payment, and health care operations, as discussed under 45 CFR 164.506. In the proposed rule, we proposed to make CJR–X participants accountable for quality and cost outcomes for CJR–X beneficiaries during an anchor hospitalization or anchor procedure and during the 30-day post-discharge period. We believed that it is necessary for the purposes of this model to offer CJR–X participants the ability to request and receive summary or raw beneficiary-identifiable claims data for a 3-year baseline period as well as on a monthly basis during the performance year to help CJR–X participants engage in care coordination and quality improvement activities for CJR–X beneficiaries in an episode. We stated that for the 3-year baseline period, CJR–X participants will only receive beneficiary-identifiable claims data for beneficiaries that initiated an episode in their hospital or hospital outpatient department in the 3-year baseline period, and the beneficiary-identifiable claims data shared with the CJR–X participant will be limited to the items and services included in the episode. In other words, the CJR–X participant will not receive beneficiary-identifiable claims data for beneficiaries that were admitted to their hospital or hospital outpatient department and did not initiate an episode in the baseline period. We also stated that nor will the CJR–X participant receive beneficiary-identifiable claims data, for beneficiaries who did initiate an episode in their hospital or hospital outpatient department during the baseline period, for items and services that are not included in an episode, such as a primary care visit five days before the episode or a hospital readmission one day after the episode ends. We proposed applying a similar approach for the beneficiary-identifiable claims data sharing during the performance year. We believed that these data will constitute the minimum information necessary to enable the CJR–X participant to understand spending patterns during the episode, appropriately coordinate care, and target care strategies toward individual beneficiaries furnished care by the CJR–X participant and other providers and suppliers.

We indicated that under the HIPAA Privacy Rule, covered entities (means a health plan, a health care clearinghouse, and a health care provider who transmits any health information in

electronic form in connection with a transaction covered in 45 CFR Subtitle A, Subchapter C) are barred from using or disclosing individually identifiable health information that is ''protected health information'' or PHI in a manner that is not permitted or required under the HIPAA Privacy Rule, without the individual's authorization. We stated that the Medicare FFS program, a ''health plan'' function of the Department, is subject to the HIPAA Privacy Rule limitations on the disclosure of PHI. Hospitals, which will be CJR–X participants, are also covered entities, provided they are ''health care providers'' as defined by 45 CFR 160.103, such as for claims transactions. Since CJR–X participants are hospitals who are covered entities and are the only entity able to request the beneficiary-identifiable data and with whom CMS will share the beneficiary-identifiable data, we believed that the proposed disclosure of the beneficiary claims data for an anchor hospitalization or an anchor procedure plus 30-day post-discharge for episodes included under the CJR–X Model will be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for ''health care operations'' purposes. We indicated that under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations purposes if both covered entities have or had a relationship with the subject of the PHI to be disclosed, the PHI pertains to that relationship, and the recipient will use the PHI for a ''health care operations'' function that falls within the first two paragraphs of the definition of ''health care operations'' in the HIPAA Privacy Rule (45 CFR 164.506(c)(4)).

We noted that the first paragraph of the definition of health care operations includes ''conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines'' and ''population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination'' (45 CFR 164.501).

We stated in the proposed rule that CJR–X participants will be using the data on their patients to evaluate the performance of the CJR–X participant and other providers and suppliers that furnished services to the patient, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health for their patients. We indicated that when done by or on behalf of a covered entity, these are covered functions and activities that will qualify as ''health care operations'' under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. Hence, as previously discussed, we believed that this provision was extensive enough to cover the uses we would expect a CJR–X participant to make of the beneficiary-identifiable data and would be permissible under the HIPAA Privacy Rule. Moreover, our proposed disclosures would be made only to HIPAA covered entities, specifically hospitals that are CJR–X participants that have (or had) a relationship with the subject of the information, the information we would disclose would pertain to such relationship, and those disclosures would be for purposes listed in the first two paragraphs of the definition of ''health care operations.''

We stated in the proposed rule that when using or disclosing PHI, or when requesting this information from another covered entity, covered entities must make ''reasonable efforts to limit'' the information that is used, disclosed, or requested to a ''minimum necessary'' to accomplish the intended purpose of the use, disclosure, or request (45 CFR 164.502(b)). We believed that the provision of the proposed data elements, as described in section X.C.2.k.(2)(c). of this proposed rule, would constitute the minimum data necessary to accomplish the CJR–X's model goals of the CJR–X participant.

We noted in the proposed rule that The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when the federal government maintains a system of records by which information about individuals is retrieved by use of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). We further indicated that The Privacy Act prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply (5 U.S.C. 552a(b)).

We stated that ''routine uses'' are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. We stated that for CJR–X, the system of records would be covered in Master Demonstration, Evaluation, and Research Studies (DERS) for the Office of Research, Development and Information (ORDI) system of record (72 FR 19705). We believed that the proposed data disclosures were consistent with the purpose for which the data discussed in the proposed rule was collected and may be disclosed in accordance with the routine uses applicable to those records.

We noted that, as was the case with the CJR Model, in the proposed rule, we proposed to disclose beneficiary-identifiable data to only the hospitals that are bearing risk for episodes and not with their collaborators. As stated in the 2015 CJR final rule (80 FR 73515), we believed that the hospitals that are specifically held financially responsible for an episode should make the determination as to which data are needed to manage care and care processes with their collaborators as well as which data they might want to re-disclose, if any, to their collaborators provided they are in compliance with the HIPAA Privacy Rule.

We stated in the proposed rule that we believe our data sharing proposals are permitted by and are consistent with the authorities and protections available under the aforementioned statutes and regulations. We sought comments on our proposals regarding the authority to share beneficiary-identifiable data with CJR–X participants. We received no comments on this proposal and therefore are finalizing this provision without modification.

(b) Summary and Raw Beneficiary-Identifiable Claims Data Reports

Based on our experience with BPCI Advanced and CJR Model participants, we recognize that CJR–X participants could vary with respect to the kinds of beneficiary-identifiable claims information that would best meet their needs. For example, while many CJR–X participants might have the ability to analyze raw claims data, other CJR–X participants could find it more useful to have a summary of these data. Given this, we proposed to make beneficiary-identifiable claims data for episodes in CJR–X available through two formats, summary and raw, both for the baseline period and on an ongoing monthly basis during their participation in the model as we do for BPCI Advanced and the CJR Model (80 FR 73308). Summary beneficiary-identifiable claims data summarizes the claims data by combining and categorizing claims data to provide a broad view of the CJR–X participant's health care expenditures and utilization. For example, a CJR–X participant may use summary beneficiary-identifiable data to identify total episode spending across all of a

CJR–X participant's episodes in a given performance year. Raw beneficiary-identifiable claims data is unrefined and has not been grouped or combined and includes the specific claims fields, as described in the minimum necessary data section X.C.2.k.(2)(c). of this proposed rule, at the episode level. For example, a CJR–X participant may use raw beneficiary-identifiable data to look at a particular episode to identify the diagnosis code(s) that were associated with a hospital readmission for a CJR–X beneficiary.

First, for CJR–X participants who wish to receive summary Medicare Parts A and B claims data, we proposed offering CJR–X participants that enter into a CJR–X data sharing agreement with CMS, as specified in section X.C.2.k.(6). of this proposed rule, the option to submit a formal data request for summary beneficiary-identifiable claims data that have been aggregated to provide summary-level spending and utilization data on CJR–X beneficiaries who would be in an episode during the baseline period and performance years in accordance with applicable privacy and security laws and established privacy and security protections. Such summary beneficiary-identifiable claims data would provide tools to monitor, understand, and manage utilization and expenditure patterns as well as to develop, target, and implement quality improvement programs and initiatives. For example, if the data provided by CMS to a particular CJR–X participant reflects that, relative to their peers, a certain provider is associated with significantly higher rates of inpatient readmissions than the rates experienced by other beneficiaries with similar care needs, that may be evidence that the CJR–X participant could consider, among other things, the appropriateness of that provider, whether other alternatives might be more appropriate, and whether there exist certain care interventions that could be incorporated post- discharge to lower readmission rates.

Secondly, for CJR–X participants who wish to receive raw Medicare Parts A and B claims data, we proposed to offer CJR–X participants that enter into a CJR–X data sharing agreement with CMS the opportunity to submit a formal data request for raw beneficiary-identifiable claims data for CJR–X beneficiaries who would be in an episode during the baseline period and performance years in accordance with applicable privacy and security laws and established privacy and security protections. These raw beneficiary-identifiable claims data would be much more detailed compared to the summary beneficiary-identifiable claims data and include all beneficiary-identifiable claims for all episodes in CJR–X. In addition, they would include episode summaries, indicators for excluded episodes, diagnosis and procedure codes, and enrollment and dual eligibility information for beneficiaries that initiate episodes in CJR–X. Through analysis, these raw beneficiary-identifiable claims data would provide CJR–X participants with information to improve their ability to coordinate and target care strategies as well as to monitor, understand, and manage utilization and expenditure patterns. Such data would also aid them in developing, targeting, and implementing quality improvement programs and initiatives.

The summary and raw beneficiary-identifiable data would allow CJR–X participants to assess summary and raw data on their relevant CJR–X beneficiary population, giving them the flexibility to utilize the data based on their analytic capacity. Therefore, for both the baseline period and as frequently as a monthly basis during an CJR–X participant's performance year, we proposed to provide CJR–X participants with an opportunity to request summary beneficiary-identifiable claims data and raw beneficiary-identifiable claims data that would meet minimum necessary requirements in 45 CFR 164.502(b) and 164.514(d) and include Medicare Parts A and B beneficiary-identifiable claims data for CJR–X beneficiaries in an episode during the 3-year baseline period and performance year. This means the summary and raw beneficiary-identifiable claims data would encompass the total expenditures and claims for the proposed episodes, including the anchor hospitalization or anchor procedure, and all non-excluded items and services in an episode covered under Medicare Parts A and B within the 30 days after discharge, including hospital care, post- acute care, and physician services for the CJR–X participant's beneficiaries.

We proposed that if a CJR–X participant wishes to receive beneficiary-identifiable claims data, they must submit a formal request for data on an annual basis in a manner form and by a date specified by CMS, indicating if they want summary beneficiary-identifiable data, raw beneficiary-identifiable data, or both, and sign a CJR–X data sharing agreement. To comply with applicable laws and safeguards, we proposed the CJR–X participant must attest that—

- The CJR–X participant is requesting claims data of CJR–X beneficiaries who would be in an episode during the baseline period or performance year as a HIPAA covered entity;
- The CJR–X participant's request reflects the minimum data necessary for the CJR–X participant to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501; and
- The CJR–X participant's use of claims data will be limited to developing processes and engaging in appropriate activities related to coordinating care and improving the quality and efficiency of care and conducting population-based activities relating to improving health or reducing health care costs that are applied uniformly to all CJR–X beneficiaries, in an episode during the baseline period or performance year, and that these data will not be used to reduce, limit or restrict care for specific Medicare beneficiaries.

We proposed that the summary and raw beneficiary-identifiable data would be packaged and sent to a data portal (to which the CJR–X participants must request and be granted access) in a ''flat'' or binary format for the CJR–X participant to retrieve. We also note that, for both the summary and raw beneficiary-identifiable claims data, we would exclude information that is subject to the regulations governing the confidentiality of substance use disorder patient records (42 CFR part 2) from the data shared with a CJR–X participant. We believe our proposal to make data available to CJR–X participants, through the most appropriate means, may be useful to CJR–X participants to determine appropriate ways to increase the coordination of care, improve quality, enhance efficiencies in the delivery system, and otherwise achieve the goals of the proposed model. CJR–X beneficiaries would be informed of CJR–X and the potential sharing of Medicare beneficiary-identifiable claims data through the beneficiary notification, as discussed in section X.C.2.c.(1). of this proposed rule. Further, CMS would make beneficiary-identifiable claims data available to a CJR–X participant for beneficiaries who may be included in episodes, in accordance with applicable privacy and security laws and only in response to the CJR–X participant's request for such data, through the use of an executed CJR–X data sharing agreement with CMS.

We requested comments on this proposal to share beneficiary-identifiable claims data with CJR–X participants at § 512.665(b).

The following is a summary of the public comments received on our

proposal to share summary and raw beneficiary-identifiable claims data reports, and our responses to these comments:

Comment: A commenter noted a drafting error in the proposed rule that referred to TEAM participant rather than the intended CJR–X participant.

Response: We thank the commenter for their diligence in identifying the error and have made corrections in this final rule ensuing the appropriate term was used.

Comment: A commenter supported the sharing of beneficiary-identifiable claims data with CJR–X participants.

Response: We thank the commenter for their support.

Comment: Some commenters requested that CMS provide target price files and methodology documentation prior to implementation so participants can validate episode pricing and identify opportunities for improvement. Some commenters requested access to 180-day lookback information used for HCC risk-adjustment flagging. A few commenters requested utilization reports, quality data, or other data to identify trends and opportunities for quality improvement. A commenter requested recommended CMS include computed risk adjustment factor values and a preliminary per-episode target price in the monthly summary files, with a clear note that the final reconciliation figure may differ. Another commenter requested the summary data be aggregated at the episode-level with beneficiary identifiers.

Response: We thank the commenters for their recommendations. We note that CJR–X participants are eligible to receive summary and raw beneficiary-identifiable and aggregate claims data pursuant to a data request and execution of the CJR–X data sharing agreement. As discussed in section X.C.2.f.(3)(i) of this final rule, we will be sharing with CJR–X participants preliminary target prices prior to the performance year starting in the late November time frame. We understand sharing prices and baseline period data earlier may help CJR–X participants better prepare for model implementation and we will strive to deliver preliminary target prices and baseline period prices as soon as practicable. In addition to preliminary target prices and baseline period data, we anticipate sharing episode and target prices specifications with CJR–X participants prior to performance year 1 starting to further help them understand how episodes and target prices are constructed.

With respect to sharing claims data in the 180-day lookback period, historically we have not shared this information because this claims data encompasses a time period before the beneficiary initiated the episode. However, we see the value in how this information could help the CJR–X participant identify whether beneficiaries entering LEJR episodes had recent post-acute care use, chronic conditions, or utilization patterns that may affect care coordination needs and episode spending. We will take this into consideration as we think about the minimum necessary data being shared with CJR–X participants.

We also want to acknowledge commenters' requests to share utilization reports and other data to help CJR–X participants identify opportunities for care improvements and efficiencies. We anticipate we may share feedback reports to help participants understand spending and utilization metrics. We also anticipate sharing quarterly reports with participants that will help them better estimate their reconciliation target price. For baseline and monthly summary data, we anticipate sharing this data at the hospital-level to help CJR–X participants monitor episode spending trends but we are open to sharing more granular data to support CJR–X participants participation in the model.

We will continue to take commenters' recommendations into consideration as we develop the operational data files and supporting documentation for CJR–X. We note that any preliminary pricing or risk-adjustment information shared during a performance year would not replace the reconciliation target price methodology or final payment calculations under CJR–X.

Comment: A few commenters requested CMS modernize their data delivery systems and use APIs rather than sharing flat files. A commenter recommended that CMS deliver CJR–X data using FHIR, preferably through the Beneficiary Claims Data API, rather than flat files. The commenter stated that standardizing on FHIR would allow vendors and hospitals to reuse existing configurations instead of building bespoke formats for each program.

Response: We appreciate the commenters' recommendations regarding modernization of CMS data delivery methods. We recognize that application programming interfaces (APIs) and interoperability standards such as Fast Healthcare Interoperability Resources (FHIR) may reduce administrative burden, support integration with existing health information technology systems, and allow participants and their vendors to leverage standardized data exchange capabilities across multiple CMS programs.

We note that for models with known beneficiary lists (like some ACO models where the participant already knows which beneficiaries are attributed to them), APIs work particularly well because of the predefined beneficiary population. The participant's system can simply query for updates on known beneficiaries, and CMS can enforce access controls against a stable attribution list. However, episode-based models like CJR–X, the challenge is different because beneficiaries are typically not known in advance. An episode only exists after an anchor hospitalization or procedure occurs. Until that event happens, CMS does not know which beneficiaries will become CJR–X beneficiaries and the hospital does not know which beneficiaries will ultimately trigger an episode. In addition, claims often arrive with processing delays and may be adjusted after submission, while episode attribution may change based on final claim coding and episode construction rules. As a result, we often generates episode-specific files after identifying beneficiaries through claims processing and attribution logic. Flat files are operationally straightforward because we can periodically determine which beneficiaries meet the episode criteria and then distribute a complete data package.

We believe it is important to ensure that data sharing methods reliably support episode identification, attribution, and participant operations before adopting alternative data delivery approaches. We see the benefits of API and FHIR-based data exchange and remain committed to improving data sharing.

Comment: A few commenters acknowledge challenges identifying beneficiaries at the point of care, and expressed the need for more timely data.

Response: We acknowledge the commenters' concerns regarding the operational challenges associated with identifying beneficiaries who may be included in an episode at the point of care. We recognize that episode-based payment models rely on episode attribution methodologies that may depend on claim submission, coding, and other administrative processes that are not always finalized during a beneficiary's hospitalization or procedure. We also acknowledge that hospitals may experience challenges identifying potential episode beneficiaries in real time, particularly when final episode attribution depends on information that becomes available after discharge.

We note that CJR–X is designed to identify episodes using specified MS–DRGs and HCPCS codes, consistent with the CJR Model and other episode-based payment models. While we recognize the value of more timely beneficiary identification, we believe it is important to ensure that episode attribution is accurate and based on complete information. We may consider opportunities to provide more timely preliminary episode identification information, recognizing that such information may be subject to change based on final claims processing and episode attribution methodologies.

Comment: A commenter recommended that hospitals be required to involve physicians in episode management through episode data sharing.

Response: We appreciate the commenter's recommendation regarding physician access to episode data. We agree that physicians play an important role in care coordination, care redesign, and episode management for beneficiaries undergoing lower extremity joint replacement procedures. We recognize that access to relevant episode information may support collaboration among hospitals, physicians, and other providers involved in a beneficiary's care.

Under CJR–X, CMS will share beneficiary-identifiable data with CJR–X participants that have requested such data and have executed a CJR–X data sharing agreement with CMS. We believe this approach appropriately protects beneficiary privacy and ensures accountability for the use and disclosure of beneficiary-identifiable information. However, a CJR–X participant is not precluded from sharing data received under the model with physicians and other downstream recipients involved in CJR–X activities, provided that such disclosures are consistent with applicable law and the requirements of the CJR–X data sharing agreement, as discussed in section X.C.2.k.(6) of this final rule. In particular, a CJR–X participant may share beneficiary-identifiable data with a downstream recipient that is acting as a business associate of the CJR–X participant, provided the participant contractually binds the downstream recipient to the same terms and conditions governing the use, disclosure, safeguarding, and protection of the data that apply to the participant under its data sharing agreement with CMS.

We do not believe it is appropriate to require CJR–X participants to share data with physicians or other downstream recipients. We believe CJR–X participants are best positioned to determine which entities require access to model data to support care coordination, quality improvement, and episode management activities based on their individual organizational structures and care delivery arrangements. Hospitals vary considerably in how they engage physicians and other providers in episode management activities, and a mandatory data-sharing requirement could impose operational burden and require disclosures that may not be necessary in all circumstances. In addition, because beneficiary-identifiable data are subject to privacy, security, and data-use requirements, we believe CJR–X participants should retain discretion to determine whether and with whom such data should be shared, subject to the protections and conditions established in the CJR–X data sharing agreement. We believe this approach appropriately balances care coordination needs, participant flexibility, and beneficiary privacy protections while preserving the ability of CJR–X participants to share data when doing so supports CJR–X activities.

After consideration of the public comments, we are finalizing without modification the proposal to share beneficiary-identifiable claims data with CJR–X participants at § 512.665(b).

(c) Minimum Necessary Data

We proposed CJR–X participants must limit their beneficiary-identifiable data requests, for CJR–X beneficiaries who are in an episode during the baseline period or performance year, to the minimum necessary to accomplish a permitted use of the data. We proposed the minimum necessary Parts A and B data elements may include but are not limited to the following data elements:

- Medicare beneficiary identifier (ID).
- Procedure code.
- Sex.
- Diagnosis code.
- Claim ID.
- The from and through dates of service.
- The provider or supplier ID.
- The claim payment type.
- Date of birth and death, if applicable.
- Tax identification number.
- National provider identifier.

We sought comment on the minimum data necessary beneficiary-identifiable information for CJR–X participants to request beneficiary-identifiable information for purposes of conducting permissible health care operations purposes under this model at § 512.665(c).

The following is a summary of the public comments received on our proposal to share the minimum data necessary for purposes of conducting permissible health care operations purposes under this model, and our responses to these comments:

Comment: A commenter recommended CMS include additional elements to the minimum data necessary that would be shared with CJR–X participants to conduct permissible health care operations. The commenter requested demographic data for patient matching, including person ID, first and last name, date of birth, legal sex, and at least one of the following: address, email, phone, or SSN. They also requested CMS share claims fields including: Paid Amount, Allowed Amount, service line details, standardized amounts, Claim ID, patient ID, adjustment and reversal information, claim type, dates of service, admit and discharge dates, ICD diagnosis and procedure codes, CPT/HCPCS codes and modifiers, NPI for rendering, billing, and prescribing provider. Another commenter requested episode ID to link episodes with claims.

Response: The minimum necessary data elements that we are finalizing in this rule are not intended to be an exhaustive list of every variable CMS may share under CJR–X. We anticipate sharing the minimum necessary data elements, some of which overlap with the commenters request, and other data elements that are similar to the data shared under the CJR model and other episode-based payment models, which includes the minimum necessary claims data regarding beneficiary, provider, item or service codes and dates, and financial details. Similarly, we anticipate sharing an episode ID to help CJR–X participants identify all the expenditures associated with a given episode in the baseline period and performance year. Any beneficiary-identifiable data shared under CJR–X would remain subject to the CJR–X data sharing agreement, applicable privacy and security requirements, and CMS' determination of the minimum data necessary for the permitted purposes. After consideration of the public comments, we are finalizing without modification the proposal at § 512.665(c) to share the minimum data necessary for purposes of conducting permissible health care operations purposes under this model.

(3) Regional Aggregate Data

As discussed in section X.C.2.f.(3). of this proposed rule, we proposed to incorporate regional pricing data when establishing target prices for CJR–X participants, similar to the CJR Model's target prices that are constructed at the

regional level. As indicated in the 2015 CJR Final Rule (80 FR 73510), we finalized our proposal to share regional pricing data with original CJR participants because it was a factor affecting target prices. Given some of the similar features between the CJR Model and CJR–X proposed in this proposed rule, particularly our proposal to incorporate regional pricing data when establishing target prices under the model, we proposed to provide regional aggregate expenditure data available for all Parts A and B claims associated with episodes in CJR–X for the U.S. Census Division in which the CJR–X participant is located, as we similarly provide to hospitals participating in the CJR Model. Specifically, we proposed to provide CJR–X participants with regional aggregate data on the total expenditures during an anchor hospitalization or anchor procedure and the 90-day post-discharge period for all Medicare FFS beneficiaries who would have initiated an episode under our proposed episode definitions in section X.C.2.d. of this final rule during the baseline period and performance years. This data would be provided at the regional level; that is, we proposed to share regional aggregate data with a CJR–X participant for episodes initiated in the U.S. Census Division where the CJR–X participant is located. These regional aggregate data would be in a format similar to the proposed summary beneficiary-identifiable claims data and would provide summary information on the average episode spending for episodes in CJR–X in the U.S. Census Division in which the CJR–X participant is located. However, the regional aggregate data would not be beneficiary-identifiable and would be de-identified in accordance with HIPAA Privacy Rule, 45 CFR 164.514(b). Further, the regional aggregate data would also comply with CMS data sharing requirements, including the CMS cell suppression policy which stipulates that no cell (for example, admissions, discharges, patients, services, etc.) containing a value of 1 to 10 can be reported directly. Given the regional aggregate data is de-identified, we proposed CJR–X participants would not have to submit a request to receive this data and the data would not be subject to the terms and conditions of the CJR–X data sharing agreement.

We sought comments on our proposal at § 512.665(d) to provide these data to CJR–X participants.

The following is a summary of the public comments received on our proposal to share regional data with CJR–X participants, and our responses to these comments:

Comment: A commenter supported the sharing regional aggregate data with CJR–X participants.

Response: We thank the commenter for their support.

After consideration of the public comments we received, we are finalizing without modification the proposal at § 512.665(d) to share regional aggregate data with CJR–X participants.

(4) Timing and Period of Baseline Period Data

We recognize that providing the ability for CJR–X participants to request the summary and raw beneficiary-identifiable claims baseline data and receive regional aggregate baseline data would be important for CJR–X participants to be able to detect unnecessary episode spending, coordinate care, and identify areas for practice transformation, and that early provision of this data, specifically before the ''model start date,'' as defined in § 512.605, could facilitate their efforts to do so. Also, as discussed in section X.C.2.f.(3)(a). of this proposed rule, target prices would be calculated using a CJR–X participant's historical episode spending during their baseline period. Further, we believe that CJR–X participants would view the episode payment model effort as one involving continuous improvement. As a result, changes initially contemplated by a CJR–X participant could be subsequently revised based on updated information and experiences.

Therefore, as with the BPCI Advanced and CJR Models (80 FR 73511), we proposed to make 3-years of baseline period data available to CJR–X participants, who enter into a CJR–X data sharing agreement with CMS, for beneficiaries who would have been included in an episode had the model been implemented during the baseline period, and intend to make these data available upon request prior to the start of each performance year and in accordance with applicable privacy and security laws and established privacy and security protections. We would provide the 3 years of baseline period data for the summary and raw beneficiary-identifiable data and for the regional aggregate data. We believe that 3 years of baseline period data is sufficient to support a CJR–X participant's ability to detect unnecessary episode spending, coordinate care, and identify areas for practice transformation. We believe that if a CJR–X participant has access to baseline period data for the 3-year period for each performance year used to set target prices, then it would be better able to assess its practice patterns, identify cost drivers, and ultimately redesign its care practices to improve efficiency and quality. We considered to propose to make available 4 years of baseline period data, or offering 1 year of baseline period data, but we believe offering 4 years of baseline period data would not be necessary since target prices in CJR–X are constructed from a 3-year baseline period and 1 year of data may not sufficiently help CJR–X participants identify areas to improve beneficiary health and care coordination or reducing health costs.

Therefore, we proposed that the 3-year period utilized for the baseline period match the baseline data used to create CJR–X participants target prices every performance year, and roll forward one year every performance year, as discussed in section X.C.2.f.(3)(a) of this proposed rule. Specifically, we proposed that the baseline period data for the summary and raw beneficiary-identifiable data reports and regional aggregate data report would be shared annually at least 1 month prior to the start of a performance year and available for episodes initiated in the baseline period, as discussed in section X.C.2.f.(3)(a). in this final rule.

We requested comments on these proposals at § 512.665(b)(6)(i) and (d)(1)(i) to share beneficiary-identifiable data and regional aggregate data for a 3-year baseline period at least 1 month prior to the start of a performance year.

The following is a summary of the public comments received on our proposal to share baseline period beneficiary-identifiable and regional aggregate data with CJR–X participants, and our responses to these comments:

Comment: A commenter supported the sharing of baseline period data with CJR–X participants.

Response: We thank the commenter for their support.

Comment: A commenter noted that CMS proposed sharing data and preliminary price targets on November, prior to the start of the PY, but if the performance year started on Oct. 1 then data would be shared after the start of the performance year.

Response: We thank the commenter for their diligence in identifying the error. We have finalized an updated start date for CJR–X, such that the model will start on January 1, 2028, as discussed in section X.C.2.a of this final rule. Given the updated start date and that performance years will now run on a calendar year basis, the original policy still stands in that we will share baseline period and preliminary target prices prior to the performance year and

anticipate it being shared in the month of November before the performance year starts.

Comment: A commenter recommended that CMS provide data for the full baseline period. The commenter stated that full baseline-period data would allow participants to evaluate recent trends and develop implementation strategies.

Response: We are finalizing our policy to provide CJR–X participants with three years of baseline data that mimics the same 3-year baseline period used in target price construction, as discussed in section X.C.2.f.(3)(a) of this final rule. We note that we use a 3-year rolling baseline period for target prices, which means each year the baseline period rolls forward a year. Therefore, before each performance year, we will be sharing baseline period data for the upcoming performance year. We believe sharing the full baseline period of data improves data transparency and allows CJR–X participants to identify opportunities for spending reductions, operational efficiencies, and quality improvement activities.

Comment: Some commenters recommended that CMS provide data at least 60 days before the start of the performance period. A commenter recommended CMS grant hospitals direct and early access to the risk-adjustment model and necessary data to project baseline performance and initiate improvement activities prior to the start of the first performance year, or at least prior to the imposition of downside risk in the second or third year of participation.

Response: We appreciate the commenters' recommendation that CMS provide baseline data and preliminary target prices earlier than November. We note that CJR–X is a two-sided risk model and that all performance years CJR–X participants are subject to two-sided risk and there are no performance years where CMS has waived downside risk. We recognize that participants value advance access to information for planning and operational purposes. However, we believe that releasing these data in November before the start of the January 1 performance year appropriately balances participant planning needs with the need to incorporate the most recent available claims experience and pricing inputs into the target price methodology. Releasing information substantially earlier would require CMS to rely on less complete claims data and could result in pricing information that is less accurate or more likely to change as additional claims are processed. We believe participants benefit from receiving preliminary target prices that reflect the most current available information and provide a reliable basis for financial planning. In addition, participants will have advance notice through this final of the model design, episode definitions, quality measures, and payment methodology well before the release of baseline data and preliminary target prices, allowing them to undertake care redesign and operational planning activities in advance of the performance year. Therefore, we believe that providing baseline data and preliminary target prices in November before the start of the performance year appropriately balances data accuracy, operational feasibility, and participant preparation needs.

After consideration of the public comments we received, we are finalizing without modification our proposal at § 512.665(b)(6)(i) and (d)(1)(i) to share beneficiary-identifiable data and regional aggregate data for a 3-year baseline period at least 1 month prior to the start of a performance year.

(5) Timing and Period of Performance Year Data

The availability of periodically updated raw and summary beneficiary-identifiable claims data and regional aggregate data would assist CJR–X participants to identify areas where they might wish to change their care practice patterns, as well as monitor the effects of any such changes. With respect to these purposes, we have considered what would be the most appropriate period for making updated raw and summary beneficiary-identifiable claims data and regional aggregate data available to CJR–X participants, while complying with the HIPAA Privacy Rule's ''minimum necessary'' provisions, described in 45 CFR 164.502(b) and 164.514(d). We believe that monthly data updates would align with a 90-day post-discharge episode window given the episode's duration and the need to share data in a timely manner and identify areas for care improvement. Accordingly, we proposed to make updated raw and summary beneficiary-identifiable claims data and regional aggregate data available for a given performance year to CJR–X participants upon receipt of a request for such information and execution of a CJR–X data sharing agreement with CMS, that meets CMS's requirements to ensure the applicable HIPAA Privacy Rule conditions for disclosure have been met, as frequently as on a monthly basis during the performance year and continue sharing the claims data for up to 6 months beyond the end of that performance year to capture claims run out. We believe 6 months of claims run out is sufficient given that an internal review of Medicare claims data found that the majority of Medicare claims had been received, and were considered final, by 6 months after the date of service and is also consistent with how we proposed claims run out for the reconciliation process, as described in section X.C.2.f.(5). of this final rule.[610]

To accomplish this for the first performance year of CJR–X, we would propose to provide, upon request and execution of a CJR–X data sharing agreement with CMS, and in accordance with the HIPAA Privacy Rule, beneficiary-identifiable claims data and aggregate regional data from October 1, 2027 to September 30, 2028 on as frequently as a running monthly basis, as claims are available. We would continue sharing beneficiary-identifiable claims data and regional aggregate data for episodes in performance year 1 for an additional 6 months, so until March 31, 2029, to capture claims run out for items and services billed during this time period. These datasets would represent all potential episodes that were initiated in 2026 and capture sufficient amount of time, up to 6 months, for relevant claims to have been processed. We would limit the content of this data set to the minimum data necessary for the CJR–X participant to conduct quality assessment and improvement activities and effectively coordinate care of its patient population. This data sharing process would continue each performance year of CJR–X. We considered to propose extending this period to capture more than 30 days of data or updating on a quarterly frequency. However, we do not believe this would benefit the CJR–X participant since it may create challenges to timely identify potential CJR–X beneficiaries for care coordination efforts. We sought comment on whether we should consider extending the period to capture more than 30 days of data or updating the data on a frequency other than as frequently as monthly.

We sought comments on this proposal at § 512.665(b)(6)(ii) and (d)(1)(ii) to make beneficiary-identifiable data and regional aggregate data available as frequently as a monthly basis and for up to 6 months after a performance year.

The following is a summary of the public comments received on our

[610] Medicare Claims Maturity: CCW White Paper accessed at *https://www2.ccwdata.org/web/guest/white-papers?p_l_back_url=%2Fweb%2Fguest%2Fsearch%3Fq%3Dmedicare%2Bclaims%2Bmaturity* on Jan, 26, 2024.

proposal to share performance year beneficiary-identifiable and regional aggregate data with CJR–X participants, and our responses to these comments:

Comment: Some commenters requested frequent episode-level data feeds during the performance year. Commenters stated that participant organizations need timely reporting to identify operational opportunities, monitor utilization, and intervene before avoidable utilization occurs. Some commenters recommended that CMS establish a minimum data-sharing standard across alternative payment models with data delivered no less frequently than monthly.

Response: We agree that timely access to episode information can assist CJR–X participants in supporting care coordination activities, identifying opportunities for operational improvement, and managing beneficiaries throughout the episode of care. We also understand the commenters' views that more frequent data updates may help participants identify potential issues earlier and support intervention before avoidable utilization occurs.

We are finalizing the policy to share performance year data on a monthly cadence. While we recognize the potential value of more frequent data feeds and greater consistency across CMS alternative payment models, we must also consider the timing of claims availability, attribution accuracy, administrative burden, and operational considerations associated with producing CJR–X participant reports. Since CJR–X episodes span a 90-day post-discharge period and rely on claims-based episode attribution and spending calculations, we believe monthly reporting provides CJR–X participants with recurring opportunities to monitor utilization and identify operational trends while allowing sufficient time for claims submission and processing. We believe this approach balances CJR–X participant needs for actionable information with the accuracy, completeness, and operational feasibility necessary for effective model administration. We will continue to consider stakeholder feedback regarding the frequency, format, and standardization of data sharing across Innovation Center models as we evaluate approaches to support participant operations under CJR–X.

After consideration of the public comments we received, we are finalizing without modification our proposal at § 512.665(b)(6)(ii) and (d)(1)(ii) to make beneficiary-identifiable data and regional aggregate data available as frequently as a monthly basis and for up to 6 months after a performance year.

(6) CJR–X Data Sharing Agreement

We proposed that if a CJR–X participant wishes to retrieve the beneficiary-identifiable data, the CJR–X participant would be required to first complete, sign, and submit—and thereby agree to the terms of—a data sharing agreement with CMS, which we would call the CJR–X data sharing agreement. We proposed to define the ''CJR–X data sharing agreement'' as an agreement between the CJR–X participant and CMS that includes the terms and conditions for any beneficiary-identifiable data being shared with the CJR–X participant under § 512.665. Further, we proposed to require CJR–X participants to comply with all applicable laws and the terms of the CJR–X data sharing agreement as a condition of retrieving the beneficiary-identifiable data. We also proposed that the CJR–X data sharing agreement would include certain protections and limitations on the CJR–X participant's use and further disclosure of the beneficiary-identifiable data and would be provided in a form and manner specified by CMS. Additionally, we proposed that a CJR–X Participant that wishes to retrieve the beneficiary-identifiable data would be required to complete, sign, and submit a signed CJR–X data sharing agreement at least annually. We believe that it is important for the CJR–X Participant to complete and submit a signed CJR–X data sharing agreement at least annually so that CMS has up-to-date information that the CJR–X participant wishes to retrieve the beneficiary-identifiable data and information on the designated data custodian(s). As described in greater detail later in this section, we proposed that a designated data custodian would be the individual(s) that a CJR–X participant would identify as responsible for ensuring compliance with all privacy and security requirements and for notifying CMS of any incidents relating to unauthorized disclosures of beneficiary-identifiable data.

We believe it is important for the CJR–X participant to first complete and submit a signed CJR–X data sharing agreement before it retrieves any beneficiary-identifiable data to help protect the privacy and security of any beneficiary-identifiable data shared by CMS with the CJR–X participant. There are important sensitivities surrounding the sharing of this type of individually identifiable health information, and CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with CJR–X participants would be further protected in an appropriate fashion.

We considered an alternative proposal under which CJR–X participants would not need to complete and submit a signed CJR–X data sharing agreement, but we concluded that, if we proceeded with this option, we would not have adequate assurances that the CJR–X participants would appropriately protect the privacy and security of the beneficiary-identifiable data that we proposed to share with them. We also considered an alternative proposal under which the CJR–X participant would need to complete and submit a signed CJR–X data sharing agreement only once for the duration of the CJR–X. However, we concluded that this similarly would not give CMS adequate assurances that the CJR–X participant would protect the privacy and security of the beneficiary-identifiable data from CMS. We concluded that it is critical that we have up-to-date information and designated data custodians, and that requiring the CJR–X participant to submit an CJR–X data sharing agreement at least annually would represent the best means of achieving this goal.

We solicited public comment on our proposal to define ''CJR–X data sharing agreement'' at § 512.605. We also sought comment on our proposal to require, in § 512.665(e)(2), that the CJR–X participant agree to comply with all applicable laws and the terms of the CJR–X data sharing agreement as a condition of retrieving the beneficiary-identifiable data, and on our proposal in § 512.665(e)(1) that the CJR–X participant would need to submit the signed CJR–X data sharing agreement at least annually if the CJR–X participant wishes to retrieve the beneficiary-identifiable data.

The following is a summary of the public comments received on our proposal to require annual submission of a CJR–X data sharing agreement, and our responses to these comments:

Comment: A few commenters requested CMS expand the number data custodians allowed to access the platform where CMS would share beneficiary-identifiable and regional aggregate data. Specifically, commenters suggested CMS should allow sufficient designated data custodians for hospital and business associate needs and should develop bulk multi-CCN retrieval or secure automated data access options that are compatible with HIPAA and data sharing agreement safeguards. A couple of commenters suggested CMS not limit the number of data custodians a hospital may elect or

at least specify an allowance of at least five designees per hospital.

Response: We acknowledge commenters' recommendations to allow sufficient data custodians to support hospital, and business associate needs to access and analyze the data shared by CMS. We do not agree that allowing an unlimited number of data custodians per CJR–X participant would be prudent for program integrity reasons since access to this data includes beneficiary-identifiable data. We believe it is important to maintain appropriate controls on access, use, disclosure, and safeguarding of the data. We have typically allowed two data custodians in other episode-based payment models but recognize that this number may have to increase given the model captures many more hospitals and there is a greater likelihood of health systems having multiple hospitals participating in the model. As we develop the CJR–X data sharing agreement, as discussed in section X.C.2.k.(6) of this final rule, we will take commenters' recommendations into consideration, including whether to increase the number of data custodians and whether there are additional operational options or system enhancements, such as bulk hospital download for health systems/hospitals that share the same data custodians, that could improve the efficiency with which hospitals retrieve their data while maintaining appropriate protections for beneficiary-identifiable information.

After consideration of the public comments we received, we are finalizing without modification the proposals at § 512.665(e)(2), that the CJR–X participant agree to comply with all applicable laws and the terms of the CJR–X data sharing agreement and at § 512.665(e)(1) that the CJR–X participant would need to submit the signed CJR–X data sharing agreement at least annually. We are also finalizing without modification our proposal at § 512.605 the definition for ''CJR–X data sharing agreement''.

(a) Content of CJR–X Data Sharing Agreement

We proposed that, under the CJR–X data sharing agreement, CJR–X participants would agree to certain terms, namely: (1) to comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA Privacy Rule and the requirements of the proposed CJR–X; (2) to comply with additional privacy, security, and breach notification requirements to be specified by CMS in the CJR–X data sharing agreement; (3) to contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the CJR–X participant or performs a similar function for the CJR–X participant, to the same terms and conditions to which the CJR–X participant is itself bound in its data sharing agreement with CMS as a condition of the downstream recipient's receipt of the beneficiary-identifiable data retrieved by the CJR–X participant under the CJR–X; and (4) that if the CJR–X participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the CJR–X data sharing agreement, the CJR–X participant would no longer be eligible to retrieve the beneficiary-identifiable data and may be subject to additional sanctions and penalties available under the law. We believe that these terms for sharing beneficiary-identifiable data with CJR–X participants are appropriate and important, as CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with CJR–X participants would be further protected by the CJR–X participant, and any business associates of the CJR–X participant, in an appropriate fashion. We believe that these proposals would allow CMS to accomplish that.

We sought public comment on the additional privacy, security, breach notification, and other requirements that we would include in the CJR–X data sharing agreement. CMS has these types of agreements in place as part of the governing documents of other models tested under section 1115A of the Act and in the Medicare Shared Savings Program. In these agreements, CMS typically requires the identification of data custodian(s) and imposes certain requirements related to administrative, physical, and technical safeguards relating to data storage and transmission; limitations on further use and disclosure of the data; procedures for responding to data incidents and breaches; and data destruction and retention. These provisions would be imposed in addition to any restrictions required by law, such as those provided in the HIPAA Privacy, Security and Breach Notification Rules (45 CFR parts 160 and 164). These provisions would not prohibit the CJR–X participant from making any disclosure of the data otherwise required by law.

We also sought public comment on what disclosures of the beneficiary-identifiable data might be appropriate to permit or prohibit under the CJR–X data sharing agreement. For example, we are considering prohibiting, in the CJR–X data sharing agreement, any further disclosure, not otherwise required by law, of the beneficiary-identifiable data to anyone who is not a ''HIPAA covered entity or business associate'', as defined in 45 CFR 160.103, or to an individual practitioner in a treatment relationship with the CJR–X beneficiary, or that practitioner's business associates. Such a prohibition would be similar to that imposed by CMS in other models tested under section 1115A of the Act in which CMS shares beneficiary-identifiable data with model participants.

We are considering these possibilities because there exist important legal and policy limitations on the sharing of the beneficiary- identifiable data and CMS must carefully consider the ways in which and reasons for which we would provide access to this data for purposes of the CJR–X. We believe that some CJR–X participants may require the assistance of business associates, such as contractors, to perform data analytics or other functions using this beneficiary-identifiable data to support the CJR–X participant's review of their care management and coordination, quality improvement activities, or clinical treatment of CJR–X beneficiaries. We also believe that this beneficiary-identifiable data may be helpful for any HIPAA covered entities who are in a treatment relationship with the CJR–X beneficiary.

We sought public comment on how a CJR–X participant might need to, and want to, disclose the beneficiary-identifiable data to other individuals and entities to accomplish the goals of the CJR–X, in accordance with applicable law.

Under our proposal, the CJR–X data sharing agreement would include other provisions, including requirements regarding data security, retention, destruction, and breach notification. For example, we are considering including, in the CJR–X data sharing agreement, a requirement that the CJR–X participant designate one or more data custodians who would be responsible for ensuring compliance with the privacy, security and breach notification requirements for the data set forth in the CJR–X data sharing agreement; various security requirements like those found in other models tested under section 1115A of the Act, but no less restrictive than those provided in the relevant Privacy Act system of records notices; how and when beneficiary-identifiable data could be retained by the CJR–X-participant or its downstream participants of the beneficiary identifiable data; procedures for notifying CMS of any breach or other

incident relating to the unauthorized disclosure of beneficiary-identifiable data; and provisions relating to destruction of the data. These are only examples and are not the only terms CMS would potentially include in the CJR–X data sharing agreement.

We solicited public comment on this proposal that CMS, by adding § 512.665(e)(1)(ii), would impose certain requirements in the CJR–X data sharing agreement related to privacy, security, data retention, breach notification, and data destruction.

Finally, we proposed, at § 512.665(e)(1)(iv), that the CJR–X data sharing agreement would include a term providing that if the CJR–X participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the CJR–X data sharing agreement, the CJR–X participant would no longer be eligible to retrieve beneficiary-identifiable data under proposed § 512.665(b) and may be subject to additional sanctions and penalties available under law. We also proposed that if CMS determines that one or more grounds for remedial action specified in § 512.665(e)(iv) has taken place, CMS may discontinue the provision of data sharing and reports to the model participant. We proposed that CMS may take remedial action if the model participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the applicable data sharing agreement.

We solicited public comment on this proposal, to prohibit the CJR–X participant from obtaining beneficiary-identifiable data pertaining to the CJR–X if the CJR–X participant fails to comply with applicable laws and regulations, the terms of the CJR–X, or the CJR–X data sharing agreement.

We received no comments on these proposals and therefore are finalizing without modification the proposal at § 512.665(e)(1)(ii) that CMS would impose certain requirements in the CJR–X data sharing agreement related to privacy, security, data retention, breach notification, and data destruction. We are also finalizing without modification our proposal at § 512.665(e)(1)(iv) that if the CJR–X participant improperly misuses or discloses the beneficiary-identifiable data the CJR–X participant would no longer be eligible to retrieve beneficiary-identifiable data and may be subject to additional sanctions and penalties available under law. Lastly, we're also finalizing without modification the proposal at § 512.665(e)(iv) that if CMS determines that one or more grounds for remedial action has taken place then CMS may discontinue the provision of data sharing and reports to the CJR–X participant.

l. Alternative Payment Model Options

(1) Background

As specified in the Quality Payment Program regulations (42 CFR 414.1415), in order to be considered an Advanced APM, an Alternative Payment Model (APM) must—

- Require use of Certified Electronic Health Record Technology (CEHRT);
- Be subject to payment based on quality measures; and
- Require entities to bear financial risk.

We sought to align the design of CJR–X with the Advanced APM criteria in the Quality Payment Program and enable CMS to have the necessary information on eligible clinicians to make the requisite Qualifying APM Participant (QP) determinations. Eligible clinicians, as defined at 42 CFR 414.1305, that are captured on a CMS-maintained list constituting an affiliated practitioner list, as defined at 42 CFR 414.1305, may be eligible to receive benefits for participating in an Advanced APM, including burden reduction and financial incentives. We proposed that the CJR–X participant would be considered the APM entity, as defined at 42 CFR 414.1305, and that the CJR–X participant's affiliated practitioners, as defined at 42 CFR 414.1305, may be assessed for QP determinations depending on whether the CEHRT criteria are met, as established at 42 CFR 414.1425(b)(2). Additionally, we sought to ensure the design of CJR–X meets the Merit-based Incentive Payment System (MIPS) APM criteria and that CMS has the necessary information on MIPS eligible clinicians, as defined in 42 CFR 414.1305, so that they may be eligible for certain scoring benefits under MIPS. We therefore proposed to adopt two different APM options for CJR–X—an ''AAPM option'' would be defined as an option in which CJR–X participants would attest to meeting the CEHRT requirement and in which the CJR–X participant's eligible clinicians may be assessed for QP determinations (as CMS has already determined that CJR–X is an Advanced APM), and a ''non-AAPM option'' would be defined as an option in which CJR–X participants would not meet the CEHRT requirements and in which the CJR–X participant's MIPS eligible clinicians may be assessed for reporting and scoring through the APM Performance Pathway (APP) (as CMS has already determined CJR–X is a MIPS APM).

(2) APM Options

As previously stated, an Advanced APM must require participants to use CEHRT (42 CFR 414.1415(a)), make payments based on quality measures (42 CFR 414.1415(b)) and meet financial risk standards (42 CFR 414.1415(c)). We proposed two APM options in CJR–X: a non-Advanced APM (non-AAPM) option and an Advanced APM (AAPM) option. The non-AAPM option would be for CJR–X participants that do not meet the CEHRT requirements. However, these CJR–X participants may still be considered APM entities in a MIPS APM. The AAPM option would be for CJR–X participants that meet the CEHRT requirement. These CJR–X participants would be considered APM entities in an Advanced APM.

We proposed to require CJR–X participants who wish to participate in the AAPM option to attest to meeting the CEHRT use requirement that meets the CEHRT definition in our regulations at 42 CFR 414.1305 on an annual basis prior to the start of each performance year in a form and manner and by a date specified by CMS. We proposed that the CJR–X participant would be required to retain and provide CMS access to the attestation upon request. We further propose that meeting and attesting to the CEHRT use criteria would be voluntary, and that CMS would assign CJR–X participants who choose not to do so to the non-AAPM option. Lastly, we proposed to require CJR–X participants who wish to participate in the AAPM option to provide their CMS Electronic Health Record (EHR) Certification IDs on an annual basis prior to the end of each performance year in a form and manner and by a date specified by CMS.

We believe that a CJR–X participant's decision to meet and attest to the CEHRT use criteria would not create significant additional administrative burden for the CJR–X participant. Moreover, the choice of whether to meet and attest to the CEHRT use criteria would not otherwise affect the CJR–X participant's requirements or opportunities under the model. However, a CJR–X participant's decision to attest to CEHRT use may affect the ability of its clinicians to qualify as a QP. In other words, if a CJR–X participant chose not to attest to CEHRT use, its clinicians would not be assessed for QPs status.

We sought comment on our proposals for the CJR–X Advanced APM options and the associated requirements at § 512.615. We also sought comment on our proposed definitions for the ''AAPM option'' and ''non-AAPM option'' at § 512.605.

Comment: A couple of commenters supported CMS creating options under CJR–X for participants' eligible clinicians to achieve QP status or participate in MIPS APM.

Response: We thank the commenters for the support.

Comment: A commenter requested clarification on entities eligible for QP determinations, specifically CJR–X collaborators, including those that are certified registered nurse anesthetists (CRNAs), would be considered QPs under the CJR–X Model assuming the CJR–X participant meets CEHRT criteria and assuming the CRNAs furnish services under the CJR–X Model during the performance period.

Response: A CJR–X collaborator, inclusive of CRNAs, that meets the definition of an eligible clinician, as defined at 42 CFR 414.1305, that is listed on a financial arrangement list or clinician engagement list for a CJR–X participant participating in the AAPM Option is eligible to be submitted for QP determinations. Eligibility for QP determinations does not guarantee QP status. To become a QP, eligible clinicians must receive at least 75 percent of Medicare Part B payments or see at least 50 percent of Medicare patients through an Advanced APM Entity during the QP Performance Period (January 1–August 31). Not all eligible clinicians who participate in an Advanced APM will meet the participation thresholds required to achieve QP status. However, some eligible clinicians may meet lower participation thresholds and become Partial QPs. To become a Partial QP, clinicians must receive at least 50 percent of Medicare Part B payments or see at least 35 percent of Medicare patients through an Advanced APM Entity during the QP performance period (January 1–August 31).

Comment: A commenter requested clarification on how CMS would determine QP status for eligible clinicians participating concurrently in other Advanced APMs.

Response: We appreciate the commentor's request for clarification regarding how we determine Qualifying APM Participant (QP) status for eligible clinicians who participate concurrently in more than one Advanced APM, for example CJR–X and the Medicare Shared Savings Program. In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77445), we finalized our policy for QP determinations at § 414.1425. In establishing this methodology, we noted (81 FR 77440) that for models, such as CJR, that provide an Affiliated Practitioner List, as defined at § 414.1305, we would provide an individual QP determination as codified at § 414.1425(b)(2). Through the 2026 QP performance period, to calculate the numerator and denominator of these determinations we identified attribution-eligible beneficiaries, as defined at § 414.1305, where for the sixth criterion the beneficiary had a minimum of one Covered Professional Service during the QP performance period. In the CY 2026 PFS final rule (90 FR 50012), we finalized an update to our methodology at §§ 414.1435 and 414.1305 to perform QP determinations using both an E/M services approach and a Covered Professional Services as defined at § 414.1305. We note that in most cases identifying beneficiaries using Covered Professional Services provides a more beneficial methodology for CJR affiliated practitioners, and we expect this to be the case for CJR–X. When calculating the QP determination for an affiliated practitioner in more than one Advanced APM we calculate the individual eligible clinician score by combining participation across all Advanced APMs to determine whether QP thresholds have been satisfied. In cases where a beneficiary is attributed more than one Advanced APM that beneficiary is counted only once in both the numerator and denominator. In cases where a beneficiary is prospectively attributed to another Advanced APM and would otherwise not be permitted to be attributed to the clinician receiving the calculation, we exclude these beneficiaries from the denominator of our calculation. We also note that for clinicians described in this scenario in addition to an individual calculation they would also be receiving calculations at the APM entity level and we would look to see if, as part of the ACO, the APM Entity group achieved a Threshold Score meeting the QP payment amount threshold or QP patient count threshold. We encourage stakeholders to consult the QPP website (*qpp.cms.gov*) where clinicians may use the QPP portal and lookup tool to view their QP determinations.

After consideration of the public comments we received, we are finalizing without modification the CJR–X Advanced APM options and the associated requirements at § 512.615. We are also finalizing without modification the definitions for ''AAPM option'' and ''non-AAPM option'' at § 512.605.

(3) Financial Arrangements List and Clinician Engagement List

We proposed that each CJR–X participant would be required to submit information about the eligible clinicians or MIPS eligible clinicians who enter into financial arrangements with the CJR–X participant for purposes of supporting the CJR–X participants' cost or quality goals as discussed in section X.C.2.i. of this final rule. Since CJR–X would be an Advanced APM and a MIPS APM, this information would enable CMS to make QP determinations for eligible clinicians or allow for APP reporting and scoring for MIPS eligible clinicians. We proposed that for purposes of CJR–X, the eligible clinicians or MIPS eligible clinicians could be: (1) CJR–X collaborators, as described in section X.C.2.i.(3). of this final rule, engaged in sharing arrangements with a CJR–X participant; (2) PGP, NPPGP, or TGP members who are collaboration agents engaged in distribution arrangements with a PGP, NPPGP, or TGP that is a CJR–X collaborator, as described in section X.C.3.i.(5) of this final rule; or (3) PGP, NPPGP, or TGP members who are downstream collaboration agents engaged in downstream distribution arrangements with a PGP, NPPGP, or TGP that is also an ACO participant in an ACO that is a CJR–X collaborator, as described in section X.C.3.i.(6). of this final rule. The list of physicians and nonphysician practitioners in these three groups that we proposed to require CJR–X participants to submit to CMS would satisfy the criteria to be considered an Affiliated Practitioner List, as defined in 42 CFR 414.1305. We proposed to use the Financial Arrangements list (FAL), submitted by CJR–X participants to CMS, to make determinations regarding which physicians and nonphysician practitioners should receive QP determinations or be reported for the APP based on the services they furnish under CJR–X.

We proposed for the reasons detailed previously that each CJR–X participant with eligible clinicians or MIPS eligible clinicians must submit to CMS a financial arrangements list in a form and manner and by the date specified by CMS on a quarterly basis during each performance year or attest that there are no individuals to report on the financial arrangements list. We believe submission of the financial arrangements list on a quarterly basis would align with the Quality Payment Program's QP determination dates, as

described in 42 CFR 414.1425. We proposed to define the ''financial arrangements list (FAL)'' at § 512.605 as the list of eligible clinicians or MIPS eligible clinicians that have a financial arrangement with the CJR–X participant, CJR–X collaborator, collaboration agent, or downstream collaboration agent. We proposed the CJR–X participant would be required to retain and provide CMS access to the financial arrangements list upon request. We proposed that the list must include the following information:

- For each CJR–X collaborator who is a physician, nonphysician practitioner, or therapist during the performance year—
  - ++ The name, tax identification number (TIN), and national provider identifier (NPI) of the CJR–X collaborator; and
  - ++ The start date and, if applicable, end date, for the sharing arrangement between the CJR–X participant and the CJR–X collaborator.
- For each collaboration agent who is a physician, nonphysician practitioner, or therapist during the performance year—
  - ++ The name, TIN, and NPI of the collaboration agent and the name and TIN of the CJR–X collaborator with which the collaboration agent has entered into a distribution arrangement; and
  - ++ The start date and, if applicable, end date, for the distribution arrangement between the CJR–X collaborator and the collaboration agent.
- For each downstream collaboration agent who is a physician or nonphysician practitioner, or therapist during the performance year—
  - ++ The name, TIN, and NPI of the downstream collaboration agent and the name and TIN of the collaboration agent; and
  - ++ The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent and the downstream collaboration agent.
- If there are no individuals that meet the reporting criteria listed previously for CJR–X collaborators, collaboration agents, or downstream collaboration agents, then the CJR–X participant must attest on a quarterly basis in a form and manner and by a date specified by CMS that there are no individuals to report on the financial arrangements list.

While the proposed submission of the financial arrangements list may create some additional administrative burdens for certain CJR–X participants, we expect that CJR–X participants could modify their contractual relationships with their CJR–X collaborators and, correspondingly, require those CJR–X collaborators to include similar requirements in their contracts with collaboration agents and in the contracts of collaboration agents with downstream collaboration agents.

We also recognize there may be physicians and nonphysician practitioners who would not be listed on the financial arrangements list because they have not entered into a financial arrangement as a CJR–X collaborator, collaboration agent, or downstream collaboration agent, but who may nevertheless participate in CJR activities, as defined at proposed § 512.605, and may be eligible for QP determinations or eligible for APP reporting because they are affiliated with and support the APM Entity. We proposed that, in order to capture these physicians and nonphysician practitioners who are not listed on the CJR–X participant's financial arrangements list for QP determinations or APP reporting, CJR–X participants must also submit to CMS a clinician engagement list in a form and manner and by a date specified by CMS on a quarterly basis every performance year. We proposed to use the clinician engagement list for assessing QP determinations and for APP reporting. The submission of the clinician engagement lists may create some additional administrative burdens for CJR–X participants, but we expect the effort to be worthwhile since some of these QP determinations may result in eligible clinicians receiving burden reduction benefits and financial incentives, and some MIPS eligible clinicians may receive MIPS APM scoring benefits.

We proposed to define the ''clinician engagement list (CEL)'' at § 512.605 as the list of eligible clinicians or MIPS eligible clinicians that participate in CJR–X activities, have a contractual relationship with the CJR–X participant, and who are not listed on the financial arrangements list. We proposed that the CJR–X participant must submit the list to CMS on a quarterly basis during each performance year in a form and manner and by a date specified by CMS or attest that there are no individuals to report on the clinician engagement list. We believe submission of the clinician engagement list on a quarterly basis would align with the Quality Payment Program's QP determination dates, as described in 42 CFR 414.1425. We proposed the CJR–X participant would be required to retain and provide CMS access to the clinician engagement list upon request. We proposed that the clinician engagement list must include the following information:

- For each physician, nonphysician practitioner, or therapist who is not listed on the CJR–X participant's financial arrangements list during the performance year, but who does have a contractual relationship with the CJR–X participant and participates in CJR–X activities during the performance year—
  - ++ The name, TIN, and NPI of the physician, nonphysician practitioner, or therapist; and
  - ++ The start date and, if applicable, end date, for the contractual relationship between the physician, nonphysician practitioner, or therapist and the CJR–X participant.
- We proposed that if there are no individuals that meet the requirements to be reported on the clinician engagement list, then the CJR–X participant must attest on a quarterly basis in a form and manner and by a date specified by CMS that there are no individuals to report on the clinician engagement list.

We sought comments on the proposal to require CJR–X participants to submit a financial arrangements list and clinician engagement list on a quarterly basis or attest that there are no individuals to report. We also sought comments about approaches to information submission, including the content of the lists, and periodicity and method of submission to CMS that would minimize the reporting burden on CJR–X participants while providing CMS with sufficient information about eligible clinicians to facilitate QP determinations and APP reporting to the extent that CJR–X is considered to be an Advanced APM and a MIPS APM.

The following is a summary of the public comments received on the proposed policy for CJR–X participants to submit a financial arrangements list and a clinician engagement list, and our responses to these comments:

Comment: A commenter requested clarification that the clinician engagement list could include clinicians, including CRNAs, who perform CJR–X activities under a CJR–X participant through a 1099 independent contractor locum tenens arrangement.

Response: The clinician engagement list must include eligible clinicians or MIPS eligible clinicians, as defined at 42 CFR 414.1305, that participate in CJR–X activities and have a contractual relationship with the CJR–X participant, and who are not listed on the financial arrangements list. Therefore, if the CNRA is an eligible clinician or MIPS eligible clinician, participates in CJR–X activities, and has a contractual relationship with the CJR–X participant

then they must be listed on the clinician engagement list.

Comment: A commenter requested clarification regarding the financial arrangements list needing to be inclusive of all contractual relationship types to facilitate inclusion of all clinicians participating in CJR–X activities as QPs.

Response: Eligible clinicians or MIPS eligible clinicians, as defined at 42 CFR 414.1305, must have a financial arrangement with the CJR–X participant, CJR–X collaborator, collaboration agent, or downstream collaboration agent to be listed on the financial arrangements list. A financial arrangement includes a sharing arrangement between the CJR–X participant and CJR–X collaborator, a distribution arrangement between the CJR–X collaborator and collaboration agent, or a downstream distribution arrangement between the collaboration agent and downstream collaboration agent, all defined at § 512.605. Therefore, eligible clinicians must have a financial arrangement to be listed on the financial arrangements list. If an eligible clinician is in a contractual relationship that does not satisfy the requirements for a financial arrangement, then they may not be listed on the financial arrangements list.

Comment: A commenter believed that CMS already had the relevant information collected on the financial arrangements list and clinician engagement list and that CMS should rely on existing data sources to construct the lists rather than requiring hospitals to submit the lists on a quarterly basis.

Response: We acknowledge the reporting burden with submitting quarterly lists, but CMS does not have access to who the CJR–X participant may have financial relationships with, nor does CMS have access to all the contractual relationships a CJR–X participant may have. We are interested in reducing participant burden and will continue to consider ways to improve the process while still ensuring clinicians can be assessed for QP determinations.

After consideration of the public comments, we are finalizing without modification the proposals at § 512.615(b) for CJR–X participants to submit a financial arrangements list and at § 512.615(c) for CJR–X participants to submit a clinician engagement list.

m. Standard Provisions

CJR–X meets the criteria for application of the Standard Provisions for Mandatory Innovation Center Models (42 CFR part 512, subpart A). Unless otherwise specified, all CJR–X participants and CJR–X beneficiaries are subject to the provisions at §§ 512.100 through 512.190, which address the following areas:

- Beneficiary Protections.
- Cooperation in Model Evaluation and Monitoring.
- Audits and Record Retention.
- Rights in Data and Intellectual Property.
- Monitoring and Compliance.
- Remedial Action.
- Innovation Center Model Termination by CMS.
- Limitations on Review.
- Miscellaneous Provisions on Bankruptcy and Other Notifications.
- Reconsideration Review Process.

We recognize the standard provisions were not intended to encompass all the terms and conditions that would apply to each Innovation Center model, because each model embodies unique design features and implementation plans that may require additional, more tailored provisions, including with respect to payment methodology, care delivery and quality measurement, that would continue to be included in each model's governing documentation. Thus, we sought public comment on whether CJR–X should set forth model-specific provisions related to any of the provisions identified previously at §§ 512.100 through 512.190.

Comment: Some commenters recommended that CMS adopt and enforce robust beneficiary protections to preserve beneficiary choice, prevent patient steering, and maintain access to clinically appropriate post-acute care. Commenters stated that financial accountability for episode spending could create incentives for participating hospitals to steer beneficiaries toward lower-cost settings or narrow referrals without sufficient attention to individual clinical needs. Another commenter stated that the level of services provided should depend on a patient's acuity and the discretion of the physician and clinical team. They stated that while some only need informal caregiving from family members or personal caregivers, others may require skilled home care or therapy from nurses or physical therapists. Some commenters recommended that CMS adopt protections similar to those used in TEAM, require clear written notice of beneficiary rights, and provide meaningful complaint, monitoring, and enforcement processes. Commenters also urged CMS to monitor for patient selection, referral narrowing, disparities in access, and improper limitations or stinting on supplies or services. They recommended that CMS explain how beneficiary protections would be monitored and enforced if CJR–X is implemented.

Response: We appreciate the commenters' concerns regarding beneficiary choice, access to medically necessary care, and potential steering in connection with CJR–X and acknowledge the suggestions to standardize messaging and create consistency. We also recognize that episode-based financial accountability could create incentives to reduce episode spending and that safeguards are important to ensure that care recommendations are based on clinical need rather than inappropriate cost savings.

We agree that beneficiary protections to maintain access and freedom of choice are necessary to ensure appropriate care is delivered to Medicare beneficiaries. We believe that the standard provisions for mandatory Innovation Center models at §§ 512.100 through 512.190 are appropriate safeguards. For instance, the beneficiary protections at § 512.120 cover freedom of choice, availability of services, and descriptive model materials and activities.

We have a special interest in ensuring that the CJR–X Model does not interfere with program integrity interests of the Medicare program. For this reason, we monitor for compliance with model requirements as well as other Medicare program rules. When we become aware of noncompliance with these requirements, it is necessary for CMS to have the ability to impose certain administrative remedial actions on a noncompliant model participant (*89 FR 36382*).

The terms of the standard Innovation Center provisions for mandatory models at §§ 512.100 through 512.190 permit CMS to impose one or more administrative remedial actions to address noncompliance by a model participant. We proposed that CJR–X would conform to the standard provisions, which would include taking remedial actions set forth in § 512.160.

Additionally, as discussed in section X.C.2.b.(2), we initially proposed at § 512.610(a)(2) to allow CMS to provide notices of termination that would terminate a CJR–X participant's participation in the model. We inadvertently limited the circumstances under which CMS could issue a notice of termination to those described in § 512.165(b), which applies only when CMS terminates the model itself. To correct this error and allow CMS to appropriately address program integrity concerns in the model, we have inserted a separate provision addressing the notice of termination at § 512.610(c).

This provision preserves CMS's ability, in its sole discretion, to terminate a CJR–X participant from the model, immediately or upon advance notice, if we determine that one or more grounds for remedial action described at § 512.160(a) applies.

CJR–X participants may provide a written notice disputing the termination within 10 calendar days of receiving a notice of termination to request review by CMS. If a participant submits a timely notice of dispute, CMS will respond to the CJR–X participant's request for review within 30 days. If the CJR–X participant fails to provide timely notification to CMS, the termination is deemed final

These processes allowing for termination of participants from CJR–X as a remedial action and for disputing a notice of termination are consistent with the CJR Model and will help ensure appropriate program integrity safeguards.

Should a CJR–X participant be terminated from the CJR–X Model, in alignment with the CJR Model, the participant hospital would remain liable for all repayments generated from episodes of care that ended prior to termination.

Therefore, in addition to the remedial actions at § 512.160(b), we are finalizing at § 512.610(c) that CMS may terminate a CJR–X participant from CJR–X if the CJR–X participant satisfies the grounds for remedial action at § 512.160(a), the CJR–X participant may appeal the termination, in accordance with § 512.610(c)(2), and terminated participants would remain liable for all negative NPRA generated from episodes of care that ended prior to termination.

n. Termination of CJR–X

The general provisions relating to termination of the model by CMS in § 512.165 would apply to CJR–X. Consistent with termination provisions of other Innovation Center models, in the event we terminate CJR–X, we would provide written notice to CJR–X participants specifying the grounds for termination and the effective date of such termination or ending. As provided by section 1115A(d)(2) of the Act, termination of the model under section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review.

We received no comments on model termination.

D. Organ Acquisition and Reasonable Cost Payment Policies, and Reimbursement Appeals for Independent Organ Procurement Organizations and Histocompatibility Laboratories

1. Reconciliation of Organ Acquisition Costs for Non-Renal Organs for IOPOs and HCLs

a. Background

(1) Overview

Organ procurement organizations (OPOs)[611] perform or coordinate the procurement, preservation, and transportation of organs from deceased donors, and maintain a system for locating prospective recipients for organ transplantation. To participate in the Medicare program, OPOs must be members of the Organ Procurement and Transplantation Network (OPTN) and must have agreements with hospitals or critical access hospitals in their service areas, to identify potential organ donors. OPOs provide both administrative and medical services that include, but are not limited to, arranging for tissue typing of donated organs; removal of the deceased donor organs (where the physicians are employed by the OPO or are under contract or agreement with the OPO); and perfusion, preservation, and transportation of the procured organs. OPOs may be independent or hospital-based. Hospital-based OPOs (HOPOs) are considered departments of their hospital and report costs for services on their transplant hospital's (TH's) Medicare cost report (MCR). Independent OPOs (IOPOs) file a separate cost report (see 42 CFR 413.420(c)(1)(i)).

Histocompatibility laboratories (HCLs) are specialized clinical laboratories that perform tissue typing and compatibility testing on potential organ donors and recipients. These labs primarily conduct HLA (Human Leukocyte Antigen) typing—identifying tissue markers for organ and tissue transplantation. They perform crossmatching tests to determine compatibility between organ donors and recipients, antibody screening to detect antibodies that could cause transplant rejection, and disease association testing—HLA typing for certain autoimmune and genetic conditions. HCLs play a critical role in organ transplantation programs, ensuring that donated organs are matched appropriately with recipients to minimize rejection risk. HCLs may also be independent or hospital-based. Hospital-based HCLs are considered departments of their hospital and report costs for services on their TH's MCR. Independent HCLs, hereinafter referred to as HCLs, file a separate cost report (see 42 CFR 413.420(c)(1)(i)).

Under section 1861(v)(1)(A), reasonable cost is the necessary cost actually incurred in the efficient delivery of needed health care services to Medicare beneficiaries. Section 413.1(a)(2)(v) identifies OPOs and HCLs as provider types to which part 413 of the regulations apply, making them expressly subject to Medicare's reasonable cost principles, including 42 CFR 413.9 regarding cost related to patient care. Currently, the Medicare program reimburses the reasonable costs related to patient care of allowable kidney acquisition services furnished by IOPOs and HCLs, provided that they have an agreement with the Secretary in accordance with 42 CFR 413.420. Kidney acquisition costs are not paid directly by Medicare to an IOPO or HCL. IOPOs and HCLs are reimbursed for their kidney acquisition services by the THs, subject to later adjustment by Medicare (see 42 CFR 413.420). Medicare currently authorizes reimbursement to designated IOPOs for kidney acquisition costs, under reasonable cost principles[612] in accordance with section 1861(v) of the Act, based on the IOPO's ratio of Medicare usable kidneys to total usable kidneys (see section 1881(b)(2)(A) of the Act). Additionally, Medicare currently authorizes reimbursement to HCLs for the reasonable costs of pre-transplant kidney histocompatibility testing, based on the HCL's ratio of pre-transplant kidney histocompatibility charges to the total of HCL charges for all tests the lab performs, in accordance with section 1861(v) of the Act and 42 CFR 413.420. In accordance with 42 CFR 413.24(f), Medicare requires THs, IOPOs, and HCLs to complete an MCR[613] on an annual basis.

In the FY 2022 IPPS/LTCH PPS final rule with comment period, published in the **Federal Register** (FR) (86 FR 73468 through 73505) December 27, 2021, we clarified and codified certain Medicare organ acquisition payment policies in new subpart L of 42 CFR part 413. In the CY 2023 OPPS proposed rule (87 FR 44769 through 44773), published July 26, 2022, we included a request for

[611] We refer to organ procurement organizations generally as ''OPOs'' throughout, unless differentiation of IOPO is required for cost reporting purposes, for OPOs that file a cost report on the CMS–216–94 (OMB No. 0938–0102).

[612] Id. Section 1138(b)(1)(F) of the Act; 42 CFR 413.1(a)(1)(ii)(A); 413.420(a).

[613] THs complete the hospital cost report, form CMS–2552–10 (OMB No. 0938–0050) and IOPOs and HCLs complete cost report form CMS–216–94 (OMB No. 0938–0102).

information (RFI) and solicited comments that would help to inform potential changes to Medicare's organ acquisition payment policies. In the CY 2023 OPPS final rule (87 FR 72150 through 72159), published November 23, 2022, we clarified and codified certain other Medicare organ acquisition payment policies.

(2) Reimbursement of Organ Acquisition Costs

Medicare's current organ acquisition policy is modeled after the kidney acquisition policy that was implemented for kidney transplants following the Social Security Amendments of 1972 (Pub. L. 92–603) that extended Medicare coverage to individuals with end stage renal disease (ESRD) who required dialysis or transplantation. In July 1973 and July 1974, CMS (then the Bureau of Health Insurance [614] (BHI)) issued Intermediary Letters (ILs) which set forth procedures and policies for Medicare reimbursement for kidney transplants.[615] The IL 73–25 (July 1, 1973) set forth policies for the reimbursement of kidney transplants and dialysis, including policies for hospital reimbursement for the acquisition of a kidney from deceased and living donors for transplant into a Medicare beneficiary. The IL 74–23 (July 1974) addressed questions related to proper treatment for Medicare reimbursement purposes of various costs associated with kidney acquisition and transplant and kidney dialysis services. The IL 74–23 noted that the hospital is expected to acquire the kidney at a reasonably cost-related charge, which the hospital would pay to the organ procurement agency (now called organ procurement organization) and include as a cost to the TH.[616]

The Medicare reimbursement policies for IOPO and HCL kidney acquisition costs were implemented in a final rule (43 FR 58370 through 58372), published December 14, 1978. In that final rule, we noted that HOPOs and hospital-based HCLs included their services in their hospital cost report, and they were reimbursed based upon reasonable cost principles. However, THs had no authority or basis for determining the reasonableness of charges from IOPOs and independent HCLs, and the charges billed by IOPOs and these HCLs were not reviewed by the Medicare contractor to determine reasonableness. As such, the potential existed for Medicare to pay more than reasonable costs for organ acquisition services. In June 1978, Congress passed Public Law 95–292 (the End Stage Renal Disease (ESRD) Program Amendment), which amended section 1881(b)(2)(A) of the Act, and required that reimbursement made under title XVIII for the services of OPOs and HCLs in procuring and furnishing organs for transplantation must not exceed the cost actually incurred by that OPO or HCL, and must be determined in accordance with section 1861(v) of the Act. Section 1861(v) of the Act requires that payments be based upon reasonable costs.[617]

We note that Public Law 95–292 refers to the costs of procuring *organs,* thus including both kidneys and non-renal organs when requiring payments to be made at reasonable cost for the actual costs incurred. The legislative history of Public Law 95–292 indicates that Congress intended for the Secretary to apply already established-principles of cost reimbursement, obtain periodic cost reports, and provide for an intermediary hearing for an IOPO or HCL which disagrees with a cost determination.[618] We believe that the legislative history also indicates that the cost of IOPO or HCL services would continue to be paid by the TH, but that the Secretary would be authorized to institute a system whereby IOPOs and HCLs could be reimbursed directly if such a system seems appropriate.[619]

We implemented section 1881(b)(2)(A) of the Act and this legislative intent by requiring that the Medicare program reimburse only the reasonable cost of IOPO and HCL services for kidney acquisitions.[620] We also required that the contractor establish IOPOs' Standard Acquisition Charge (SAC) and HCL testing rates for kidney acquisitions. In addition, we required the contractor to review IOPOs' and HCLs' kidney acquisition costs and reconcile and settle those costs through the MCR. These measures were implemented to ensure that kidney acquisition costs would be paid on a reasonable cost basis, in accordance with the statute at sections 1881(b)(2)(A) and 1861(v) of the Act. We note that Medicare currently reconciles the organ acquisition costs incurred by HOPOs for all organs they procure, renal and non-renal, as part of the hospital cost report reconciliation.[621] Therefore, our discussion of reasonable cost for organ acquisition and cost reconciliation is focused on IOPOs and HCLs, but not HOPOs.

Over the years, through various rulings and national coverage determinations (NCDs), Medicare added coverage for transplantation of non-renal organs such as heart, liver, lungs, and pancreas. Non-renal organs were covered for transplantation through a CMS Ruling (for heart transplants) and through NCDs (for other non-renal organs),[622] and payment policies were subsequently implemented through notice-and-comment rulemaking.[623] While we modeled our reimbursement for non-renal organ acquisition costs based on existing kidney acquisition policies, we did not address reasonable cost reimbursement and reconciliation of the non-renal organs to IOPOs and HCLs. Non-renal organ acquisition charges are billed to THs, and THs have no basis for determining the reasonableness of the charges from the IOPOs and HCLs, as previously noted, creating opportunity for Medicare to pay more than reasonable cost for these services (43 FR 58370).

Currently IOPOs determine their charges for non-renal organ acquisition costs and those amounts are billed to and paid by THs. THs subsequently include those charges in their organ acquisition costs without the ability for determining reasonableness. We are concerned about reports from our Medicare contractor, discussed in an OIG report,[624] that opportunities and incentives exist for IOPOs to inflate their non-renal SACs and exceed their

[614] To implement the Medicare statute, the Social Security Administration was reorganized and the Bureau of Health Insurance (BHI) was established on July 30, 1965. The BHI then became responsible for the development of health insurance policy before the creation of the Health Care Financing Administration (HCFA), later renamed the Centers for Medicare & Medicaid (CMS). CMS Milestones 1937–2015 (July 2015).

[615] *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2022-ipps-proposed-rule-home-page.*

[616] *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2022-ipps-proposed-rule-home-page;* see page 10 of IL 74–23.

[617] See sections 1882(b)(2)(A) and 1861(v) of the Act.

[618] 43 FR 58370 and 58371. See also S. Rep. No. 95–714, 95th Cong., 2d Sess. 12–13 (1978); H. Rep. No. 95–549, 95th Cong., 1st Sess., 14 (1977).

[619] 43 FR 58371.

[620] *Ibid.* Note that in 1978, the only organs Medicare covered for transplant were kidneys. As such, we did not address non-renal organ acquisition costs.

[621] PRM–2, chapter 40, section 4028.

[622] See CMS Ruling 87–1, April 1987; National Coverage Determinations Manual, IOM 100–03, chapter 1, Part 4, section 260 (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf*).

[623] 52 FR 33034, September 1, 1987 (heart); 55 FR 8545, March 8, 1990, and 56 FR 15013, April 12, 1991 (liver); 60 FR 6537, February 2, 1995 (lung); 64 FR 41497, July 30, 1999 (pancreas); 66 FR 39828, August 1, 2001 (intestine, with reasonable cost coverage of acquisition costs beginning October 1, 2001).''

[624] *https://oig.hhs.gov/documents/audit/9634/A-09-21-03020-Complete%20Report.pdf,* page 14.

reasonable costs for procurement services. IOPO cost report data for annual cost reporting periods ending in 2024 [625] showed that non-renal organ revenue exceeded non-renal organ acquisition costs by $100 million. OPOs are required to operate as non-profit organizations [626] under Federal statute and to only recover their reasonable costs associated with organ procurement activities. The fundamental principle is that human organs are donated gifts, not commodities for sale. While OPOs can recover their reasonable and necessary operational costs, they cannot profit from the organs themselves.[627]

In accordance with our current requirements at § 413.404(c)(1), for each non-renal organ type, an IOPO is supposed to establish its organ-specific non-renal acquisition charges by estimating the reasonable and necessary organ acquisition costs it expects to incur, divided by the projected number of organs it expects to procure, in its cost reporting period. The existing cost report data enables the Medicare contractor to determine if those acquisition charges the IOPO establishes are higher than what the acquisition charges should have been based on costs actually incurred. When an IOPO establishes a non-renal acquisition charge that is higher than its reasonable costs actually incurred, and the IOPO bills that inflated charge to a TH (or other OPO), that inflated charge is reported by the TH (or other OPO) as an organ acquisition cost on its cost report, Medicare then shares in those inflated costs. To correct this situation and ensure IOPOs and HCLs are held to reasonable costs, similar to HOPOs and hospital-based HCLs, in the 2027 IPPS proposed rule, we proposed to reconcile IOPO and HCL costs for non-renal organs similar to how we reconcile IOPO and HCL kidney costs. We proposed to require that IOPO and HCL non-renal organ acquisition costs be reviewed and analyzed by the Medicare contractor to ensure those costs are reasonable, necessary, related to patient care, and reconciled to payments made by or payable by THs and other OPOs. Without reconciliation, reasonable costs cannot be determined for non-renal organs leading to inflated organ acquisition costs to the THs and inflated costs throughout the transplant ecosystem.

b. Reconciling Non-Renal Organ Acquisition Costs for IOPOs and HCLs

Section 413.420(a)(1) explains that covered services furnished by IOPOs and HCLs in connection with kidney acquisition and transplantation are reimbursed under the principles for determining reasonable cost. As noted previously, section 1881(b)(2)(A) of the Act was amended in 1978 to require that reimbursement for the services of OPOs and HCLs in procuring and furnishing organs for transplantation must not exceed the cost actually incurred by that OPO or HCL. We also noted that HOPOs and hospital-based HCLs are reimbursed under reasonable cost principles for their services through the hospital cost report. Lastly, we noted that over the years, through various rulings and NCDs, Medicare added coverage for transplantation of non-renal organs such as heart, liver, lungs, and pancreas and payment policies were subsequently implemented through notice-and-comment rulemaking. While we modeled our reimbursement for non-renal organ acquisition costs based on existing kidney acquisition policies, we did not address reasonable cost reimbursement and reconciliation of the non-renal organs for IOPOs and HCLs.

In the 2027 IPPS proposed rule, we proposed to hold IOPOs and HCLs to reasonable cost reimbursement for organ acquisition and transplantation services in accordance with section 1861(v) of the Act. We proposed to revise the title of § 413.420 to change ''kidney'' to ''organ'' and to define the acronym IOPOs after independent organ procurement organizations and the acronym HCLs after histocompatibility laboratories. Throughout § 413.420, we also proposed to use the acronym HCL and its permutations in every title, paragraph, or subparagraph where a histocompatibility laboratory or laboratory, and their various permutations, are mentioned. This would revise the regulation text at § 413.420(a)(1), (a)(2), (c) paragraph heading, (c)(1), (c)(1)(ii), (c)(1)(iv), (c)(2), (d)(1) through (d)(4), (e)(1), (e)(1)(i), (e)(2), (e)(2)(ii), and (g).

In addition, we proposed to revise 42 CFR 413.420(a)(1) and to add paragraphs (a)(1)(i) and (ii). Specifically, we proposed to revise § 413.420(a)(1) to specify that covered services furnished by IOPOs and HCLs in connection with organ acquisition and transplantation are reimbursed under the principles for determining reasonable cost as specified in paragraphs (a)(1)(i) and (ii). We also proposed to add § 413.420(a)(1)(i) to specify that kidney acquisition and transplantation services furnished by IOPOs and HCLs are reimbursed under the principles for determining reasonable cost. For non-renal organs, we proposed to add § 413.420(a)(1)(ii) to specify that for non-renal organ acquisition and transplantation services furnished for cost reporting periods beginning on or after October 1, 2027,[628] IOPOs and HCLs are reimbursed under the principles for determining reasonable cost. This included a proposed delay in implementation which would allow time to update the IOPO and HCL cost reporting form CMS–216–94, OMB control number 0938–0102. The delay would also allow IOPOs and HCLs time to prepare and implement the changes from the new policy.

We proposed to revise § 413.420(a)(2) to include OPOs as payors of IOPOs and HCLs and specified that services furnished by IOPOs and HCLs that have an agreement with the Secretary, in accordance with § 413.420(c), are paid directly by the TH or OPO using a kidney SAC (for an IOPO) or contractor-established rates (for an HCL). Under the proposal, we also specified that the reasonable costs of services furnished by IOPOs or HCLs are reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.

Section 413.420(c), which concerns agreements with IOPOs and HCLs, currently specifies that any IOPO or HCL that wishes to have the cost of its pre-transplant services reimbursed under the Medicare program must file an agreement with CMS under which the IOPO or HCL agrees to the following:

- To file a cost report in accordance with § 413.24(f) within 5 months following the close of the period covered by the report.
- To permit CMS to designate a contractor to determine the interim reimbursement rate, payable by the THs for services provided by the IOPO or HCL, and to determine Medicare's reasonable cost based upon the cost report filed by the IOPO or HCL.
- To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate.
- To pay to CMS amounts that have been paid by CMS to THs and that are determined to be in excess of the

[625] 42 CFR 413.20(b) requires that cost reporting periods are based on the provider's accounting year. In this analysis, 77 percent of IOPOs have a January 1–December 31 accounting year; 11 percent have a July 1–June 30 accounting year; 9 percent have an October 1 to September 30 accounting year; and the remaining 3 percent have a June 1–May 31 accounting year.

[626] 42 U.S.C. 273(b)(1)(A).

[627] Public Law 98–507, National Organ Transplant Act, Section 301.

[628] We realize reconciliation for non-renal organs will require changes to the MCR form CMS–216–94, as well as procedural changes for IOPOs, HCLs and the Medicare contractor. Therefore, in the 2027 IPPS proposed rule, we proposed a 1-year implementation delay.

reasonable cost of the services provided by the IOPO or HCL.

- Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1881 of the Act.

Because of the proposed change to the title of § 413.420, paragraph (c) would apply to both kidney and non-renal organs. We proposed to revise § 413.420(c)(1)(ii) to include OPOs as entities that pay IOPOs and HCLs. We also proposed to revise § 413.420(c)(1)(iv) to specify that the IOPO or HCL agrees to pay to CMS amounts that have been received or are receivable by IOPOs or HCLs from THs and OPOs, and that are in excess of the reasonable costs of the services provided by the IOPO or HCL. This rephrasing to use ''have been received or are receivable'' reflects the accrual basis of accounting required at § 413.24(a) and reflects that the payments are made to IOPOs and HCLs by THs and OPOs.

Section 413.420(d)(1) currently specifies that THs with approved kidney transplant programs pay the IOPO or HCL for their pre-transplantation services on the basis of interim rates established by the contractor for that IOPO or HCL. The authority to allow the contractor to establish the interim rate is described in § 413.420(c)(ii). The interim rate currently described in § 413.420(d)(2) is a kidney SAC or contractor established rates, based on costs associated with procuring a kidney for transplantation, incurred by an IOPO or HCL respectively, during its previous fiscal year. If there is not adequate cost data to determine the initial interim rate, the contractor determines it according to the IOPO's or HCL's estimate of its projected costs for the fiscal year. Section 413.420(d)(3) goes on to specify that payments made by THs on the basis of interim rates are reconciled directly with the IOPO or HCL after the close of its fiscal year, in accordance with § 413.420(e). Lastly, § 413.420(d)(4) currently specifies that information on the interim rate for all IOPOs and HCLs must be disseminated to all THs and contractors.

In accordance with § 413.420(c)(ii), and to ensure that non-renal SACs and non-renal testing rates are an accurate estimate of actual costs, and to increase transparency around non-renal SACs and non-renal testing rates, we further proposed to require the contractor to establish (and adjust if necessary) non-renal SACs. This proposed change also required conforming changes to § 413.420(d)(1). As noted previously, § 413.420(d)(1) specifies that THs with approved kidney transplant programs pay the IOPO or HCL for their pre-transplantation services on the basis of an interim rate established by the contractor for that IOPO or HCL. However, we proposed to revise § 413.420(d)(1) to specify that THs with approved transplant programs and OPOs pay the IOPO or HCL for their pre-transplantation services based on interim rates established by the contractor for that IOPO or HCL as described under proposed paragraphs (d)(1)(i) and (d)(1)(ii). OPOs are also entities that pay IOPOs and HCLs for their pre-transplant services using the interim rates.

We proposed to add § 413.420(d)(1)(i) to specify that THs with approved kidney transplant programs and OPOs pay the IOPO or HCL for their kidney pre-transplantation services, based on interim rates established by the contractor for that IOPO or HCL. In addition, we proposed to add § 413.420(d)(1)(ii) to specify that THs with approved non-renal transplant programs and OPOs pay the IOPO or HCL for their non-renal organ pre-transplantation services furnished for cost reporting periods beginning on or after October 1, 2027, based on interim rates established by the contractor for that IOPO or HCL. The establishment of these interim rates is the first step in preparing for the reconciliation for non-renal organ acquisition costs.

Section 413.420(d)(2) currently provides that the interim rate established by the contractor for an IOPO is a kidney SAC, and the interim rates established for an HCL are contractor established rates, based on costs associated with procuring a kidney for transplantation, and incurred by an IOPO or HCL during its previous fiscal year. If there is not adequate cost data to determine the initial interim rate, the contractor determines it according to the IOPO's or HCL's estimate of its projected costs for the fiscal year. We proposed that the contractor follow the same procedures for establishing, adjusting, and publishing non-renal SACs that are used for establishing, adjusting, and publishing kidney SACs. To implement this proposed change, we proposed to revise § 413.420(d)(2) and to add paragraphs (d)(2)(i) and (ii).

We proposed to revise § 413.420(d)(2) to specify that interim rates are contractor established rates, based on costs associated with procuring an organ for transplantation, incurred by an IOPO or HCL during its previous fiscal year as described under proposed § 413.420(d)(2)(i) and (ii). We also proposed to move language specific to kidney from the existing § 413.420(d)(2) to proposed § 413.420(d)(2)(i) and to specify that the interim rates for kidneys are a contractor established kidney SAC or contractor established rates, associated with procuring kidneys for transplantation, incurred by an IOPO or HCL, respectively, during its previous fiscal year. We proposed that if there is not adequate cost data to determine the initial interim rate, the contractor would determine it according to the IOPO's or HCL's estimate of its projected costs for the fiscal year.

Rates for non-renal organs are currently established by the IOPOs and HCLs in accordance with § 413.404(c)(1) and billed to THs or other OPOs. THs and OPOs pay the rates established by these entities; however, there is no ability for the THs or other OPOs to determine the reasonableness of these rates. We proposed that the contractor establish, adjust (if necessary), and publish the non-renal organ interim rates for IOPOs and HCLs. Our proposal would ensure compliance with reasonable cost principles, result in lower costs throughout the transplant ecosystem, enhance payment accuracy, provide financial protection to OPOs and HCLs for their reasonable costs, increase transparency surrounding costs, and provide robust oversight in response to Congressional and OIG concerns. Therefore, we proposed to add § 413.420(d)(2)(ii) to specify that for services furnished for cost reporting periods beginning on or after October 1, 2027, the interim rates for non-renal organs are contractor established non-renal organ-specific SACs or contractor established rates, based on costs associated with procuring each specific type of non-renal organ for transplantation, incurred by an IOPO or HCL, respectively, during its previous fiscal year. We proposed that if there is not adequate cost data to determine the initial interim rates, the contractor would determine them according to the IOPO's or HCL's estimate of its projected costs for the fiscal year.

Section 413.420(d)(3) currently specifies that payments made by THs based on interim rates are reconciled directly with the IOPO or HCL after the close of its fiscal year, in accordance with § 413.420(e). We proposed to revise § 413.420(d)(3) to specify that payments or amounts payable from THs and OPOs based on interim rates as proposed in § 413.420(d)(2)(i), are reconciled directly with the IOPO or HCL after the close of its fiscal year in accordance with § 413.420(e). Additionally, under § 413.420(d)(3), we proposed to specify that for cost reporting periods beginning on or after October 1, 2027, payments or amounts payable from THs and OPOs based on interim rates as proposed in

§ 413.420(d)(2)(ii), are reconciled directly with the IOPO or HCL after the close of its fiscal year in accordance with § 413.420(e).

We proposed to revise § 413.420(d)(4) to change ''interim rate'' to ''interim rates'' and to specify that when a contractor establishes interim rates for IOPOs and HCLs, it must disseminate those interim rates to all THs, OPOs, and contractors. Our proposed language adds OPOs to the list of entities that would receive the interim rate information since OPOs also pay IOPOs for organs.

We did not propose changes to § 413.420(e)(1) except to use the acronym HCLs instead of ''histocompatibility laboratories'' because the existing language specifies cost reporting requirements that are unchanged, and which apply to IOPOs and HCLs currently and would continue to apply once our proposed changes would be effective.

We did not propose to revise § 413.420(e)(2) except to use the acronym HCL instead of ''histocompatibility laboratory'' as this paragraph applies to the current policy. We proposed to revise § 413.420(e)(2)(i) to add the word ''kidney'' before ''interim rate'' to be clearer that this regulation applies to the existing policy. We also proposed to revise the sentence to reflect the accrual basis of accounting required at § 413.24(a) by specifying that a retroactive adjustment of the amounts received or receivable by the IOPO or HCL under the kidney interim rate is made in accordance with § 413.64(f).

We proposed to revise § 413.420(e)(2)(ii) to add the word ''kidney'' before ''interim reimbursement rate'' to be clearer that this regulation applies to the existing policy. We also proposed to revise the sentence to reflect the accrual basis of accounting required at § 413.24(a), and to include OPOs as entities that pay IOPOs and HCLs. Therefore, we proposed to specify that if the determination of reasonable cost reveals an overpayment or underpayment resulting from the kidney interim reimbursement rates received or receivable by the IOPO or HCL from THs and OPOs, a lump sum adjustment is made directly between the contractor and the IOPO or HCL.

We proposed to add § 413.420(e)(3) to specify that for cost reporting periods beginning on or after October 1, 2027, a cost report submitted by an IOPO or HCL is reviewed by the contractor and new interim reimbursement rates for non-renal organ acquisition costs for the subsequent fiscal year are established by the contractor based upon this review. This proposed language is similar to the existing language at § 413.420(e)(2) except it includes the effective date of the proposed new policy and refers to non-renal organ acquisition costs rather than kidney acquisition costs.

We proposed to add § 413.420(e)(3)(i) to specify that a retroactive adjustment of the amounts received or receivable by the IOPO or HCL under the non-renal organ-specific interim rates is made in accordance with § 413.64(f). This proposed language is similar to the existing language at § 413.420(e)(2)(i) except it refers to the ''non-renal organ-specific interim rates'' rather than the ''interim rate'' to reflect our proposed policy and also refers to amounts ''received or receivable'' to reflect the accrual basis of accounting required at § 413.24(a).

We proposed to add § 413.420(e)(3)(ii) to state that if the determination of reasonable cost reveals an overpayment or underpayment resulting from the non-renal organ-specific interim reimbursement rates received or receivable by the IOPO or HCL from THs and OPOs, a lump sum adjustment is made directly between the contractor and the IOPO or HCL. This proposed language refers to non-renal organ-specific interim reimbursement rates rather than kidney interim reimbursement rates to reflect the proposed policy. It also indicates that payments are received or receivable by IOPOs or HCLs from THs and OPOs to reflect our reconciliation process, which is in accordance with the accrual basis of accounting required at § 413.24(a), and it identifies both THs and OPOs as the entities paying IOPOs and HCLs.

We also proposed changes to § 413.404 to conform to the changes proposed to § 413.420(d), which require the contractor to establish the non-renal organ-specific interim rates, which are the same as the non-renal organ-specific SACs, following the same procedures used for establishing kidney SACs. We also proposed that only the contractor adjust the non-renal SACs if necessary, and that the contractor disseminate the interim rates to all THs, OPOs, and contractors.

As noted previously, we proposed a 1-year delay in implementing our proposed changes. Therefore, we need to indicate when these regulations would be effective. As such, we proposed to change the title of § 413.404(c) to specify that it is for cost reporting periods beginning before October 1, 2027. This proposed change would clarify for readers that all the existing regulatory text under § 413.404(c) is effective for cost reporting periods beginning before October 1, 2027. We also proposed to add new § 413.404(d) with a title that specifies that it is for Independent OPO organ SACs, for cost reporting periods beginning on or after October 1, 2027, and which would incorporate our proposed changes. This new paragraph (d) is for all organs, renal and non-renal.

We proposed to add new § 413.404(d)(1), to state that for each organ type, the contractor establishes the organ-specific SAC based on an estimate of, initial year projected or subsequent years' actual, reasonable and necessary costs that the IOPO expects to incur to procure deceased donor organs during the IOPO's cost reporting period, divided by the initial year projected or subsequent years' actual, number of usable deceased donor organs the IOPO expects to procure. This is modeled after the existing kidney SAC regulations at § 413.404(c)(2)(i), except we proposed to add ''For each organ type,'' at the start of the paragraph, and we replaced kidney SAC with organ-specific SAC and replaced deceased donor kidneys with deceased donor organs.

We also proposed to add § 413.404(d)(1)(i) to specify how the non-renal and kidney SACs would be calculated in their initial year, by modelling after the existing regulation text at § 413.404(c)(2)(ii). We also proposed to add § 413.404(d)(1)(i) to specify how the non-renal and kidney SACs would be calculated in their initial year, by modelling after the existing regulation text at § 413.404(c)(2)(ii). The proposed text added at new § 413.404(d)(1)(i) would specify that for each organ type, the contractor develops the IOPO's initial organ-specific SAC based on the IOPO's budget information.

We also proposed to add § 413.404(d)(1)(ii) to specify how the non-renal and kidney SACs would be calculated in subsequent years, by modelling after the existing regulation text at § 413.404(c)(2)(iii). The proposed § 413.404(d)(1)(ii) would state that for each organ type, the contractor computes the organ-specific SAC for subsequent years using the IOPO's costs related to organ acquisition that were incurred in the prior cost reporting period and dividing those costs by the number of usable deceased donor organs procured during that cost reporting period.

We proposed to add § 413.404(d)(1)(iii), to state that each organ-specific SAC amount is the organ-specific interim payment the TH or other OPO pays to the IOPO, as set forth in § 413.420(d)(2)(i) and (ii). This language would make clear that the

organ-specific SAC is the same as the organ-specific interim payment.

We also proposed to add § 413.404(d)(1)(iv) to provide a listing of allowable organ acquisition costs for the contractor to use when establishing IOPO organ-specific SACs. In the FY 2022 IPPS/LTCH PPS final rule with comment period, we wrote that an IOPO establishes its non-renal SACs based on its costs of procuring organs, similar to procedures followed by THs (86 FR 73478). However, the listing of organ acquisition costs IOPOs may use when developing their deceased donor SACs was omitted when we codified the regulations related to IOPO SACs in the FY 2022 IPPS/LTCH PPS final rule with comment period (86 FR 73478 through 73480). Therefore, we proposed to use the same listing given in § 413.404(b)(3)(ii)(C) for TH deceased donor SACs, except to exclude registry fees, which are costs incurred by THs not OPOs. We proposed to add § 413.404(d)(1)(iv) to specify that costs that may be used to develop the IOPO deceased donor SACs include, but are not limited to the following:

- Costs of organs acquired from other THs or OPOs.
- Costs of transportation as specified in § 413.402(b)(8).
- Surgeons' fees for excising deceased donor organs (limited to $1,250 for kidneys).
- Costs of tissue typing services, including those furnished by independent laboratories.
- Organ preservation and perfusion costs.
- General routine and special care service costs (for example, intensive care unit or critical care unit services related to the donor).
- Operating room and other inpatient ancillary service costs.

We proposed to add § 413.404(d)(1)(v) to require that only the contractor may adjust the organ SACs. This is a proposed change from the existing policy, where the IOPO currently can adjust its non-renal SACs as needed and use that adjusted SAC without contractor approval; we also included the word ''only'' to make it clear that only the contractor may adjust organ SACs. We also proposed that IOPOs may request that the contractor make an adjustment in accordance with § 413.64(e), or the contractor may initiate an adjustment, in accordance with § 413.64(d)(2) or § 413.64(e) as applicable.

While we modelled our proposed regulation text after the existing regulations for IOPO kidney SACs, we did not propose to add a subparagraph (vi), similar to the existing regulation at § 413.404(c)(2)(vi), which currently states that the IOPO cannot use or change its kidney SAC without the contractor's approval. That language is not necessary because proposed subparagraph (v) already makes it clear that only the contractor can adjust the organ SACs, and any SAC the contractor establishes would already be contractor approved.

Finally, we proposed to add § 413.404(d)(2) to state that when an IOPO obtains an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC. The receiving IOPO uses its SAC for each organ type, and not the procuring IOPO's SAC, when billing the TH receiving the organ. This is the same as the existing requirement at § 413.404(c)(3), and we are continuing this policy without change.

To reconcile Medicare's share of non-renal organ acquisition costs, the contractor would review the MCR to determine if the costs are reasonable. This would entail the contractor's review of all IOPO and HCL organ acquisition costs that IOPOs and HCLs report annually on their MCRs and would ensure that IOPOs' and HCLs' organ acquisition costs are allowable and are reasonable and necessary, in accordance with section 1861(v) of the Act, the regulations, and Provider Reimbursement Manual (PRM), CMS Pub. 15–1 (herein referred to as PRM–1).[629]

In determining Medicare's share of non-renal organ acquisition costs, we proposed that IOPOs and HCLs would follow the same procedures used for kidney reconciliation, which assumes that all usable organs or tests for usable organs intended for transplant are for Medicare beneficiaries, except for usable organs, or tests for usable organs, sent to military hospitals, U.S. Department of Veterans Affairs hospitals, or foreign countries. We believe that even with this limitation, our proposal would rein in excess costs; provide more robust oversight of IOPO and HCL costs; increase payment accuracy, in accordance with reasonable cost principles; and be responsive to Congressional and OIG concerns. Should this proposal be finalized, we would also update the IOPO and HCL cost report form CMS–216–94 to enable reconciliation of costs and revenues for each organ type.

Comments on these proposals are found at the end of this section.

[629] CMS Pub. 15–1 can be found at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929*.

c. Discussion of OPO Comments in Response to the July 2022 RFI on Non-Renal Organ Acquisition Cost Reconciliation

In the CY 2023 OPPS/ASC proposed rule (87 FR 44769 through 44773), we issued an RFI (hereafter referred to as the ''July 2022 RFI'') and inquired about reconciling non-renal organ acquisition costs, mirroring our current approach for determining Medicare's reimbursement of IOPOs' kidney acquisition costs. We received several comments related to non-renal organ reconciliation and have carefully reviewed each one.

(1) Supportive Comments

We received a few comments in response to the July 2022 RFI from a TH, a patient advocacy group, and a provider of high-cost perfusion services supporting Medicare's non-renal SAC reconciliation. A commenter fully supported Medicare's non-renal reconciliation and wrote that the data show that many OPOs are failing in their organ recovery efforts; this commenter wrote that the current reimbursement policies are insufficient to incentivize productive resource allocation. Several commenters supported additional oversight of IOPO non-renal organ acquisition costs, saying it would strengthen fiscal integrity. A commenter noted that the distinction between how we account for renal versus non-renal organ acquisition costs creates powerful incentives for cost shifting to kidney acquisition cost centers on the MCR. We agree with these commenters and thank them for their support.

(2) Effects on Organ Procurement

Other comments we received in response to the July 2022 RFI were from OPOs, OPO industry groups, or OPO consultants that expressed opposition to Medicare's reconciling non-renal organ acquisition costs. These commenters believed that reconciling non-renal organ acquisition costs would undercut their ability to procure marginal organs, leading to fewer organs and therefore fewer transplants. Specifically, some OPO commenters wrote that the costs of procuring, or attempting to procure, marginal organs that are subsequently found not suitable for transplant would create losses, as there would be no revenue from those organs. As such, these commenters wrote that they may have to scale back efforts to procure marginal organs. However, these commenters seemed to misunderstand Medicare's organ acquisition payment policy, which allows reasonable costs of

procuring or attempting to procure an organ intended for transplant, even if it is subsequently found not suitable for transplant (see our regulations at § 413.412(a)(2) and (d)(2)). Medicare's reconciliation of organ acquisition costs for renal and non-renal organs would make IOPOs whole when total organ acquisition costs exceed total revenue, but this currently only occurs for kidneys.

In contrast to these OPO commenters, multiple other OPO commenters who also opposed Medicare's reconciling non-renal organ acquisition costs (because they were concerned about potential financial swings and the need to have large cash reserves) wrote that their procurement of organs would not be affected by such a policy, as they try to procure every organ, every time. Furthermore, several commenters stated that OPOs are incentivized to procure as many organs as possible through their organ performance metrics, which affect their tier rating. A perfusion provider commented that reconciling non-renal organs would increase organ procurement by removing the financial risk if an organ is procured but subsequently not transplanted. We agree and further assert that Medicare's reconciliation of non-renal organs could *encourage* the pursuit of marginal organs by protecting OPOs from financial losses on their procurement of marginal non-renal organs that are later found unsuitable for transplant, thus reinforcing our goal to support organ procurement and organ transplantation.

(3) Costs for Organ Perfusion

Several commenters were concerned about situations where OPOs expend resources procuring organs that undergo costly interventions (for example, perfusion) but are later declined by THs and determined to be unsuitable for transplantation. A commenter wrote that if Medicare reconciles non-renal organ acquisition costs for IOPOs, those costly interventions would be considered unallowable, and the OPO would bear the cost. We disagree as our regulations at § 413.402(b)(5) allow perfusion costs; as noted previously, costs incurred for organs intended for transplant are allowable even if the organ is subsequently not transplanted (see §§ 413.412(a)(2) and 413.412(d)(2)). Therefore, if an IOPO authorized the perfusion of a non-renal organ intended for transplant that was subsequently not transplanted, those costs would be allowable (if a TH authorized the perfusion, the perfusion costs would belong to that TH and should be directly billed to that hospital). If Medicare reconciled IOPOs' costs for procuring all organs, it could reimburse more since it would cover acquisition costs for all organ types, not just kidneys as under the current policy.

(4) ''Losses'' Due to Nonallowable Costs

Several commenters wrote that they have ''losses'' when procuring kidneys, because in reconciling, the contractor finds some costs that OPOs report on their MCRs to be unallowable. While OPOs can recover their allowable and reasonable operational costs, we cannot reimburse costs that are statutorily or regulatorily prohibited or specified in the PRM–1 as non-allowable or unreasonable. In sections X.D.2. and X.D.3. of the preamble of this final rule, we are clarifying existing policy and finalizing proposals (some with modifications) to codify certain longstanding reasonable cost policies, as well as revising certain other Medicare reasonable cost reimbursement policies, to assist all providers, including OPOs, in understanding what is not allowable under Medicare's reasonable cost principles.

Some commenters wrote that they make up for these monetary ''losses'' they experience when procuring kidneys through the revenue they receive for procuring non-renal organs. A few OPOs and industry groups acknowledged that their non-renal organ SACs result in ''excess'' revenue which they are using to fund non-allowable or unreasonable costs. That excess revenue is a result of inflated non-renal SACs, which are billed to THs or other OPOs, inflating costs throughout the transplant ecosystem. Medicare ends up reimbursing its share of those inflated costs when it reimburses the TH, which violates our reasonable cost principles. We are committed to carefully and responsibly stewarding the tax dollars in the Medicare Trust Fund, and we believe that Medicare's reconciliation of OPOs' non-renal organ acquisition costs would result in Medicare more accurately reimbursing organ acquisition costs.

(5) Burden

IOPOs indicated in comments submitted in response to the July 2022 RFI that they had concerns about the burden for IOPOs if Medicare reconciled IOPOs' costs for non-renal organs. We do not believe Medicare's reconciliation of IOPOs' costs for non-renal organs would impose additional data collection burden to IOPOs, as they already collect the data needed for reconciliation. However, we recognize there may be additional reporting burden to enable the contractor to reconcile non-renal organ acquisition costs.

A few OPOs also commented that there would be additional burden on the contractor if reconciliation of non-renal organs were to become policy. We do not agree that there would be additional burden on the contractor. Burden implies a cost that is not reimbursed. Our contractor would have increased administrative costs if we were to finalize our proposals that the contractor establish, adjust if necessary, and publish non-renal SACs and HCL testing rates, and reconcile IOPO and HCL non-renal organ acquisition costs. However, these increased administrative costs would be offset by the estimated savings of $100 million beginning in FY 2028, the proposed year that the policies would be effective, if the proposal is finalized. See section I.G.13. of Appendix A of this final rule for a discussion of the impacts including burden effects of our proposals.

(6) Financial Concerns

A few commenters to the July 2022 RFI wrote that if non-renal organ acquisition costs are reconciled, they would have to build large financial reserves in case they may have to repay Medicare a share of those excess funds. If IOPOs' SACs more accurately estimate actual, reasonable costs, then we do not anticipate that reconciliation would result in large payments back to Medicare, therefore limiting the need for large financial reserves. We note that SACs can be adjusted during the year if IOPOs believe they are too high or too low. This can help IOPOs avoid owing large sums to Medicare after the year-end reconciliation takes place in cases where the SAC is overestimating costs. If an IOPO's SACs were underestimated, and costs are exceeding revenue, the contractor can also provide a lump sum adjustment during the accounting period; currently this only occurs with the kidney SAC (see 42 CFR 413.420(e)(2)(ii)) but our proposal would also allow it for non-renal organ SACs. Any lump sum adjustment would be accounted for when making a retroactive adjustment at cost report settlement.

Other commenters wrote that Medicare's reconciliation of non-renal organs would have a detrimental effect on the financial viability of IOPOs and cited section 371(b) of the Public Health Service Act (PHSA), which requires OPOs to have accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization. These IOPOs were concerned about losing ''excess'' revenue. However, we believe that reconciliation is an accounting procedure that helps to ensure the

financial integrity and stability of the IOPO or HCL and would be in accord with the requirements of section 371(b) of the PHSA by providing fiscal stability to the OPO. The reconciliation process for all non-renal organs would also entail the contractor's disseminating the non-renal SACs for each IOPO to THs, OPOs, and other contractors, thereby increasing transparency of organ procurement costs within the transplant community.

Commenters cited high-cost perfusion and transportation expenses that can make accurately estimating a non-renal SAC more difficult, leaving them vulnerable to financial losses. We conducted an analysis of 2024 IOPO MCR data and found that 20 percent of IOPOs had non-renal organ acquisition costs that exceeded their non-renal revenue; these IOPOs would have been made whole by Medicare had reconciliation for non-renal organ acquisition costs been Medicare's policy at that time. We believe that reconciliation would provide a measure of financial security to IOPOs, because it would protect them from losses if their non-renal SACs underestimate non-renal organ acquisition costs. Furthermore, we believe that if Medicare were to reconcile OPOs' costs for non-renal organs, the Medicare Trust Fund's tax dollars would be protected from inappropriate spending on unreasonable or non-allowable costs.

We appreciate the input we received from July 2022 RFI commenters. For the reasons given in this section, we do not find the interested parties' concerns against reconciling IOPOs' non-renal organ acquisition costs to be compelling. We believe that reconciling IOPOs' non-renal organ acquisition costs would ensure that Medicare is paying organ acquisition costs on a reasonable cost basis, without hindering organ procurement. We also believe there is a need for the contractor to provide more robust oversight of IOPOs' non-renal organ acquisition costs and non-renal SACs to ensure that reasonable cost principles are followed, to be responsive to OIG and Congressional concerns, to protect the transplant ecosystem, and to protect the Medicare Trust Fund.

d. Concerns Related to HCLs

Like IOPOs, HCLs are compensated on a reasonable cost basis, and currently Medicare only reconciles their pre-transplant kidney histocompatibility testing costs. Based on our review of HCL MCR data, we have concerns that some HCLs may be over-allocating overhead costs to kidney acquisition cost centers, which increases Medicare's reimbursement. Additionally, a 2018 OIG report identified questionable accounting procedures at a large HCL. This HCL made numerous errors in reporting cost report data, such as reporting some non-reimbursable costs as reimbursable and including costs that were incurred outside of the cost reporting timeframe.[630] A recent internal review of 2022 and 2023 MCR data for HCLs revealed missing data and a lack of transparency in reporting costs. For example, 29 percent of HCLs did not complete worksheet A–1 (''Administrative and General (A&G) Expenses'') of the HCL cost report for their fiscal year ending in 2023; 36 percent had significant unexplained costs reported and labeled as ''Other'' or ''Miscellaneous'' on their worksheet A–3 (''Tissue Typing Laboratory Costs''). Of those providers with significant unexplained costs reported, 30 percent had unexplained amounts that ranged from 19 percent to 33 percent of their total worksheet A–3 costs. Because we pay HCLs based on their reasonable costs, this lack of transparency is concerning and raises many questions about Medicare's payment accuracy on a reasonable cost basis.

In summary, in the proposed rule, we proposed to reconcile IOPOs' and HCLs' organ acquisition costs for non-renal organs, following the same process we currently use to reconcile kidney acquisition costs, and to require the contractor to establish, adjust, if necessary, and disseminate the non-renal interim rates, using the same process followed for kidney interim rates. We proposed a 1-year delay to provide time for us to update the IOPO and HCL cost report, and to provide time for IOPOs and HCLs to prepare for increased reporting of non-renal costs and revenue on their MCRs and greater contractor oversight of their non-renal SACs and HCL testing rates, with an effective date for cost reporting periods beginning on or after October 1, 2027. We believed these proposals, if finalized, would protect the Medicare Trust fund, reduce inappropriate spending, increase compliance with our reasonable cost principles, and protect IOPOs and HCLs from certain financial losses while continuing to support the transplant ecosystem.

Comment: Many OPOs questioned our authority to change OPO payment policies for non-renal organs to a reasonable cost basis. Some commenters said that Public Law 95–292, which amended section 1881 of the Social Security Act (the Act) in June 1978, was for kidneys only. Commenters also cited the Supreme Court's 2024 decision in *Loper Bright Enterprises* v. *Raimondo,* which requires courts to independently assess whether an agency's statutory interpretation represents the best reading of the text. A few commenters asserted that even if there were some ambiguity regarding whether Congress intended for CMS to engage in reasonable cost-based reconciliation with OPOs for non-renal acquisition costs, courts routinely apply the canon of *expressio unius est exclusio alterius,* meaning ''[t]he expression of one thing implies the exclusion of others.'' These commenters said that Congress's targeted reference to ''kidneys'' instead of ''organs'' supports the interpretation that Congress intended the Medicare program to subsidize the cost for kidneys directly to OPOs, not all organs.

A commenter added that if CMS lacks statutory authority to pay OPOs directly for non-renal organ acquisition, then CMS likewise lacks authority to ''reconcile'' those payments or to recover any amounts that exceed actual costs. Commenters noted that CMS's own regulatory history of more than 30 years reflects an implicit recognition of the different statutory scope applicable to non-renal organs. Commenters noted that when CMS later expanded coverage to non-renal organ acquisition costs, it adopted payment policies through notice-and-comment rulemaking without applying reasonable cost reimbursement and reconciliation for non-renal organs.

Response: We disagree with the commenters' position that statutory authority does not exist for Medicare to reimburse OPOs (or HCLs) for their procurement of all organs under Medicare's reasonable cost principles. The commenter asserts that because Public Law 95–292 amended SSA 1881 in June 1978, and its title referenced End Stage Renal Disease patients, Congress' intent was limited to kidneys. However, courts have consistently held that statutory titles are not operative law and cannot override or restrict the substantive provisions of a statute (see *Brotherhood of R.R. Trainmen* v. *Baltimore & Ohio R.R.,* 331 U.S. 519 (1947)). While Public Law 95–292 (1978) was originally enacted to address the End-Stage Renal Disease (ESRD) program, the reasonable cost limitation principle it established was incorporated into the broader Medicare payment framework.

When we later extended Medicare coverage to heart transplants (1987) and

[630] *https://oig.hhs.gov/reports/all/2018/national-institute-of-transplantation-an-independent-histocompatibility-laboratory-did-not-fully-comply-with-medicares-cost-reporting-requirements/.*

other solid organs,[631] we did so without creating a separate, distinct payment standard for non-renal organs. Section 1871 of the Act requires the Secretary to issue regulations necessary to carry out the Medicare program, and mandates notice-and-comment rulemaking for any substantive change in the regulations. Through notice-and-comment rulemaking, non-renal organ acquisition costs were paid to hospitals on a reasonable cost basis. Although we did not implement the reasonable cost reimbursement for IOPO (or HCL) non-renal organ acquisition costs when the coverage for hospital non-renal organ transplants and acquisition costs was added under Medicare, we have always reserved the right to do so. Hospital-based OPOs and hospital-based HCLs have always had their non-renal organ acquisition costs reimbursed and reconciled by Medicare on a reasonable cost basis alongside their associated hospitals. Independent OPOs and independent HCLs, despite performing the identical organ procurement functions as their hospital-based counterparts, have been excluded from this same reconciliation process—an inequity that lacks statutory justification and that CMS's proposal appropriately remedies.

As discussed in the proposed rule, we are bringing consistency and transparency to the organ acquisition payment system by also paying IOPOs and HCLs on a reasonable cost basis for non-renal organ acquisition costs, as we currently do for kidneys. We have the authority under section 1871 of the Act to implement reasonable cost reimbursement for IOPO and HCL non-renal organ acquisition costs through notice-and-comment rulemaking.

The absence of a distinct payment standard for non-renal organ acquisition costs in subsequent legislation strongly supports the conclusion that Congress intended the existing reasonable cost framework—already operative under the Social Security Act—to govern all organ procurement activities, not solely kidney acquisition. Where Congress has not carved out an exception, the default statutory payment standard applies.

Additionally, the National Organ Transplant Act (NOTA) of 1984 [632] established the OPTN and created a unified framework for all solid organ procurement—not just kidneys. The Omnibus Budget Reconciliation Act (OBRA) of 1986 and 1987 [633] extended Medicare coverage to heart, liver, and other non-renal organ transplants and directed that OPO payment rules apply across organ types, reinforcing a unified procurement payment structure. This legislative trajectory supports our position that Congress intended a unified OPO payment framework for all solid organs. We also note that the regulations at 42 CFR parts 486 and 493 govern conditions for coverage for OPOs and laboratory standards for HCLs, respectively, and apply to all organs, not just kidneys. These regulations were promulgated under the authority of the Social Security Act and reflect CMS's longstanding interpretation that OPO and HCL payment rules apply to all organs.

By 1978, there had been several successful organ transplants performed for various organ types. In addition to kidney transplants, in 1966, there was a successful kidney/pancreas transplant; in 1967, there was a successful liver transplant; and in 1968, there was a successful pancreas transplant and a successful heart transplant.[634] Although kidney transplants were the only type of organ transplant recognized by Medicare for payment from the Medicare Trust Fund in 1978 when Public Law 95–292 was enacted, Congress was forward-thinking in their selection and use of the word ''organ'' when legislating. In its Senate Report 95–714,[635] Congress first describes the fiscal problem for the Medicare program for which the legislation was enacted to solve. In the Senate Report, Congress stated that pretransplant services furnished by OPOs and HCLs are reimbursed as inpatient hospital services at the time of transplantation. This policy was effective in providing coverage of pre-transplant services; however, it did not provide the program with adequate fiscal controls. The Senate Report continued to explain the inadequate fiscal control by the Medicare program, using kidneys *as an example,* and stated that when an OPO provided a kidney to a TH, it billed to the hospital directly, and the components of the charge were not subject to the review of the Medicare contractor as are other services provided directly by the hospital. By legislating with precision and intention using the word ''organ,'' Congress intended for all ''organs'' procured by statutorily created and regulated OPOs to be paid under reasonable cost by Medicare, not just kidneys. We believe that Congress's targeted reference to ''organs'' instead of ''kidneys'' supports the interpretation that Congress intended the Medicare program to pay for all organs, not just kidneys, on a reasonable cost basis. If Congress wanted to use the word ''kidney'' in its legislation, it would have done so. In the Public Law 95–292 (92 Stat. 309, June 13, 1978), Congress specifically intended to solve Medicare's ''fiscal problem'' for the procurement of all organs paid under reasonable cost by the Medicare program by legislating with cogent and succinct language that, with respect to payments for services for which payments may be made under part A of Title 18, the amount of such payments (which amounts shall not exceed, in respect to costs in procuring organs, attributable to payments made to an OPO or HCL, the cost incurred by that OPO or laboratory) shall be determined in accordance with section 1861(v).[636] This precise language speaks for itself; payment made under part A of Title 18 with respect to the procurement of organs must be determined in accordance with Medicare's reasonable cost statute and principles. CMS is the steward of the American tax dollars in the Medicare Trust Fund, and we must administer the Trust Fund with the ''fiscal controls'' envisioned and devised by Congress in its specific legislation with respect to OPOs' procurement of all ''organs'' for transplant and ensure that Medicare reimburses OPOs for their reasonable cost to procure them.

Comment: Many commenters stated that OPOs have structured their operations around the existing payment policy for non-renal organs for decades, and that the Administrative Procedures Act requires CMS to provide a reasoned explanation and a more detailed justification when changing policy in the face of serious reliance interests. Some commenters wrote that changing the payment methodology that has been in place for years was arbitrary and capricious. Commenters argued that CMS failed to meet these standards,

[631] 52 FR 33034, September 1, 1987 (heart); 55 FR 8545, March 8, 1990 and 56 FR 15013, April 12, 1991 (liver); 60 FR 6537, February 2, 1995 (lung); 64 FR 41497, July 30, 1999 (pancreas); 66 FR 39828, August 1, 2001 (intestine, with reasonable cost coverage of acquisition costs beginning October 1, 2001). The regulation at 42 CFR 412.2(d)(4) excluded kidney acquisition costs from inpatient prospective payment system and specified that those costs were to be paid on a reasonable cost basis. Heart and liver were added to the regulation at 42 CFR 412.2(d)(4) in 1990 (55 FR 36068). The regulation was relocated to § 412.2(e)(4) in 1994 and lung was added (59 FR 45396); pancreas was added in 1999 (64 FR 41540) and intestine in 2001 (64 FR 39933).

[632] *https://www.congress.gov/bill/98th-congress/senate-bill/2048/text.*

[633] *https://www.congress.gov/bill/99th-congress/house-bill/5300; https://www.congress.gov/bill/100th-congress/house-bill/3545.*

[634] See *https://unos.org/about/unos-history/; https://pmc.ncbi.nlm.nih.gov/articles/PMC8682823/.*

[635] S. Report 95–714 (Mar. 22, 1978).

[636] Section 1881(b)(2)(A).

saying that the proposed rule did not include any new Congressional directive, updated factual findings, or a detailed policy justification to explain what changed since CMS decided decades ago not to apply the renal reconciliation model to non-renal organs. Commenters suggested that at a minimum, CMS provide a clear and detailed legal and policy rationale for departing from decades-long practices and adopt meaningful transition protections to preserve the operational stability of OPOs and HCLs.

Response: We acknowledge that the existing non-renal organ acquisition reimbursement framework has been in place for a significant period and that IOPOs have made operational and financial decisions based upon that framework. However, the Administrative Procedure Act (APA) and the Supreme Court's decisions in *Motor Vehicle Manufacturers Association of United States Inc.* v. *State Farm Mutual Automobile Insurance Company,* 463 U.S. 29 (1983) and *Federal Communications Commission* v. *Fox Television Stations, Inc.,* 566 U.S. 502 (2009) do not prohibit agencies from changing course—they require only that the agency provide a reasoned explanation for doing so, acknowledge the change, and, where serious reliance interests exist, provide a more detailed justification. We believe the record in this rulemaking satisfies that standard.

As detailed in the proposed rule (91 FR 19729 to 19730) and in our previous comment response, our proposal to apply reasonable cost reconciliation to non-renal organ acquisition costs is grounded in the Agency's longstanding statutory authority under the Social Security Act to ensure that Medicare payments accurately reflect actual, reasonable costs. The current payment framework, which does not subject non-renal organ acquisition costs to the same reconciliation discipline applied to kidney acquisition, creates the potential for Medicare to pay amounts that exceed the actual costs incurred by IOPOs. Ensuring payment accuracy and maintaining program integrity are core statutory responsibilities of CMS, and the proposed change represents a reasonable and appropriate exercise of that authority. Additionally, as highlighted in the proposed rule, hospital based OPOs and HCLs are already reimbursed on a reasonable cost basis, and this proposal establishes consistency by paying IOPOs and independent HCLs on a reasonable cost basis as well; thereby promoting equitable and uniform treatment across all organ procurement entities participating in the Medicare program.

While our goal is to increase compliance with Medicare's reasonable cost principles, we realize that a change to IOPO payment policy may result in financial and cash flow challenges, administrative and cost reporting burden, and audit exposure, and it may require operational restructuring. As such, in the FY 2027 IPPS/LTCH proposed rule, as part of our detailed rationale and justification for proposing to reconcile non-renal organ acquisition costs, we included an extensive discussion of comments from OPOs on non-renal organ acquisition cost reconciliation from the Request for Information (RFI) that was included in the CY 2023 OPPS/ASC proposed rule (87 FR 44772 and 44773). The RFI sought comments about reconciling non-renal organ acquisition costs, mirroring our current approach for determining Medicare's reimbursement of IOPOs' kidney acquisition costs. In the FY 2027 IPPS/LTCH proposed rule, we addressed RFI comments that expressed concerns about the effects of reconciling non-renal organs on procurement, particularly for organs intended for transplant but which subsequently are not transplanted; we noted that the regulations at §§ 413.412(a)(2) and 413.412(d)(2) allow costs for procuring or attempting to procure organs intended for transplant even if the organ is not subsequently transplanted. This includes costs for high-cost interventions like perfusion. We wrote that our payment policy regarding these costs actually incentivizes procurement of these organs; by removing the potential to incur a financial loss on these organs, we are removing a disincentive to procurement. We also wrote that several IOPOs commented that their procurement efforts would be unaffected by reconciling non-renal organ acquisition costs. Those IOPOs wrote that their organ performance metrics incentivize them to maximize procurement.

We noted that reconciling non-renal organ acquisition costs would ensure that OPOs are protected in situations where they have incurred costs for an organ but receive no revenue for the organ because it is subsequently found unsuitable for transplant, as Medicare would make them whole if their revenue is less than their reasonable costs.

We addressed concerns about ''losses'' incurred due to contractor review of kidney acquisition costs, resulting in disallowance of costs that are not allowable or reasonable, and noted that sections X.D.2. and X.D.3. of the FY 2027 IPPS/LTCH proposed rule included extensive discussion of reasonable cost principles. Those sections of that proposed rule and of this final rule provide detailed explanations about the allowability of certain types of costs, including costs that may have previously resulted in contractor disallowance (for example, some public or professional education costs, and some sponsorships). Many IOPOs already comply with our reasonable cost principles; however, we need *all* IOPOs to understand that Medicare will not cover and pay for certain types of costs that are excessive or unreasonable. Such an understanding will avoid situations where ''losses'' occur because excessive, unreasonable, or non-allowable costs are disallowed by the contractor.

We recognized IOPO concerns about additional reporting burden, though we believe there would be very little additional data needed to reconcile non-renal organ acquisition costs (for example, we would need information about non-renal organs sent to military or Department of Veterans Affairs (VA) hospitals, or to foreign countries). We also addressed concerns about contractor burden, noting that there would be no administrative burden for the Medicare contractor because burden implies a cost that is not reimbursed, and while the Medicare contractor would have additional costs to handle the increased workload, those administrative costs would be absorbed administratively by the Medicare Program.

In our discussion of the July 2022 RFI comments in the FY 2027 IPPS/LTCH proposed rule, we addressed financial concerns related to cash flow and cash reserves, financial viability, and to SAC estimation which are further discussed in separate comments that follow, and provided our reasons why non-renal reconciliation would protect IOPO viability and how adjustments and lump sum payments during the cost reporting period are available. We included findings of an analysis of OPO cost report data for cost reporting periods ending in 2024 and noted the section of the FY 2027 IPPS/LTCH proposed rule where there was a detailed discussion of the impacts and burden effects. In our discussion of the July 2022 RFI comments in the FY2027 IPPS/LTCH proposed rule, we wrote that we believed that reconciling IOPOs' non-renal organ acquisition costs would ensure that Medicare is paying for those costs on a reasonable cost basis without hindering organ procurement. By thoughtfully considering and

responding to the July 2022 RFI comments related to reconciling non-renal organ acquisition costs, we addressed operational concerns related to our proposed reconciliation of non-renal organ acquisition costs in detail. We also provided a history of how organ acquisition costs have been paid and discussed concerns about inflated costs moving from the IOPOs to the THs, which have no ability to determine their reasonableness. As we stated in the FY2027 IPPS/LTCH proposed rule, because Medicare pays THs their organ acquisition costs for all organs on a reasonable cost basis, when an IOPO establishes a non-renal acquisition charge that is higher than its reasonable costs actually incurred, and the IOPO bills that inflated charge to a TH (or other OPO), that inflated charge is reported by the TH (or other OPO) as an organ acquisition cost on its cost report, Medicare then shares in those inflated costs. To correct this situation and ensure IOPOs and HCLs are held to reasonable costs, similar to HOPOs and hospital-based HCLs, we proposed to reconcile IOPO and HCL costs for non-renal organs similar to how we reconcile IOPO and HCL kidney costs. Those concerns date back years, as they were noted in 1978 rulemaking, and more recently, in our July 2022 RFI questions about non-renal organ acquisition cost reconciliation. In making our proposals, we considered both IOPO and HCL reliance interests and have provided detailed explanation of and justification for our proposals.

Comment: We received a few comments about HCL-related issues from hospitals, OPOs, an association, and HCLs. A few commenters supported our proposals. A commenter requested that CMS clarify whether the reasonable cost reconciliation proposal for HCLs only applies to hospital-based HCLs or whether it would also include independent HCLs. Some commenters asked that we develop our proposed changes with direct input from transplant programs, finance teams, OPOs, and Medicare reimbursement experts. Another commenter wrote that changes for HCLs will threaten laboratory readiness and transplant matching capacity.

Response: We thank those commenters who were supportive of our proposals. These proposals were focused on independent HCLs who file the independent OPO/HCL Medicare cost report form CMS–216–94 and do not affect hospital-based HCLs, which are already reimbursed under reasonable costs. We have received input from a variety of stakeholders during the 60-day public comment period and will continue to engage with stakeholders as we effectuate our final policies. We recognize that both IOPOs and HCLs operate in an environment that requires 24/7 availability regardless of testing volume and that our final policies will bring changes to HCL operations and payment; we do not believe that our final policies, which are discussed in later responses, will threaten HCL operational readiness or transplant matching capacity. As discussed in a later response, we have modified the proposed 1-year delay to be a 2-year delay, with implementation for cost reporting periods beginning on or after October 1, 2028. We believe this lengthier delay will allow time for all stakeholders, including HCLs, to prepare. We are also committed to providing educational resources to stakeholders to assist them in understanding the finalized policies. Our final policies are discussed in the comments that follow.

Comment: Multiple commenters emphasized that OPOs are currently navigating an unprecedented convergence of regulatory changes, including ongoing recertification cycles, expanded survey and enforcement protocols, new performance measures, and broader federal modernization initiatives. Some commenters suggested that CMS should evaluate the proposed reimbursement framework in light of this intensifying regulatory environment, cautioning that layering major payment methodology changes on top of existing compliance demands could destabilize OPO operations and undermine their core mission of maximizing organ donation opportunities. A commenter acknowledged CMS's concerns about rising non-renal organ acquisition costs but similarly cautioned that payment changes must not further destabilize organ procurement during a period of substantial operational transition. A commenter wrote that the proposed delay was not sufficient time for the cost reporting forms to be updated to accommodate non-renal reconciliation, and that we did not mention updates to the cost reporting instructions.

Nearly all commenters opposed CMS's proposed 1-year implementation delay to FY 2028 as insufficient. Many commenters urged CMS to delay implementation of contractor-established non-renal SACs and non-renal organ acquisition cost reconciliation until FY 2030. Several commenters requested a phased approach to all the IOPO proposals in the proposed rule, asserting that a single fiscal year is inadequate for IOPOs to conduct the financial modeling necessary to determine reasonable organizational margins and construct secure financial models. Commenters asked that each phase be accompanied by clear sub-regulatory guidance, updated cost report instructions, and meaningful stakeholder engagement. Commenters stressed that OPOs will need sufficient time to develop the infrastructure, processes, and financial capacity necessary to operate under a reconciliation framework without risking operational disruption.

Response: We acknowledge commenters' concerns that the proposed 1-year implementation delay, with changes taking effect for cost reporting periods beginning on or after October 1, 2027, may be insufficient given the operational, financial, and regulatory demands currently facing OPOs. We also recognize that OPOs are simultaneously managing recertification requirements, survey and enforcement activity, performance measures, and other federal modernization initiatives. We agree that the cumulative burden of these changes warrants careful consideration, and we are committed to ensuring that payment methodology reforms do not inadvertently destabilize the organ donation and transplantation system or reduce the availability of life-saving organs.

After careful consideration of the comments received, we are modifying the proposed implementation timeline from a 1-year delay to a 2-year delay so that the finalized policies related to reconciliation of non-renal organ acquisition costs for IOPOs and independent HCLs, and finalized policy with modifications for the Medicare contractor to review (to ensure reasonableness), approve, adjust if necessary, and publish non-renal SACs and HCL testing rates (discussed in the following comment response), will take effect for cost reporting periods beginning on or after October 1, 2028.

We plan to update the IOPO/HCL MCR to accommodate non-renal organ acquisition cost reconciliation, in a forthcoming Paperwork Reduction Act package with the updated cost report forms and instructions that will be published in the **Federal Register** for public comment. We will also issue sub-regulatory guidance to provide OPOs and independent HCLs with the clarity and lead time necessary to adapt their financial models and operational processes. We are modifying the regulation text to be consistent with our final policy. Specifically, we are modifying the regulation text at §§ 413.404(c), 413.404(d), 413.420(a)(1)(ii), 413.420(d)(1)(ii), 413.420(d)(2)(ii), 413.420(d)(3), and

413.420(e)(3) to change the year shown in the text from 2027 to 2028.

Comment: Most commenters opposed our proposal to require the Medicare contractor to establish and adjust, if necessary, IOPO non-renal organ acquisition charges. Commenters wrote that the proposed SAC calculation would create a lag between the SAC rates and actual costs, affecting OPOs' ability to adjust to market conditions in a dynamic clinical environment, particularly for complex donors which often involve significant upfront costs and uncertain outcomes. Multiple IOPOs wrote that they incur costs to maintain operational readiness on a 24/7 basis, regardless of procurement volumes. A commenter noted that independent HCLs maintain highly specialized personnel, accreditation standards, quality systems, and testing capabilities on a 24/7 basis regardless of testing volume; unlike many clinical laboratories, transplant testing demand is unpredictable and frequently time-sensitive. This commenter was concerned that a reimbursement methodology that fails to recognize these readiness costs could undermine the laboratory infrastructure necessary to support timely organ allocation and transplantation.

Several commenters wrote that the SAC proposal would introduce financial risk, fiscal and cash flow instability, and long-term operational uncertainty. Some commenters argued that national average SACs would mask significant regional variation between OPOs and would fail to reflect the actual procurement costs in rural, geographically dispersed, or operationally complex service areas.

A few commenters wrote that CMS was exceeding its authority by undertaking government price setting. Some expressed concerns that Medicare would be dictating the charges levied to non-Medicare payors, who dominate the coverage of non-renal organs and their associated organ acquisition costs. A commenter was concerned that the contractor would have unchecked authority to set rates, reconcile costs, and impose lump sum payment obligations without requiring that contractor staff possess organ procurement expertise or consult with clinical professionals before setting rates or disallowing costs; and there was no formal stakeholder input process before the contractors establish or adjust non-renal SACs and no non-discretionary right of administrative appeal. Another commenter was concerned about inconsistent Medicare contractor practices across service areas affecting SAC establishment. A commenter supported the prudent buyer principle, that reimbursement should reflect reasonable costs and that providers should be expected to manage expenses as a prudent, cost-conscious purchaser would and argued that setting the SAC through the Medicare contractor was inconsistent with the prudent buyer principle.

Some commenters noted that the proposed rule did not clarify whether SACs would be calculated on a total program or a Medicare-only basis, creating fundamental ambiguity regarding the methodology. Several commenters asked that CMS require contractors to consider both prior year costs and a reasonable estimate of projected current-year costs for each non-renal organ type or to allow a margin above the prior year costs, such as the 101 percent of cost that CAHs receive. A commenter recommended that the kidney surgeon fees, which are part of the SAC and which have remained fixed since 1987, be increased. This commenter recommended establishing reasonable fees for non-renal surgeons, stand-by fees, and surgeon travel costs.

Multiple commenters wrote that unlike kidneys, non-renal organs exhibit greater cost variability due to lower case volume, geographic dispersion, donor complexity, transportation logistics, and organ utilization patterns, making cost estimation more difficult. Several commenters suggested that CMS consider an innovation carve-out from the SAC calculation to allow IOPOs to pass through the costs of FDA-approved, clinically validated preservation and transportation technologies with contractor approval, or that CMS carve out high-cost items like perfusion and some transportation, to allow outlier or supplemental payments, or an add-on or adjustment mechanism. A commenter asked CMS to clarify its statement in the proposed rule that if a TH authorizes perfusion services, those services should be directly billed to the TH. Another commenter wrote that CMS acknowledged in the FY 2022 Final Rule that OPOs should develop non-renal SACs ''sufficient to cover'' their procurement costs, and that phrasing contemplated that SAC revenue might exceed actual costs. A commenter noted the uncertainty involved in estimating SACs, and wrote that when actual procurement volumes exceed projections, per-unit costs decrease and SAC revenue appears to ''exceed'' costs; this commenter stated that this reflects the success of procurement efforts, not price-gouging. A commenter wrote that CMS's proposal that the Medicare contractor would publish all SACs for all organs for independent OPOs would not achieve total transparency because organ pricing for hospital-based OPOs would remain opaque.

A few commenters noted that the proposal would require more funding for the Medicare contractors; a commenter asked the cost of the additional Medicare contractor workload, noting that we said it would be offset by the $100 million in estimated savings. Several commenters requested that CMS require Medicare contractors to review and approve SACs and SAC adjustments within a specified timeframe, provide a detailed explanation of the SAC adjustment request process, and establish explicit standards and data requirements for obtaining an adjustment. A commenter requested that contractors be required to make timely lump-sum adjustments during the accounting period rather than relying solely on a one-time post-period adjustment. Another commenter cautioned that frequent mid-year SAC changes would be disruptive to THs, which negotiate payor contracts annually with limited ability to revise rates mid-year, potentially creating financial and operational challenges for transplant centers.

Response: We appreciate these comments regarding non-renal SACs and clarify that we did not propose national non-renal SACs, which we agree would not recognize local differences in procurement costs. We proposed that the contractor would establish non-renal organ SACs for each IOPO, based on that IOPO's prior year actual costs and actual number of usable deceased donor organs; we modeled this process and regulation text after the existing process and regulation text related to the manner in which kidney SACs are established. Kidney SACs are unique to each provider, based on each IOPO's cost report data.

The proposed regulation text at 42 CFR 413.420(e)(3) and 42 CFR 413.404(d)(1) uses the singular in referring to the contractor's establishment of the non-renal SACs (see 91 FR 19733). Since we proposed that the contractor would establish the SAC for each IOPO based on that IOPO's own cost report data, differences in non-renal SACs from one IOPO to another reflect the real-world variation in costs and procurement volumes that occurs between IOPOs. As specified in the proposed rule, the proposed non-renal SAC calculation would, for each organ type, use the provider's total prior year costs divided by the provider's total prior year number of organs procured; it is not a calculation based on Medicare costs and Medicare usable organs. The

charge for procuring an organ should not vary based on payor, and indeed, IOPOs frequently do not know whom the intended organ recipient is at the time of procurement.

We agree with commenters that if the contractor sets the non-renal SACs based solely on prior year actual costs and procurement data, it could limit an IOPO's operational flexibility and create cash-flow issues. We modeled the proposed language on the existing process for establishing kidney SACs. While the existing regulation text for kidney SAC establishment at § 413.404(c)(2) sets forth that the kidney SAC is based on prior year costs and organs procured, the regulation text at § 413.404(c)(iv) allows the Medicare contractor to adjust the SAC as needed for cost changes. Therefore, the prior year costs and utilization are a starting point for determining the SAC. However, through discussions with the Medicare contractor, we note that the process currently used by them in establishing the kidney SAC uses prior year actual costs and number of organs procured, as well as projected budget information, both provided by the IOPO to the contractor.

Based on the comments we received, we agree that each IOPO would be in the best position to estimate its future organ volumes, and the future costs associated with how it plans to operate in the subsequent year similar to what they are currently doing for kidneys. We also believe that each HCL would be in the best position to estimate its future testing costs and volumes associated with how it plans to operate in the subsequent year. Therefore, we are finalizing our proposal with modifications to require that the IOPO would provide the Medicare contractor its reasonable estimate for each organ SAC based upon its prior year costs and organ procurement volumes and its reasonable and documented estimate of its projected costs and organ procurement volumes for the subsequent year, for contractor review (to ensure reasonableness) and approval. For independent HCLs, we are finalizing our proposal with modifications to specify that the HCL would provide the Medicare contractor with its reasonable estimate of its testing rates based on its prior year costs and reasonable and documented estimate of its projected testing costs and volumes for the subsequent year, for contractor review (to ensure reasonableness) and approval.

We believe this modification will allay provider concerns about government ''price-setting,'' of the non-renal SACs; we are not ''price setting'' because the SACs will be devised with the engagement of the IOPOs, based on their historical and reasonable and documented projected costs. Our finalized policy also eliminates IOPO concerns about a lag between rates and actual costs. We believe this modification also addresses IOPOs' concerns about local differences in procurement costs. Furthermore, our modification addresses concerns about failing to uphold the prudent buyer principle, as the IOPO is better able to ensure the costs used in its estimates meet the prudent buyer principle. Additionally, it will enable IOPOs and HCLs to successfully navigate a dynamic clinical environment that must be ready 24/7, regardless of procurement or testing volumes and should not affect procurement decisions, even with complex cases, which can have significant upfront costs. Finalizing our proposal with this modification will also provide IOPOs and HCLs with more flexibility and will better support organ procurement. This final policy allows IOPO and HCL involvement in estimating their non-renal SACs and non-renal testing rates, respectively, and recognizes that at the time of procurement, IOPOs often do not know who the intended recipient is or the recipient's payor status. Our final policy includes a modification to recognize the value of engagement between IOPOs and their contractor. We note that there is one dedicated Medicare contractor with extensive experience with IOPOs and HCLs; therefore, all IOPOs and HCLs should be treated and reviewed with consistency. With our final policy, the SACs and HCL testing rates are not established by the Medicare contractor but are approved by the Medicare contractor with IOPO and HCL, respectively, input and cost projections. The Medicare contractor has access to medical expertise should the contractor have clinical questions related to organ procurement and can also consult the IOPO for more information. Administrative appeal is discussed in section X.D.4. of this final rule.

We are finalizing our proposal that the Medicare contractor will publish non-renal SACs and HCL testing rates used in billing THs and OPOs for transparency. Regarding the comment that hospital-based OPO SACs are not published, creating a disparity in pricing transparency, we disagree. Hospital-based OPOs costs are reported on the THs Medicare cost report. They are held to reasonable cost standards and their cost report is publicly available. The TH's cost report identifies total costs and total usable organs by organ type and an average acquisition charge can easily be computed from this publicly available document. We are finalizing as proposed that the Medicare contractor publish all non-renal IOPO and HCL SACs and testing rates.

We appreciate the comments about including a margin in the SAC calculation, such as 101 percent of cost used by Critical Access Hospitals. However, IOPOs are statutorily required to be reimbursed by Medicare on a reasonable cost basis, which means we cannot reimburse above 100 percent of cost. This is also true for HCL reimbursement. We received a few comments on our proposed listing of allowable costs, that may be included in deceased donor SACs, regarding surgeon's fees for kidney procurement. We may consider kidney surgeon fees, currently capped at $1,250, in future rulemaking. We did not specify surgeon fees for non-renal organs or surgical team travel costs, except that all procurement costs, including surgeon's fees and travel costs, must be reasonable. We are finalizing that listing in § 413.404(d)(1)(iv) as proposed.

We are clarifying that when a TH authorizes high-cost perfusion that is performed by an entity other than the OPO, the perfusion charges are billed directly to the TH and not to the OPO for those services. Additionally, our regulations at §§ 413.412(a)(2) and 413.412(d) allow THs (as well as OPOs) to include as organ acquisition costs those costs incurred that are associated with an organ recovered for transplant (such as perfusion). We appreciate commenters' suggestions about carving out high-cost items from the SAC, making outlier, supplemental, or add-on payments, creating an innovation payment or other adjustments and may consider those comments in future rulemaking.

Regarding the SAC calculation being ''sufficient to cover procurement costs,'' the commenter has not included the full context of what we wrote in the FY 2022 IPPS final rule (86 FR 73479); we stated that the IOPO should have fiscal procedures that include carefully estimating costs for the subsequent year when developing its non-renal SAC, so that ''the non-renal SAC is an average charge sufficient to cover procurement costs of non-renal organs. The SAC should be a reasonable estimate of average costs rather than an inflated estimate of average costs.'' We recognize that the SAC is an average cost for each organ type and an estimated charge based on future projections and therefore may turn out to be higher or lower than a provider's actual costs; however, it should a ''reasonable

estimate.'' We note that rate reviews can adjust the SAC to bring it more in line with costs. Regarding the uncertainty involved in estimating SACs, we recognize that there are instances when actual procurement volumes may exceed projections, decreasing per-unit costs and resulting in SAC revenue that is greater than cost. We agree that in this example, this excess is not due to price-gouging, but we do not believe this example explains all the excess revenue over cost we found in the IOPO cost report data.

As noted in the FY 2027 IPPS proposed rule, the contractor may adjust the SAC if necessary; this would typically be a mid-year review of the SAC to determine how accurate the estimate is. This is also true for HCL testing rates. IOPOs and HCLs may request a review or the contractor may initiate a review at other times in the accounting period in accordance with § 413.64(d)(2) or § 413.64(e) as applicable (see 91 FR 19734). In response to comments related to frequent SAC changes, we are limiting IOPO SAC and HCL testing rate adjustments to occur no more than quarterly. We believe the ability to adjust the SAC or HCL testing rates provides flexibility and is a protection for IOPOs and HCLs, since their initial SACs and testing rates are estimates based upon reasonable projections.

Regarding comments about the need to create reserves to avoid large year end overpayments, the IOPO or HCL should first submit a request to the Medicare contractor to adjust their SAC or rates accordingly. If a rate adjustment occurred because the IOPO SAC or HCL rates were too high, the IOPO or HCL may request to make a lump sum adjustment to Medicare, reducing any year end overpayments due. Likewise, an IOPO or HCL may be eligible to receive a lump adjustment after a rate adjustment has occurred if the IOPO's SAC or the HCL's testing rates were lower than cost, and the IOPO or HCL requests a lump sum adjustment from the Medicare contractor. To alleviate cash-flow concerns and minimize overpayments at cost report year-end, requests to adjust the SAC or testing rates should be made no more than on a quarterly basis. In this final rule, as a result of comments received, we are modifying the proposed regulation text at § 413.420(e)(3)(ii) to specify that if the determination of reasonable cost reveals an overpayment or underpayment resulting from the organ-specific interim reimbursement rates received or receivable by the IOPO or HCL from THs and OPOs, an adjustment to the interim rate may be initiated by the contractor or requested by the IOPO or HCL. If a rate adjustment is made, then an IOPO or HCL may request that a lump sum adjustment be made directly between the contractor and the IOPO or HCL.

If an IOPO or HCL that is eligible for a lump sum adjustment does not request one, the contractor will wait until the cost report is submitted and reviewed by the contractor to reconcile the costs with the IOPO or HCL and reimburse any costs that exceed revenue. The ability to make adjustments to the SAC or rates during the year, and the ability to receive or make lump sum adjustments, allow the IOPO or the HCL to minimize cash-flow concerns and potential overpayments or underpayments at the cost report year-end, thus enhancing their operational flexibility. In accordance with existing regulations at § 413.64(b), the intent is that interim payments (SACs and testing rates) shall approximate actual costs as nearly as is practicable, so that the retroactive adjustment based on actual costs will be as small as possible.

The documentation provided to the Medicare contractor when establishing SACs should clearly explain how the IOPO or HCL arrived at its estimates, including any data or assumptions used about procurement costs and organ volume predictions for the subsequent year. If the estimated SACs or testing rates for the subsequent year differ significantly from the existing non-renal organ SACs or testing rates, the provider should expect more scrutiny from the contractor and therefore, should ensure that the documentation is sufficiently detailed to support its estimate. The most common reason for a delay in the Medicare contractor's approval of SACs or testing rates is lack of documentation. Supporting documentation can include projected costs based on budget, or notable trends, in a format that mimics the actual cost report. Additionally, including financial information and donor information from the prior year, when establishing a subsequent year's SAC may assist in avoiding delays in subsequent SAC approvals.

To request a review and an interim rate adjustment or lump sum adjustment, an IOPO or HCL must follow the procedures given in § 413.64(c)(4). Similar to the process used when establishing the SAC or testing rates at the beginning of the cost period, as a result of comments received, in this final rule we are modifying the proposed regulation text at § 413.404(d)(1)(v) to specify that IOPOs may request that the contractor make an adjustment in accordance with § 413.64(e), or the contractor may initiate an adjustment, in accordance with § 413.64(d)(2) or § 413.64(e), as applicable, but no more than quarterly. Additionally, the IOPO must provide the Medicare contractor with an estimated adjusted SAC based on its actual cost data and its reasonable and documented estimate of costs through the end of its accounting period, to enable the Medicare contractor to review (to ensure reasonableness) and approve the SAC adjustment. We did not receive any detailed comments related to HCL rate-setting, but for consistency in organ acquisition payment policy, we are extending the same benefits to HCLs, to specify that the HCL must provide the Medicare contractor with adjusted rates based on actual cost data and its reasonable and documented estimate of costs through the end of its accounting period, to enable the Medicare contractor to review (to ensure reasonableness) and approve the interim rate adjustment. The Medicare contractor will publish updated SACs and testing rates so that the information is publicly available to other OPOs, THs, and contractors.

Regarding required timeframes for Medicare contractor review and approval of non-renal interim rates or interim rate adjustments, reconciliation, and lump sum adjustments, we understand the importance of timely contractor reviews, and we will keep these comments in mind as we work toward effectuating the final policy with our Medicare contractor.

We disagree with the commenter who wrote that changing the SAC frequently could cause financial or operational challenges to THs. On the contrary, we believe our proposals will more accurately reflect reasonable costs to THs and throughout the transplant ecosystem and provide THs with more transparency about IOPO and HCL pricing. THs are the primary payor of organ procurement services, and the costs they incur should reflect reasonable costs; when those costs fluctuate, rates will change, but to mitigate the frequency we are limiting the change in SACS or rates charged by IOPOs or HCLs, respectively, to no more than 4 times per year. We received no comments from hospitals regarding concerns with SAC or HCL testing rate changes; in fact, several THs supported our proposals. Finally, we acknowledge that the Medicare contractor's workload will increase to review and approve, adjust (if necessary), and publish IOPO non-renal SACs and HCL testing rates; however, this is not an increased burden but an increase in workload that is addressed within their contract. Any changes in costs to the Medicare

Program will be included in the forthcoming Paperwork Reduction Act package with the updated IOPO/HCL forms and instructions.

In summary, we are finalizing our proposal with modifications, to require that the Medicare contractor will approve the non-renal SACs and testing rates at the beginning of the cost reporting period based on the IOPO's or HCL's prior cost reporting year costs and the IOPO's or HCL's reasonable and documented estimate of its costs for the subsequent cost reporting year; the Medicare contractor will review the documentation the IOPO or HCL provides to ensure reasonableness, and approve the reasonable non-renal SACs and testing rates. When an interim rate review occurs during the year, the IOPO or HCL will provide the Medicare contractor its actual cost data and its reasonable and documented estimate of its costs for the remainder of the cost reporting year. The Medicare contractor will review the documentation the IOPO or HCL provides to ensure reasonableness and approve reasonable adjustments to the non-renal SACs or testing rates. Lastly, we are finalizing as proposed that the Medicare contractor will publish the non-renal SACs (including adjusted SACs) and testing rates (including adjusted testing rates) so that the information is available to THs, OPOs and contractors. As noted previously, we have extended the delay in implementation of these policies to FY 2029, for cost reporting periods beginning on or after October 1, 2028, to allow IOPOs and HCLs more time to prepare. To implement this policy with the modifications discussed, we are also modifying the proposed regulation text as follows:

- We are modifying the proposed regulation text at § 413.404(d)(1) to specify that for each organ type, the contractor approves the organ-specific SAC based on submission from the IOPO of an estimate of initial cost reporting year projected costs, divided by the initial cost reporting year projected number of usable deceased donor organs that the IOPO expects to procure. For subsequent cost reporting years, the contractor approves the organ-specific SAC submission from the IOPO based on the prior year's actual, reasonable and necessary costs and the IOPO's reasonable estimate of the costs it expects to incur to procure deceased donor organs during the IOPO's cost reporting period, divided by the subsequent cost reporting year's projected number of usable deceased donor organs the IOPO expects to procure during that cost reporting period.
- We are modifying the proposed regulation text at § 413.404(d)(1)(i) to specify that in the initial year, for each organ type, the contractor approves the IOPO's initial organ-specific SAC, based on the IOPO's budget information.
- We are modifying the proposed regulation text at § 413.404(d)(1)(ii) to specify that in subsequent years, for each organ type, the IOPO must provide the Medicare contractor with its reasonable estimated SAC based upon its prior cost reporting period's costs and organ procurement volumes, and its reasonable and documented estimate of its projected costs and procurement volumes for the subsequent cost reporting period, for contractor review to ensure reasonableness, and approval.
- We are modifying the proposed regulation text at § 413.404(d)(1)(v), to also specify that IOPOs may request that the contractor make an adjustment in accordance with § 413.64(e), or the contractor may initiate an adjustment, in accordance with § 413.64(d)(2) or § 413.64(e), as applicable, but no more than quarterly. Additionally, the IOPO must provide the Medicare contractor with an estimated adjusted SAC based on its actual cost data and its reasonable and documented estimate of costs through the end of its accounting period, to enable the Medicare contractor to review to ensure reasonableness, and approve the adjusted SAC.
- We are modifying the proposed regulation text at § 413.404(d)(2) to specify that when an IOPO obtains an organ from another OPO, the receiving IOPO is responsible for paying the procuring OPO's SAC. The receiving IOPO uses its SAC for each organ type, and the procuring OPO's SAC, when billing the TH receiving the organ. The proposed regulation text included typographical errors, referring to an IOPO instead of an OPO when referencing the entity providing the organ to the IOPO.
- We are modifying the proposed regulation text at § 413.420(a)(2) to specify that services furnished by IOPOs and HCLs, that have an agreement with the Secretary in accordance with § 413.420(c) are paid directly by the TH or OPO using a contractor-approved kidney SAC (for an IOPO) or contractor-approved kidney rates (for an HCL). Effective for cost reporting periods beginning on or after October 1, 2028, services furnished by IOPOs and HCLs, that have an agreement with the Secretary in accordance with § 413.420(c), are paid directly by the TH or OPO using a contractor-approved non-renal organ SAC (for an IOPO) or contractor-approved non-renal rates (for an HCL). (The reasonable costs of services furnished by IOPOs or HCLs are reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.).
- We are modifying the proposed regulation text at § 413.420(c)(1)(ii) to specify that the IOPO or HCL agrees to permit CMS to designate a contractor to approve the interim reimbursement rate, payable by the THs or OPOs for services provided by the IOPO or HCL, and to determine Medicare's reasonable cost based upon the cost report filed by the IOPO or HCL.
- We are modifying the regulation text at § 413.420(c)(1)(iii) to specify that the IOPO or HCL agrees to provide such budget or cost projection information as may be required for the contractor to approve an initial interim rate.
- We are modifying the proposed regulation text at § 413.420(d)(1) and at § 413.420(d)(1)(i) and § 413.420(d)(1)(ii) to change ''established'' to ''approved''.
- We are modifying the proposed regulation text at § 413.420(d)(2) to specify that the interim rates are contractor approved rates, based on costs associated with procuring an organ for transplantation incurred by an IOPO or HCL, respectively, during its previous fiscal year and on the IOPO's or HCL's reasonable and documented estimate of its projected costs in its subsequent fiscal year, as follows.
- We are modifying the proposed regulation text at § 413.420(d)(2)(i) to more accurately reflect the current rate-setting process for kidneys, to specify that the interim rates for kidneys are a contractor approved kidney SAC or contractor approved rates, based on costs associated with procuring kidneys for transplantation, incurred by an IOPO or HCL, respectively, during its previous fiscal year and on the IOPO's or HCL's reasonable and documented estimate of its projected costs in its subsequent fiscal year. If there is not adequate cost data to determine the initial interim rate, the contractor approves it according to the IOPO's or HCL's estimate of its projected costs for the fiscal year.
- We are modifying the proposed regulation text at § 413.420(d)(2)(ii) to specify that for services furnished for cost reporting periods beginning on or after October 1, 2028, the interim rates for non-renal organs are contractor approved non-renal organ-specific SACs or contractor approved rates, based on costs associated with procuring each specific type of non-renal organ for transplantation incurred by an IOPO or HCL, respectively, during its previous fiscal year and on the IOPO's or HCL's reasonable and documented estimate of

its projected costs in its subsequent fiscal year. If there is not adequate cost data to determine the initial interim rates, the contractor approves them according to the IOPO's or HCL's estimate of its projected costs for the fiscal year.

- We are modifying the proposed regulation text at § 413.420(d)(4) to change ''establishes'' to ''approves''.
- We are modifying the title of the regulation text at § 413.420(e)(2) to add the effective date, so that the paragraph title indicates that it is for Audit and adjustment for cost reporting periods beginning before October 1, 2028, and to changed ''established'' to ''approved''.
- We are modifying the proposed regulation text at § 413.420(e)(3), to set forth *Audit and adjustment for cost reporting periods beginning on or after October 1, 2028.* A cost report submitted by an IOPO or HCL is reviewed by the contractor and new interim reimbursement rates for non-renal organ acquisition costs for the subsequent fiscal year are approved by the contractor based upon this review and upon the IOPO's or HCL's reasonable estimate of its costs for organ procurement and testing, respectively, in the subsequent fiscal year.
- We are modifying the proposed regulation text at § 413.420(e)(3)(i) to remove the word ''non-renal'' as this text will apply to all organs.
- We are modifying the proposed regulation text at § 413.420(e)(3)(ii) to specify that if the determination of reasonable cost reveals an overpayment or underpayment resulting from the organ-specific interim reimbursement rates received or receivable by the IOPO or HCL from THs and OPOs, an adjustment to the interim rate may be initiated by the contractor or requested by the IOPO or HCL, but no more than quarterly. If a rate adjustment is made, then an IOPO or HCL may request that a lump sum adjustment be made directly between the contractor and the IOPO or HCL.

Comment: Most commenters requested that CMS not finalize its proposal to reconcile non-renal organ acquisition costs. A few commenters were unclear as to whether the proposed reconciliation of non-renal organs was for all non-renal organs or just for Medicare non-renal organs. Commenters requested more detail on the reconciliation process. Several commenters wrote that a reimbursement model built for kidneys, which have a higher volume of procurements than non-renal organs, may not fit lower-volume non-renal organ procurement, which have greater cost variability. A commenter noted that a small number of complex non-renal cases can materially affect annual costs and utilization.

Several commenters noted that based on OPTN or SRTR data, the majority of non-renal organs are transplanted into non-Medicare beneficiaries. Some commenters wrote that reconciling for all non-renal organs would violate the statutory prohibition of cross-subsidization in section 1861(v)(1)(A) of the Social Security Act, and CMS's longstanding policy that Medicare should only pay for covered services to Medicare beneficiaries and should not subsidize or pay for non-Medicare services. Because non-renal organ transplants are predominantly financed by private, non-Medicare payers, commenters contended that this approach would result in Medicare dictating the pricing structure for services that are largely outside the Medicare program's scope, thereby impermissibly shifting the cost burden to non-Medicare patients and payers. Commenters characterized this as significant regulatory overreach that is contrary to law.

Several commenters expressed concerns that cost report reconciliation takes 2 years from the close of the cost reporting period and that timeframe does not include time for appeals of amounts in dispute. During the appeals process, OPOs must pay the amount in dispute up front, which can create operational cash flow issues which will be magnified if there is no margin or reserves.

Response: As noted previously, we maintain that our authority to reimburse non-renal organ acquisition costs on a reasonable cost basis is grounded in section 1881(b)(2)(A) of the Act, as amended by Public Law 95–292, which references the cost of procuring organs broadly. We interpret this language as encompassing both renal and non-renal organs, consistent with the broader statutory purpose of ensuring that Medicare payments accurately reflect the actual, reasonable costs incurred by OPOs in the procurement of organs for Medicare beneficiaries. We note that the absence of an explicit reconciliation mechanism for non-renal organ acquisition costs has created payment integrity vulnerabilities and has resulted in Medicare paying amounts that do not accurately reflect actual OPO costs. As we described in the proposed rule, when an IOPO establishes a non-renal acquisition charge that is higher than its reasonable costs actually incurred, and the IOPO bills that inflated charge to a TH (or other OPO), that inflated charge is reported by the TH (or other OPO) as an acquisition charge on its cost report. Medicare then shares in those inflated charges when reconciling TH's organ acquisition costs, because we are settling with the TH based on costs which were inflated. The TH has no way to determine the reasonableness of the charges it receives from OPOs or HCLs. Without reconciliation, IOPO non-renal organ acquisition charges would continue to be passed to THs without any mechanism to ensure those charges reflect actual, reasonable cost—resulting in inflated and unverified costs cascading throughout the transplant ecosystem. The absence of a reconciliation requirement for IOPOs and independent HCLs creates a fundamental accountability gap; unlike their hospital-based counterparts, independent IOPOs and HCLs operate without the cost discipline that the annual Medicare cost reporting reconciliation process imposes. As noted previously, hospital-based OPOs and hospital-based HCLs are already held to reasonable cost for their non-renal organ acquisition costs through the annual Medicare cost reporting reconciliation process. There is no principled basis for exempting IOPOs and independent HCLs from the same standard—consistency, cost integrity, and equitable treatment across the transplant ecosystem demand that reconciliation apply uniformly to all OPOs and HCLs.

We recognize that non-renal organs have significantly more cost variability than kidneys and believe that cost variability is a strong argument for reconciling non-renal organs, because as a commenter noted, a small number of complex non-renal cases can materially affect annual costs and utilization. Reconciling non-renal organs will protect IOPOs from potential losses on non-renal organ acquisition costs, including for complex cases where an organ is subsequently not transplanted.

We proposed that the reconciliation process for non-renal organ acquisition costs mirror the process we use for reconciling kidney acquisition costs, which IOPOs and HCLs are already familiar with. Generally, reconciliation compares total revenue to total costs, and if total costs are greater than total revenue, Medicare makes up the difference to make the provider whole. Likewise, if total costs are less than total revenue, the provider pays Medicare the difference.

Following the procedures we currently use for reconciling kidney acquisition costs, the Medicare contractor would first review the IOPO's and the HCL's organ acquisition costs to ensure that they are allowable and reasonable. The contractor would follow the reasonable cost principles set forth

in section 1861(v)(1)(A) of the Act and our regulations (including new or updated regulations related to the reasonable cost provisions described and finalized in sections X.D.2. and X.D.3. of this final rule). We would then determine Medicare's share of the non-renal organ acquisition costs. Our current policy assumes that all usable kidneys are transplanted into Medicare beneficiaries, with the exception of kidneys sent to VA hospitals, to military hospitals without an agreement as described in § 413.202, or to foreign countries. We would apply this same assumption to non-renal organs, assuming that all usable non-renal organs are transplanted into Medicare beneficiaries, with the exception of those sent to VA hospitals, any military hospital, or to foreign countries. We do not have any agreements with military hospitals related to non-renal organs, so none of the non-renal organs sent to a military hospital would be allowable as Medicare organs.

While we agree that the majority of non-renal organs are transplanted into non-Medicare beneficiaries, based on OPTN or SRTR data, we would not consider this proposed method a violation of statute that prohibits cross-subsidization in section 1861(v)(1)(A) of the Social Security Act. Medicare must only pay for covered services to Medicare beneficiaries and must not subsidize or pay for non-Medicare services; however, IOPOs an HCLs are paid primarily by the THs and other OPOs for the services they provide, not by Medicare. The reconciliation process is to ensure Medicare's reasonable cost principles are applied. Additionally, because Medicare is approving IOPO SACs and HCL testing rates under its reasonable cost principles, and because those SACs or testing rates are estimates of actual costs, the only way to make the IOPO or HCL whole when the SAC or HCL testing rate is not a close approximation to cost is by reconciling those costs.

Similar to kidneys, we would calculate a Medicare ratio for each type of non-renal organ, with the numerator being the total usable organs less the usable organs sent to military or VA hospitals or to foreign countries, and the denominator being the total usable non-renal organs. The Medicare ratio for kidneys is used to compute Medicare's share of the allowable organ acquisition costs. For example, if an IOPO procured 200 usable livers, but sent 5 of those usable livers to military or VA hospitals, the liver Medicare Ratio would be (200 − 5)/200, or 0.975000 (97.5000 percent). We apply the Medicare ratio for liver to the total organ acquisition costs for liver, to determine Medicare's share of the organ acquisition costs for liver. We would apply the same methodology, multiplying each organ specific Medicare ratio by its associated total acquisition costs to determine the Medicare share of organ acquisition costs for each organ type.

Next, similar to kidneys, we would reconcile the costs with the revenue. The process requires that we subtract the total payments received or receivable from OPOs and THs for non-renal organs furnished from the Medicare share of the organ acquisition costs. If the costs exceed revenue, Medicare would have a liability to the IOPO; if revenue exceeds costs, the IOPO would have a liability to Medicare, before accounting for sequestration and interim payments such as lump sum adjustments made during the cost reporting period.

The process for HCLs is similar. Currently, Medicare's share of kidney HCL testing costs is calculated on the OPO/HCL Medicare cost report. The HCL calculates a Medicare ratio by dividing its total gross charges for kidney pre-transplant HCL testing by its total gross charges for all HCL testing. This ratio is multiplied by the total HCL costs (called tissue typing laboratory costs on the current IOPO/HCL cost report form) for kidney pre-transplant testing. The result is Medicare's share of the tissue typing laboratory's costs. Any revenue for HCL services furnished to military or VA hospitals or to foreign countries is subtracted from the Medicare HCL kidney acquisition costs and then the total payments received or receivable from OPOs or THs for pre-transplant kidney laboratory services are subtracted, to determine the liability before sequestration or any interim payments are accounted for. If the result is a positive number, it means that the total Medicare HCL testing costs exceeded the total HCL revenue, and Medicare owes the HCL the difference. If the result is a negative number, it means that the total HCL testing costs were less than the total HCL revenue, and the HCL owes Medicare the difference. We would then subtract the sequestration adjustment and account for interim payments before determining a net balance due to the HCL from Medicare, or from Medicare to the HCL. This process would occur for testing costs for each non-renal organ, following the same steps. As noted previously, after considering the comments received, we are finalizing our proposal with a delayed implementation to cost reporting periods beginning on or after October 1, 2028, to allow IOPOs and HCLs time to prepare and to adjust their operations as necessary.

We are finalizing our proposal to reconcile non-renal organ acquisition costs by adopting an approach that is analogous to the methodology long applied to kidney acquisition cost reconciliation and currently applied to HOPOs and hospital-based HCLs. Because THs and OPOs are the primary payors to IOPOs and HCLs for non-renal organ acquisition services, this methodology does not constitute cross-subsidization—the costs being reconciled are costs that Medicare-participating entities are already directly bearing and passing through the transplant ecosystem. Reconciliation simply ensures that those costs are reasonable and verifiable, not that Medicare is assuming costs properly attributable to other payors. Just as we have historically treated all procured kidneys as Medicare kidneys—except those sent to certain military hospitals, to VA hospitals or to foreign countries—we will apply a similar presumptive Medicare attribution methodology to non-renal organs for purposes of Medicare's reasonable cost reconciliation. This approach reflects the practical impossibility of organ-level Medicare/non-Medicare attribution at the time of procurement and is consistent with the methodology that has long governed kidney acquisition cost reconciliation. For HCL testing costs, we will adopt a similar approach, treating all tests for non-renal organs as performed for Medicare beneficiaries, while excluding costs associated with testing for military or VA hospitals, or for foreign countries by offsetting the Medicare share of the HCL costs by the revenue received for those tests.

We believe that this approach represents the most operationally sound method of implementing reasonable cost reconciliation for non-renal organ acquisition costs in a manner that is consistent with Medicare's anti-cross-subsidization principles. CMS will continue to evaluate whether refinements to this methodology are warranted as additional data and operational experience become available.

For the reasons set forth above, and in the responses to comments that follow, we are finalizing our proposal to reconcile non-renal organ acquisition costs following the same procedures used for kidney reconciliation as proposed, effective for cost reporting periods beginning on or after October 1, 2028. In determining Medicare's share of non-renal organ acquisition costs and non-renal HCL testing costs, our final reconciliation policy will consider all

usable non-renal organs to be Medicare usable organs except for those organs provided to military or VA hospitals, or to foreign countries.

Comment: While multiple commenters supported CMS's goals of transparency, accountability, and stewardship, commenters asserted that our proposed policy to reconcile non-renal organ acquisition costs would eliminate operating margins and, when accounting for the 2 percent Medicare sequestration reduction, would result in zero or negative net reimbursement. Many commenters requested that CMS adopt a reimbursement methodology set at 101 or 102 percent of cost, similar to the payment model used for Critical Access Hospitals. Several commenters argued that a zero-margin reimbursement model is inconsistent with the Public Health Service Act (PHSA) requirement at section 371(b)(1)(B) to maintain fiscal stability; a commenter noted that CMS did not acknowledge in the proposed rule that reconciliation to ''break even'' effectively results in a net loss once sequestration is applied. Many commenters said their long-term financial viability would be threatened. A few commenters also noted that IOPOs experience unreimbursed losses on surgical fees for kidneys, further compounding the financial impact; some commenters noted that kidney costs, which are subject to cost-based reimbursement, have increased greatly in a short period of time despite their being reconciled. A commenter was concerned that a zero-margin reimbursement model would negatively impact IOPO's fiscal security, with a few commenters citing OPTN policies or modernization that can result in increased costs. A commenter used the change in the allocation model and the resulting increased transportation and recovery expenses as an example.

Multiple commenters emphasized that operating margins are not discretionary but are essential to sustaining OPO operations. Commenters noted that OPOs have fixed or semi-fixed costs and that OPOs and HCLs must maintain 24/7 operational readiness regardless of donor volume or organ utilization or test volume, without the benefit of diversified revenue streams. A number of commenters cautioned that a zero-margin model would erode capital reserves and inhibit investment in critical areas such as innovation, transportation logistics, organ preservation technologies, referral automation, cybersecurity infrastructure, and donor care centers—all of which require upfront capital that cost-only reimbursement cannot finance. Some commenters further noted that lenders would be unlikely to extend credit to organizations unable to generate a margin, limiting IOPOs' access to capital necessary for infrastructure investment.

Several commenters raised concerns about the operational and mission-related consequences of the proposed methodology. They argued that financial constraints would force IOPOs to divert resources away from mission-critical programs—including donor identification, donor family support, organ preservation, and community outreach—in order to build reserves to manage cost volatility. Commenters also warned that retrospective reconciliation would incentivize a more risk-averse operating model, discouraging the pursuit of medically complex or marginal donors and organs that may ultimately be unsuitable for transplant, thereby reducing the total number of organs recovered and transplants performed.

Commenters highlighted broader systemic risks associated with the proposed approach. Some noted that there is no other instance in healthcare where CMS has eliminated all operating margin and established a reconciliation process applicable to Medicare and all other payers. Some commenters were concerned that prolonged reimbursement delays, retroactive repayment obligations, and reimbursement uncertainty would impair OPOs' ability to make the investments necessary to maximize donation and transplantation and could adversely affect cash flow. Other commenters were concerned that IOPOs would be unable to compete in a competitive healthcare labor market or to respond to supply chain volatility. Some commenters expressed concern that CMS's characterization of IOPOs as non-profits in the proposed rule implied that margins are unnecessary; some commenters clarified that margins are currently reinvested into organizational missions and that operating without a margin would constitute irresponsible governance. A commenter wrote that IOPOs may be compelled to seek revenue from unrelated business activities, jeopardizing their non-profit status. Additionally, commenters noted that IOPOs need reserves to address unpaid receivables from THs and potential hospital bankruptcies.

Finally, commenters raised concerns about the downstream impact on Medicare expenditures and the broader transplant system. A few commenters noted that organ procurement and transplantation reduce long-term Medicare costs by decreasing reliance on expensive treatments for end-stage organ failure and warned that policies discouraging pursuit of complex donors or constraining organ utilization efforts could result in fewer transplants, worse patient outcomes, and higher downstream Medicare costs. Commenters also noted that the financial burden of coordinating imported organs, including absorbing losses due to other OPOs' variable SACs, may lead some IOPOs to discontinue this service, which would shift coordination responsibilities to transplant centers, resulting in duplicative costs and inconsistent service delivery.

Response: We thank the commenters for expressing their concerns. Pursuant to section 1881(b)(2)(A), OPOs are entitled to reimbursement at reasonable cost for organ acquisition, and CMS is charged with ensuring compliance with this requirement. While we agree that kidney costs have increased, we maintain that such increases are the result of factors unrelated to cost-based reimbursement policy; namely rising transportation costs associated with the new organ allocation system and the broader adoption of advanced perfusion and preservation technologies.

Our proposals to hold IOPOs to reasonable costs for non-renal organ procurement means limiting reimbursement to cost. As such, we are unable to reimburse providers above 100 per cent of cost. We agree that sequestration, which originated with Public Law 112–25 and is governed by Congress, affects many providers and further reduces their reimbursements. We recognize that our final policy to reconcile non-renal organ acquisition costs will be a significant change for IOPOs, affecting their finances and operations. That is one reason why we proposed a delay in implementation, and why, after evaluating public comments, we are extending the delay in implementation to cost reporting periods beginning on or after October 1, 2028.

Regarding unreimbursed surgical fees for kidneys, in the FY 2022 IPPS/LTCH rulemaking, we solicited data and information on surgeon's fees for deceased donor kidney retrievals. We did not receive data in the comment responses we received, which are discussed in the FY 2022 IPPS/LTCH final rule (91 FR 73504 and 73504), however, we may consider this topic in future rulemaking. Regarding increased operating costs resulting from OPTN policy changes or modernization efforts, as long as the costs meet the requirements for organ acquisition costs set forth at § 413.402 and are reasonable,

then they would be allowable costs and reimbursable, and therefore would not threaten the IOPO's fiscal security. Reasonable labor costs and reasonable costs incurred to address supply chain volatility, and which meet the definition of organ acquisition costs specified at § 413.402(a) and (b), are allowable costs and can be included in the IOPO's SACs.

We disagree with commenters who wrote that IOPOs do not benefit from diversified revenue streams. While OPOs may only be reimbursed at reasonable cost for solid organs, many OPOs provide other services like tissue recovery, heart valve, bone, cornea and bone marrow that are not impacted by this proposal to reconcile their reasonable costs. OPOs are required to have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all usable tissues are obtained from potential donors. IOPOs receive payments for tissue that can, and often do, include a margin. In fact, in the FY 2022 IPPS/LTCH final rule, we indicated that a comment we received on the FY 2022 IPPS/LTCH proposed rule made note of an OPO using tissue revenue to subsidize certain costs (86 FR 73505). Tissue procurement is integrated into OPO operations at initial referral, in interactions with the donor family, and in screening, coordinating tissue procurement, preserving, packaging, storing or shipping tissues. We believe that if an IOPO needs capital for investment, lenders would look at the IOPO's financial viability based on its entire operations, considering both organ and tissue margins. Additionally, many IOPOs have foundations, and those entities can also assist IOPOs with costs such as infrastructure investment. As we frequently see donations to IOPOs from their foundations reported on their cost reports, we believe IOPOs have more financial options than these comments suggest, and that they would still be able to invest in critical areas such as innovation, logistics, new technologies, automation, etc. The reasonable costs of these investments would be allowable (through depreciation for long-term assets, or as allowable expenses) if they are related to organ acquisition. For all of these reasons, we do not believe that an IOPO's access to capital for infrastructure investment would be limited.

Regarding operational and mission-related consequences of non-renal reconciliation, some of the activities commenters cited (such as donor family events and certain types of public education costs) are not allowable by Medicare and must not be funded by taxpayer dollars. Those activities may be funded instead by private donations or by gifts from the IOPO's foundation. However, many IOPOs are able to raise awareness and increase the number of registered donors using effective approaches that are reasonable in cost and allowable. We refer readers to section X.D.2. of this final rule pertaining to reasonable cost provisions, for a more detailed discussion. If an IOPO incurs reasonable organ preservation costs for an organ intended for transplant, even if the organ is subsequently found unsuitable for transplant, such as can occur with complex donors or marginal organs, the cost is allowable (see § 413.412(a)(2) and (d)(2)). In our proposed rule, we proposed to codify a listing of costs used to develop the deceased donor IOPO SACs at § 413.404(d)(1)(iv), and that listing includes perfusion and preservation costs (as previously noted, we are finalizing that proposal as proposed). Therefore, we do not believe that our final policies would hinder procurement from complex or marginal donors. In the FY 2027 IPPS/LTCH proposed rule, we also noted that many commenters to our July 2022 RFI wrote that their organ procurement would be unaffected by non-renal reconciliation as they are incentivized by their organ quality metrics to procure every organ, every time. For these reasons, we do not believe the policies we are finalizing in this rule will hinder mission related activities or that our policies finalized in this final rule will result in a reduction in registrations or procurements.

As noted in a prior comment response, we understand the importance of timely reimbursement of retroactive payment obligations and will keep these comments about contractor timeliness in mind as we work toward effectuating the policy with the Medicare contractor; more importantly, payment is initially made by the TH or other OPO and the accuracy of the SAC ensures the accuracy of the payment at the time service is rendered. We recognize IOPO cash flow concerns and the need for IOPOs to have operating reserves, which is a standard business practice. We have provided flexibility in our final policies, allowing IOPOs to estimate their SACs and SAC adjustments and allowing lump sum payments to address cash flow concerns. Our extending the delay in implementation for an additional year provides more time for IOPOs to build reserves.

The discussion of reasonable cost provisions in section X.D.2. of this final rule will give providers a better understanding of the costs that are not allowable. We agree that non-profit status does not mean that a non-profit entity must have a zero margin, however, we reiterate that section 1881(b)(2)(A) of the Act limits OPO reimbursement for solid organs to reasonable costs. We cannot comment on the business decisions IOPOs choose to pursue regarding other revenue-producing operations, but IOPOs will be responsible for ensuring that they uphold their statutory mission to procure as many organs as possible, and to ensure those operations are in accordance with their conditions for coverage and any OPTN requirements, and do not jeopardize their non-profit status. Regarding unpaid receivables and bankruptcies, IOPOs must have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization (42 U.S.C. 273(b)(1)(B)) and are required to have procedures to obtain payment for non-renal organs provided to transplant centers (42 U.S.C. 273(b)(1)(E)). Maintaining a reserve is an option for addressing issues with accounts receivable or potential TH bankruptcies, but such a policy would be independent of our proposals and likely would be longstanding internal IOPO accounting policy.

We do not anticipate that organ procurements will be reduced, and therefore we do not anticipate negative downstream effects on Medicare expenditures. Finally, we appreciate the comment about the potential for more IOPOs to stop coordinating imported organs because of the burden and the potential losses if the sending OPO's SAC is greater than the receiving OPO's SAC, and the potential for additional costs to transplant centers, and ultimately to the Medicare program. We will monitor for unintended consequences on the transplant ecosystem from both of these scenarios.

Comment: A few commenters wrote that the proposed rule contained uncertainties and omissions that deprived stakeholders of the opportunity to share their views, and that the Administrative Procedures Act requires that stakeholders have a meanigful opportunity to comment. A commenter listed uncertainties and omissions including whether CMS would reconcile all non-renal organs or just those for Medicare patients; a discussion of the organ acquisition costs specific to non-renal organs; the implications of the Medicare contractor mandated non-renal SACs when many

more implicated patients are non-Medicare patients than Medicare patients; providing an opportunity for public comment on the major changes to the cost report; payment for situations in which transplant surgery is cancelled after the intended recipient is brought to the hospital; and how CMS envisions reconciliation when both Medicare and another payor are involved.

Response: We disagree that the proposed rule omitted or was unclear about any of the issues the commenter noted. First, we proposed that in determining Medicare's share of non-renal organ acquisition costs, we would follow the same statutory and regulatory procedures used for kidney reconciliation. We also wrote that we would assume that all usable organs or tests for usable organs intended for transplant are for Medicare beneficiaries, with a few exceptions for usable organs or tests for usable organs sent to military hospitals, VA hospitals, or to foreign countries (see 91 FR 19734). We believe our proposal was clear that we would assume that all non-renal organs were for Medicare beneficiaries with these exceptions.

We also discussed organ acquisition costs applicable to non-renal organs in the proposed rule and we noted that there was not a listing of allowable organ acquisition costs that can be included when calculating the IOPO organ-specific SACs. In the proposed rule, we discussed allowable organ acquisition costs and proposed to codify the same list of organ acquisition costs that we have previously codified for TH deceased donor SACs except that we excluded registry fees, which are not an OPO cost. (See 91 FR 19733 and 19734.) We received a few comments about the surgeon's fees for kidney retrieval included in that listing, but no other comments about the listing, suggesting that OPOs are familiar with these costs. We also note that allowable organ acquisition costs are specified in § 413.402(a) and (b), and costs not related to organ acquisition are specified in § 413.402(d).

Regarding the comments about the implications of the Medicare contractor applying the same SAC to Medicare and non-Medicare organs, the SAC is an average cost for procuring a specific organ type (kidney, heart, lung, liver, pancreas, or intestine). At procurement, OPOs may not know the intended organ recipient or which transplant hospital will receive the organ; therefore, the cost to procure an organ should not vary by the recipient's payor status, and using the same organ-specific SAC for all organs of a given type is appropriate.

Regarding the opportunity to comment on resulting changes to the OPO/HCL cost report, in the proposed rule we noted that these changes would be included in a forthcoming Paperwork Reduction Act (PRA) package (91 FR 19765), and as noted previously in this final rule, that package will include cost reporting forms and instructions. As part of the PRA process, a notice will be published in the **Federal Register** with a 60-day comment period. After reviewing and responding to those comments, another **Federal Register** notice will be published, with an additional 30-day comment period. In this way, the public will have two opportunities to comment on the updates to the OPO/HCL cost report before it is finalized.

Our regulations at § 413.412(a)(2) are clear that OPOs must identify costs associated with recovered and unrecovered organs that were intended for transplant and apportion those costs to the appropriate cost centers by organ type. Therefore, if an IOPO recovers an organ that is intended for transplant but is subsequently not transplanted, the IOPO's reasonable costs to procure that organ are allowable costs. Likewise, if an organ is intended for transplant, and a surgical team arrives to procure the organ from a DCD patient, but the team cannot proceed with procurement, the reasonable cost of the dry run would be an allowable organ acquisition cost. We believe this policy supports OPOs in trying to procure every available organ.

Regarding the question about how reconciliation works when there is a second payor in addition to Medicare, IOPOs are not paid directly by Medicare or other third-party payors but are paid their SAC amounts directly by the entities to which they provide organs: THs or other OPOs. Therefore, the IOPO reconciliation of Medicare organs is unaffected by the presence of a payor in addition to Medicare. For example, if the IOPO sends a TH an organ that is intended for transplant into a Medicare beneficiary where Medicare is the secondary payor, that does not affect the IOPO's reconciliation; it is solely a TH accounting issue, handled in accordance with our regulations at § 413.414. Likewise, if the IOPO sends a TH an organ that is intended for transplant into a Medicare beneficiary where Medicare is the primary payor, and the beneficiary also has a second form of insurance, it does not affect the IOPO's reconciliation.

We believe our proposed rule provided the information stakeholders need to provide comments, and that our proposals were clear and did not omit key information. Therefore, we believe that we have complied with the Administrative Procedures Act's requirement that stakeholders have a meaningful opportunity to comment.

Comment: A few commenters cited possible unintended consequences of our proposals. A commenter wrote there was a risk of cost shifting rather than overall system savings. Another commenter stated that organ and tissue recovery systems are deeply connected and was concerned there may be impacts on tissue processors, transplant partners, and the patients who depend upon tissue transplants if IOPO financial stability is weakened.

A few other commenters expressed concerns that extending reconciliation to non-renal organs would risk for-profit vendors exploiting a ''make-whole'' reimbursement framework by inflating prices for technologies and services that IOPOs must purchase to meet clinical, operational, and regulatory standards. These commenters wrote that applying the prudent buyer standard does not eliminate this vulnerability as the IOPO operating environment constrains their ability to delay purchases, aggregate demand across large networks, or credibly threaten to switch suppliers. The commenter added that there could also be distorted procurement incentives that favor higher-priced reimbursable purchases over cost-effective innovation, and uneven access across regions, where smaller or rural IOPOs may be disproportionately affected by limited vendor competition. A commenter wrote that the proposed rule may unintentionally promote financial relationships that undermine the Agency's conflict-of-interest standards if an IOPO is pushed to eliminate or seek alternative vendor arrangements to support what are currently part of their portfolio of standardized services for transplant centers, such as coordinating imported organs.

Response: We appreciate these comments and agree that some IOPOs may attempt to impermissibly shift non-reimbursable tissue costs to organ acquisition cost centers. We will ensure that the updated IOPO/HCL cost report will include explicit instructions for reporting tissue costs and tissue revenue, and for properly allocating tissue costs, to prevent cost shifting. We agree with commenters that organ recovery and tissue recovery are deeply intertwined, as OPOs may conduct tissue recovery but must work with any tissue bank that a hospital has an agreement with. The Public Health Service (PHS) Act section 371(b)(3)(I) requires that OPOs shall have arrangements to cooperate with tissue

banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all usable tissues are obtained from potential donors. We do not believe that tissue procurement will be adversely affected by our final policies. While IOPOs will be held to reasonable cost reimbursement for all solid organs resulting from our proposals, currently there is no such requirement for their tissue reimbursement. Rather than hindering tissue procurement, we believe that our final policies may incentivize it. We will continue to monitor cost report data related to tissue to identify any unintended consequences related to tissue.

We appreciate the comments about possible vendor cost increases for needed IOPO services and supplies and will monitor cost report data for any unintended consequences. We appreciate that smaller or rural IOPOs may have fewer options for obtaining certain services than larger IOPOs and more challenges in negotiating prices. The prudent buyer standard has been longstanding Medicare policy and has always applied to OPOs because it is a reasonable cost principle. We refer these commenters to the discussion of the prudent buyer standard that is found in section X.D.2.b.(1) that follows. Finally, we agree that IOPOs' providing imported organ coordination services to THs is a valuable service and will monitor for unintended consequences related to those services. No rationale was provided for the commenter's suggestion that our proposal would unintentionally promote financial relationships that undermine the Agency's conflict-of-interest standards. Without more detail, are unable to respond to that portion of the comment.

Comment: A commenter was concerned that the IOPO proposals would introduce financial risk to THs if a Medicare contractor retroactively disallows IOPO costs. This commenter was concerned that THs would face the threat of retroactive payment adjustments, recoupments, and cost report discrepancies, despite already having paid the IOPO in good faith. The commenter requested that CMS implement a good faith safe harbor to shield THs from financial penalties or recoupment during its own reconciliation. This commenter wrote that financial liability for unallowable costs should remain strictly with the OPO that incurred them, rather than being passed through to the hospital.

Response: We thank the commenter for sharing these concerns. The financial liability for unallowable costs incurred by an OPO remains with the OPO. THs will not face retroactive payment adjustments or recoupments of OPO costs after paying OPOs in good faith. As we noted in the proposed rule, THs do not have the ability to determine whether the IOPO's costs are reasonable, which is one of the reasons why we proposed our policy to reconcile IOPO non-renal organ acquisition costs.

Comment: A commenter asserted that IOPOs cannot recover the full reasonable costs associated with organs transplanted at VA transplant centers and if CMS expands cost reconciliation to include all organ types, this same disadvantage will extend beyond renal transplants and affect non-renal organs transplanted at VA transplant centers as well. The commenter asked CMS to clarify how this proposal would affect billing to VA transplant centers and whether IOPOs may bill VA transplant centers using a different SAC that captures final reasonable costs in full.

Response: Our regulations at § 413.404(a)(3) require that IOPOs that provide non-renal organs to a hospital or another entity must bill the receiving entity the appropriate organ specific SAC. Our proposals do not affect this process. If the IOPO's SAC is an accurate estimate of the average cost for the IOPO to procure a certain organ type, we believe the SAC would cover the cost. IOPOs may not use different SACs for different hospitals; the cost to procure an organ should not vary by payor.

Public comments on the impacts of our proposals are discussed in Appendix A, Section I.G.14. of this final rule. Public comments on burden are discussed in Section XII.B.10. of this final rule.

Summary of final policies: For the reasons provided in this final rule we are finalizing our proposal to reconcile non-renal organ acquisition costs following the same procedures used for kidney reconciliation as proposed, effective for cost reporting periods beginning on or after October 1, 2028, for IOPOs and HCLs. In determining Medicare's share of non-renal organ acquisition costs and non-renal HCL testing costs, we are finalizing our proposed policy that all usable non-renal organs are Medicare usable organs except for those organs provided to military or VA hospitals, or to foreign countries. We are finalizing our proposed SAC and HCL testing rates policies with modifications to require that for each organ type, the IOPO must provide the Medicare contractor with its reasonable estimated SAC based upon its prior cost reporting period's costs and organ procurement volumes and its reasonable and documented estimate of its projected costs and organ procurement volumes for the subsequent cost reporting period, for contractor review to ensure reasonableness, and approval. For independent HCLs, we are finalizing our proposal with modifications to specify that the HCL would provide the Medicare contractor with it reasonable estimate of its testing rates based on its prior year costs and reasonable and documented estimate of its projected testing costs and volumes for the subsequent year, for contractor review to ensure reasonableness, and approval.

We are finalizing our proposed IOPO SAC or HCL testing rate adjustment policies with modifications, so that IOPOs or HCLs may request that the contractor make an adjustment in accordance with § 413.64(e), or the contractor may initiate an adjustment, in accordance with § 413.64(d)(2) or § 413.64(e), as applicable, but no more than quarterly. Additionally, the IOPO or HCL must provide the Medicare contractor with an estimated adjusted SAC or testing rates, respectively, based on its actual cost data and its reasonable and documented estimate of costs through the end of its accounting period, to enable the Medicare contractor to review to ensure reasonableness, and approve the adjusted SAC or testing rate, respectively.

We are finalizing our proposed listing of organ acquisition costs that may be included in the IOPO SACs as proposed.

We are finalizing that if the determination of reasonable cost reveals an overpayment or underpayment resulting from the organ-specific interim reimbursement rates received or receivable by the IOPO or HCL from THs and OPOs, an adjustment to the interim rate or may be initiated by the contractor or requested by the IOPO or HCL. If a rate adjustment is made, then an IOPO or HCL may request that a lump sum adjustment be made directly between the contractor and the IOPO or HCL.

We are finalizing our proposal that the Medicare contractor will publish non-renal SACs and HCL testing rates used in billing THs and OPOs for transparency as proposed.

Finally, we are finalizing our proposal to delay implementation of these policies with modification, to extend the delay for an additional year, so that the final policies are effective for cost reporting periods beginning on or after October 1, 2028.

We believe these final policies support organ procurement and the transplant ecosystem, and will increase transparency, accountability,

compliance with reasonable cost principles, and the responsible stewardship of the Medicare Trust Fund.

2. Reasonable Cost Payment Policies

a. Background

Medicare is often required, under section 1814(b) of the Act (for services covered under Part A) and under section 1833(a)(2) of the Act (for services covered under Part B), to pay for services furnished by providers on the basis of reasonable costs as defined in section 1861(v) of the Act, or the provider's customary charges for those services, if lower. Medicare reasonable costs are determined based on the provisions of section 1861(v) of the Act, and existing regulations under 42 CFR part 413. Medicare payments to providers of services must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries.[637] Medicare's reasonable cost principles are also set forth in the CMS Pub. 15–1 (herein referred to as PRM–1).[638]

Under Medicare's reasonable cost reimbursement principles, Medicare reimburses providers for actual costs incurred for Medicare-related items and services, excluding unnecessary costs, in the efficient delivery of needed health services. The Medicare ''reasonable cost'' statute at section 1861(v) of the Act allows the Secretary to develop methods for measuring reimbursable costs such that the necessary costs of efficiently delivering covered services to Medicare beneficiaries will not be borne by non-Medicare beneficiaries, and the costs with respect to individuals who are not Medicare beneficiaries will not be borne by Medicare.

Some providers are reimbursed for all or some of their services on a reasonable cost basis such as critical access hospitals (CAHs) reimbursed at 101 percent of their reasonable costs; CAH swing-bed skilled nursing facilities (SNFs) reimbursed at 101 percent of their reasonable costs; rural health clinics (RHCs) reimbursed under the all-inclusive rate up to their payment limit; OPOs and HCLs reimbursed based on their reasonable cost for organ acquisition and tissue typing services; TEFRA hospitals (that is, children's hospitals, cancer hospitals, long term care hospitals classified as extended neoplastic disease care hospitals, and hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) reimbursed for their reasonable costs up to the TEFRA limit.

In general, Medicare makes interim payments to providers through claims processing and additionally, for any pass-through costs such as organ acquisition or nursing and allied health cost, based on estimated costs or predetermined rates. These payments are typically made on a biweekly basis throughout the year, ensuring a steady cash flow to providers until final cost determinations are made. After the cost reporting period ends, providers submit an MCR documenting their actual allowable costs. The contractor reviews the provider's cost report and calculates a settlement by comparing total interim payments made to the provider during the year with the provider's actual allowable reasonable costs as determined from the provider's cost report. It is this process by which Medicare determines a provider's reasonable costs. If interim payments exceed the provider's actual allowable reasonable costs, the provider must pay Medicare for the overpayment. If actual allowable costs exceeded interim payments, Medicare pays the provider the additional amount owed.

b. Reasonable Cost Proposals

Section 1102 of the Act authorizes the Secretary to publish rules and regulations necessary for the efficient administration of the functions with which the Secretary is charged under the Act. Section 1871(a) of the Act also authorizes the Secretary to prescribe such regulations as may be necessary to carry out the administration of the Medicare Program. Additionally, under section 1861(v)(1)(A) of the Act, the Secretary has authority to determine reasonable costs of providing patient care to Medicare beneficiaries. In the proposed rule, we clarified existing policy and proposed to codify certain longstanding Medicare reasonable cost reimbursement policies as well as to change certain other Medicare reasonable cost reimbursement policies.

In addition to the Medicare ''reasonable cost'' statute at section 1861(v) of the Act, part 413 of the regulations establishes Medicare's principles of reasonable cost reimbursement. Under 42 CFR 413.1(a)(2), these regulations in part 413 govern Medicare payment for services provided to beneficiaries by the following provider types: hospitals, CAHs, rural emergency hospitals (REHs), skilled nursing facilities (SNFs), home health agencies (HHAs), ESRD facilities, OPOs, and HCLs.

Section 413.1(a)(2)(v) identifies OPOs as a provider type to which part 413 of the regulations apply, making them expressly subject to Medicare's reasonable cost principles, including 42 CFR 413.9 regarding costs related to patient care. We find it necessary to restate this because certain OPOs have asserted in certain administrative appeals that reasonable cost principles and rules do not apply to them because they do not provide direct patient care. OPOs provide services directly related to patient care by procuring, perfusing, and transporting organs for transplantation into all organ recipients, including Medicare beneficiaries. An OPO must enter into an agreement with CMS, if it seeks payment under Medicare for organ procurement costs. An OPO incurs organ procurement costs for providing THs with organs for transplantation and for which the TH pays the OPO. When a Medicare beneficiary receives an organ transplant, the TH bills Medicare for the transplant and organ acquisition costs. As such, an OPO's organ acquisition costs that are paid by the TH and passed on to Medicare clearly arise under the Medicare statute under section 1861(v) and are governed by the statutory requirements and implementing regulations. As previously stated in section X.D.1.a.(2) of this final rule, Public Law 95–292 required that the amounts of payments to OPOs and HCLs made under title XVIII for procuring organs must not exceed the costs incurred by OPOs and HCLs and must be determined in accordance with section 1861(v) of the Act. Accordingly, OPOs are subject to Medicare's reasonable cost principles, the regulations in part 413, and the reasonable cost payment proposals finalized in this final rule.

The Office of Inspector General (OIG) has issued reports identifying instances in which providers including CAHs, transplant hospitals, and OPOs have claimed unallowable costs on their MCRs.[639] In these reports, the OIG has attributed the costs not meeting

[637] Section 1861(v)(1)(A) of the Act; 42 CFR 413.9.

[638] PRM–1, chapters 21 and 23. CMS Pub. 15–1 can be found at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929*).

[639] *https://oig.hhs.gov/oas/reports/region9/90800033.pdf; https://oig.hhs.gov/oas/reports/region9/90900087.pdf; https://oig.hhs.gov/oas/reports/region9/90500034A.pdf; https://oig.hhs.gov/reports/all/2011/review-of-select-medicare-conditions-of-participation-and-costs-claimed-at-richards-memorial-hospital-from-october-1-2004-through-september-30-2007/; https://oig.hhs.gov/oas/reports/region9/91102039.pdf; https://oig.hhs.gov/reports/all/2023/medicare-paid-independent-organ-procurement-organizations-over-half-a-million-dollars-for-professional-and-public-education-overhead-costs-that-did-not-meet-medicare-requirements/.*

Medicare requirements to several factors including, the costs were not related to patient care, were not reasonable and necessary, were not adequately documented, and in some cases were unallowable entertainment costs. In its 2023 report, the OIG found that certain OPOs claimed unallowable costs because they misunderstood Medicare's reasonable cost principles and provisions and recommended CMS update applicable Medicare requirements to clarify the allowability of certain overhead costs.[640] In the proposed rule, we proposed the following provisions to address key issues identified by the OIG regarding Medicare's reasonable cost principles and to provide clarity for all providers who seek reimbursement for services under Medicare's reasonable cost provisions.

Comment: Many commenters generally supported our reasonable cost proposals based on the overarching goals of greater fiscal accountability and responsible stewarding of the Medicare Trust Fund, but either opposed or sought clarifications or exceptions to certain provisions of these proposals.

Response: We appreciate commenters' support for our reasonable cost proposals. We provide responses to commenters that either opposed or requested clarifications or exceptions to specific provisions of our reasonable cost proposals in this section.

Comment: A commenter asked whether costs for preparing bids, including unsuccessful bids, and financing the legal, organizational and operational expenses required to expand into other donation service areas (DSAs) would be recognized as ''related to patient care'' under traditional cost reimbursement principles.

Response: We appreciate the commenter's inquiry regarding DSA expansion-related expenses. Costs that are reasonable and necessary for expanding the DSA are generally considered allowable under Medicare cost reporting. This cost may include staffing costs, facility costs, transportation costs, outreach and education, and technology and equipment. Major capital expenditures that meet or exceed certain capitalization thresholds (for example, new facilities or major equipment) must be depreciated over the useful life of the asset rather than expensed in a single cost reporting period. Cost of preparing bids and unsuccessful bids to compete for DSA designation are business development costs which are generally unallowable under Medicare cost reimbursement.

Comment: While a few commenters agreed that 42 CFR 413.9, *Cost related to patient care,* applies to OPOs, some requested that CMS define 'related to patient care' as it applies to meals, education, and travel, to reflect how these items support an OPO's core mission of procuring available organs for transplantation. A few commenters suggested that during the audit process, they have not received clear explanations as to what constitutes ''related to patient care'' for OPOs. The commenters recommended CMS adopt a specific interpretation in regulation and subregulatory guidance, such as the CMS Contractor Hearing Officer's interpretation, related to increasing registered organ donors, coordinating organ donation, organ procurement, preservation, and transportation to transplant hospitals, and providing professional and public education, suggesting this would reduce stakeholder confusion.

Response: We thank the commenters for their feedback regarding our clarification on 42 CFR 413.9, *Cost related to patient care.* We agree that an OPO's mission includes providing education on organ donation, increasing the number of registered organ donors and coordinating the organ donation process and we recognize that the OPOs' mission includes acquiring all available organ for transplant. We are affirming our statement in the FY 2027 IPPS proposed rule, that OPOs provide services directly related to patient care that are encompassed in a multitude of their activities, including procuring, perfusing, and transporting organs for transplantation into all organ recipients, including Medicare beneficiaries. We believe our current statement is sufficient and comprehensive as written, and the addition of further language would be unnecessary.

(1) Prudent Buyer Principles

Medicare's longstanding prudent buyer principles are set forth in the PRM–1, chapter 21, section 2103, issued in 1975. Medicare's prudent buyer principles also coincide with the principles set forth in the regulations at 42 CFR 413.9, Cost related to patient care. Implicit in the policy that payment is determined based on costs that are reasonable is the expectation that the provider will seek to minimize its costs and that its actual costs will not exceed what a prudent and cost-conscious buyer would pay for a given item or service. The prudent and cost-conscious buyer not only refuses to pay more than the going price for an item or service but also seeks to economize by minimizing cost. This is especially so when the buyer is an institution or organization which makes bulk purchases and can, therefore, often gain discounts because of the size of its purchases. In addition, bulk purchase of items or services often gives the buyer leverage in bargaining with suppliers for other items or services. Another way to minimize cost is to obtain free replacements or reduced charges under warranties for medical devices. Any alert and cost-conscious buyer seeks such advantages, and it is expected that Medicare providers of services will also seek them. If costs are determined to exceed the level that prudent buyers incur, the excess costs are not allowable and not reimbursable under Medicare in the absence of clear evidence that the higher costs were unavoidable.

In the proposed rule, we noted that the PRM–1, chapter 21, section 2103 sets forth the following examples of the application of the prudent buyer principle where costs are not reimbursable because the prudent buyer principle has not been applied by the provider:

- Provider A consistently purchases supplies from supplier R and makes no effort to obtain the most advantageous price for its supplies. Supplier W sells identical or equivalent supplies at a lower cost and is also convenient to A. Unless the provider can clearly justify its practice of purchasing supplies from R rather than W, any excess of R's charges over W's charges is excluded from the provider's costs.
- Supplier L supplies drugs to skilled nursing facility B and rents space from B to store the drugs to be used there. The rental paid by L to B for the space would generally constitute an indirect discount on the cost of drugs and must be reflected as a reduction of the cost of drugs supplied.
- Dr. C, a hospital-based radiologist, purchases radiology equipment which he then leases to the provider where he is a staff member. Costs to the provider in this case are higher than if the equipment had been leased through competitive bidding from an outside source. The Medicare contractor reimburses the provider only for those costs which a prudent and cost-conscious buyer would pay. Therefore, those costs which the provider pays for the equipment leased from the staff radiologist which are in excess of costs for equivalent equipment obtained through competitive bidding are denied.
- Provider B purchases cardiac pacemakers or their components for use in replacing malfunctioning or obsolete equipment, without asking the supplier/

[640] *https://oig.hhs.gov/documents/audit/9634/A-09-21-03020-Complete%20Report.pdf.*

manufacturer for full or partial credits or payments available under the terms of the warranty covering the replaced equipment. The credits or payments that could have been obtained must be reflected as a reduction of the cost of the equipment supplied.

Providers may incur costs that are not allowable under Medicare when they fail to apply the prudent buyer principle. Other examples where the prudent buyer principle has not been applied by the provider include, but are not limited to, fees paid to consultants, attorneys, or other professionals that are excessive compared to market rates or for services not directly related to patient care; equipment purchases that are more expensive or sophisticated than necessary for the provider's patient population; and costs for items that are not necessary for patient care or that represent luxury items may be disallowed.

The application of the prudent buyer principle is set forth in PRM 15–1, chapter 21, section 2103 and includes the following examples of methods that contractors [641] may employ for detecting and investigating situations in which costs seem excessive: comparing the prices paid by providers to the prices paid for similar items or services by comparable purchasers, spot-checking, and querying providers about indirect, as well as direct, discounts. We note that in addition to these examples contractors may employ other methods for determining which costs seem excessive, including but not limited to: use of Internal Revenue Service (IRS) Form 990 in comparing reasonableness of executive and employee compensation with those at comparable institutions, use of federal per diem rates in determining the reasonableness of accommodations or meeting spaces for conferences and seminars for patient-care related activities and use of the provider's own records in determining whether costs of certain activities are reasonable and necessary. The geographic location of the provider should also be considered as rates may vary across regions.

In the proposed rule, we stated, we believe the use of IRS Form 990 is appropriate to compare compensation because the information provided is widely recognized in the industry, standardized and publicly available. Additionally, in the proposed rule, we stated, we believe the use of Federal per diem rates are an appropriate method of comparison because they reflect industry norms and are established based on extensive data collection and analysis, account for geographic variations and are transparent. In the proposed rule, we also noted these methods align with Medicare's reasonable cost regulation under § 413.9(c) which provides that actual costs may vary among providers, however, costs must not be substantially out of line with similar institutions in the same area and of comparable size, scope, utilization and other relevant factors. Amounts not related to patient care, or flowing from the provision of luxury items or services are not reimbursable under the program and are not allowable costs.

The PRM–1, chapter 21, section 2103 also provides where a group of institutions has a joint purchasing arrangement which seems to result in participating members getting lower prices because of the advantages gained from bulk purchasing, any potentially eligible providers in the area which do not participate in the group may be called upon to justify any higher prices paid. Also, the manual provides that when most of the costs of a service are reimbursed by Medicare (for example, for a home health agency which treats only Medicare beneficiaries), examine the costs with particular care. In those cases where a contractor notes that a provider pays more than the going price for a supply or service or does not try to realize savings available under warranties for medical devices or other items, in the absence of clear justification for the premium, the contractor excludes excess costs in determining allowable costs under Medicare.

In the proposed rule, we proposed to codify a definition of the prudent buyer in accordance with the principle set forth in PRM–1, section 2103 and that reflects similar terminology used across financial, legal, and insurance fields as well as proposed to codify the application of the prudent buyer principle currently set forth in PRM–1, section 2103. Specifically, in the proposed rule, we proposed to revise section 413.9(b) to add paragraph (b)(3) to specify that the prudent buyer is a person, provider type or entity that purchases items or property with caution, good judgment, and a sensible approach, aiming to make a sound, informed decision that minimizes risk and avoids unnecessary financial loss. This person, provider type or entity thoughtfully evaluates the condition, legal, and financial aspects of a purchase, much like a reasonably prudent person would in a similar situation.

In the proposed rule, we proposed to revise § 413.9(c) to add paragraph (c)(4) to codify the application of the prudent buyer principle to providers to specify that providers are expected to economize by not paying more than the going price for an item or service and seeking to minimize their costs, so that their actual costs will not exceed what a prudent and cost-conscious buyer would pay for a given item or service. If costs are determined to exceed the level that prudent buyers incur, the excess costs are not reimbursable in the absence of clear evidence that the higher costs were unavoidable.

Comment: Many OPOs supported applying a general prudent-buyer standard to OPO overhead administrative expenses; however, most of these OPOs also requested that CMS further clarify the standard. Specifically, these commenters noted the unique challenges of organ procurement, including time constraints, geographical barriers, and higher costs in certain areas, and requested clarification and modification on how the prudent-buyer standard would apply to OPOs. Some commenters noted that the prudent-buyer standard in PRM 15–1 was designed for patient care facilities and that its examples do not reflect OPO activities. A commenter noted that OPOs are obligated to pursue every transplantable organ regardless of cost, leaving little ability to ''shop for the best price''. Another sought clarification on whether quality is factored into the standard, and whether higher costs may be justified by higher quality services or products. A commenter requested CMS develop separate definitions for ''overhead reasonable costs'' and ''recovery reasonable costs'' that set appropriate standards for each. Many commenters requested CMS modify the proposal to adopt objective, published benchmarks for the prudent buyer standard proposed at § 413.9(c)(4), including safe harbors for competitively sourced services, market-rate employment agreements, and mission-critical costs in high-cost labor markets. The commenters stressed the need for uniform enforcement to promote consistent application.

Some commenters stated that without clearer CMS guidance, the prudent-buyer standard could create an uneven playing field, holding OPOs to strict cost limitations while third-party providers face none, potentially driving up costs, reducing efficiency, and discouraging innovation in organ transplantation. A commenter that opposed codifying the provision suggested the prudent buyer standard is already addressed under § 413.9, the term ''prudent'' is too subjective and risks inconsistent enforcement across

[641] (79 FR 49854 at 50199 on August 22, 2014).

Medicare contractors and regions, CMS lacked both the required reasoned explanation under administrative law, and congressional authority to determine the ''best price'' for consulting services, educational costs, executive compensation, or other expenses, and such determinations are outside of the Medicare contractor's core competencies. A few commenters suggested that IRS Form 990, *Return of Organization Exempt From Income Tax,* should not serve as the sole basis for determining reasonable compensation, as it fails to account for employees' specific responsibilities, oversight, and experience. The commenter contended that relying on a single data source reflects a misunderstanding of how executive compensation is determined. A few commenters disagreed with CMS's use of Federal per diem rates as a benchmark for reasonableness, contending that these rates are fixed government limits that do not reflect the actual costs of private, non-profit organizations. They further noted that federal travel and lodging rates are available only to government employees and that Medicare contractors have incorrectly applied these rates to OPO employees.

Response: We appreciate commenters' support for our proposal to codify the prudent buyer standard and acknowledge their requests for clarification and modification. The prudent buyer standard in general is not a new requirement, but rather longstanding policy grounded in Medicare's reasonable cost statute and regulations, which has been applied to all Medicare providers for decades, including OPOs which were statutorily created by Congress and mandated to receive reimbursement on the basis of reasonable cost. Our proposal to codify the prudent buyer standard does not constitute a new policy but we are codifying it in our regulations to ensure that all outside stakeholders are aware of its application.

We disagree with the commenter's assertion that Congress did not grant CMS or Medicare contractors the authority to determine best prices with regard to reasonable costs and the commenter's assertion that evaluating expenses is outside of a Medicare contractor's core competencies. The Medicare contractors do not determine the ''best price'' for any given service or expense; rather, they apply longstanding cost principles under 42 CFR 413.9 to evaluate whether reported costs are reasonable and consistent with what other similarly situated providers incur. This is a well-established and core function of the Medicare contractors' cost report review responsibilities. Furthermore, the prudent buyer standard provides a reasonable framework to ensure Medicare funds are used responsibly and that costs claimed on cost reports are reasonable and necessary. Congress assigned this responsibility to CMS through section 1861(v) of the Act, which CMS codified in regulations throughout 42 CFR part 413.

We appreciate the commenter's support for clear and standardized guidelines regarding administrative costs and executive compensation and consistent application. We note that there is one Medicare contractor responsible for reviewing both OPO and HCL cost reports, which inherently promotes uniformity and consistency in the review process. We also acknowledge OPOs' concerns regarding the applicability of the prudent-buyer examples to them as set forth in PRM–1, section 2103. Here, we provide an additional example of the prudent buyer application:

- OPO A consistently purchases sterile surgical gloves and gowns (required during organ recovery procedures) from Supplier R, at $800 per case. OPO A makes no effort to seek more competitive pricing. Supplier W offers identical gloves and gowns at $575 per case and is equally accessible to OPO A. OPO A cannot justify its preference for Supplier R over Supplier W that offers the identical supplies, therefore, the excess $225 will be deemed an unallowable cost.

We also acknowledge commenters' request that CMS define ''overhead reasonable costs'' and ''recovery reasonable costs'' and set appropriate standards for each. However, we believe this comment is outside the scope of this provision. We recognize the commenters' concerns regarding the possibility for different outcomes between OPOs and third-party providers. We also acknowledge the unique challenges OPOs face including time constraints, geographical barriers, and elevated costs for perfusion and transportation in high-cost or rural areas. We understand that an OPO cannot decline to recover a viable organ solely due to high transportation costs or limited vendor availability in rural areas. We acknowledge that there may be some costs outside of the OPO's control with regard to these unique instances in organ procurement, however, there remains an expectation to attempt to procure competitive pricing when available. As such, it is our intent to apply the prudent buyer standard in a manner that is appropriate for OPOs.

We appreciate the commenters' feedback regarding the use of IRS Form 990 and Federal per diem rates as benchmarks for determining reasonable compensation and travel costs. We are clarifying that the examples set forth in the proposed rule were intended to serve as suggested options for OPOs and Medicare contractors to consider and were not meant to be the sole basis for determining reasonable cost. Additionally, we recognize the limitations commenters identified with respect to both IRS Form 990 data and Federal per diem rates. We understand that non-profit organizations commonly reference per diem rates established by the General Services Administration (GSA) when setting their own per diem rates. However, we acknowledge the concerns raised by commenters regarding the use of both IRS 990 data and Federal per diem rates as benchmarking tools. In response to those concerns, we suggest organizations use a multi-data source approach, and consider a broader range of reference sources, which may include, but are not limited to U.S. Bureau of Labor Statistics Occupational Outlook Handbook, salary survey reports from recognized industry sources, crowdsourced databases by sector, travel cost indexes, as well as GSA data, the IRS Form 990 or use of the IRS high low method for cost comparison. We urge providers to keep Medicare's reasonable cost principles in mind with regard to cost containment when planning expenditures.

Respectfully, we disagree that codifying the prudent buyer principle is unnecessary. We believe codifying this standard for all providers, including OPOs, is necessary because it supports payment accuracy and provides clarity and consistency for both OPOs, other institutional providers and Medicare contractors, which supports consistent policy application.

After consideration of the public comments received, we are finalizing our proposal without modification, to codify at 42 CFR 413.9(b)(3) that the prudent buyer is a person, provider type or entity that purchases items or property with caution, good judgment, and a sensible approach, aiming to make a sound, informed decision that minimizes risk and avoids unnecessary financial loss. This person, provider type or entity thoughtfully evaluates the condition, legal, and financial aspects of a purchase, much like a reasonably prudent person would in a similar situation. Additionally, we are finalizing our proposal without modification to codify at § 413.9(c)(4) the application of the prudent buyer

principle to providers to specify that providers are expected to economize by not paying more than the going price for an item or service and seeking to minimize their costs, so that their actual costs will not exceed what a prudent and cost-conscious buyer would pay for a given item or service. If costs are determined to exceed the level that prudent buyers incur, the excess costs are not reimbursable in the absence of clear evidence that the higher costs were unavoidable.

To address commenters' concerns, we are clarifying that when applying the prudent buyer standard for OPOs, providers and Medicare contractors should consider the unique operational challenges OPOs may encounter in fulfilling their organ procurement requirements. We believe OPOs and Medicare contractors should consider several factors when applying the prudent buyer principle for OPOs. These factors include, but are not limited to, time constraints for procurement; geographic availability of alternative vendors or service providers; efforts made to negotiate pricing; clinical rationale for vendor selection; pre-negotiated contracts with perfusion vendors, transport providers, and procurement teams; periodic market analyses to ensure contract rates remain competitive; and documented cost justifications for high-cost procurements. Regarding quality, CMS is affirming that quality that advances the objective of ensuring all available organs are procured for transplant is an integral component of the prudent buyer standard. OPOs and Medicare contractors should consider the clinical necessity of the service or technology (for example, normothermic regional perfusion or machine perfusion to improve organ viability) when applying the prudent buyer principle.

(2) Entertainment and OPOs' Public Education and Outreach for Organ Donation Awareness

Under section 1861(v)(8) of the Act, costs for entertainment, including tickets to sporting and other entertainment events, must not be included in a provider's costs for Medicare reimbursement purposes because they are not reasonable costs related to patient care. The PRM–1, chapter 21, section 2105.8 sets forth that ''Costs incurred by providers for entertainment, including tickets to sporting or other events, alcoholic beverages, golf outings, ski trips, cruises, professional musicians or other entertainers, are not allowable.'' Additionally, PRM–1, chapter 21, section 2102.3 provides that, ''Costs not related to patient care are costs which are not appropriate or necessary and proper in developing and maintaining the operation of patient care facilities and activities. Costs which are not necessary include costs which usually are not common or accepted occurrences in the field of the provider's activity. Such costs are not allowable in computing reimbursable costs and include, for example: cost of meals sold to visitors; cost of drugs sold to other than patients; cost of operation of a gift shop; cost of alcoholic beverages furnished to employees or to others regardless of how or where furnished, such as cost of alcoholic beverages furnished at a provider picnic or furnished as a fringe benefit; cost of gifts or donations; cost of entertainment, including tickets to sporting and other entertainment events; cost of personal use of motor vehicles; cost of fines or penalties resulting from violations of Federal, State, or local laws; cost of educational expenses for spouses or other dependents of providers of services, their employees or contractors, if they are not active employees of the provider or contractor; cost of meals served to executives that exceed the cost of meals served to ordinary employees due to the use of separate executive dining facilities (capital and capital-related costs), duplicative or additional food service staff (chef, waiters/waitresses, etc.), upgraded or gourmet menus, etc.; and cost of travel incurred in connection with non-patient care related purposes.''

Despite this instruction, some providers continue to include inappropriate expenses for entertainment and sporting activities on their MCRs, and CMS's disallowance of these costs often results in appeals. For example, some OPOs are reporting costs on their OPO/HCL MCR, Form CMS–216–94, (OMB control number 0938–0102), (hereinafter referred to as OPO/HCL MCR), for items such as the sponsorship of professional sports teams, sponsorship of race car drivers at nationally viewed racing events, sponsorship of floats at nationally viewed parades, and costs for musical entertainment and performers at these events. Some of these sponsorships have included items such as, full season tickets to professional basketball games, autographed items, tickets to racing events, entrance to hospitality suites, sponsorship of Indy Car teams and dirt track race cars, rides in an Indy Car, pit lane and garage tours and driver appearances at off-track events. These types of costs are not reasonable costs related to patient care and therefore, are unallowable under Medicare's reasonable cost principles.

Under section 371(b)(3)(B) of the PHSA, OPOs are responsible to ''conduct and participate in systematic efforts, including professional education, to acquire all useable organs from potential donors,'' and ''assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.'' We have recognized the importance of OPOs implementing public education activities to increase organ donation awareness and increase the donor registration. (In the context of OPOs' public education activities, we note that the terms public education, public outreach, and public awareness have the same meaning and may be used interchangeably.) We have historically afforded OPOs the flexibility to allocate educational resources based on their individual donation service area (DSA) needs.[642] Medicare currently recognizes the costs incurred by OPOs for public education regarding organ donation awareness as allowable costs if they are reasonable and necessary and related to patient care. The current OPO/HCL MCR instructions set forth that public education costs are expenses associated with organizing awareness programs designed to inform the ''general public'' of the need for organs and organ transplant services.[643] OPOs include professional and public education costs as OPO overhead costs on their OPO/HCL MCR, and Medicare shares in these costs.

Some OPOs have asserted that their engagement in entertainment and sporting events, such as sponsoring parade floats, purchasing tickets to sporting events, engaging or purchasing tickets for musical entertainers and performers, lodging, food and beverages, and sponsoring professional race car driving events, are types of public education costs that serve to reach large audiences to educate potential donors regarding the benefits of organ donation, and thus recruit candidates for organ donor registries. OPOs' sponsorship costs for these entertainment and

[642] 71 FR 31027, May 31, 2006. CMS defines DSA to mean a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area or does not include any part of such an area and that meets the standards of 42 CFR 486.302 subpart G. Once an OPO is certified and assigned a geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under section 1138(b)(1)(F) of the Act. (42 CFR 486.302).

[643] PRM–2, chapter 33, section 3304, Worksheet A, line 11.

sporting events, asserted by certain OPOs in reimbursement appeals to be public education events, vary depending upon the event type and additional items the OPO can select for the sponsorship level that may increase the cost to the OPO.

One report indicated that costs to build a float in the Rose Bowl Parade may be in the vicinity of $125,000 to $500,000 per parade event.[644] In one report, the OIG found that an OPO incurred $327,278 of costs related to the 2006 Rose Parade and Rose Bowl, and reported $153,513 costs as public education overhead costs on its OPO/HCL MCR related to the Rose Parade and Rose Bowl.[645] The OIG categorized these costs as unallowable because they were incurred for entertainment and sporting events, in accordance with PRM–1, chapter 21, sections 2102.3 and 2105.8.[646] The unallowable costs identified by OIG included costs for: float design, lodging, receptions, banquets and use of hotel ballroom, chartered buses, shuttles and limousines for parade day, media expenses, such as audiovisual equipment, photography and television coverage, musical performances, and other costs such as food and beverage, public storage and flowers.[647] We have also seen some OPOs reporting sponsorship costs for a race car driver, at an Indy Car event in the hundreds of thousands of dollars per sponsorship. These types of OPO-sponsored entertainment and sporting events far exceed what a cost-conscious buyer, in this case an OPO, should spend for providing targeted public education regarding organ donation within its DSA. The result is OPOs including costs on their OPO/HCL MCR that are in excess than those generally considered necessary for the provision of needed health services, and therefore, unallowable under Medicare's reasonable cost principles and § 413.9, Cost related to patient care. While these entertainment and sporting events may attract wide viewership and occur within the OPO's DSA, such factors do not constitute targeted public education initiatives, measure attendees or focused educational conversations, or demonstrate measurable successes and increases in donor registration.

We are aware of several OPOs conducting successful, cost-effective public education events within their DSAs while observing Medicare's reasonable cost principles and fulfilling their objectives of increasing donor registrations. These public education events have successfully increased the number of registered donors and effectively reached underrepresented groups within their DSA. For example, some OPOs have engaged with local high schools and colleges, Health Occupational Student Associations, and participated in local multicultural outreach events and set up booths at minor league baseball games and events within their communities and demonstrated successful organ donor registration at these engagements.

We believe for OPOs' public education costs to be allowable under Medicare, the costs incurred must be for direct engagement in public outreach and education events for efforts that are more direct and systematic to target populations within their DSAs and where one-on-one activity and conversations can take place to educate and register individuals for organ donation. Specifically, we believe allowable OPO public education costs are for an OPO's community-based and locally focused efforts and effects, that include opportunities to register donors and track the number of registrations obtained during each effort. The OPO staff should be available to answer questions directly about the organ donation process and may provide modest token items and educational materials to individuals to support organ donation awareness (for example, pens, awareness bracelets, buttons, stickers, cups, or electronic and print materials that include the OPO's website address, QR codes linking to donor registration platforms, or information on upcoming community-based organ donation awareness events).

We believe that allowable costs under Medicare for OPO public education initiatives include costs that directly support organ donation and align with Medicare's reasonable cost principles. Examples would include OPOs' participation and engagement in settings that can facilitate direct conversations with individuals regarding organ donation such as, setting up booths at local farmer's markets, health fairs, high school or local college sporting events, partnering with community organizations, faith-based groups, schools and health care facilities, participating in local multicultural festivals, providing education at driver's education programs and at local Department of Motor Vehicles (DMV) and Department of Natural Resources so that individuals can register to become an organ donor while obtaining a driver's license or fishing license.

The 2025 National Survey of Organ Donation Attitudes and Practices: Report of Findings[648] reported that 89.3 percent of people who registered to be organ donors did so at a state DMV or similar State motor vehicle administration office. According to the report, other methods of donor registration include 12.4 percent who had registered through donor drives, 10.3 percent through mobile apps, 11.6 percent through a website, 9.6 percent through the U.S. military and 11.8 percent through some other way. The report also noted that those under age 50 as well as Black, Asian, Hispanic, and other/multiple races were more likely to register through a donor drive, mobile app, or website. Although most organ donors are registered via the DMV, there remain underrepresented groups within OPOs' DSAs whose registration rates could benefit from targeted community-based outreach.[649]

We do not believe that OPOs should incur costs and seek reimbursement from Medicare for engaging in national organ donor awareness campaigns. Health Resources and Services Administration (HRSA) is authorized, on behalf of the Secretary of Health and Human Services, to develop a public awareness program that partners with existing national campaigns to inform the public about organ donation.[650] In the past, HRSA received Federal funding for public awareness of organ donation programs.[651] Additionally, some of HRSA's past public outreach activities have consisted of developing and disseminating consumer-focused materials, including downloadable posters; fact sheets and brochures; radio, print, and television Public Service Announcements; educational videos; paid media advertisements; radio media tours; billboards, wall graphics at major airports, and social media messages.[652] HRSA currently manages ongoing resources such as *Organdonor.gov,* the U.S. government's central resource for comprehensive, trusted information on organ, eye, and tissue donation and uses this website to educate the public, encourage donor registration, and

[644] *https://spectrumnews1.com/ca/southern-california/news/2021/07/09/parade-float-builder-faces-steep-costs-as-rose-parade-preparations-begin#:~:text=Estes%20said%20each%20float%20takes,ranges%20from%20%24125%2C000%20to%20%24500%2C000.*

[645] *https://oig.hhs.gov/oas/reports/region9/90800033.pdf.*

[646] Id.

[647] Id.

[648] *2025 National Survey of Organ Donation Attitudes and Practices Report of Findings.*

[649] *https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#.*

[650] 42 U.S.C. 274f–1(a).

[651] *https://www.congress.gov/bill/108th-congress/house-bill/3926/text/statute?format=txt.*

[652] *https://www.govinfo.gov/content/pkg/CMR-HE20_9000-00192981/pdf/CMR-HE20_9000-00192981.pdf.*

provide access to a library of outreach and educational materials.[653] OPOs are permitted to use HRSA's outreach materials library to access free educational resources for organ donation awareness activities. We believe utilizing these materials may represent more cost-effective methods of increasing awareness than sponsoring national entertainment-oriented events that incur substantial expenditures. Considering the past Federal expenditures and ongoing efforts from HRSA for national public awareness, it seems that an individual OPO's request for reimbursement from Medicare for national-level outreach activities of a similar nature may be duplicative of HRSA's efforts for national awareness purposes.

We are committed to carefully and responsibly stewarding the tax dollars in the Medicare Trust Fund, and do not believe that providers should be claiming unreasonable, non-allowable, or non-reimbursable costs for reimbursement under Medicare on the Medicare cost report. Therefore, in the proposed rule, we proposed to codify existing policy set forth in PRM–1, chapter 21, sections 2102.3 and 2105.8, while also providing greater specificity regarding unallowable entertainment costs for providers, including to specify that such unallowable costs include sponsorship of sporting events, teams or athletes, including race car drivers or motorsports activities, retreats held at spas or luxury resorts, spa services or treatments, and recreational excursions. In the proposed rule, we also proposed to codify the current policy set forth in the OPO/HCL MCR;[654] in doing so, we also proposed to provide greater specificity regarding allowable public education costs for OPOs.

Specifically, we proposed to add § 413.5(c)(10) to specify that costs incurred by providers for entertainment, including costs associated with entertainment activities, or that are entertainment in nature, are not allowable costs. We also proposed to add § 413.5(c)(10)(i) to specify that—(1) paragraph (c)(10) includes costs that OPOs incur to engage in public education to increase awareness of organ donation and increase donor registration; and (2) non-allowable entertainment costs include, but are not limited to the following:

- Tickets, admission fees, or entry to sporting or other events, including national or professional sporting events.
- Sponsorship of sporting events, teams or athletes, including race car drivers or motorsports activities.
- Sponsorship of floats in national parades.
- Concert, theater, or performing arts events, professional musicians or other entertainers.
- Wine tours or alcoholic beverages.
- Retreats held at spas or luxury resorts, spa services or treatments.
- Golf outings, ski trips, cruises and similar recreational excursions.

In the proposed rule, we also proposed to add § 413.5(c)(11) to specify that costs incurred by an OPO to engage in public education within its donation service area to increase awareness of organ donation and increase donor registration are allowable if they are reasonable and do not violate § 413.5(c)(10). We also proposed to amend § 413.402(a) and (d)(2)(v) to cross-reference the policy set forth in § 413.5(c)(11) regarding OPOs' public education costs. We refer readers to section X.D.2.b.(5) for our final policies with respect to our proposals to amend § 413.402(a) and (d)(2)(v).

Additionally, in the proposed rule, we proposed to codify our longstanding policy in PRM–1 chapter 21, section 2102.3 regarding certain unallowable costs incurred by providers for drugs sold to other than patients, fines and penalties, and expenses associated with operating a gift shop. Specifically, we proposed to add § 413.5(c)(17) to specify that costs incurred by providers for drugs sold to other than patients are not related to patient care and are not allowable costs. We proposed to add § 413.5(c)(18) to specify that costs incurred by providers for fines or penalties resulting from Federal, State or local laws are not allowable costs. Lastly, we proposed to add § 413.5(c)(19) to specify that costs incurred by providers for operation of a gift shop are not allowable costs. We refer readers to section X.D.2.b.(6) for our final policies with respect to the proposals pertaining to costs incurred by providers for drugs sold to other than patients, fines and penalties, and operation of a gift shop.

Comment: Several commenters supported CMS's efforts to responsibly fund OPOs' public education and outreach on organ donation awareness. A commenter noted that CMS's proposals pertaining to public outreach, sponsorship and staff training costs, reflected the national priority of eliminating fraud, waste and abuse in healthcare, ensuring taxpayer and beneficiary dollars are being used appropriately and responsibly. Additionally, a few commenters remarked that the disallowance of pure entertainment expenditures is consistent with longstanding Medicare cost principles and raises no operational concern for well-managed OPOs. Lastly, another commenter pointed out that prohibiting activities, such as marketing events and entertainment, as unallowable costs is an important step in protecting the financial integrity of the system.

Response: We thank the commenters for their support.

Comment: Most commenters opposed CMS's proposal to add § 413.5(c)(10) to specify that entertainment-related OPO public education activities on organ donation awareness and registration, including sponsorship of sporting events, are not allowable costs. Many commenters were concerned that under the proposal CMS would broadly disallow the costs for all sponsorships of sports teams and events, as well as the costs for public education activities based on the venue type and audience size rather than on the nature and substance of the OPO public education activities themselves.

A commenter contended that CMS's classification of sporting event sponsorships as 'entertainment' under section 1861(v)(8)(i) of the Act is inconsistent with the statutory text and suggested while the statute prohibits entertainment, including tickets to sporting and other entertainment events, it does not prohibit use of a sporting venue for delivering public education. The commenter concluded that CMS's proposed expansion of ''entertainment'' is not the best reading of the statute under *Loper Bright Enterprises* v. *Raimondo,* 603 U.S. 369, 400 (2024). Additionally, the commenter believed that the term ''entertainment'' in the Medicare statute (42 U.S.C. 1395x(v)(8)) should be interpreted consistently with its definition under the Internal Revenue Code (26 U.S.C. 274(a)(1)(A)), which defines entertainment as activities generally considered to constitute amusement or recreation. The commenter suggested, under the established legal canon that Congress typically assigns the same term the same meaning across statutes, ''entertainment'' should mean activities whose inherent purpose is amusement or recreation not public education provided at a venue that offers entertainment. Additionally, the commenter contended that even if the OPO's sponsorship-based activities have an incidental connection to entertainment, the associated costs should not be deemed unallowable under the primary purpose test applied in prior Agency decisions (the primary

[653] *https://www.organdonor.gov/professionals/outreach-materials.*

[654] PRM–2, chapter 33, section 3304, Worksheet A, line 11.

purpose test from *Piedmont Hospital,* PRRB Hearing Dec. No. 82–D14 (Nov. 13, 1981) and *Rancho Los Amigos,* HCFA Administrator Decision (Jan. 3, 1986).

Response: We appreciate the comments received on our proposal to specify that entertainment-related OPO public education activities on organ donation awareness and registration, including sponsorship of sporting events, are not allowable costs. Although the statutory text at section 1861(v)(8)(i) of the Act designates entertainment as an item unrelated to patient care, including tickets to sporting and other entertainment events, we believe the reference to ''tickets to sporting and other entertainment events'' is illustrative, not exhaustive. The word ''including'' signals a non-limiting list, and the Secretary's authority to define the broader category of ''entertainment'' extends beyond the specific examples provided in the statute.

Regarding the commenter's claim that CMS's interpretation under *Loper Bright* is not the best reading of the statute, and their request that CMS adopt the same meaning of entertainment as what is defined in the Internal Revenue Code, we disagree with the commenter's assertions. We believe our proposal is grounded in Medicare's longstanding authority under 42 U.S.C. 1395x(v)(1)(A) to define and establish principles for Medicare's reasonable cost reimbursement. We also note that the Supreme Court has recognized that ''the meaning of a word cannot be determined in isolation but must be drawn from the context in which it is used.''—*Deal* v. *United States,* 508 U.S. 129, 132 (1993). The Medicare statute and the Internal Revenue Code serve fundamentally different purposes. Moreover, with respect to the term ''entertainment'' itself, the IRS code is directed at entertainment, amusement, or recreation (importantly, not defining entertainment as amusement or recreation). This contrasts with the Medicare statute where Congress uses the one term, entertainment, and includes the example of ''tickets and other sporting events.'' These various formulations of ''entertainment,'' made by Congress in different statutes at different times, sheds little light on what should be considered a reasonable expense in the delivery of healthcare-related services.

Additionally, regarding a commenter's reference to the use of the ''primary purpose'' test as applied by the PRRB when examining the nature and intent of an expenditure in prior Agency decisions, we believe that applying a primary purpose test to our proposal would be inappropriate, subjective and result in an inaccurate policy application. An OPO's public education activities, for Medicare reimbursement purposes, must serve to educate the community regarding organ donation in targeted and meaningful ways, and to sign up as many donors as possible, not to serve as means or venue with respect to an entertainment or sporting event.

Comment: A commenter requested CMS withdraw its proposal, contending the statute was intended to prohibit entertainment consumption, not the use of public venues for targeted donor education. Another commenter suggested that sporting venues can serve as legitimate platforms for public education, citing a CMS Hearing Officer's finding that OPO staff and donor families engaging attendees at staffed sporting venues within their DSA constitutes legitimate public education. The commenters believed that disallowing the costs of public education at all sporting venues would result in missed opportunities for donor registration.

A commenter contended that CMS's categorical prohibition on sponsorship-based public education activities draws arbitrary distinctions unsupported by fact, law, or policy, suggesting that educational activities at larger venues such as stadiums and speedways are functionally identical to those CMS would permit at smaller venues, yet reach larger audiences. Another commenter believed that entertainment costs of a general nature should not be an allowable cost but can be allowable when effectively used for organ donation public education and outreach. Several commenters believed that CMS did not adequately distinguish between permitted ''community outreach'' and disallowed ''entertainment sponsorship,'' particularly in scenarios where OPOs sponsor high-traffic venues and deploy trained staff, donor recipients, and donor families to engage attendees on organ donation and registration. A commenter further emphasized that high-attendance events, such as those at regional colleges or minor league baseball games, especially in non-metropolitan areas, are valuable for building long-term community trust and organ donation awareness, further noting that an event's large scale does not diminish its effectiveness.

Several commenters asked whether CMS's proposal at § 413.5(c)(10)(ii)(B) would apply to sponsorships of locally focused events and teams, including events at universities within their DSA that gain the attention of the OPO's target population yet draw both local and national audiences. A few commenters noted that CMS's own examples of allowable OPO public education activities in the FY 2027 IPPS proposed rule, such as booths at high schools, local colleges, and minor league sporting events, demonstrate that such settings can serve as effective public education vehicles.

A few commenters noted that while their programs are geographically within their DSA, CMS's narrow framing of what qualifies as allowable public education, such as one-on-one engagement, booths, and direct conversations, does not account for programs that are successful, but do not fit CMS's limited examples. The commenters contended that CMS's proposal is focused on the form of expenditure rather than its goal of increasing donor awareness and could potentially disallow costs of activities that serve a public education mission.

Response: We acknowledge the commenters' request to withdraw our proposal and recognize the commenters' assertion that sporting venues can be used to provide public education. We respectfully disagree with the characterization that our proposal reflects arbitrary distinctions that lack basis in fact, law, or policy. We acknowledge the commenters' concern that we did not distinguish between allowable ''community outreach'' and disallowed ''entertainment sponsorship.'' The proposal was not intended to disallow all OPO public education activities at any type of sporting event or venue, rather it seeks to provide a distinction between targeted community-based educational outreach activities where more meaningful individualized conversations can take place with potential organ donors and not large-scale commercial sponsorships of sporting events, athletes, nationally televised parades and sports figures and personalities. We believe that all entertainment costs are unallowable, regardless of the purpose or context in which they are incurred.

We are clarifying that the characterization of entertainment and sponsorship costs as allowable simply because they are associated with public education and community outreach on organ donation does not change their classification. Entertainment and sponsorship remain unallowable and are not subject to exception based on intent or perceived benefit. Additionally, in response to the commenters' concerns surrounding public education activities at sporting

events or high-attendance venues, and events within the OPO's DSA that draw local and national crowds, we are clarifying that entertainment and sporting sponsorship of any kind is not an allowable OPO public education cost.

However, we recognize that opportunities exist for OPOs to conduct focused public education and community outreach at high-traffic venues, including racing venues, national sporting event stadiums, and regional and collegiate venues within their DSA, that attract both local and national audiences. The intent of our proposal was to disallow sponsorships of sports teams, individual athletes and sports figures, race cars, and sponsorship of the venue itself. We do not intend to broadly disallow OPO-staffed, purposeful public education initiatives and activities held at high-traffic or prominent venues, as long as the costs associated with delivering targeted public education is reasonable and does not involve sponsoring the team or venue. OPOs must maintain clear documentation demonstrating that costs claimed as public education are directly tied to organ donation awareness activities and donor registration. Costs associated with sporting event sponsorships, even those with an educational component, must be allocated appropriately on the Medicare cost report, with only the portion directly attributable to legitimate public education being potentially allowable.

Comment: A commenter requested CMS further define and clarify what constitutes a ''national'' parade and believed it would be irresponsible to sponsor a float in the Macy's Thanksgiving Day Parade. Specifically, the commenter sought clarification on whether sponsoring a float in a large-scale regional parade that takes place within the organization's DSA is an allowable cost.

Response: We appreciate the commenter's request for clarification regarding what constitutes a national parade. We agree that sponsoring a float in the Macy's Thanksgiving Day Parade would not be an allowable cost. We similarly believe that sponsorship of a float in the Rose Bowl Parade or of similar scale and nature of the Rose Bowl Parade would not be an allowable cost. After further consideration of comments, we believe that clarification is necessary as our intention was to allow OPOs to participate in small, local community-based types of events. We believe that both large-scale regional and national parades are of a similar scale and nature and therefore, these types of parades, float sponsorships and parade activities are not allowable costs under Medicare's reasonable cost principles. Parade floats, by nature, are primarily for the purpose of entertainment and performative rather than directly supporting the objectives of an OPO's community-based public education activities to educate individuals about organ donation and register organ donors. Additionally, sponsoring floats can involve considerable costs, such as route permitting fees, float construction and decoration, costumes, and equipment rentals. For these reasons, we believe that costs associated with sponsoring a float, whether for a large-scale regional or national parade, are not allowable under Medicare's reasonable cost principles. Accordingly, we are finalizing our proposal with a modification to specify that the sponsorship of floats in large-scale regional and national parades is not an allowable cost under Medicare. We believe this modification is consistent with the intent of our original proposal and is within the scope of the changes we proposed. We believe that an OPO sponsoring a float in a small-scale regional parade within the OPO's DSA may be allowable, provided the costs are reasonable, the activity is geographically targeted, and it offers opportunities for donor engagement and registration tailored to the DSA's specific needs.

Comment: A few OPOs questioned CMS's assertion in the proposed rule that sponsorship events attracting wide viewership within the DSA do not constitute targeted or measurable public education initiatives and a commenter provided examples of how their sponsorship based-public education provided targeted, measurable education and increased organ donation. The OPO credited its sponsorship-based public education activities as a contributing factor in its advancement in CMS's performance measure ratings, citing this progression as evidence of the effectiveness of broad-reach outreach efforts. Additionally, a few commenters provided examples of the benefits experienced through team or game day sponsorships and claimed such events have enabled them to deliver effective public education on organ donation, including but not limited to, in-person presence at games and events, traditional and social media messaging, signage, handouts, public address announcements at games, sharing donor family messages on jumbotrons and use of team mascots at motor vehicles departments. Additionally, a commenter questioned CMS's categorization of sponsorship costs as entertainment because they include items such as tickets to games and hospitality suites. The commenter stated such costs were identified, assigned a fair market value and then adjusted off their Medicare cost report.

Another commenter asserted that CMS's claim that OPO-sponsored sporting events exceed what a ''cost-conscious buyer'' would spend is contradicted by their own experience. Several commenters claimed that leveraging national sponsorships of sports teams and nationally televised parades allows OPOs to reach significantly more viewers than direct engagement, at a marginal cost, and provided statistics such as media impressions to justify their claim. A commenter suggested CMS has not explained how limiting OPOs to supposedly higher-cost, lower-reach outreach activities aligns with its prudent buyer proposal, suggesting CMS's goal is to cut OPO reimbursement rather than promote reasonableness. The commenter further asserted that Congress directed CMS to pay reasonable cost, not reduce payments, and that CMS has provided no evidence that longstanding principles are no longer effective. Lastly, a commenter contended CMS's own prior guidance acknowledged that ''OPOs need the flexibility to decide how they will use their educational resources'' (71 FR 30982, 31027, May 31, 2006), a position that stands in direct conflict with the proposed ''categorical'' prohibition of sponsorships.

Response: We appreciate the examples commenters shared with us regarding benefits experienced through team or game day sponsorships, which they suggest has enabled them to deliver effective public education on organ donation. Additionally, we acknowledge the commenters' assertions that leveraging national sponsorships of sports teams and nationally televised parades, at a marginal cost, allows OPOs to reach significantly more viewers than direct engagement, along with the statistical evidence submitted by a few commenters in support of this claim. We do not believe that our proposal would require OPOs to engage in supposedly higher-cost, lower-reach public education activities, nor do we believe our proposal does not align with our prudent buyer proposal. While we acknowledge that leveraging a professional sports team's social media platform or sponsoring a float in a nationally televised parade may offer a

broad reach, the overall cost structure of such sponsorship arrangements such as naming rights, promotional fees, sponsorship salaries paid to athletes and sports figures, and associated expenses, must be considered unallowable costs under Medicare's reasonable cost principles. These sponsorship arrangements are primarily for the purpose of promotional or sporting activities, rather than directly supporting the objectives of an OPO's community-based public education activities to educate individuals about organ donation and sign up organ donors and are not allowable costs under Medicare's reasonable cost principles. We believe that it is difficult to determine the effectiveness of public education when those efforts are generalized and lack direct interaction or a targeted audience.

We continue to believe that OPOs' systematic identification of donation barriers, paired with targeted public education initiatives, can increase donor registration rates among specific populations. We are also affirming that OPOs should retain meaningful flexibility in determining how to deploy their educational resources. However, that flexibility must operate within Medicare's reasonable cost principles that protect the integrity of federal funding. This final rule seeks to establish those boundaries in a clear and consistent manner, ensuring that public education expenditures remain aligned with the core mission of increasing organ donation rates rather than subsidizing broad commercial entertainment and sporting events and partnerships. By contrast, sponsorship arrangements with major professional sports franchises and large commercial venues involve financial commitments of a fundamentally different scale and nature, which warrants closer scrutiny to ensure that public funds are being used appropriately. As recipients of federal funds, OPOs are held to a standard of fiscal responsibility. Furthermore, we note that Medicare does not dictate or restrict an organization's decision to enter into sponsorship arrangements, or sponsor a sports team; however, such sponsorship or entertainment costs are not allowable under the Medicare program and must not be claimed as reimbursable costs on the Medicare cost report.

We appreciate the commenters' concerns regarding sponsorship costs that include tickets and the commenter that indicated unallowable costs such as tickets to games and hospitality suites were adjusted off their Medicare care report. We are reiterating that providers must ensure that all unallowable costs, such as tickets, alcoholic beverages, box suites, entrance to hospitality suites, pit lane and garage tours, are properly excluded from the Medicare cost report, as including such costs, whether directly or indirectly, may result in inaccurate payment or a future disallowance during cost report reconciliation. Adequate documentation must be maintained to support the proper treatment of these costs, including records demonstrating that unallowable costs have been excluded and that any donations related to allowable costs have been appropriately offset. This documentation must be available for review upon request by CMS in accordance with the regulations at §§ 413.20 and 413.24.

Comment: Several commenters suggested CMS adopt alternative approaches, such as a principles-based framework that allows CMS to articulate targeted accountability mechanisms, and a substance-based test for cost allowability, that evaluates whether an expenditure supports structured educational engagement through factors such as staffed presence, distribution of educational materials, active outreach, and donor registration tracking rather than broadly disallowing costs. A few of the commenters requested that sponsorship fees that enable meaningful donor education be treated differently from fees that simply place an OPO's name on a scoreboard. A commenter urged CMS to set clear expectations for large-scale events rather than broadly disallowing their costs, suggesting measurable requirements, such as branded apparel with donor registration QR codes or tracking one-on-one conversations, and the establishment of allowable marketing materials to promote financial stewardship and consistent compliance.

Response: We appreciate the commenters' suggestion to establish a substance-based test and accountability framework to reach the broad goals of supporting the OPO's mission of increasing organ donation, while increasing fiscal accountability, and maintaining stewardship of the Medicare trust fund. Additionally, we appreciate the examples provided by commenters to help demonstrate impact of the public education activity. We also acknowledge the commenter's request to allow sponsorship fees that allow for meaningful donor education to be treated differently from fees that merely place an OPO's name on a scoreboard. We agree with the commenter that placing an OPO's name on a scoreboard does not constitute meaningful donor engagement and education.

We are affirming our statement and examples provided in the proposed rule that we believe allowable costs under Medicare for OPO public education initiatives include costs that directly support organ donation and align with Medicare's reasonable cost principles. Examples would include OPOs' participation and engagement in settings that can facilitate direct conversations with individuals regarding organ donation and provide opportunities to register donors and track the number of registrations obtained during each effort such as, setting up booths at local farmer's markets, health fairs, high school or local college events, partnering with community organizations, faith-based groups, schools and health care facilities, participating in local multicultural festivals, as well as providing education at driver's education programs and at local Department of Motor Vehicles (DMV) and Department of Natural Resources so that individuals can register to become an organ donor while obtaining a driver's license or fishing license. We believe the OPO staff should be available to discuss, educate and answer questions directly about the organ donation process and may provide modest token items and educational materials to individuals to support organ donation awareness (for example, pens, awareness bracelets, buttons, stickers, cups, or electronic and print materials that include the OPO's website address, QR codes linking to donor registration platforms, or information on upcoming community-based organ donation awareness events) to represent the mission-driven engagement that is consistent with the responsibilities of OPOs and responsible stewardship of the Medicare Trust Fund.

In general, for OPO public education costs to be considered allowable, such costs must not be incurred for entertainment, including sponsorship of sporting events, teams or athletes. CMS expects public education costs to be targeted public education efforts, where OPO staff are present to engage individuals on organ donation awareness and register potential organ donors; these costs must be reasonable and necessary, and must be distinct from entertainment such as tickets, hospitality or team sponsorships. The OPO must provide adequate documentation in accordance with 42 CFR 413.20 and 413.24, to demonstrate that costs of public education activities are directly tied to organ donation awareness activities and donor registration. We believe this

requirement, in addition to the examples we provided, promotes transparency, accountability and fiscal responsibility regarding OPO public education costs.

After consideration of the comments received, we are finalizing our proposal at 42 CFR 413.5(c)(10) to specify, costs incurred by providers for entertainment, including costs associated with entertainment activities, or that are entertainment in nature, are not allowable costs. We are also finalizing our proposal at § 413.5(c)(10)(i) to specify costs as described in § 413.5(c)(10) that OPOs incur to engage in public education to increase awareness of organ donation and increase donor registration are non-allowable costs. Additionally, we are finalizing § 413.5(c)(10)(ii)(C) with a modification to specify costs incurred for sponsorship of floats in large-scale regional and national parades are not allowable costs. With this modification, § 413.5(c)(10)(ii) specifies non-allowable entertainment costs include, but are not limited to the following:

- Tickets, admission fees, or entry to sporting or other events, including national or professional sporting events.
- Sponsorship of sporting events, teams or athletes, including race car drivers or motorsports activities.
- Sponsorship of floats in large-scale regional and national parades.
- Concert, theater, or performing arts events, professional musicians or other entertainers.
- Wine tours or alcoholic beverages.
- Retreats held at spas or luxury resorts, spa services or treatments.
- Golf outings, ski trips, cruises, and similar recreational excursions.

Comment: Regarding our proposal at 42 CFR 413.5(c)(11) pertaining to allowable OPO public education costs within an OPO's DSA, a few commenters noted that allowability of community-based educational outreach within a DSA is appropriate; however, some requested clarification or modification of certain provisions to avoid unintended consequences related to the core activities of OPOs. A commenter supported requirements that strengthen and standardize public education activities within the DSA such as targeted outreach, education, and community partnerships. The commenter indicated that focused DSA engagement fosters public trust, promotes consistent donor awareness, improves authorization rates, and reinforces equitable access to donation opportunities across diverse populations. Additionally, the commenter noted such requirements align with broader system goals of transparency and improved donation outcomes.

Many commenters expressed concern that if CMS's proposal prohibited broad reaching public education activities, such as social media campaigns, the effectiveness of public education programs could be undermined, resulting in fewer donor registrations. Several commenters noted that disinformation and skepticism continue to undermine the donation process despite increased public awareness, urging CMS to continue allowing broad-reaching public education activities. Many commenters noted that CMS's proposal did not account for the nature of digital content and social media, which extends beyond an OPO's DSA or that organ donor registration and family authorization typically require multiple interactions across diverse channels over time. Another commenter suggested that because individuals may learn about organ donation through many channels, the 2025 National Survey of Organ Donation Attitudes and Practices cited by CMS in the FY 2027 IPPS proposed rule, should not be used to dismiss the impact of the Rose Bowl Parade or other entertainment-based awareness campaigns may have on individuals' decisions to register as organ donors.

A commenter suggested CMS's proposal to limit outreach to local, one-on-one engagement, and require donor registration opportunities, on-site OPO staff, and allow for modest giveaways incorrectly assumes face-to-face engagement is the primary driver of donor registration. The commenter cited examples of OPO paid media and social media campaigns that ran alongside increases in donor registration rates. Another commenter supported CMS's goal of funding public education on organ donation but contended that traditional outreach methods, such as farmer's market booths, health fairs, and multicultural festivals, may no longer be sufficient or cost-effective given rising donation after circulatory death (DCD) rates and declining public sentiment toward organ donation. Many commenters claimed broader community engagement strategies, such as billboards, radio campaigns, school-based education, and donor recognition events are allowable costs. These commenters stated that broader reaching engagement is often more cost-effective than one-time events and requested CMS clarify that these costs continue to be allowable Medicare costs.

Response: We appreciate the comments received regarding our proposal at 42 CFR 413.5(c)(11). Additionally, we agree with the commenter's assertion that focused DSA engagement fosters public trust, promotes consistent donor awareness, improves authorization rates, and reinforces equitable access to donation opportunities across diverse populations. We acknowledge commenters' concerns that our proposal could undermine an OPO's public education programs and could result in fewer donor registrations. We appreciate the commenters' detailed feedback regarding our proposal and the examples provided by some OPO's of their broad reaching public education efforts. Additionally, we note that donor recognition events are not, and have never been, allowable organ acquisition costs under Medicare, as discussed further below in this section.

We continue to believe that the OPOs' primary objective should be DSA focused, community-based public education efforts. We believe these targeted engagements are best positioned to address the needs of the local community and are effective to increase donation awareness and donor registration in the OPO's DSA. However, based on commenter's feedback, we recognize that certain broad reaching public education strategies, such as online campaigns, can serve as effective tools for increasing donor registration and awareness, if the costs of such activities align with Medicare's reasonable cost principles and do not serve an entertainment purpose, and that narrowing outreach efforts to local, one-on-one engagement may not reflect the full range of reasonable and effective OPO public education strategies. Accordingly, based on commenters' suggestions, we agree that such activities may include, but are not limited to, community-based events, local school education programs, local driver's education programs, partnerships with driver's license bureaus, workplace outreach initiatives, faith-based outreach programs, radio and social media campaigns and billboards within the DSA. We believe these types of public education activities must not be entertainment related or include sponsorship costs, or salaries paid to sponsor individuals such as public figures, celebrities, or athletes. These activities must be targeted to the OPO's DSA community and designed to increase donor registration awareness within the OPO's DSA. Furthermore, to be allowable, such public education activities must meet Medicare's reasonable cost principles and must be documented in accordance with 42 CFR 413.20 and 413.24.

Comment: A commenter noted that the ''December 2020 Final Rule''

focused on two outcome measures: donation rate and transplantation rate and in that Final Rule, CMS noted that OPOs can adopt policies and practices responsive to the community they serve and have better results. The commenter suggested that this position, and the GAO's benefit-to-cost ratio provided in the Final Rule, implies public education is a means for meeting these goals. The commenter contended that categorially disallowing broad-reaching public education activities risks destabilizing the benefits CMS counted on to justify the December 2020 Final Rule. The commenter requested CMS withdraw its proposal to limit allowable OPO public education to face-to-face interactions only, contending that this limitation contradicts the evidentiary record, conflicts with CMS's own prior guidance, and would eliminate the broad-reach education methods that have demonstrated the greatest effectiveness in supporting organ donation.

Response: Regarding the commenter's concerns specific to the December 2020 Final Rule and the role of public education in supporting donor registration efforts, we acknowledge that the December 2020 Final Rule recognized the importance of public education in driving donor registration. However, we respectfully disagree with the commenter's suggestion that our proposal risks destabilizing the benefits CMS counted on to justify the December 2020 Final Rule and request to withdraw our proposal. Rather, we believe that focusing OPO resources on targeted, DSA public education activities, while allowing certain broad reaching public education activities within the OPO's DSA, will strengthen the effectiveness of donor registration efforts, comport with Medicare's reasonable cost principles, and ensure that public funds are used responsibly and efficiently.

Comment: Several commenters appreciated and supported HRSA's organ donation campaigns and indicated that HRSA alone does not provide sufficient public education, awareness, or donor engagement resources to support nationwide donor registration efforts. These commenters noted that OPOs' complementary national, and local, outreach activities such as high school and driver's education programs and partnerships with driver's license bureaus, workplaces, faith-based outreach, media relations should continue to be recognized as allowable costs. Several commenters urged CMS to preserve flexibility for national initiatives to the extent they are not duplicative of HRSA's existing nationwide donation campaigns, and few commenters suggested CMS establish guardrails to ensure an OPOs national education efforts do not duplicate HRSA's efforts.

Response: We acknowledge and understand the concerns raised by some commenters that HRSA alone does not provide sufficient public education, awareness, or donor engagement resources to support nationwide donor registration efforts. Additionally, we recognize that an OPO's broad reaching, public education activities, when provided in parallel to HRSA's national awareness programs, are critical to supporting donor registration efforts and should be recognized as allowable costs. We agree with commenters that OPO public education and outreach efforts must not duplicate HRSA's efforts and acknowledge their request to establish guardrails to prevent duplication.

To address commenter's concerns regarding the establishment of guardrails, we believe that OPO's must ensure their public education activity is targeted to the OPO's DSA and may consider including details such as DSA-specific demographics, regional statistics and cultural considerations aimed at increasing organ donor registration within its DSA to differentiate its activities from HRSA's efforts. In accordance with 42 CFR 413.20 and 413.24, providers are required to maintain auditable and verifiable information and make information available to the Medicare contractor upon request. As such, we believe it is appropriate to require OPO's to conduct and document a review of HRSA's current social media activities, including content published on HRSA's official channels (for example, *organdonor.gov*, HRSA social media platforms) to ensure the OPO's broad reaching public education activity is targeted to its DSA community, rather than duplicating HRSA's national efforts.

Comment: Many commenters urged CMS to preserve OPO public awareness and education resources for donor families and expressed concern that new limitations on allowable outreach and education costs may limit capacity to educate hospital staff and decrease hospital referrals, limit effectiveness of public education and donor family support, ultimately lessening the number of lifesaving organs that can be recovered. Several commenters requested CMS confirm that the costs of donor family support and outreach activities remain allowable costs, while other commenters requested CMS allow costs of aftercare and bereavement services for families, such as donor family support and outreach, and donor recognition and remembrance events as allowable costs. Some commenters suggested activities such as providing public and professional education and donor family aftercare are explicitly required under federal regulations and contended that it is unreasonable to require OPOs perform such services but not reimburse them. Lastly, several comments reflected donor-family narratives and sentiments regarding their experience with organ donation, rather than specific proposals, and were outside the scope of this rulemaking.

Response: We appreciate the comments regarding the importance of OPO provided education and family support services. We believe that our final policies will continue to allow OPOs to provide public education, awareness and outreach to potential donors and donor families in accordance with existing public education requirements. Additionally, we appreciate the commenters' feedback regarding bereavement and aftercare services and acknowledge the important role these services play in supporting donor families during an incredibly difficult time. However, we respectfully disagree that aftercare and bereavement services are allowable organ acquisition costs under the Medicare program. While we recognize the compassionate intent behind providing bereavement and aftercare services to donor families, these services are provided after the organ procurement process is complete. We believe it would not be an appropriate use of the Medicare trust fund to reimburse such services, as organ acquisition costs. Accordingly, we maintain that bereavement and aftercare services for donor families are not, and have never been, allowable organ acquisition costs under the Medicare program.

After consideration of the comments received, we are modifying our proposal at 42 CFR 413.5(c)(11) to allow the costs of certain broad reaching public education activities within an OPO's DSA. Specifically, costs incurred by an OPO to engage in public education within its DSA, including public education activities designed to reach a broad audience within its DSA, such as but not limited to, billboards, radio advertisements, and social media campaigns, to increase awareness of organ donation and increase donor registration within its DSA are allowable if they are reasonable, and do not violate § 413.5(c)(10).

(3) Activities for Employees and Non-Employees of the Provider

The PRM–1, chapter 21, section 2105.8 sets forth that ''Costs incurred by providers for entertainment, including tickets to sporting or other events, alcoholic beverages, golf outings, ski trips, cruises, professional musicians or other entertainers, are not allowable.'' We continue to believe that these costs are appropriately excluded from allowable costs. However, PRM–1, chapter 21, section 2105.8 also states that ''Costs incurred by providers for purposes of employee morale, specifically, for an annual employee picnic, an annual Christmas or holiday party, an annual employee award ceremony or for sponsorship of employee athletic programs (for example, bowling, softball, basketball teams, etc.), are allowable to the extent that they are reasonable.'' After further consideration, we stated in the proposed rule that we believe that costs incurred by providers for events for their employees and non-employees such as employee picnics, parties, award ceremonies or for the sponsorship of employee athletic programs should not be allowable costs under Medicare, as they are not costs a provider incurs to provide patient care. While we understand the significance of employee events provided by providers for their employees' morale, we stated in the proposed rule that we believe that costs associated with employee and non-employee entertainment do not coincide with Medicare's reasonable cost principles and are not costs related to patient care as required under 42 CFR 413.9.

We noted that there are many cost-effective methods for improving employee morale that do not require entertainment expenses. Flexible work schedules, wellness programs, recognition for achievements, and creating a positive workplace culture are just a few examples of ways to support employees without impacting healthcare resources. (These items are separate from a provider's cost of fringe benefits provided to employees under the PRM–1, chapter 21, section 2144.4 that may be recognized as a provider's costs for Medicare reimbursement purposes. Employee fringe benefits that are part of a formal written policy and considered reasonable compensation (for example, health insurance, retirement plans) are generally allowable costs under Medicare.)

Therefore, in the proposed rule we proposed to change the current policy provided in PRM–1, chapter 21, section 2105.8 to disallow costs incurred by providers for employees or non-employees or anyone for entertainment expenses for employee entertainment activities and employee morale, including but not limited to those set forth in PRM–1, chapter 21, section 2105.8, because they are not related to providing patient care. Specifically, we proposed to add 42 CFR 413.5(c)(12) to specify that costs incurred by providers for anyone for purposes of employee and non-employee entertainment activities and employee morale, which include, but are not limited to, picnics, parties, performers, entertainment, award ceremonies, or the sponsorship of scholarships or athletic programs are not allowable costs.

Comment: Most commenters, the majority of which were OPOs, opposed our proposal to disallow costs for employee morale and engagement activities. These commenters disagreed with CMS's view that costs for employee morale and engagement do not coincide with Medicare's reasonable cost principles and are not costs related to patient care under 42 CFR 413.9. Most commenters suggested employee morale and engagement activities are necessary for recruiting and retaining highly specialized staff. A few commenters believed that retention also directly affects patient outcomes and suggested that experienced staff are essential to maximizing the number of viable organs recovered for transplantation. A commenter suggested CMS's proposed policy change to disallow costs incurred by providers for employee or non-employee entertainment activities that are intended to boost employee morale would be counter-intuitive to CMS's goals of encouraging cohesiveness and collaboration within the organ transplantation system. An OPO commented that costs associated with employee morale should be allowable indirect costs and suggested that retaining experienced staff directly affects the quality and volume of organ procurement. The commenter cited a 2009 *American Journal of Transplantation* study to support its position that such costs should be allowable indirect costs. Another commenter suggested that under § 413.9(b)(1), reasonable costs include both direct and indirect costs, and that employee morale activities, while not directly tied to OPO operations, fall within the existing regulatory framework for allowable indirect costs.

Some commenters acknowledged CMS's examples in the FY 2027 IPPS proposed rule of cost-effective methods for improving employee morale such as flexible work schedules, wellness programs, recognition for achievements and positive workplace culture; however, these commenters suggested that, because OPO employees often encounter unpredictable schedules, long hours, and last-minute travel, traditional flexibility and wellness programs are difficult to implement, and employee engagement activities are a necessary substitute for work-life balance provisions available in other healthcare settings. A few commenters suggested that employee morale initiatives may be more cost-effective than recruiting, onboarding and training new hires. A commenter suggested that CMS has not provided any evidence of OPOs that have engaged in extravagant OPO spending for employee morale activities to justify the proposal to disallow all employee morale related costs, and a few commenters suggested, rather than disallowing all employee morale costs, CMS should use the existing ''substantially out of line'' standard to distinguish excessive or entertainment related costs, as well as provide guidance to the Medicare contractors regarding allowable employee morale costs.

Several commenters supported establishing reasonable guardrails on employee engagement spending but opposed overly restrictive limits, and suggested that effective retention requires ongoing, team-based recognition activities. Some commenters suggested that CMS establish reasonable parameters for allowable employee morale and engagement costs, including consideration of federal per diem principles where appropriate and a few of these commenters suggested parameters are critical under a potential zero-margin reimbursement methodology for OPOs, where limited reimbursement could severely hinder recruitment and retention of clinical and non-clinical staff performing demanding, unpredictable work. The majority of commenters urged CMS to retain its current standard of allowing de minimis or reasonable costs associated with employee engagement, morale, and retention when those costs are modest, mission-related, and consistent with prudent non-profit management.

Response: We appreciate the detailed feedback provided by commenters regarding our proposed disallowance of costs associated with employee morale activities. We acknowledge the commenters' concerns regarding workforce retention, cost effectiveness, and unique operational demands of OPOs. In addition, we agree with the commenters' assertion that such costs are indirect costs of doing business. We

also agree that 42 CFR 413.9(c) provides the regulatory limitations sufficient to address excessive employee morale and engagement costs, and combined with continued Medicare contractor oversight, is the appropriate mechanism for addressing any excessive expenditures associated with employee morale and engagement activities. However, under Medicare reasonable cost reimbursement, we believe that any employee morale and engagement activities must be limited to employees of the provider.

Regarding commenters' request for CMS to set parameters for allowable employee morale and engagement costs, we agree that consideration of federal per diem principles, where appropriate, provides a workable and objective benchmark for determining the allowability of such costs. We recognize that de minimis or modest costs for employee morale activities, such as picnics, parties and award ceremonies, may be allowable costs under section 1861(v)(1)(A) of Act. We believe such costs must be reasonable in amount, and not lavish, extravagant, or substantially out of line with costs incurred by comparable organizations; consistent with prudent nonprofit management; reasonably related to engagement of employees necessary to carry out the provider's mission; and properly documented in accordance with 42 CFR 413.24. Consistent with our proposal in the proposed rule, we continue to believe costs incurred by providers for entertainment or performers are not allowable costs in accordance with section 1861(v)(1)(8) of the Act.

After careful consideration of the comments received, we are finalizing our proposal with modification at 42 CFR 413.5(c)(12) to specify that de minimis or modest costs incurred by providers for employees for purposes of improving employee morale are allowable costs, provided that such costs do not violate the limitations set forth in 42 CFR 413.9(c).

(4) Alcoholic Beverages

The PRM–1, chapter 21, section 2105.8 sets forth that costs incurred by providers for alcoholic beverages are not allowable. Additionally, PRM–1, chapter 21, section 2102.3 sets forth that a provider's ''cost of alcoholic beverages furnished to employees or to others regardless of how or where furnished, such as cost of alcoholic beverages furnished at a provider picnic or furnished as a fringe benefit, are not allowable in computing reimbursable costs.'' Three OIG reports have found that some OPOs have included costs for furnishing alcohol in their MCRs, despite these prohibitions outlined in the PRM–1.[655] We have also seen instances of this in certain reimbursement appeals. A provider's costs to furnish alcohol to anyone are not related to patient care and are not appropriate, necessary, or proper in developing and maintaining the operation of patient care facilities and activities. Therefore, in the proposed rule, we proposed to codify these longstanding provisions into the regulations by adding § 413.5(c)(13) to specify that costs incurred by providers to furnish alcoholic beverages to anyone are not allowable costs.

Comment: All commenters agreed that costs incurred by providers to furnish alcoholic beverages are not allowable costs under Medicare. Some commenters emphasized that alcohol-related incidents involving OPO staff, patients, families, and others should be investigated and that individuals who violate this guidance should be held appropriately accountable. However, a commenter opposed codifying this requirement in regulation, noting that under PRM–1, chapter 21, section 2102.3, these costs are already clearly non-allowable. The commenter believed that CMS's example in the proposed rule does not reflect a widespread issue, and suggested, rather than codifying this requirement, OPOs should strengthen their internal controls to prevent such costs from being inadvertently reported on the Medicare cost report.

Response: We appreciate the commenters' feedback and support of our proposal. We believe that all providers, including OPOs, should strengthen internal controls to prevent unallowable costs from being reported on the cost report; however, we respectfully disagree with the commenter's position that codification of this provision is unnecessary. We believe that while PRM–1, chapter 21, section 2102.3 already identifies these costs as non-allowable, codifying this policy in regulation provides explicit regulatory clarity, promotes uniform compliance across all providers, strengthens CMS's ability to enforce accountability and serves as a proactive measure to deter future occurrences, regardless of their prevalence. After consideration of the public comments we received, we are codifying our proposal as proposed at § 413.5(c)(13), to specify that costs incurred by providers to furnish alcoholic beverages to anyone are not allowable costs.

(5) Professional Education and Travel

(a) Costs for OPO Professional Education

Regarding allowable professional education costs for OPOs, under section 371(b)(3)(B) of the PHSA, OPOs are responsible to ''conduct and participate in systematic efforts, including professional education, to acquire all useable organs from potential donors,'' and ''assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.'' Medicare has recognized the costs incurred by OPOs' for providing professional education for increasing organ donation awareness and acquiring organs for transplantation as allowable costs, if such costs are reasonable, necessary and related to patient care. OPOs include professional education costs as OPO overhead costs on the OPO/HCL MCR, and Medicare shares in these costs. The current guidance regarding allowable professional education costs is set forth in the OPO/HCL MCR and includes, ''costs associated with the education of donor hospital personnel and physicians, including the expenses of meetings, seminars, slide shows, and presentations.'' [656]

In 2023, the OIG reviewed OPOs' expenses and found that Medicare paid for costs incurred for professional and public education activities that did not meet Medicare requirements.[657] The OIG recommended CMS update the applicable requirements to clarify what types of professional and public education costs are unallowable.[658] We note that we discuss public education costs in section X.D.2.b.(2) of the preamble of this final rule. In the proposed rule, we proposed to establish in regulation that the types of professional education provided by OPOs to the clinical staff of hospitals should be focused on organ donation to acquire all usable organs from potential donors in accordance with section 371(b)(3)(B) of the PHSA.

In response to comment in the FY 2022 IPPS/LTCH PPS final rule with comment period, we stated that costs of an OPO-sponsored seminar that does not provide continuing education credits, regardless of whether the seminar is provided to the OPO staff, may be an allowable cost if it relates to

[655] *https://oig.hhs.gov/oas/reports/region9/90800033.pdf; https://oig.hhs.gov/oas/reports/region9/90900087.pdf; https://oig.hhs.gov/documents/audit/9634/A-09-21-03020-Complete%20Report.pdf.*

[656] PRM–2, chapter 33, section 3304, Worksheet A, line 10.

[657] *https://oig.hhs.gov/reports/all/2023/medicare-paid-independent-organ-procurement-organizations-over-half-a-million-dollars-for-professional-and-public-education-overhead-costs-that-did-not-meet-medicare-requirements/.*

[658] Id.

patient care and meets the requirements at 42 CFR 413.9. (see 86 FR 73476). In the proposed rule we provided additional specificity regarding both the nature of the education offered at OPO-sponsored seminars and the intended audience for such seminars as referenced in our previous statement. In the proposed rule, we stated, OPO-sponsored seminars may include meetings, presentations, and other professional education activities that do not offer continuing education credits, provided to clinical staff such as OPO personnel, donor hospital staff, and physicians and the content is directly related to organ donation and the acquisition of all available organs for transplantation. These costs must meet Medicare's reasonable cost principles and be related to patient care as set forth at § 413.9. Therefore, in accordance with OIG's recommendations regarding clarification of allowable professional education costs, in the proposed rule, we proposed to codify existing policy, with certain modifications to provide greater specificity, set forth in OPO/HCL MCR instructions and requirements under section 371(b)(3)(B) of the PHSA regarding OPO professional education costs.

In the proposed rule, we proposed to add new § 413.9(c)(14)(i) to specify that the costs incurred by OPOs for professional education such as meetings, seminars, and presentations on organ donation to acquire all useable organs from potential donors, where continuing education credits are not given and where the attendee is clinical staff such as OPO staff, donor hospital staff, and physicians, are allowable costs.

Additionally, in response to a comment in the FY 2022 IPPS Final Rule with comment period, (86 FR 73476), we stated, the reasonable cost of an OPO-sponsored seminar that provides continuing education credits, may be an allowable administrative and general cost limited to the OPO staff (as described at § 486.326(b)) if the seminar is related to patient care and meets the requirements at § 413.9. In the proposed rule, we proposed to codify the existing policy regarding allowable costs of OPO-sponsored seminars where continuing education credits are given to the OPO staff. Specifically, we proposed to add new paragraph (c)(14)(ii) to specify, the costs for OPO-sponsored seminars where continuing education credits are given and where the attendee is on the OPO staff are allowable costs to the extent that they are patient care related, reasonable and necessary and we also proposed to add new paragraph (c)(14)(iii) in accordance with existing requirements under § 413.402(d)(2)(v) to specify, that costs incurred by OPOs for OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO staff are not allowable costs. Lastly, we proposed to amend sections 413.402(a) and (d)(2)(v) to cross-reference the policy set forth in § 413.5(c)(14)(iii) regarding OPOs professional education costs.

(b) Costs for Education and Travel

The PRM–1, chapter 21 sets forth that the costs of staff training and education are allowable, provided they are reasonable and related to patient care. Specifically, the PRM–1, chapter 21 section 2128 states that orientation and on-the-job training costs are recognized as normal operating expenses and are therefore allowable. Such training is typically conducted within the provider's own setting; however, if outside instruction is required, those costs are also considered allowable. Additionally, the PRM–1, chapter 21, section 2144.6 provides that the cost of items provided to the employee for the convenience of the provider, such as the cost of provider-paid educational courses, uniforms, and operating day care centers for the children of employees are not classified as fringe benefits and may be included in a provider's allowable cost to the extent they are reasonable and related to patient care. The PRM–1, chapter 21, section 2162.7 D. also specifies that providers are required to maintain continuous safety initiatives and professional and employee training programs aimed at reducing the severity of incidents related to malpractice, comprehensive general liability, and workers' compensation incidents.

Regarding travel costs, the PRM–1, chapter 21, section 2105.6 sets forth that costs incurred by providers in conjunction with employee travel are generally allowable to the extent that they are patient care related and reasonable. However, travel costs incurred in conjunction with non-patient care related employee travel are not allowable. Foreign travel costs are allowable only where the provider can clearly substantiate the reasonableness and patient care relatedness of the travel costs to the satisfaction of the Medicare contractor.

When providers incur costs for their employees or staff to travel to professional education activities, these costs must be for activities related to patient care, reasonable and necessary in accordance with Medicare's reasonable cost principles. In the proposed rule, we clarified that overnight travel costs incurred by a provider on behalf of its employees or staff for activities related to patient care to attend a professional education course, meeting, or similar event should be considered allowable when the event is located more than 50 miles away from the employee's workplace and requires more than 8 hours of attendance. We believe this clarification reflects standard business practices. An 8-hour workday is widely recognized across industries, and many federal agencies define local travel as occurring within a 50-mile radius of an employee's official worksite.[659] We believe providers are expected to minimize travel-related costs to professional education activities by selecting economy or coach class accommodations. Additionally, in the proposed rule we stated that section 1861(v)(8)(iii) of the Act and PRM–1, chapter 21, section 2105.9 also provides that the costs incurred by providers related to employee personal use of provider vehicles are not allowable costs.

Under section 1861(v)(8)(v) of the Act, education expenses for spouses or other dependents of providers of services, their employees or contractors are unrelated to patient care and not allowable. We note a 1998 PRRB decision permitted the provider's cost of an educational seminar that took place on a cruise ship as an allowable educational activity, *McCurry's Home Health, Inc.* v. *Blue Cross & Blue Shield Ass'n/Blue Cross & Blue Shield of Iowa,* (Decision 98–D38, 1998 WL 598425 (H.C.F.A. June 5, 1998)).[660] In *McCurry's Home Health, Inc.,* the Administrator reviewed and overturned the PRRB decision and declared that Medicare, as a prudent purchaser of health care services, was correct to question the reasonableness of the costs. The Administrator also declared that costs incurred by providers for cruises are not costs that are ''common and accepted occurrences in the field of the provider's activity'' within the definition of necessary and proper costs under 42 CFR 413.9. Additionally, the Administrator said that the provider's

[659] *https://www.irs.gov/irm/part1/irm_01-032-001#:~:text=(11)%201.32.,local%20long%2Dterm%20taxable%20travel; https://www.gsa.gov/directives/files?file=2025-07%2FCC050151%20OAS%205770.1B%20Local%20Travel%20Policy%20%28Clearance%29%20%281%29.pdf https://www.transportation.gov/media/1751#:~:text=Local%20Travel:%20DOT%20defines%20local%20travel%20as%20travel%20for%20official%20government%20business%20within%20a.*

[660] *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/Downloads/1998D038.pdf#:~:text=The%20Provider%20contends%20that%20the,administrative%20functions%20of%20the%20job.*

contention that there were no other seminars in its area or nearby that offered comparable educational information was not sufficient to make costs associated with a 7-day cruise to Alaska for employees based in Kansas City reimbursable, despite the 32 continuing education credits provided by the seminar. The Administrator declared that costs associated with the cruise other than the $350 per attendee in actual costs of the seminar were unreasonable.

We agree that the costs of a cruise, regardless of whether continuing education credits are provided, are not common and accepted occurrences in the field of the provider's activity, are not reasonable and necessary and are not patient care related. We believe that entertainment, travel and vacation type of expenses, are not related to patient care and are not appropriate or allowable as professional educational expenses. Such expenses are not necessary or proper in developing and maintaining the operation of patient care facilities and activities.

In the proposed rule, we proposed to codify the existing policy in PRM–1, chapter 21, sections 2105.6, 2105.9, 2128, 2144.6, and 2162.7 D. with certain modifications to provide greater specificity regarding education and travel costs. Specifically, in the proposed rule we proposed to add new 42 CFR 413.5(c)(15) to specify that costs incurred by providers:

- For employee travel are generally allowable to the extent that they are patient care related, reasonable and necessary. Costs for travel not related to patient care are not allowable costs.
- To conduct, or send its employees or staff to, patient care related professional education refresher programs, seminars and workshops that increase the quality of patient care or operating efficiency of the provider, are generally allowable costs to the extent that they are patient care related, reasonable and necessary.
- For entertainment and vacation travel expenses such as travel on cruises or to resorts or spas, or transportation to entertainment or sporting events, are not allowable costs regardless of whether they are or are not incurred in connection with professional educational seminars or continuing education.
- Related to the personal use of provider vehicles are not allowable costs.

Comment: Many commenters opposed our proposals to codify provisions pertaining to professional education costs at 42 CFR 413.5(c)(14). Most commenters broadly requested that we expand allowable professional education costs to include meetings, seminars, and presentation where continuing education credits are given; and professional education provided to non-clinical staff. A commenter claimed that CMS did not explain its distinction for allowing continuing education events based on a clinical staff member's employment status. Commenters noted that limiting allowable costs to ''W–2 employees'' would exclude mission-critical contracted staff such as medical directors, recovery surgeons, and perfusionists, as well as non-clinical personnel in finance, IT, HR, and compliance who must maintain professional credentials to support OPO operations. The commenters urged CMS to broaden its proposal to permit reimbursement for professional education, including continuing education credits, for both contracted clinical and non-clinical staff whose roles are essential to OPO compliance and mission delivery.

Response: We appreciate the commenters' feedback and acknowledge commenters' requests to expand certain provisions of our proposal pertaining to OPOs' professional education costs. We continue to believe that OPO-sponsored seminars, where the attendee is not an OPO staff member and continuing education units are awarded, are not allowable OPO education costs, as such expenditures represent a benefit of the employer rather than a reimbursable program cost. Accordingly, we do not believe expanding allowable professional education costs to include OPO-sponsored seminars where continuing education credits are given to non-OPO staff attendees would be a prudent use of Medicare funds. To further clarify, the intent of proposed 42 CFR 413.5(c)(14)(i) is to allow costs incurred for OPOs that provide professional education at donor hospitals to acquire all useable organs from potential donors because OPOs work directly with donor hospitals during the organ donation process. In such settings, providing continuing education units (CEUs) to donor hospital employees during training is not a necessary component of an OPO's efforts to increase the number of organs available for transplant. OPOs are not responsible for subsidizing the professional development or credentialing requirements of hospital staff.

We also appreciate the commenters' request to expand allowable professional education costs to include non-OPO administrative staff. We agree with providers that asserted that costs associated with non-OPO staff and contracted staff who directly support the donor hospitals and OPO's operational role should be allowable, as these individuals contribute to the OPO's ability to fulfill its core mission of increasing organ donation. We believe this position appropriately recognizes the collaborative nature of OPO operations while ensuring that allowable costs remain tied to activities that meaningfully advance OPOs' goals while maintaining the integrity of Medicare's reasonable cost principles.

Comment: The majority of commenters either opposed our proposals pertaining to education and travel at proposed 42 CFR 413.5(c)(15) or requested the proposals be clarified or modified. A few commenters expressed concern regarding a 50-mile radius for local travel and the 8-hour attendance requirement for overnight travel reimbursement. The commenters argued this standard is overly restrictive, particularly for OPOs serving large rural service areas where one-way travel for organ procurement to a hospital can exceed four hours; the commenter noted this can pose safety risks and potentially unintended consequences of declining services provided to rural areas. Another commenter noted that heavy traffic, particularly in urban hours, can make same day travel impractical. The commenters recommended CMS clarify that the 8-hour requirement is general guideline rather than a requirement. A commenter suggested allowing for documented exceptions.

Several commenters urged CMS to modify its proposal to expand allowable travel and education expenses to include costs for non-clinical staff as well as non-employees, such as contracted staff that includes medical directors, recovery surgeons, and perfusionists. The commenters noted these individuals would be disadvantaged by the proposed limitation on non-clinical staff and non-employees of the provider. The commenters emphasized that restricting these costs could disincentivize OPOs from maintaining trained and credentialed staff essential to their objectives.

A few commenters opposed codifying the allowability of education and travel costs suggesting that § 413.9 and PRM–1, chapter 21 addresses these topics. A few commenters requested we remove the statement, ''costs for travel not related to patient care are not allowable,'' from proposed § 413.5(c)(15)(i) because it is repetitive. Additionally, the commenter requested CMS remove language from proposed

§ 413.5(c)(15)(iii), ''regardless of whether they are or are not incurred in connection with a professional education seminars or continuing education,'' suggesting that branding such as ''resort'' or ''spa'' should not affect cost allowability. The commenter contended that many legitimate continuing education conferences are held at such venues and that branding alone does not indicate attendees are participating in entertainment or recreation rather than education.

A few commenters expressed concern that CMS's framing of patient care is too narrow for OPOs, which are statutorily required under section 371(b)(3)(B) of the PHSA to conduct professional education and assist hospitals with organ donation protocols. The commenter also cited PRM 15–1, chapter 21, section 2102.3 suggesting costs necessary to develop and maintain OPO operations including travel and education are inherently patient care-related and should be treated as allowable costs. The commenters urged CMS to consider costs that are used to develop and maintain the operation of an OPO, which is not just about an organ donor or an organ recipient, but also donor families, and the external personnel to OPOs that they train to facilitate their efforts on organ donation and transplantation as allowable costs. The commenter urged CMS modify its proposal and allow for costs related to essential education, including travel and attendance costs for educational seminars, about OPO operations even if such education is not directly ''patient care'' focused.

Response: We appreciate the concerns shared by commenters regarding our clarification in the proposed rule pertaining to a 50-mile commute and more than 8 hours of attendance for allowable overnight travel reimbursement. Although we continue to believe this standard is appropriate for such costs to be allowable under Medicare, we acknowledge that in certain scenarios it is appropriate to provide greater flexibility. Therefore, we are clarifying that exceptions are permitted; however, reasons for an exception must be documented and available for inspection upon request, in accordance with 42 CFR 413.20 and 413.24.

We also acknowledge commenters' requests to expand allowable travel and education costs as proposed at § 413.5(c)(15)(i) and (ii) to include non-clinical staff as well as non-employees. We maintain that a providers' allowable travel and education costs must not include non-employees because non-employees must secure travel and education costs from their own employer. We also note that our proposal did not limit such allowable travel and education costs to non-clinical staff. However, we agree that for OPOs, limiting allowable travel and education expenses to an OPO's employees or staff would not accurately reflect the operational realities of the OPO. As such, we believe expanding the scope of allowable expenses to employees and contracted employees and personnel facilitates OPOs' ability to accomplish their mission to maximize organ procurement. We also acknowledge the commenter's request to expand allowable travel and attendance costs to include educational seminars that are not directly related to patient care. However, to align with Medicare's reasonable cost principles and to protect the Medicare trust fund, we maintain that allowable costs must have a clear and demonstrable relationship to patient care. We refer the commenter to the discussion of ''related to patient care'' as it pertains to OPOs in section X.D.2.b. of this rule for further guidance.

CMS continues to believe that costs providers incur to host events, including executive and board meetings, educational or otherwise, at resorts or spas are not allowable under Medicare's reasonable cost principles, or a prudent use of the Medicare trust fund. Regardless of the educational content or intent, the venue selection in such cases introduces an entertainment or luxury component that cannot be justified as a reasonable or necessary cost related to patient care. Providers are encouraged to seek alternative, cost-appropriate venues for educational events, as CMS does not consider it appropriate to subsidize costs that are entertainment-oriented or luxurious in nature. Protecting the integrity of the Medicare trust fund remains a priority, and CMS expects providers to exercise sound fiscal judgment when planning and reporting education-related expenditures. Accordingly, we respectfully disagree with the commenter's suggestion to remove the language ''regardless of whether they are or are not incurred in connection with a professional education seminars or continuing education.''

Regarding commenters' request to remove the statement from the proposed § 413.5(c)(15) ''Costs for travel not related to patient care are not allowable costs;'' we agree it is repetitive and we will remove it from the regulation. We respectfully disagree with the commenter that suggested that codification of allowable professional education and travel expenses for providers at § 413.5(c)(15) is not necessary. We believe codifying a policy specifically pertaining to the allowability of costs providers incur for professional education and travel ensures consistency and uniformity, regulatory clarity and transparency, and supports fiscal accountability and stewardship of the Medicare trust fund. We did not receive any comments pertaining to our proposal to disallow costs associated with the personal use of provider vehicles.

Comment: A commenter requested CMS to confirm that reasonable expenses associated with transporting an intended donor to a donor care unit are allowable organ acquisition costs when the transportation is clinically appropriate and necessary to preserve donation potential, support donor management, or avoid the loss of transplantable organs.

Response: We acknowledge the commenter's request; however, this is outside of the scope of this rulemaking and our proposals. We note that allowable transportation costs are set forth in 42 CFR 413.402(b)(8).

After consideration of the comments received, we are finalizing our proposal at 42 CFR 413.5(c)(14) with certain modifications. Specifically, we are modifying proposed § 413.5(c)(14)(i) to specify that costs incurred by OPOs for professional education such as meetings, seminars, and presentations on organ donation to acquire all useable organs from potential donors where continuing education credits are not given and where the attendee is clinical staff, non-clinical staff, or contracted staff including, but not limited to, OPO staff, donor hospital staff, and physicians whose role is essential to the OPO's objectives are allowable costs. We are finalizing our proposed § 413.5(c)(14)(ii) with a modification, to specify that costs incurred by OPOs for OPO-sponsored seminars where continuing education credits are given and where the attendee is a member of the OPO staff are allowable costs to the extent that they are patient care-related, reasonable and necessary. We are also finalizing our proposed § 413.5(c)(14)(iii), with a modification, to specify that costs incurred by OPOs for OPO-sponsored seminars where continuing education credits are given and where the attendee is not a member of the OPO staff, are not allowable costs, in accordance with § 413.402(d)(2)(v). Additionally, we are finalizing our proposal at 42 CFR 413.5(c)(15) with certain modifications. We are finalizing our proposal at § 413.5(c)(15)(i), with modification, to specify that costs incurred by providers for employee travel are generally allowable to the

extent that they are patient care related, reasonable, and necessary, and to remove the repetitive statement ''costs for travel not related to patient care are not allowable costs.'' We are also finalizing our proposal at § 413.5(c)(15)(ii), with modifications, to specify that costs incurred by a provider to conduct, or send its employees, or staff, including contracted employees to, patient care related professional education refresher programs, seminars and workshops that increase the quality of patient care or operating efficiency of the provider, are generally allowable costs to the extent that they are patient care related, reasonable, and necessary. We are also finalizing § 413.5(c)(15)(iii), as proposed, to specify that costs incurred by providers for entertainment and vacation travel expenses such as travel on cruises or to resorts or spas, or transportation to entertainment or sporting events, are not allowable costs regardless of whether they are or are not incurred in connection with professional educational seminars or continuing education. Additionally, we are finalizing § 413.5(c)(15)(iv), as proposed, to specify that costs incurred by providers related to the personal use of provider vehicles are not allowable costs.

Finally, we received no comments on our proposals to amend § 413.402(a) and § 413.402(d)(2)(v) to cross-reference the proposed policies in § 413.5(c)(11) and § 413.5(c)(14)(iii) regarding OPOs' public and professional education costs, respectively. As such we are finalizing § 413.402(a), as proposed, to specify that costs recognized in § 413.402(b) are allowable costs incurred in the acquisition of organs intended for transplant, including those organs that are subsequently determined unsuitable for transplant and furnished for research from a living donor or a deceased donor by the hospital, or from a deceased donor by an OPO. Additionally, there are administrative and general costs that may be allowable and included on the cost report for an OPO or a TH. Costs incurred by OPOs for public education within its donation service area in accordance with § 413.5(c)(11) and professional education in accordance with § 413.5(c)(14)(iii) are allowable overhead costs and are included on the cost report for an OPO. We are also finalizing § 413.402(d)(2)(v), as proposed, to specify, costs associated with and incurred for OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO's staff (as described at § 486.326(b)). Costs incurred by OPOs for public education within their donation service area in accordance with § 413.5(c)(11) and professional education in accordance with § 413.5(c)(14)(iii) are allowable overhead costs.

(6) Meals Provided to Employees and Non-Personnel

Medicare's longstanding manual provisions regarding the allowability of a provider's costs for meals for its employees/personnel and meals provided to those other than the personnel of the provider are provided in PRM–1, chapter 21, sections 2105.2, 2105.5, and 2145, and meals sold to visitors are provided in section 2102.3. These policies were established decades ago and we believe they require updating to ensure costs are reasonable and necessary and are incurred for patient care activities, in accordance with Medicare's reasonable cost principles.

Section 2105.2 of PRM–1, chapter 21 states that the cost of meals for other than provider personnel is unallowable because it is not related to patient care. We have seen some OPOs assert in reimbursement appeals that meals provided to hospital staff during organ donation and management meetings constituted professional education overhead costs related to patient care and were therefore allowable. In 2023, the OIG reviewed certain OPOs' overhead costs and found some costs for meals were attributable to non-OPO employees. In its review, the OIG sampled 20 professional and public education overhead costs (reported by eight OPOs), totaling $4,637, and found instances where meals were provided to non-OPO employees, with Medicare payments of $1,797.[661] OIG recommended that we clarify whether costs of meals provided to non-OPO employees were allowable.

Additionally, in response to comment in the FY 2022 IPPS/LTCH final rule with comment period (86 FR 73416), we said that meals (excluding alcohol) provided to attendees of OPO-sponsored seminars (without continuing education credits) could be allowable administrative and general costs, provided the seminar related to patient care and met requirements under § 413.9 (86 FR 73476). However, upon further review, we stated in the proposed rule that we believe the cost of meals at OPO-sponsored seminars is a benefit to the seminar attendees, rather than a direct cost necessary for patient care. In the proposed rule, we proposed to change our previous position to better align with Medicare's reasonable cost principles, 42 CFR 413.9 and section 2105.2 of PRM–1, which provides that the costs for meals provided to non-employees of the provider are unallowable costs.

In a PRRB decision, the Board allowed a portion of costs incurred by a provider for refreshments at a community health education event, *McCurry's Home Health, Inc.* v. *Blue Cross & Blue Shield Ass'n/Blue Cross & Blue Shield of Iowa* (Decision 98–D38, 1998 WL 598425 (H.C.F.A. June 5, 1998)).[662] Upon Administrator review of the PRRB decision, the Administrator declared that the provider's costs for refreshments at the educational event were not reasonable costs related to the care of the provider's own patients, citing the provisions of § 413.9. In the proposed rule, we stated that we believe that meals provided to anyone, regardless of whether they are or are not employees or staff of the provider, would represent personal expenses and therefore should not be considered allowable costs directly related to patient care services.

PRM–1, chapter 21, section 2105.5 provides that excess costs for executive or management employee meals—such as separate dining facilities, additional staff, or upgraded menus—are not allowable. However, PRM–1, chapter 21, section 2105.5 sets forth that unrecovered costs for executive or management meals served from common menus in shared employee dining facilities are allowable if otherwise reasonable. Under PRM–1, chapter 21, section 2145, providers may claim reasonable unrecovered costs for employee meals in two circumstances when meals: (1) qualify as a fringe benefit (see PRM–1, chapter 21, section 2144.4E) related to patient care; and (2) are provided solely for the provider's benefit and related to patient care, as outlined in PRM–1, chapter 21, section 2102.2. For example, this includes meals served to personnel who must remain on-call on the premises during mealtime to provide patient care, where the meal cost is not classified as a fringe benefit.

We stated in the proposed rule that we believe the existing manual provisions under PRM–1, chapter 21, sections 2105.2, 2105.5, and 2145 should be revised to better align with Medicare's reasonable cost principles, including § 413.9. As noted, we believe

[661] *https://oig.hhs.gov/reports/all/2023/medicare-paid-independent-organ-procurement-organizations-over-half-a-million-dollars-for-professional-and-public-education-overhead-costs-that-did-not-meet-medicare-requirements/.*

[662] *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/Downloads/1998D038.pdf.*

that meals provided to employees or staff of the provider would generally be considered a personal benefit to staff rather than a direct cost necessary for patient care under Medicare and therefore should not be considered allowable costs. For the foregoing reasons, in the proposed rule, we proposed to codify certain longstanding policies in PRM–1, chapter 21, section 2102.3 and revise the existing policies in sections PRM–1, chapter 21, sections 2105.2, 2105.5, and 2145.

Specifically, we proposed to add § 413.5(c)(16) to specify that costs incurred by providers for meals sold to visitors and meals for their employees or staff (including executives and management) and non-personnel (including attending physicians) are not allowable costs. We also proposed to specify that the costs of meals and refreshments provided to attendees at educational events, including attendees of OPO-sponsored seminars (with or without continuing education credits) are not allowable costs.

Comment: The majority of commenters opposed our proposal to add § 413.5(c)(16) to specify that costs incurred by providers for meals sold to visitors and meals for their employees or staff, as well as the costs of meals and refreshments provided to attendees at educational events, including attendees of OPO-sponsored seminars (with or without continuing education credits) are not allowable costs. The commenters requested CMS maintain its longstanding policy, or to allow for certain exceptions, or establish limits on allowable costs for meals to ensure fiscal responsibility.

Many commenters contended that meals are a legitimate operational necessity and should be considered allowable costs. The commenters specified that the costs of meals should be allowable for staff, specifically organ procurement coordinators, when they are required to be on call or work extended shifts (12–16 hours), or travel long distances between facilities during the organ procurement process. Many commenters also requested the cost of meals or modest refreshments be allowable costs for employees and non-employees attending educational events, including OPO-sponsored seminars and suggested that providing meals and refreshments encourages employee participation and retention. Several commenters suggested CMS establish guidelines and limitations for allowable meal costs, such as establishing per diem rates based on IRS or GSA rates, cap the costs at the IRS per diem rate or require the provider to link the cost of the meal to an auditable organ donation procedure. Several commenters requested CMS modify its proposal to classify meals as standard business expenses (rather than personal expenses), when meals are provided for the convenience of the employer, or allow costs as de minimis fringe benefits to align CMS policy with IRS guidelines that meals are a business expense and deductible. The commenter noted that CMS already relied on IRS and federal guidance elsewhere in the rulemaking, and stated that categorizing these costs as ''personal expenses'' is inconsistent with established business practice.

A few commenters disagreed with CMS's proposal that the costs of meals provided to staff during professional education events to increase the number of registered donors are not allowable costs related to patient care and suggested the costs should be recognized in accordance with § 413.9. Another commenter framed nutrition as a patient safety issue, for organ procurement coordinators, linking inadequate nutrition to risk of clinical errors during the organ procurement process. A commenter suggested that the proposed codification of meals is unnecessary because existing regulations at § 413.9, and subregulatory guidance at PRM 15–1, chapter 21 guidance already address cost allowability. The commenter reiterated their previous position that most instructions in the PRM 15–1 were developed for hospitals and facilities treating patients and agreed that staff meals, for the general benefit of the staff, are not patient care-related and should remain unallowable.

Response: We thank commenters for their detailed feedback on our proposal. We recognize that meals under certain scenarios, for example when an employee is required to travel away from their primary work location and an overnight stay may be required, such as when completing educational training sessions on patient care-related topics. In this scenario, the employee is without reasonable access to their usual meal arrangements, creating an unavoidable expense directly tied to a legitimate, organization-approved purpose that benefits patient care. For these reasons, we believe it would be appropriate to consider the costs of meals or refreshments for employees, including contracted employees, at educational events pertaining to patient care, including OPO-sponsored seminars (with or without continuing education credits) when overnight stay is required. Meal allowances in these scenarios must be reasonable and necessary and align with 42 CFR 413.9, which requires such costs to be reasonable and not substantially out of line with those incurred by similarly situated organizations.

However, we continue to believe that it is not an appropriate use of the Medicare trust fund to pay providers' costs for meals provided to non-employees attending educational events, including OPO sponsored seminars, regardless of whether continuing education units are provided. While CMS acknowledges concerns regarding employee nutrition, and the nature of some positions that require an employee to work extended hours or be on-call, it is not Medicare's intent to subsidize the personal meal costs of employees while performing their regular job duties. Furthermore, we believe allowing all providers to claim these costs across the full spectrum of Medicare-participating entities would not be an appropriate use of Medicare trust fund dollars. Medicare does not prohibit providers, including OPOs, from paying for employee or non-employee meals for their employees, for example during a lengthy organ procurement process, or for convenience to the provider; however, we believe there are many instances where such costs are not allowable in computing reimbursable costs under Medicare.

Regarding establishing caps, we thank the commenters for their suggestion; however, we believe the allowance for meals should remain a business decision made by the organization. To assist providers in determining whether costs are reasonable and necessary, providers may consider reviewing IRS rates and GSA per diem rates as optional guidelines to assist with substantiating the reasonableness of such expenses. However, as we note in the prudent buyer section X.D.2.b.(1) of this final rule, the use of these rates is not a requirement. For the costs of meals to be allowable under Medicare, such costs must be reasonable and necessary and not substantially out of line in accordance with 42 CFR 413.9. We believe this approach preserves organizational flexibility while providing a transparent and defensible framework for cost reasonableness determinations.

We respectfully disagree with the commenter that suggested codification of provisions pertaining to the allowability of meals is not necessary. We believe codifying a policy specifically pertaining to the allowability of costs for meals ensures consistency and uniformity, regulatory clarity and transparency and supports fiscal accountability and stewardship of the Medicare trust fund.

Based on commenters' concerns, we agree that our broad disallowance of meal costs in the proposed rule was overly expansive. Accordingly, we are revising our proposal to permit, as allowable costs, meals provided to staff during overnight travel for educational or training events related to patient care, as well as de minimis snacks, such as water, coffee, granola bars, crackers, fruit, etc., provided to employees and attendees of professional education events. In accordance with section 1861(v) of the Act and 42 CFR part 413 we believe it is appropriate to modify our proposal to be responsive to commenters' concerns while continuing to protect the Medicare trust fund.

After consideration of the comments received, to address commenters concerns, we are finalizing our proposal at 42 CFR 413.5(c)(16) with certain modifications. We are finalizing our proposal at § 413.5(c)(16)(i), to specify that costs incurred by providers for meals sold to visitors, meals for their employees and staff (including executives and management) and non-personnel (including attending physicians) are not allowable costs. We are also finalizing our proposal at § 413.5(c)(16)(ii), with modifications, to specify that costs incurred by providers for de minimis refreshments provided to attendees at educational events, including attendees of OPO-sponsored seminars (with or without continuing education credits) are allowable costs. Finally, based on comments received, we are adding new § 413.5(c)(16)(iii), to specify that costs incurred by providers for meals for employees and contracted staff, whose role is essential to the provider's objectives, when an employee or contracted staff is required to travel away from their primary work location and an overnight stay is required, such as when completing trainings or education, provided such trainings are patient care related, are allowable costs.

We did not receive any comments pertaining to our proposals to codify longstanding policy pertaining to non-allowable costs for drugs sold to non-patients, fines or penalties, and gift shops. Therefore, we are finalizing our proposals at § 413.5(c)(17) to specify that costs incurred by providers for drugs sold to other than patients are not related to patient care and are not allowable costs. We are also finalizing our proposals at § 413.5(c)(18) to specify that costs incurred by providers for fines or penalties resulting from Federal, State or local laws are not allowable costs. Finally, we are finalizing our proposals at § 413.5(c)(19) to specify that costs incurred by providers for operation of a gift shop are not allowable costs.

Comment: A few commenters requested that CMS ensure the reasonable cost provisions be implemented with adequate transition time and several OPOs requested the implementation of the reasonable cost provisions be delayed until FY 2028, citing some OPOs may need to modify documentation processes to comply with potential changes or expansion of prudent buyer, employee morale, professional education and public education standards or restructure their public education activities. They noted delaying implementation would also recognize commenters' concerns regarding broad, ongoing federal OPO performance and modernization initiatives that are occurring in parallel with this rule.

Response: We appreciate the commenters' concerns regarding potential changes to documentation processes and potential restructuring of OPO public education activities. Regarding our prudent buyer proposal, discussed in section X.D.2.b.(1) of this final rule, we maintain that the final regulation text reflects the codification of our longstanding prudent buyer principle set forth in PRM–1, chapter 21, section 2103. In response to commenters' concerns about the unique challenges of the organ procurement process, we have provided additional clarification regarding the application of the prudent buyer principle for OPOs in section X.D.2.b.(1) of this final rule. Based on this clarification, we do not believe a delayed implementation date for the prudent buyer principle for OPOs is necessary.

Additionally, with respect to our proposal on OPO public education activities, discussed in section X.D.2.b.(2) of this final rule, we maintain that the final regulation text reflects the codification of the disallowance of entertainment costs set forth under section 1861(v)(8) of the Act and longstanding provisions on costs not related to patient care as detailed in PRM–1, sections 2102.3 and 2105.8. We are finalizing our provisions pertaining to OPO public education costs under 42 CFR 413.5(c)(10)(i), (c)(10)(ii), and (c)(11) to be effective with the effective date of this final rule and allowing a 1-year delay in enforcement in response to comments that certain OPOs will need time to update their public education programs to comply with this final rule. We believe this 1-year delay in enforcement with regard to OPO public education provisions in this final rule responds to commenters' concerns while still advancing the goals of fiscal accountability and oversight of the Medicare Program.

Finally, regarding commenters' requests that CMS ensure the reasonable cost provisions are implemented with adequate transition time, we are finalizing our proposals pertaining to employee morale in section X.D.2.b.(3) and meals in section X.D.2.b.(6) of this final rule with modifications. We believe these modifications address commenters' concerns and do not believe a delay in the implementation date is necessary.

3. Clarification and Codification of Cost Allocation Principles

Medicare's reasonable cost reimbursement principles require correct allocation of such costs to arrive at equitable and proper payment for services to Medicare beneficiaries. Medicare regulations at 42 CFR 413.24 require that providers receiving payment on the basis of reimbursable cost provide adequate cost data based on their financial and statistical records which must be capable of verification by qualified auditors, and the cost data must be based on an approved method of cost finding.

Medicare's reasonable cost principles take into account both direct and indirect costs of providers of services. Direct costs are costs that are specifically identifiable and attributable to an individual patient, a particular cost center, or a department.[663] Examples of direct costs are salaries and wages of staff working exclusively in a specific department (for example, a nurse in the ICU), medical supplies used directly in patient care, medications administered to patients, supplies used in specific departments (for example, the operating room or radiology department), CAR–T cell biologics administered to patients, and organs purchased from organ procurement organizations and transplant hospitals for transplant into patients. Indirect costs, on the other hand, are costs that are not chargeable based on actual usage and must be allocated on a basis of a statistical surrogate (for example, square feet, dollar value, FTEs, gross salaries, accumulated cost, and costed requisition). Examples of indirect costs are administration, rent, depreciation, utilities, housekeeping, maintenance, medical records, and employee benefits. Cost finding is the process of recasting the data derived from the accounts ordinarily kept by a provider to ascertain costs of the various types of services furnished to patients by the

[663] PRM–1, chapter 23, section 2302.10.

allocation of direct costs and proration of indirect, or overhead, costs.

Departments within a provider are usually divided into two types: (1) those that produce patient care revenue (for example, routine services and radiology); and (2) those that do not directly generate patient care revenue but are utilized as a service by other departments (for example, administration, laundry and linen, housekeeping and dietary).[664] The two types of departments are commonly referred to as ''revenue-producing cost centers'' and ''nonrevenue-producing cost centers.'' [665] Cost finding employs the computation needed in determining the full costs of departments.

The Step-Down method of cost finding used by providers for cost reporting periods after December 31, 1971, recognizes that services rendered by certain nonrevenue-producing departments or centers are utilized by certain other nonrevenue-producing centers, as well as by the revenue-producing centers.[666] A provider's general service costs (that is, overhead costs) must be properly allocated to all centers which they serve, regardless of whether these centers produce revenue, to ensure costs for services to Medicare beneficiaries are correctly calculated.[667] This allocation process for Medicare cost reporting purposes is made through cost finding using a statistical basis that measures the benefit received by each cost center. The statistical basis must reflect the cause-and-effect relationship between the cost and the activities or services receiving the allocation, that is, the benefit received by each cost center.[668] The statistical measure must demonstrate how costs incurred relate to the consumption of resources.[669]

The Medicare cost report's (MCR's) recommended statistical bases include square footage for facility costs, gross salaries for employee benefits, accumulated costs for administrative and general (A&G) costs, meals served for dietary, and other bases that distribute costs in proportion to the relative benefits received, or resources consumed, by each cost center.[670] When a statistical basis, such as accumulated cost improperly includes costs that receive no benefit or resources, those costs included in the accumulated cost statistic must not be used to allocate cost to a department or cost center.[671] The MCR provides instruction for providers to adjust the accumulated cost statistics accordingly.[672]

Including a statistical cost that does not have a beneficial relationship to A&G expenses being allocated causes an improper distribution of overhead. Section 413.24(b)(1) explains that cost finding is the process of recasting the data derived from the accounts ordinarily kept by a provider to ascertain costs of the various types of services furnished. It is the determination of these costs by the allocation of direct costs and proration of indirect costs. Section 413.24(c) sets forth that adequate cost information must be obtained from the provider's records to support payments made for services furnished to beneficiaries, and that the provider's cost information must be accurate and in sufficient detail to accomplish the purposes for which it is intended. Additionally, § 413.24(d)(6) provides specific requirements for certain purchased services and how including these costs in the accumulated cost statistic when the costs do not relate to services or resource provided by the A&G department may cause an improper distribution of overhead and could result in improper Medicare payment.

Upon review of cost report data of various provider types, we have found that providers are not utilizing the Medicare cost report instructions regarding cost allocation,[673] resulting in providers allocating overhead costs imprecisely which could cause inflated and improper reimbursement from Medicare. A&G costs can be improperly allocated when the statistic, ''accumulated cost,'' is used, resulting in an overinflation of the actual benefit or resources provided to various departments of the provider. As an example, when services are purchased under arrangement, the provider is paying for the complete service from an external entity. The provider's A&G cost center does not support or benefit these external purchases and there is no relationship between the hospital's overhead and the purchased services. Some providers are reporting the amounts paid for purchased services or products and including them in the accumulated cost statistic on their cost report. However, this is not correct. Purchased services are already fully costed by the external entity and directly assigned to the benefiting department. Including them in the accumulated cost statistic improperly allocates the provider's overhead to a cost center that already contains the full purchase price of the service as well as the entity's overhead costs and profit. For example, transplant hospitals that purchase organs from OPOs, and other transplant hospitals for transplantation, place the ''purchase cost'' for organs in the appropriate organ acquisition cost center. If these purchase costs are also included in the accumulated cost statistic used to allocate A&G costs, the overhead A&G are improperly shifted, that is allocated, to the cost center as well. The amounts paid by the transplant hospitals to OPOs or other transplant hospitals for purchased organs has increased significantly over the years. This increases improper allocation of overhead costs. Another example of this is when hospitals purchase CAR T-cell biologicals. The purchase price includes costs for the complete process of extracting and preparing the biological for infusion. Including these direct costs in the accumulated cost statistic would improperly and disproportionately allocate overhead to the CAR T-cell cost center without any relationship between the hospital's overhead and the purchased biological. Including these purchased services, or supplies, in the accumulated cost statistic causes overhead A&G costs to shift and be allocated from the hospital's cost centers that benefit from A&G to the cost reimbursed areas of the hospital without any causal or beneficial relationship. In this regard, including in the accumulated cost statistic the purchased services, supplies, or products that are directly assigned to a department, and that include in the purchase price the full cost from the external entity, including overhead and profit, results in an improper and excessive allocation of overhead to the cost center.

When a provider purchases services through a contract for service or purchases supplies and the amount of direct costs reported and paid to external entities includes the entities' overhead and profit, including these costs in the accumulated cost statistic overinflates the allocation and results in improper Medicare payment to the provider. In accordance with the MCR instructions,[674] if costs in a cost center or department include direct assignment of purchased products, organs, or services, the provider must remove the directly assigned costs (purchased costs) from its allocation statistic to assure a

[664] PRM–1, chapter 23, section 2306.

[665] Id.

[666] 42 CFR 413.24(d) and PRM–1, chapter 23, section 2306.1.

[667] PRM–1, chapter 23, section 2307.

[668] PRM–1, chapter 23, section 2307.

[669] PRM–1, chapter 23, section 2306.

[670] PRM–2, chapter 40, section 4020.

[671] PRM–2, chapter 40, section 4095, Table 3, ECR specifications for Worksheet B–1.

[672] Id.

[673] For example, PRM–2, chapter 40, section 4020 for hospitals.

[674] PRM 15–2, chapter 40, section 4020.

proper allocation of overhead. Purchased services are reported as direct costs and must bypass the step-down allocation process. This process ensures appropriate Medicare payment and ensures that the provider's cost centers do not receive an improper distribution of overhead costs without the overhead cost center providing support or a benefit. These longstanding Medicare cost finding principles are in accordance with § 413.24(c) and (d) and previously have been set forth in the MCR instructions.[675]

Similar issues with overhead allocations may exist for CAHs and some CAHs have requested that CMS clarify the cost allocation rules with more explicit cost reporting instructions. Because CAHs are reimbursed by Medicare at 101 percent of their reasonable costs, they may face undesirable financial consequences if their overhead A&G costs are improperly allocated on their cost reports. This can occur when CAHs improperly allocate their costs to all cost centers or departments of the CAH based on the accumulated cost statistic without any causal or beneficial relationship. A CAH's costs can be shifted if they improperly allocate their costs without a causal relationship, such as to areas that do not benefit or are not serviced by overhead cost centers. This can impact the CAH's reimbursement if an improper allocation of A&G costs reduces the calculation of the CAH's operational costs and overall reimbursement.

We believe that the proper allocation of indirect costs by all providers is important in facilitating appropriate Medicare payment. Inflated A&G costs may inaccurately increase provider payment rates resulting in increased Medicare spending.

As an example, for hospitals, there are longstanding MCR instructions in PRM–2, chapter 40, section 4020 when providers use accumulated costs as a statistic for allocation. These longstanding instructions provide two methods that a provider can use to allocate its costs when adjustments are necessary. In this regard, a provider can use either method or both methods.

The first method to adjust the allocation statistic uses a negative adjustment of either (a) a negative one (−1) in the accumulated cost column to identify the cost center which should be excluded from receiving any allocation of A&G costs; or (b) if some of the costs from that cost center are to receive A&G costs, by reporting in the reconciliation column as a negative adjustment, the amount of accumulated costs that are not to receive A&G costs to assure that only those costs to receive overhead receive the proper allocation. We refer to this method as the Negative Adjustment Method in this section. When direct costs are reported in a cost center or department that includes purchased services or supplies, costs other than the purchased service costs may receive an allocation of A&G costs, and the purchased service costs that are not to receive A&G must be identified and removed from the allocation statistic using the reconciliation column on Worksheet B–1. Including a statistical cost which does not relate to the allocation of A&G expenses causes an improper distribution of overhead.

If there are some costs in A&G that may have a causal relationship to the purchased service cost, a second method to correct improper allocation of overhead is set forth in the MCR instructions and PRM–1, chapter 23, section 2307.B., ''*Direct Assignment of Costs to Provider Components.*'' Under this method, to accommodate additional general service cost centers, the provider must add additional columns (also known as ''components,'' ''fragments,'' or ''subscripts'') to the allocation worksheets, to document the step-down of a broad A&G cost center into more than one cost center and use a more accurate statistic to allocate the costs. We refer to this method as the 'Componentizing' of the A&G costs. In this regard, the provider establishes multiple A&G cost centers to allow for a more granular, accurate allocation to ensure that overhead costs are properly assigned to reimbursable departments. By establishing multiple A&G cost centers, providers can more precisely track and allocate overhead costs based on actual resource consumption. For example, different administrative functions, such as human resources, IT, and facilities management, can be separated and allocated using different statistical bases that better reflect their utilization. Additionally, detailed cost center structures provide clearer documentation of how overhead costs are distributed, ensuring a more granular review for providers, auditors, and industry-interested parties.

For providers that desire to change their cost finding methods, PRM–1, chapter 23, section 2312 instructs providers to request this change from their Medicare contractor. This request must be submitted in writing to their contractor 90 days prior to the end of the cost reporting period to which the request for change applies. Under section 2312, the contractor's determination of a provider's request to change methods will be furnished to the provider in writing and will be considered binding on the provider as of the date of the contractor's written notice. Additionally, under section 2312, where the contractor approves the provider's request to change methods, the provider must use this method for the cost reporting period to which the request applies and for all subsequent cost reporting periods, unless the contractor approves a subsequent request by the provider to change its cost finding methods.

In the proposed rule, we proposed to codify these overhead cost allocation requirements that are set forth generally in existing cost reporting instructions, to ensure that providers' costs of providing services to Medicare beneficiaries are correctly calculated. We believe this will provide additional clarity to providers so that they will correctly allocate overhead costs by ensuring that cost statistics are not used to disproportionately allocate costs resulting in inappropriate maximizing or minimizing reimbursement to providers.

Specifically, in the proposed rule we proposed to add § 413.24(d)(8) to specify that providers must not include a statistical cost which does not relate to the allocation of A&G expenses when it causes an improper distribution of overhead. For example, when a hospital performs organ transplants, it may purchase organs (kidneys, hearts, livers) from outside sources such as OPOs. These purchased organs carry a very high dollar value but have no causal relationship to administrative overhead compared to other hospital services, and these purchased organs include all the OPOs overhead in their cost. During the step-down cost allocation process on the Medicare Cost Report, when purchased organ costs are included in the accumulated cost statistic used to allocate Administrative & General (A&G) costs the allocation disproportionately allocates cost as seen in this Table X.D.-03.

[675] PRM 15–2, chapter 40, section 4020; and section 4095 for Worksheet B–1.

TABLE X.D.-03: ADMINISTRATIVE & GENERAL (A&G) COSTS THE ALLOCATION

Cost Center	Accumulated Costs	% of Total	A&G Allocated
Medical/Surgical Routine Care	$5,000,000	31.25%	$500,000
ICU	$2,000,000	12.50%	$200,000
Organ Acquisition (Purchased Organs)	$8,000,000	50.00%	$800,000
Radiology	$1,000,000	6.25%	$100,000
Total A&G costs to be allocated $1,600,000		100%	$1,600,000

When the purchased organ costs are removed from the accumulated cost statistic (as CMS guidelines instruct), the remaining base is $8,000,000 and the accumulated cost statistic properly reflects the allocation of A&G costs as shown in this Table X.D.-04.

TABLE X.D.-04: ADMINISTRATIVE & GENERAL (A&G) COSTS THE ALLOCATION

Cost Center	Accumulated Costs	% of Total	A&G Allocated
Medical/Surgical Routine Care	$5,000,000	62.50%	$1,000,000
ICU	$2,000,000	25.00%	$400,000
Organ Acquisition (Purchased Organs)	$0 (excluded)	0%	$0
Radiology	$1,000,000	12.50%	$200,000
Total A&G costs to be allocated $1,600,000		100%	$1,600,000

We also proposed to add § 413.24(d)(8)(i) to specify that providers must employ either a Negative Adjustment Method, or a Fragmenting (Componentizing) A&G Method, or both, to adjust the allocation statistic as it relates to accumulated costs to prevent an improper allocation of overhead on the MCR.

We proposed to add § 413.24(d)(8)(ii) to set forth the Negative Adjustment Method for accumulated costs to specify that when direct costs are reported in a cost center or department that includes purchased services or supplies, costs other than the purchased service costs may receive an allocation of A&G costs, and the purchased service costs that are not to receive A&G must be identified and removed. We also proposed to add § 413.24(d)(8)(ii)(A) to instruct that, on the MCR, in any column using accumulated costs as the statistical basis for allocating costs providers must identify any cost center that is not to receive an allocation by entering a negative 1 (−1) on the appropriate line in the accumulated cost column, or by entering the total accumulated cost as a negative amount on the appropriate line in the reconciliation column. For those cost centers using accumulated costs that are to receive partial allocation of costs, we proposed to instruct providers to enter a negative amount for the costs that are to be excluded from the statistic on the appropriate line in the reconciliation column.

We also proposed to add § 413.24(d)(8)(ii)(B) to instruct providers that cost centers that are not to receive an allocation must not have entries in both the reconciliation and accumulated cost columns when the accumulated cost statistic is offset to zero. We also proposed to add § 413.24(d)(8)(ii)(C) to instruct providers that, for those cost centers that are to receive partial allocation of costs for costs other than purchased services, the cost to be excluded from the statistic must be reported as a negative amount on the appropriate line in the reconciliation column. This will result in entries in both the reconciliation column and accumulated cost column simultaneously on the same line where a partial accumulated cost statistic is offset.

In the proposed rule, we proposed to add § 413.24(d)(8)(iii) to set forth the Fragmenting (Componentizing) A&G Method, to specify that when a provider chooses to fragment, or componentize A&G costs, the provider must fragment (that is, subscript), the A&G cost center into two or more cost centers using accurate statistics to allocate its costs and ensure that overhead costs are accurately assigned to departments benefiting from the services provided. When creating multiple A&G cost centers, a provider must track and allocate overhead expenses based on actual resource consumption.

In the proposed rule, we also proposed to add § 413.24(d)(8)(iv) to specify procedures for a provider to request to change its cost finding method. We proposed to add § 413.24(d)(8)(iv)(A) to specify that a provider that wishes to change its cost finding method must submit a request to its contractor, in writing, 90 days prior to the end of the cost reporting period to which the provider's request for change applies. We also proposed to add § 413.24(d)(8)(iv)(B) to specify that the contractor's determination of a provider's request to change methods will be furnished to the provider in writing and will be binding on the provider as of the date of the contractor's written notice. Finally, we proposed to add § 413.24(d)(8)(iv)(C) to specify that when the contractor approves the provider's request to change methods, the provider must use this method for the cost reporting period to which the request applies and for all subsequent cost reporting periods, unless the contractor approves a subsequent request by the provider to change its cost finding methods.

Comment: Several commenters expressed support for CMS's objective to improve cost reporting accuracy and the allocation of A&G overhead costs.

Response: We thank commenters for supporting our objectives to adhere to Medicare's reasonable cost principles and improve cost reporting accuracy with regard to providers' allocation of A&G overhead costs.

Comment: Some commenters asserted that the accumulated cost statistic is a longstanding, simplified, and acceptable method for allocating overhead, and that CMS is departing from it without justification. Some commenters asserted

that the proposal conflicts with the 42 CFR part 413 cost-apportionment principles and Medicare's reasonable cost statute's recognition of both direct and indirect costs actually incurred. Some commenters also expressed that CMS's proposed codification of § 413.24(d)(8), *Improper allocation of overhead prohibited,* and the two methods providers can use to adjust the accumulated cost statistic, the Negative Adjustment Method and the Componentizing Method, represents a new prescriptive policy rather than a clarification of existing rules, is vague and would allow contractors to second guess providers' legitimate cost allocation decisions. A few commenters asserted that the Provider Reimbursement Manual does not reflect the policies CMS proposes to clarify and codify. Several commenters cited an increase in providers' administrative burden, including the burden to track purchased services if the proposals are finalized.

Response: We disagree with commenters' assertions that CMS is departing from using the accumulated cost statistic as a valid and accepted allocation basis under Medicare's longstanding cost-finding principles. We also disagree that the cost allocation principles set forth in our proposed codification of § 413.24(d)(8) are new or vague. Our proposal is designed to prevent cost-shifting, and enforce Medicare's longstanding, fundamental cost-finding requirements, as set forth in § 413.24 and cost reporting instructions, that any statistical basis must reflect a causal and beneficial relationship between the cost center and the overhead being allocated. Additionally, as we discussed in the proposed rule (see 91 FR 19745–46), the allocation principles which we proposed to codify at § 413.24(d)(8) are long-standing and have been set forth collectively in statute, regulations and various sections of the Provider Reimbursement Manual. As we explained in the proposed rule, § 413.24(b)(1) defines cost finding as the allocation of direct costs and proration of indirect costs. Allocable costs are a cost item or group of cost items assigned to one or more objects, processes, or operations based on cost responsibilities, benefits received, or another identifiable metric of application or consumption (commonly referred to as general service costs).[676] Using the accumulated cost statistic has always required the provider to demonstrate a causal and beneficial relationship between the cost and the overhead being allocated.[677] The accumulated cost statistic is not being abolished in this proposal. We remind providers of the longstanding requirement set forth in 42 CFR 413.24(c) which requires that cost data be accurate, verifiable, and in sufficient detail to support Medicare payments. Medicare's reasonable cost statute at 1861(v)(1)(A) of the Act requires that Medicare payments reflect costs that are reasonable and actually incurred in providing services to Medicare beneficiaries, not inflated costs resulting from improper statistical allocations. As we discussed in our proposal, some providers have not been following Medicare's longstanding reasonable cost principles and Medicare's cost report instructions. Our proposal to codify these allocation principles and instructions into the regulations does not convert them into new policy. CMS is simply proposing, through notice and comment rulemaking, to clarify and codify the longstanding statutory reasonable cost principles regarding certain cost reporting instructions into regulatory text to prevent cost shifting and to ensure uniform compliance across all provider types, and greater legal certainty for providers, and contractors. We appreciate commenters' sharing their concerns regarding an increase in administrative burden to providers, however, as previously stated, we proposed to codify into the regulations at new § 413.24(d)(8) longstanding instructions on the proper allocation of overhead costs. We believe these proposals enforce the causal and beneficial relationship of properly proportioning a provider's costs to overhead expense that is fundamental to Medicare's reasonable cost principles. There should be no additional burden to adhere to the longstanding requirement to properly report and allocate costs. We note that our proposal at § 413.24(d)(8)(i) states that providers must use the Negative Adjustment Method or the Fragmenting (componentizing) Method, or both, if needed, to prevent the improper allocation of overhead on the Medicare cost report. We also note that the Negative Adjustment Method, one of the two compliance options provided in proposed § 413.24(d)(8)(i), is a straightforward adjustment already described in existing MCR instructions (PRM–2, Chapter 40, Section 4020). Providers familiar with Worksheet B–1 can implement this method with minimal additional burden beyond current cost reporting practices. We also note that the Componentizing Method is an optional alternative for providers that wish to more granularly allocate A&G costs. It is not mandated for all providers, and providers retain flexibility to choose the method most appropriate for their cost structure. Because program integrity and safeguarding the Medicare Trust Fund is a core CMS responsibility, we believe that the administrative burden of accurate cost reporting is a reasonable and necessary cost of participating in the Medicare program.

Comment: Many commenters disagreed with the proposal that requires providers to remove purchase costs from the accumulated cost statistic used to allocate A&G costs and said that CMS has presented no evidence to show that including purchased services and supplies in the accumulated cost statistic results in improper Medicare payments. Many commenters asserted that hospitals still incur their own A&G costs (contracting, legal, procurement, compliance, accounts payable, etc.) related to purchased services and therefore should not be excluded from the allocation base. Commenters suggested that removing purchase costs from the accumulated cost statistic could require removing nearly half of hospital costs and create a new Worksheet B–1 information collection requiring PRA review. Some commenters asserted that CMS has not considered the possibility that exclusion of purchased services and supplies could increase aggregate Medicare expenditures, while other commenters noted that alternative allocation bases such as square footage, salaries, and FTEs already understate overhead for items such as organ acquisition costs and CAR–T cell therapies, and the overall reimbursement impact may be immaterial. Another commenter asserted that the title of § 413.24(d)(6) indicates that it is only applicable to provider-based entities and departments. This commenter suggested that the title contributes to the misunderstanding of how § 413.24(d)(6) applies to the departments of all hospitals and suggested that we consider re-wording the heading to something like ''Preventing duplication of costs: departments and provider-based entities'' to help providers understand that the section applies to more than just provider-based entities.

Response: We understand commenters' desire to continue to include purchase costs in the accumulated cost statistic, however, in the proposed rule we explained, with an example, how including purchased services and supplies in the

[676] See PRM–1, chapter 23, section 2302.4.

[677] See PRM–1, chapter 23, sections 2302.4, 2306.1, 2307, and 2313.1.

accumulated cost statistic can result in improper Medicare payments. We would like to clarify that we are not requiring all purchased service costs be removed from the accumulated cost statistic. Instead, we are referring to purchased services provided under contract that should be removed from the accumulated cost statistic. The purpose of an accumulated cost statistic is to measure internal resource utilization. Contract services are performed by the external/supplying parties and the purchased contract amount does not represent the hospital's own resource consumption and therefore, the purchase contract amount should not influence how the hospital's overhead costs are distributed. We would also like to clarify that we are not requiring all supplies be removed from the accumulated cost statistic. For supplies, we are referring to supplies such as organs, donor tissue, blood products, and CAR–T, that are acquired on behalf of a patient and passed directly to the payer without markup, including costs that are highly variable and not representative of routine costs reimbursed separately outside of standard DRG/APC rates, and costs the hospital acquires or procures on a case-by-case basis that are not stocked routinely. Inclusions of these types of costs significantly skew CCRs and cost allocation. Our position is based, in part, on the structural logic of the cost allocation methodology. We have reviewed publicly available cost report data from multiple provider types and identified systematic misallocation resulting in inflated Medicare payments. We understand that providers may, in certain circumstances, incur a limited amount of A&G costs related to purchased services (for example, contract management, legal review, procurement, accounts payable processing, etc.), however, the provider's A&G costs related to contract management, legal review, procurement, and accounts payable processing are already captured in the provider's A&G cost center and are allocated to departments that have a genuine causal relationship to those functions. Our proposal does not prevent providers from recovering these administrative costs. Instead, it prevents these administrative costs from being disproportionately amplified by the high dollar value of purchased services or products. The issue is one of proportionality and accuracy. Additionally, the cost report framework under PRM § 4013 is designed to allocate A&G costs based on a proxy that reflects the relative consumption of administrative resources. Including purchased services and supplies in the accumulated cost statistic inflates the statistical base of cost centers that do not meaningfully consume A&G resources on an ongoing operational basis, thereby diluting the allocation to cost centers that do. Our position is that the accumulated cost statistic should reflect costs that are genuinely driven by, and benefit from, the A&G cost center, a standard that purchased services and supplies do not meet to the same degree as direct labor and operational costs. We believe that purchased services and supplies, by definition, represent costs that have already been externally administered by a third-party vendor or contractor. The purchase price paid to an OPO for purchased organs or to a CAR–T manufacturer, for example, already includes that external entity's full overhead and profit. When a hospital includes the full purchase price in its accumulated cost statistic, it is effectively using the external entity's overhead as a lever to pull the hospital's own A&G overhead into the purchased-service cost center which we believe results in a clear and demonstrable double-counting of overhead and is inconsistent with Medicare's reasonable cost principles. We also note that § 413.24(d)(6), *Provider-based entities and departments: Preventing duplication of cost,* already provides specific requirements for purchased services including the requirement that they be removed and separately identified for appropriate cost allocation that does not result in overallocation and improper Medicare payment to the provider. We believe the proposed § 413.24(d)(8) is a logical and consistent extension of the framework that exists in § 413.24(d)(6), not a departure from it.

Regarding commenters' assertions that the proposal could create a new Worksheet B–1 information collection requiring PRA review, we disagree. Negative adjustments and componentizing have been longstanding methods available to providers in the Medicare cost reporting instructions and the Worksheet B–1 so that providers can remove inappropriate costs from the accumulated cost statistic. This is also evidenced by § 413.24(d)(6) regarding the removal of purchased services. The heading for § 413.24(d)(6) is ''Provider-based entities and departments: Preventing duplication of cost,'' however, this section pertains to the removal of duplicated costs for both provider-based entities and departments. We agree with the commenter who suggested that CMS re-word the paragraph heading in § 413.24(d)(6) to assist providers in understanding that § 413.24(d)(6) applies to more than just provider-based entities. The intention of § 413.24(d)(6) is to prompt providers to remove directly assigned costs that already include a share of overhead costs that result in improperly allocated costs to the cost center because including such costs duplicates the directly assigned costs.

Regarding commenters' concerns that exclusion of purchased services and supplies could increase aggregate Medicare expenditures, we believe this assertion is speculative and unsupported by any data. Regarding commenters' concerns that the reimbursement impact is immaterial as a result of the proposals, we believe that appropriate reporting and allocation of costs is important to maintain the integrity of the Medicare trust fund regardless of whether the provider believes their reimbursement impact is immaterial. Additionally, there should be no increased administrative burden to comply with Medicare's longstanding cost reporting instructions in PRM–2 chapter 40 and manual provisions in PRM–1 chapter 23, to appropriately allocate costs. We believe that if there is a material reimbursement impact to providers, then this could signify commensurate material improper payments from Medicare that CMS has an obligation to address in furtherance of program integrity. We reiterate our intended goal of accuracy and integrity of the cost allocation process at the individual provider level.

Comment: Some commenters requested clearer definitions of ''purchased services,'' ''purchased clinical services,'' and ''purchased products,'' and asked whether the proposed policy applies broadly beyond organs and CAR–T cell therapies to other high-cost drugs, biologics, devices, and cell and gene therapies. Some commenters requested a materiality threshold and documentation safe harbor. Some commenters asserted that CAR–T cell therapies and autologous biologics differ from purchased organs because hospitals incur uncompensated collection, storage, processing, shipping, chain-of-custody, and care-coordination costs that are not included in the manufacturer's product price. Commenters also note that autologous cell therapy patient journeys vary and that collection may occur at different sites and settings.

Response: We thank commenters for their request for additional clarity. As stated previously, we are not requiring

all purchased service costs be removed from the accumulated cost statistic. To clarify, we are referring to purchased services provided under contract that should be removed from the accumulated cost statistic. The purpose of the accumulated cost statistic is to measure internal resource utilization. Contract services are performed by the external/supplying entities and the purchased contract amount does not represent the hospital's own resource consumption and therefore, the purchase contract amount should not influence how the hospital's overhead costs are distributed. Certain clinical services or supplies purchased from outside vendors at a high cost that are charged directly to a cost center, thereby increasing that cost center's total costs, and thus its share of overhead, should be excluded or reduced when used as an allocation base. Examples of these services are purchased radiology services, purchased laboratory services, purchased therapy services, purchased dialysis services, anesthesia services, and medical education costs. We would also like to clarify that we are not requiring all supplies be removed from the accumulated cost statistic. However, we are referring to the removal of supplies such as organs, donor tissue, blood products, and CAR–T cell therapies, that are acquired on behalf of a patient and passed directly to the payer without markup, including costs that are highly variable and not representative of routine costs reimbursed separately outside of standard DRG/APC rates, as well as costs the hospital acquires or procures on a case-by-case basis that are not stocked routinely. Inclusions of these types of costs significantly and improperly skew CCRs and cost allocation. As we discussed in the proposed rule, the statistical basis must reflect the cause-and-effect relationship between the cost and the activities or services receiving the allocation, that is, the benefit received by each cost center.[678] Additionally, we remind providers that the statistical measure must demonstrate how costs incurred relate to the consumption of resources.[679]

Regarding commenters who requested a safe harbor threshold, we cannot provide a safe harbor threshold of a specific dollar amount, however, if the cost in question is immaterial (*i.e.,* it would not significantly affect the Medicare cost report outcome), providers may not be required to remove the cost to make the adjustment. However, if the cost in question is material (*i.e.,* it would significantly affect the Medicare cost report outcome), providers are required to remove the cost to make the adjustment.

Comment: Several transplant hospitals commented that the allocation proposal would underpay them by excluding organ acquisition costs from the accumulated cost statistic. They asserted that the proposal failed to recognize their program management, compliance, coordination, and infrastructure costs. Commenters warn that reduced reimbursement could threaten access to transplant services for vulnerable patients. Other commenters asserted that safety-net hospitals may face downstream effects because cost report data affects DSH surveys and community benefit reporting. Commenters urged that any cost-allocation revision be uniform, transparent, and consistent with longstanding Medicare principles.

Response: CMS's proposal does not eliminate reimbursement for transplant program management, coordination, compliance, or infrastructure costs. We also do not believe that our proposal will be a detriment to a hospital's DSH or community benefit reporting. Accurate cost reporting does not reduce legitimate reimbursement. Our proposals are designed to correct inflated cost statistics that produce inaccurate CCRs. Providers are still reimbursed for all reasonable and necessary costs, however, they are not permitted to inflate cost statistics in ways that distort payment calculations for all providers. If cost report data has been improperly inflated, then downstream calculations based on that improperly inflated data have also been inaccurate. Correcting the underlying data improves the integrity of all downstream calculations, including DSH surveys. Administrative and general costs are directly reportable in the appropriate cost centers on the Medicare Cost Report and are reimbursable as reasonable costs under existing Medicare principles. The proposal addresses only the mechanism by which A&G overhead is allocated, not whether transplant-related administrative costs are allowable, or how DSH or a hospital's community benefit is reported. Transplant hospitals can and should report their own A&G costs and allocate accordingly using a statistically valid basis that reflects a causal and beneficial relationship. We maintain that allowable transplant A&G costs remain fully reportable and reimbursable.

Comment: A couple of commenters argued that CMS's proposal is a departure from what the commenters characterize as CMS's longstanding practice of accepting that although ''certain A&G costs might be allocated disproportionately to Medicare or non-Medicare patients,'' any imprecision in cost allocation would be cured by the ''averaging principle'' as articulated by CMS in previous court cases. (*Humana of Aurora* v. *Heckler,* 753 F.2d 1580 (10th Cir. 1985) and *St. James Hosp.* v. *Heckler,* 760 F.2d 1460, 1472 (7th Cir. 1985)). These commenters suggested that the 'averaging principle' means that for every dollar over-allocated to Medicare, another dollar is under-allocated away from Medicare and assert that CMS has never mandated that providers adjust their accumulated cost statistics for costs that receive no benefit or resource from A&G.

Response: CMS disagrees with the commenters' characterization that CMS's prior use of an 'averaging principle' represents a departure from our current proposal and prevents CMS from clarifying and codifying longstanding cost allocation principles. The averaging principle was described by the Agency in Intermediary Letter No. 234 (June 2, 1967) in the context of reasonable cost allocation and is appropriate when all cost centers in the pool have some relationship to the overhead being allocated. The averaging principle, as recognized in *Humana of Aurora* and *St. James Hosp.,* permits reasonable approximations in cost allocation where the statistical basis bears a reasonable relationship to the costs being allocated. The 'averaging principle' does not override the requirement that a causal or beneficial relationship must exist to the overhead being distributed. Our proposal is consistent with the 'averaging principle' and with CMS's longstanding statutory authority to establish cost-finding methodologies that produce accurate and reasonable Medicare payments. Our proposal preserves the accumulated cost statistic and the averaging methodology because it requires that the statistical base accurately reflect the cost centers that actually benefit from A&G overhead. CMS's use of 'averaging principle' in prior, unrelated cases does not prevent CMS from refining policy where necessary and required under the Medicare statute (42 U.S.C. 1395x(v)(1)(A)) to ensure that Medicare payments reflect the actual costs of services rendered to Medicare beneficiaries. Where a specific allocation methodology results in distortions, even if the distortion may ''average out'' across the system, CMS is not required to perpetuate that

[678] PRM–1, chapter 23, section 2307.

[679] PRM–1, chapter 23, section 2306.

distortion. Although *Humana of Aurora* and *St. James Hospital* describe the ''averaging principle,'' neither case holds that CMS is prohibited from clarifying and codifying a cost allocation methodology.

Comment: Some commenters requested that the proposal be applied prospectively, not retroactively or used to reopen settled cost reports.

Response: We appreciate commenters sharing their concerns, however, as previously discussed, these proposals represent the codification of longstanding cost allocation principles as already set forth in the PRM and cost reporting instructions. Our codifications of these provisions do not predetermine whether providers, for past cost reporting periods, have or have not acted consistently with existing regulations and the Provider Reimbursement Manual and cost reporting instructions. Whether an adjustment should be made for any prior cost reporting periods will be determined by reference to the regulations and PRM provisions applicable to those earlier periods, including the regulations governing reopenings.

After careful consideration of the public comments received on our proposed clarification and codification of cost allocation principles, we are finalizing § 413.24(d)(8) as proposed. This section of this final rule clarifies and codifies longstanding Medicare cost-finding principles, as set forth in the Provider Reimbursement Manual and existing Medicare Cost Report instructions, into regulatory text to ensure that providers' costs of providing services to Medicare beneficiaries are correctly calculated and that Medicare payments are accurate and appropriate. Based on a comment received and to provide greater clarity and guidance to providers, we are also revising the paragraph heading of § 413.24(d)(6) ''Provider-based entities and departments: Preventing duplication of cost'' to instead specify ''Preventing duplication of costs: departments and provider-based entities'' to better reflect the instruction in that paragraph on preventing duplication of costs, for both departments and provider-based entities. We believe this change will assist providers in their understanding of the applicability of § 413.24(d)(6). We note that we are revising only the paragraph heading of § 413.24(d)(6) and are not making any other changes to the text of paragraph § 413.24(d)(6).

4. Discretionary CMS Administrator Review of CMS Reviewing Official Determination With Respect to Appeals Under 42 CFR 413.420(g) for Independent Organ Procurement Organizations and Histocompatibility Laboratories

a. Background

Upon receipt of a provider's cost report, the Medicare contractor reviews or audits the cost report, makes any necessary adjustments to the provider's Medicare reimbursement for the cost reporting period, and finally determines the total amount of reimbursement due the provider. This year-end reconciliation of Medicare payment for the provider's cost reporting period constitutes a contractor determination, as defined in 42 CFR 405.1801(a). Under 42 CFR 405.1801(a)(1) and (2), and 405.1803, the contractor must give the provider written notice of the contractor determination for the cost period in a notice of the total amount of program reimbursement (NPR). The NPR is an appealable determination, subject to the jurisdictional and other requirements of the statute and regulations.

Currently, the regulations at § 413.420(g) provide that an Independent Organ Procurement Organization (IOPO) or a Histocompatibility Laboratory (HCL) that is dissatisfied with a Medicare contractor's cost report determination may request a hearing before a contractor hearing officer if the amount in controversy is $1,000 or more, in accordance with the procedures and requirements set forth in 42 CFR 405.1811 through 405.1833. Once the contractor hearing officer decision is issued, an IOPO, HCL is entitled to obtain review by a CMS reviewing official (*see* 42 CFR 405.1801(b), 405.1833, 405.1834(b) and (c)). Section 405.1834 currently specifies that the designated CMS reviewing official reviews a final decision by the contractor hearing officer and then issues a decision on behalf of the Administrator (§ 405.1834(a)). The CMS reviewing official, on behalf of the Administrator, currently has discretion to take own-motion review (that is, review that is not at a request of a party) of a contractor hearing officer decision (§ 405.1834(a), (b)(1)(ii), and (d)). The CMS reviewing official decision may be reopened and revised by a CMS reviewing official in accordance with §§ 405.1885 through 405.1889 (see § 405.1834(f)(1)).

On May 2, 2023, the CMS Administrator issued Standing Order 2023–1, to allow IOPOs and HCLs to request that the Administrator review a CMS reviewing official decision and to confirm that the Administrator can review a CMS reviewing official decision on his or her own motion. In the 2027 IPPS proposed rule, we proposed these regulatory changes to confirm, clarify, and explicitly provide that the Administrator has discretionary authority to review CMS reviewing official decisions and contractor hearing officer decisions for reimbursement appeals for IOPOs and HCLs. We did so for several reasons. Among other things, we proposed these changes to: provide consistency with other Agency administrative review processes; provide clearer notice of this aspect of the administrative review procedures applicable to IOPOs and HCLs; ensure that interested parties can comment; improve the quality of Agency decision making; and so that the Agency may ultimately have clear and publicly available regulations regarding administrative review for IOPOs and HCLs on the books. These proposals are in many respects similar to the CMS proposal to codify the process by which the Administrator may exercise discretionary review when CMS de-certifies an OPO or otherwise takes action that would be subject to appeal under 42 CFR 486.314.[680] We also proposed conforming changes to certain appeals regulations, as well as proposed certain changes to certain other appeals regulations for clarity.

b. Proposals

(1) Proposal for Appeals Available to IOPOs and HCLs

In the 2027 IPPS proposed rule, we proposed to make changes to various regulatory provisions to confirm, clarify, and explicitly provide that a party to a CMS reviewing official decision may request that the Administrator review a CMS reviewing official decision, and that the Administrator may review a CMS reviewing official decision on his or her own motion, consistent with the intent of the Standing Order 2023–01. We believed the proposed changes in the proposed rule would afford an opportunity to IOPOs and HCLs that desire to have CMS reviewing official decisions further reviewed by the Administrator. These proposed changes will also ensure that the regulations explicitly provide that a principal officer of the United States (the CMS Administrator) will have discretionary authority to issue a final decision binding the U.S. Department of Health and Human Services. These proposed changes will also bring the § 413.420(g)

[680] 91 FR 4190, January 30, 2026.

appeals process into greater conformity with other CMS appeals processes that provide for discretionary Administrator review of administrative decisions rendered by Agency tribunals, Agency officials or other individuals. Our proposed changes are within the Secretary's general rulemaking authority under sections 1102 and 1871 of the Act.

Specifically, in the proposed rule we proposed to revise § 405.1801(a) so that it states that Administrator review means review provided for in section 1878(f) of the Act (42 U.S.C. 1395oo(f)) and 42 CFR 405.1875 and 405.1834. This proposed change reflects the changes that would be made to § 405.1834 if the proposed rule is finalized.

In the proposed rule, we also proposed to revise § 405.1803(d)(1)(ii) so that it reflects the fact that a final Agency decision by the Administrator is not just ''as described in § 405.1875(e)(4),'' but also is as described in § 405.1834. This proposed change reflects the changes that would be made to § 405.1834 if this final rule is finalized.

With respect to the required amount in controversy for the right to a contractor hearing for IOPOs and HCLs, in the proposed rule, we proposed to revise § 405.1811(a)(2) and § 405.1811(c)(3) to specify that IOPOs and HCLs are subject to an amount in controversy as set forth in 42 CFR 413.420(g), which is $1,000 or more.

In the proposed rule, we also proposed to revise 42 CFR 405.1813(e)(1) and add new paragraphs (e)(1)(i), (e)(1)(ii), and (e)(1)(iii) to reflect that a contractor hearing decision denying an extension request under this section and dismissing the appeal is final and binding on the provider, unless the dismissal decision is reviewed by a CMS reviewing official in accordance with § 405.1834(b)(2)(i), or the Administrator, or is reopened and revised by the contractor hearing officer(s) in accordance with §§ 405.1885 through 405.1889. We also proposed to revise § 405.1813(e)(2) to specify that the contractor hearing officer(s) promptly sends the decision to the appropriate component of CMS (currently the Center for Medicare).

In the proposed rule, we also proposed to add new § 405.1813(e)(3), (e)(3)(i), and (e)(3)(ii) to reflect that a contractor hearing officer's decision granting an extension request is not subject to immediate review by a CMS reviewing official (as described in § 405.1834(b)(3)), and any decision granting an extension request may be examined during the course of a CMS reviewing official's review of a final jurisdictional dismissal decision or a final hearing decision by the contractor hearing officer(s) (as described in § 405.1834(b)(2)(i) and (ii)) or during the Administrator's review of a CMS reviewing official decision.

In the proposed rule, we also proposed to revise § 405.1814(a)(5) to reflect that final jurisdictional findings and jurisdictional dismissal decisions by the contractor hearing officer(s) are subject to the CMS reviewing official procedure in accordance with §§ 405.1814(d) and 405.1834(b)(2)(i) and (ii), as well as the possibility of review by the Administrator. We also proposed to revise § 405.1814(c)(3) by adding paragraphs (c)(3)(i), (c)(3)(ii) and (c)(3)(iii) to reflect that a jurisdictional dismissal decision by the contractor hearing officer under § 405.1814(c)(2) is final and binding on the parties, unless the decision is reviewed by a CMS reviewing official in accordance with § 405.1834, or is subsequently reviewed by the Administrator in accordance with § 405.1834, or is reopened and revised by the contractor hearing officer in accordance with §§ 405.1885 through 405.1889.

In the proposed rule we also proposed to revise the title of § 405.1814(d) so that it would refer to jurisdictional decisions and include the possibility of Administrator review. We also proposed to revise § 405.1814(d) so that it states that any finding by the contractor hearing officer as to whether he or she has jurisdiction to grant a hearing on a specific matter at issue in an appeal is not subject to further administrative review, except as provided in § 405.1814(d). The revised subsection will also explain that a contractor hearing officer's jurisdictional findings as to specific matters at issue in an appeal may be reviewed solely during the course of the CMS reviewing official review of one of the contractor hearing officer decisions specified in § 405.1834(b)(2), or during the course of the Administrator's review of a CMS reviewing official decision.

Regarding the reviewability of a contractor hearing officer's discovery or disclosure rulings, in the proposed rule we also proposed to revise § 405.1821(d)(2) to specify that to the extent a ruling authorizes discovery or disclosure of a matter for which an objection based on privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the contractor hearing officer(s), that portion of the discovery or disclosure ruling may immediately be reviewed by a CMS reviewing official or the Administrator in accordance with § 405.1834. We also proposed to revise § 405.1821(d)(2)(i) to remove the phrase ''the Administrator through'' so it reflects that upon notice to the contractor hearing officer that the provider intends to seek immediate review of a ruling, or that the contractor or other affected nonparty intends to suggest that the CMS reviewing official or the Administrator, take own motion review of the ruling, the contractor hearing officer stays all proceedings affected by the ruling. To conform with this proposal, we also proposed to revise the introductory text of § 405.1821(d)(2)(iii) to delete the words ''Administrator through the,'' so that the first line states ''If the CMS reviewing official or the Administrator''

Regarding the effect of a contractor hearing officer's decision, in the proposed rule we also proposed to amend § 405.1833 by adding paragraphs (a), (a)(1), and (a)(2) so that they reflect that a contractor hearing officer's decision issued in accordance with § 405.1831 is final and binding on all parties to the contractor hearing and on the contractor, unless the contractor hearing officer's decision is reviewed by a CMS reviewing official, or is reviewed by a CMS reviewing official and then is in turn reviewed by the Administrator in accordance with § 405.1834, or is reopened and revised by the contractor hearing officer(s) in accordance with §§ 405.1885 through 405.1889. We also proposed to amend § 405.1833 by adding paragraph (b) to specify that final contractor hearing decisions are subject to the provisions of § 405.1803(d).

In the proposed rule, we also proposed to revise the section heading of § 405.1834 so that it references the possibilities of and procedures for review by the CMS reviewing official and Administrator review of a reviewing official decision. We also proposed to revise § 405.1834(a) so that it no longer states that a review of a contractor hearing officer is conducted ''on behalf of the Administrator'' by a designated CMS reviewing official, and no longer indicates that the CMS reviewing official issues a decision ''on behalf of the Administrator.'' We proposed that § 405.1834(a) states that CMS or a provider that is a party to, and dissatisfied with, a final decision by the contractor hearing officer(s), upon submitting a request that meets the requirements of § 405.1834(c), is entitled to further administrative review of the decision by a CMS reviewing official, and that the decision may be reviewed at the discretion of first a designated CMS reviewing official and discretionary review by the

Administrator. Additionally, we proposed to revise § 405.1834(a) so that it states that the review of a contractor hearing officer's decision is conducted first by a designated CMS reviewing official who considers whether the decision of the contractor hearing officer(s) is consistent with the controlling legal authority (as described in § 405.1834(e)(1)) and the evidence in the record, and that the CMS reviewing official's decision may then be subject to further discretionary review by the Administrator.

We also proposed to revise the general rules in § 405.1834(b)(1)(ii) to specify that the CMS reviewing official exercises this review authority in response to a request from a provider party to the appeal that meets the requirements of § 405.1834(c), or in response to a request from CMS, or may exercise his or her discretion to take own motion review. Additionally, we proposed to revise the general rules in § 405.1834(b)(4) to require the contractor hearing officer(s) to promptly send copies of any decision specified in § 405.1834(b)(2) or (3), or in § 405.1821(d)(2) and the underlying contractor hearing officer's administrative record to the appropriate component of CMS (currently the Center for Medicare). We also proposed to revise § 405.1834(b)(4)(ii) to specify that the appropriate CMS component examines each contractor hearing officer decision that is reviewable under § 405.1834(b)(2) or (3), or § 405.1821(d)(2), along with any review requests and any other submissions made by a party or CMS in accordance with § 405.1834, in order to assist the CMS reviewing official's and the Administrator's exercise of this review authority.

To correct a typographical error in § 405.1834(c) regarding the granting of a provider's request for review by a CMS reviewing official, we proposed to revise § 405.1834(c)(1)(i) to change the word from ''or'' to ''and'' at the end of § 405.1834(c)(1)(i). This proposed revision would reflect that a provider's request for review by a CMS reviewing official is granted if § 405.1834(c)(1)(i) and § 405.1834(c)(1)(ii) are met by requiring that the date of receipt by the appropriate CMS component of the review request is no later than 60 days after the date of receipt by the provider of the contractor hearing officer decision; and the request seeks review of a decision listed in § 405.1834(b)(2), and the provider complies with the requirements of § 405.1834(c)(2).

Regarding a request for immediate review of a contractor hearing officer ruling authorizing discovery or disclosure, we proposed to revise § 405.1834(c)(3) and (c)(3)(i) to specify that a request from a party or CMS for immediate review of a contractor hearing officer ruling authorizing discovery or disclosure in accordance with § 405.1834(b)(3) must be made as soon as practicable after the ruling is made, but in no event later than 5 business days after the date the requesting party or CMS received notice of the ruling.

To reorganize and house the provisions together in § 405.1834(d) for the own motion review of a CMS reviewing official, in the proposed rule, we proposed to revise the paragraph title of § 405.1834(d) so that it states ''Own motion review of a CMS reviewing official.'' We also proposed to revise § 405.1834(d)(1) to reflect that the CMS reviewing official has discretion to take own motion review of a contractor hearing decision (regardless of whether the decision was favorable or unfavorable to the provider) or other reviewable action. We also proposed to add new § 405.1834(d)(4) to specify that if the CMS reviewing official does not notify the parties and the contractor that he or she intends to review the contractor hearing officer decision or other reviewable action within 90 days after the date of the contractor hearing officer's decision, then the Administrator may issue a notice instructing the CMS reviewing official to review the contractor hearing officer decision and issue a decision if the CMS reviewing official fails to do so. Additionally, we proposed to add new § 405.1834(d)(4)(i) to specify that the Administrator shall promptly provide copies of the notice instructing the CMS reviewing official to review the contractor hearing officer decision to the parties, the contractor, and to the appropriate component of CMS. We proposed to add new § 405.1834(d)(4)(ii) to specify that after the CMS reviewing official's receipt of the Administrator's notice (instructing the CMS reviewing official to review the contractor hearing officer decision and issue a decision), the CMS reviewing official must allow the parties a reasonable period to comment on the issues identified by the Administrator for review. Finally, we proposed to add new § 405.1834(d)(5) to specify that if no party requests review of the contractor hearing decision and the CMS reviewing official does not take review on its own motion or at the direction of the Administrator within the time periods specified in § 405.1834(d), the contractor hearing officer decision is final in accordance with § 405.1833.

Regarding the reviewing official's review procedures for contractor hearing officer's decisions, in the proposed rule, we proposed to revise the introductory text in § 405.1834(e)(1) to state ''In reviewing a contractor hearing officer decision specified in paragraph (b)(2) or (b)(3) of this section, the CMS reviewing official must—.'' We also proposed to revise § 405.1834(e)(3) to specify that upon completion of the review of a contractor hearing decision in § 405.1834(b)(2) or § 405.1834(b)(3), the CMS reviewing official issues a written decision that includes findings of fact and conclusions of law on jurisdictional issues and on the merits of each issue under review over which the CMS reviewing official has jurisdiction and affirms, reverses, or modifies the contractor hearing decision or remands the contractor hearing decision to the contractor hearing officer for further proceedings. A copy of the decision must be sent promptly to each party, to the contractor, and to the appropriate component of CMS (currently the Center for Medicare).

To reflect the possibility of Administrator review of a reviewing official's decision, in the proposed rule, we proposed to revise § 405.1834(f) from ''Effect of a decision: Remand'' to ''Effect of a reviewing official's decision, remand, and the possibility of Administrator review.'' We also proposed to revise § 405.1834(f)(1) to specify that a decision of affirmation, reversal, or modification by the CMS reviewing official is final and binding on each party and the contractor except as set forth in § 405.1834(g). The CMS reviewing official's decision may be reopened and revised by the CMS reviewing official in accordance with §§ 405.1885 through 405.1889. Decisions of a CMS reviewing official are subject to the provisions of § 405.1803(d). A decision by a CMS reviewing official remanding an appeal to the contractor hearing officer(s) for further proceedings under § 405.1834(f)(2) is not a final decision.

We also proposed to revise the introductory text of § 405.1834(f)(2) to state ''A remand to the contractor hearing officer(s) by the CMS reviewing official must do all of the following:''

In the proposed rule, we also proposed to add § 405.1834(f)(3) to specify that the CMS reviewing official must promptly send copies of the CMS reviewing official decision, along with any other submissions made by a party or CMS in accordance with the provisions of this section, to the appropriate component of CMS (currently the Center for Medicare) and

to the Administrator c/o the CMS Office of the Attorney Advisor.

In the proposed rule, we also proposed to add new paragraph (g) entitled ''Administrator review of a CMS reviewing official's decision'' to § 405.1834 to further specify and elaborate on the procedures for the Administrator's review of a CMS reviewing official's decision. Specifically, we proposed to add § 405.1834(g)(1) to specify that CMS or any party to a CMS reviewing official decision may request Administrator review of a CMS reviewing official decision in accordance with § 405.1834. No other provider, individual, or entity may request review. The Administrator may grant or deny review of a CMS reviewing official decision at his or her discretion. The Administrator may also review any decision of the CMS reviewing official on his or her own motion (regardless of whether the decision was favorable or unfavorable to the provider). In the proposed rule, we also proposed to add § 405.1834(g)(2) to specify that a party, or CMS may request that the Administrator review a CMS reviewing official decision within 15 days of their receipt of a final CMS reviewing official decision. *See* 42 CFR 405.1801 (defining the term ''date of receipt.''). We also proposed to add § 405.1834(g)(2)(i) to specify that all requests for Administrator review and any other submissions to the Administrator under § 405.1834(g)(2) must be sent to the Office of the Attorney Advisor. The request for review must be in writing, attach a copy of the CMS reviewing official decision for which it seeks review, and include a brief description of all of the following: those aspects of the CMS reviewing official decision with which the requestor is dissatisfied; the reasons for the requestor's dissatisfaction; any argument or record evidence the requestor believes supports its position; and any additional, extra-record evidence relied on by the provider, along with a demonstration that such evidence was improperly excluded in proceedings (as described in § 405.1823).

In the proposed rule, we also proposed to add § 405.1834(g)(2)(ii) to specify that the Administrator must issue a Notice advising the parties of his or her intent to review or to decline to review within 30 days of the Administrator's receipt of a request for review from CMS or any party to the CMS reviewing official's decision. That Notice must be promptly sent to the parties, the contractor, and the appropriate component of CMS. A Notice advising the parties of the Administrator's intent to review must contain a brief statement of the issues under ''review and solicit comments from the parties, the contractor, and CMS. A Notice that the Administrator is declining to review need not set forth the basis for the Administrator's decision to decline review the CMS reviewing official's decision. We also proposed to add § 405.1834(g)(2)(iii) to specify that if the Administrator declines to review the reviewing official decision or the Administrator does not issue a determination regarding review of the reviewing official decision within 30 days of the Administrator's receipt of a request to review, the decision of the CMS reviewing official is final. We also proposed that § 405.1834(g)(2)(iii) specify that upon issuance of a Notice, within 30 days of a request for Administrator review of a CMS reviewing official decision, that the Administrator is declining to review the reviewing official's decision, the CMS reviewing official's decision becomes final in accordance with § 405.1834(f)(1).

In the proposed rule, we also proposed to add § 405.1834(g)(3) to specify that within 45 days of Administrator's receipt of a CMS reviewing official's decision, the Administrator may issue a Notice of Review on his or her own motion. The Notice of Review must be sent to the parties, the contractor, and the appropriate component of CMS. The Notice of Review must contain a brief statement of the issues under review and solicit comments from the parties, contractor, and CMS. If the Administrator does not issue a determination regarding his or her own motion review within 45 days of the Administrator's receipt of a CMS reviewing official's decision, the decision of the CMS reviewing official is final.

In the proposed rule, we also proposed to add § 405.1834(g)(4), (g)(4)(i) and (g)(4)(ii) to set forth that if the Administrator elects to review the CMS reviewing official's decision, the Administrator will set deadlines for the parties and affected nonparties to submit comments; and the Administrator's decision affirming, reversing, or modifying the CMS reviewing official's decision is final and binding on each party and the contractor. A decision remanding an appeal to the CMS reviewing official, or contractor hearing officer(s) is not a final decision. Decisions of the Administrator are subject to the provisions of § 405.1803(d).

In the proposed rule, we also proposed to add § 405.1834(g)(5) to specify that if the Administrator does not issue a written decision that affirms, reverses, modifies or remands the CMS reviewing official's decision within 60 days of the date of issuance of the Notice of Review, the CMS reviewing official's decision becomes final in accordance with § 405.1834(f)(1). We also proposed to add § 405.1834(g)(6) to specify that the Administrator may remand the CMS reviewing official's decision to the CMS reviewing official, to the contractor hearing officer, or to the contractor. A remand by the Administrator must do all of the following: vacate the CMS reviewing official's and/or the contractor hearing officer decisions as to the specific issues remanded; be governed by the same criteria that apply to remands by the Administrator to the Board under § 405.1875(f)(2), and require the entity to which the matter is remanded to take specific actions on remand; and result in the CMS reviewing official, contractor hearing officer(s), or contractor taking the actions required on remand and issuing a new decision.

Comment: Some commenters asserted the Administrator's interpretation of *United States* v. *Arthrex, Inc.,* 594 U.S. 1 (2021) (*Arthrex*) is self-serving and inaccurate, claiming there is no constitutional requirement for extra Administrator review. They opined that the existing Agency review process complies with the Appointments Clause, as confirmed by the Supreme Court in *Arthrex.*

Response: We disagree with the commenters who asserted our proposal was prompted by or reflects a particular interpretation of *Arthrex,* let alone one that is self-serving and inaccurate. We did not mention *Arthrex* in the proposed rule. However, we believe our proposal is consistent with, and is supported by, the framework and spirit of the Supreme Court's decision in *Arthrex,* as well as the Appointments Clause. We also agree with the commenters who asserted that the existing Agency review process complies with the Appointments Clause and the *Arthrex* decision.

The central holding of *Arthrex* was that Congress may not impose statutory restrictions that prevent a principal officer from reviewing adjudicatory decisions that are issued by inferior officers who are also insulated from at-will removal by the Department Head. *See Arthrex,* 594 U.S. at 25–27. No such statutory restriction on review is at issue here. *Arthrex* did not involve a purported or actual regulatory restriction on review by principal officers. Specifically, in *Arthrex,* a statute expressly precluded review by a

superior, principal officer and reserved the sole authority to grant rehearings to the Patent Trial and Appeal Board, which was composed of APJs, who were insulated from at-will removal under 5 U.S.C. 7513. *See Arthrex,* 594 U.S. at 25 (citing 35 U.S.C. 6). The Supreme Court held that in that context, the Constitution ''forbids the enforcement of *statutory* restrictions on the Director that insulate the decisions of APJs from his direction and supervision.'' *Id.* at 27 (emphasis added). The Court contrasted this situation with ''a handful of contemporary officers who are appointed by heads of departments but who nevertheless purportedly exercise final decisionmaking authority,'' noting that the latter scenarios ''involve inferior officers whose decisions a superior executive officer can review or implement a system for reviewing.'' *Id.* at 20. The current appeals process for IOPO and HCL appeals is a creature of regulatory rather than statutory creation. The decisions of the CMS Reviewing Official for example under that procedure derive their authority and significance and binding nature from the regulations, and this from the discretion and delegated authority of the Secretary and Administrator. In this context, agency regulations are not the same as statutes, and delegated administrative authority is not the same as statutory restriction. *See Rodriguez* v. *SSA,* 118 F.4th 1302, 1312–13 (11th Cir. 2024) (''In this context, agency regulations are not the same as statutes, and delegated administrative authority is not the same as statutory restriction''). Moreover, the current regulations do not expressly address the CMS Administrator's discretionary power to review decisions in the IOPO and HCL context.

Our proposal in the proposed rule would make explicit and more clear that the CMS Administrator, a Senate-confirmed principal officer of the United States, will have discretionary authority to issue a final decision binding the U.S. Department of Health and Human Services for reimbursement appeals for IOPOs and HCLs and sets forth a detailed predictable procedure for that potential review. As such, it is certainly in keeping with the spirit of *Arthrex,* even if it is not required by the decision. We also note that *Arthrex* did not require that a principal officer review every decision, only that a statute not prevent a principal officer from doing so. We believe that changing the regulations so that they provide for discretionary Administrator review here will promote the values of democratic accountability (ensuring that all final decisions in IOPO and HCL appeals reflect the views and priorities of the executive branch), as well as the values of predictability and consistency (by eliminating the danger that different reviewing officials and hearing officers may render decisions that are inconsistent). Our proposed codification is being made under the Secretary's statutory rulemaking authority under sections 1102, 1871, and 1878(f) of the Act. By engaging in this notice-and-comment rulemaking, and codifying the Standing Order 2023–1, into the Code of Federal Regulations, the affected parties, including IOPOs and HCLs, will have clear, enforceable, more publicly accessible, published rights. Codifying the right of a party to request Administrator review of a CMS reviewing official decision ensures that affected entities have a formal, legally recognized avenue for appeals. Lastly, our proposal brings the § 413.420(g) appeals process into conformity with other well-established CMS appeals processes that already provide for discretionary Administrator review, by ensuring that the CMS Administrator has clear and codified review authority.

Comment: A few commenters disagreed with our proposal and asserted that the proposal creates a structure in which the Administrator reviews a determination already made in the Administrator's name because the CMS reviewing official issues decisions on behalf of the Administrator. These commenters expressed the concern that an IOPO that prevails before the hearing officer remains exposed to reversal through two successive CMS-controlled stages, with no corresponding right of de novo review in a neutral forum. These commenters asserted that the proposal unfairly vests the Administrator with authority to function as both a party to the dispute and the final adjudicator. These commenters requested that CMS adopt a single layer of Administrator-level oversight above the Hearing Officer, and eliminate the reviewing official level of review, to be consistent with how Administrator review functions in other Medicare cost report appeal contexts. A few commenters requested that CMS clarify the purpose of retaining the reviewing official level of review if the proposal is finalized.

Response: We disagree with the commenters. The CMS reviewing official operates within the CMS organizational structure, however, the reviewing official's decisions are not legally equivalent to decisions of the Administrator. The CMS reviewing official is not the Administrator but is an inferior officer or agency employee exercising delegated authority. Our proposal to codify the discretionary Administrator review of IOPO and HCL reimbursement decisions does not create a circular structure but creates a hierarchical appellate structure that is standard in administrative adjudication. We do not believe that the discretionary Administrator review possibility, with successive agency-level review stages, renders the process unconstitutional or procedurally unfair. Far from being unprecedented, analogous schemes involving multiple levels of administrative review are common across federal agencies and have been consistently upheld.

The commenters' concern that the proposal vests the Administrator with authority to function as both a party to the dispute and the final adjudicator conflates two distinct roles. In administrative adjudication, agencies routinely serve in a dual capacity as both the entity whose determinations are being challenged and the body responsible for adjudicating those challenges. Our proposal is that the Administrator's review would be discretionary; the Administrator would not be a mandatory participant in every reimbursement appeal. We believe that the commenters' proposed remedy to eliminate the CMS reviewing official level would reduce procedural protections for IOPO and HCL reimbursement appeals. A commenter noted in another context, CMS reviewing officials have a significant amount of valuable experience adjudicating IOPO and HCL reimbursement appeals. Moreover, the CMS reviewing official level of review serves important functions, such as providing an intermediate review on contractor hearing officer decisions before they become final and allowing for the correction of errors at the agency level without burdening the Administrator with numerous appeals. The CMS reviewing official level of review would also help to ensure that the factual record is fully developed before the Administrator's discretionary review is sought. Eliminating the CMS reviewing official level of review would overburden the Administrator with routine appeals and could result in fewer cases receiving meaningful review, neither of which serves the interests of IOPOs, HCLs, or the public.

Comment: Some commenters requested that if CMS finalizes this proposal, then the Administrator's own-motion review authority be constrained by objective triggering standards, defined timelines, and substantive criteria because they expressed that unconstrained own-motion review

allows CMS to reopen any settled determination indefinitely. Other commenters requested that CMS establish clear recusal standards and ensure the Administrator's review is limited to questions of law, not de novo factual determinations. Other commenters requested that if the proposal is finalized that CMS establish the scope and standard of Administrator review including whether review will be de novo, deferential to contractor determinations, or limited to identified issues on appeal, and ensure the parties have sufficient opportunity to prepare and submit supporting documentation relevant to an appeal. Other commenters requested that the Administrator's Notice declining a review include a brief explanation to better inform OPOs' understanding of the reasonable cost principles.

Response: While CMS appreciates the commenters' concerns and suggestions, we believe that imposing rigid triggering standards and substantive criteria on the Administrator's own-motion review authority would undermine the very purpose of discretionary review and would be inconsistent with the approach Congress and the Agency have historically taken when establishing and refining and describing administrative appeal regimes in Medicare, Medicaid, Affordable Care Act, and other related contexts. An overly prescriptive criteria would limit the Administrator's ability to address novel or unforeseen legal questions, prevent the correction of errors that fall outside of narrowly defined triggering criteria, and reduce the general flexibility necessary for sound administrative review. While we understand that clarity regarding the Administrator's standard of review is important, we note that the standard of review applicable to the Administrator's discretionary review will be informed by the nature of the issues presented and the existing reimbursement appeals regulatory framework with respect to contractor hearing officer decisions and CMS reviewing official decisions. Consistent with other CMS administrative appeals contexts, the CMS Administrator's discretionary review is generally not intended to function as a full de novo proceeding but rather as a discretionary review of legal and policy questions. With regard to the commenters who requested defined timelines and those who expressed concerns about CMS being able to reopen any settled determination indefinitely, we note that our proposed changes set forth clear and explicit timing deadlines for each stage of review, including timing deadlines applicable to various facets of the CMS Administrator's review and that the more general regulations governing reopening set forth explicit timeframes as well. See example, 42 CFR 405.1885.

With respect to the commenters' request for a recusal process, the Administrator and CMS staff are already subject to existing federal ethics rules and conflict of interest standards that govern agency adjudications. CMS takes seriously the importance of impartiality and procedural integrity in the appeals process. We believe that these existing frameworks provide meaningful protections without the need for additional rule-specific recusal standards. With respect to commenters' requests that CMS limit the Administrator's review to questions of law, we believe that the Administrator's review is generally focused on significant legal and policy questions rather than routine factual disputes, consistent with how Administrator review functions in other Medicare appeals contexts. However, categorically prohibiting the Administrator from reviewing issues of fact could prevent the Administrator from correcting clear factual errors that have significant programmatic consequences. Regarding commenters' concerns that parties have sufficient opportunity to prepare and submit supporting documentation relevant to an appeal, CMS is committed to ensuring that parties have a meaningful opportunity to submit relevant documentation and arguments in connection with any Administrator review proceeding. With respect to commenters' requests that an Administrator's declination of review include an explanation for the declination of review to better inform OPOs' understanding of reasonable cost principles, CMS notes that the discretionary nature of Administrator review means that a declination does not constitute a substantive ruling on the merits, therefore, there is no need to provide a substantive statement on why the Administrator has declined to review a matter. Additionally, we note that the Administrator does not for example include an explanation for the declination of review when a party to a Provider Reimbursement Review Board (PRRB) matter requests the CMS Administrator review a PRRB decision; instead, the Administrator issues a simple notice of their declination to review.

Comment: A couple of commenters opined that the proposed Administrator review timelines and discretionary review criteria could reduce predictability and fairness for OPOs challenging contractor and CMS reviewing official decisions, and could increase legal costs for all parties, as well as increase the risk of reasonable cost disputes for OPOs. These commenters also asserted that the proposal would impose significant harm by adding further delay to an already protracted appeals process and asserted that OPOs are currently experiencing extensive delays, with appeals stretching back more than a decade. These commenters asserted that CMS has not explained why the benefits of this additional review layer justify these costs.

Response: CMS acknowledges the commenters' concern about protracted appeals and remains committed to addressing systemic delays through operational improvements and resource allocation, however, we believe the commenters' concerns are distinct from the legal and procedural questions addressed by this rulemaking. We believe that any delays currently experienced by IOPOs or HCLs are attributable to pre-existing systemic factors that predate this rulemaking and are not a result of our proposed discretionary Administrator review structure.

We believe that delaying or abandoning this rulemaking would not resolve the pre-existing backlog of which the commenters complain and would leave the constitutional and legal deficiencies in the current framework of the Agency's Standing Order unaddressed.

Additionally, we do not believe that the proposal would create new delays because this rulemaking codifies existing framework already established in the Agency's Standing Order 2023–1. IOPOs and HCLs are already operating under a similar review structure under the existing Standing Order. Additionally, codifying the Administrator's discretionary review authority does not mandate that every case undergo Administrator review. Because the Administrator's review is discretionary, many cases will not be subject to this additional layer of review by the Administrator. We believe the commenters' concerns about increased legal costs and delays are speculative, not supported by evidence, and assume that the Administrator's discretionary review will be invoked routinely and broadly. Because the Administrator's review authority is discretionary, additional legal costs may only be incurred in a subset of cases where review is actually sought or initiated. We believe that the Administrator's discretionary review ensures that Medicare's reasonable cost principles are applied consistently across all IOPO

and HCL appeals, reducing the risk of conflicting decisions and promoting long-term predictability. We also believe that the long-term cost savings associated with the Agency's greater policy clarity and consistent application of Medicare's reasonable cost principles are likely to outweigh any increase in legal costs associated with the Administrator's discretionary review.

Comment: A few commenters raised a concern about retroactivity and fundamental fairness because the proposal was proposed to be effective for pending appeals. These commenters said that OPOs that initiated appeals years ago did so under established procedural rules and changing the rules mid-stream disrupts settled expectations and moves the goalposts for providers that have already invested significant time and resources.

Response: We disagree with the commenters who asserted that applying this proposal to pending appeals is unfair or implicates retroactivity. Additionally, we do not believe that CMS has changed the rules mid-stream, disrupted settled expectations, or has moved any ''goalposts.'' The Administrator's review authority was already established under the Standing Order 2023–1, which predates this rulemaking. Accordingly, this rule clarifies and codifies and elaborates upon the Agency's existing practice and framework and does not introduce a new procedural framework. This proposal also clarifies and codifies procedural rules and the process by which decisions are reviewed at the Agency level. This proposal adds a potential avenue for Administrator review; it does not remove any existing right or remedy available to IOPOs or HCLs.

Additionally, this proposal is procedural in nature because it does not create new substantive requirements or obligations for IOPOs or HCLs, alter the legal standards governing reasonable cost determinations, or change the underlying merits of any pending appeal. Moreover, applying procedural changes to pending appeals is a well-established and legally permissible practice in administrative law. Under the Supreme Court's framework in *Landgraf* v. *USI Film Products,* 511 U.S. 244 (1994), a rule has impermissible retroactive effect only if it impairs rights a party possessed when it acted, increases a party's liability for past conduct, or imposes new duties with respect to transactions already completed. *See id.* at 280. But ''[c]hanges in procedural rules may often be applied in suits arising before their enactment without raising concerns about retroactivity.'' *Id.* at 275; *see also see., Combs* v. *Commissioner of Social Security,* 459 F.3d 640, 647 (6th Cir. 2006) (recognizing that ''the Supreme Court in *Landgraf* and *Altmann,* and our court in *Patel,* have recognized that changes to procedural rules generally do not have retroactive effect because procedural rules regulate secondary as opposed to primary conduct'' and that a rule is procedural and not impermissibly retroactive if ''[t]he substantive requirements . . . have not changed, only the way in which the agency goes about determining whether they are present,'' and even if the procedural ''change may be outcome-determinative for some claimants''); *id.* at 649 (also recognizing that ''[an agency] may freely change rules that purely govern the conduct of adjudication, without fear of retroactive effect, if those changes apply only to pending cases.'')

This proposal does none of these things because it does not impair any right IOPOs or HCLs possessed when they filed their appeals; it does not increase liability for any past conduct; and it does not impose new substantive duties on IOPOs or HCLs.

We understand the commenters' argument that IOPOs and HCLs have invested significant time and resources in the existing appeals process, however, this does not constitute a legal bar to this rulemaking. We note that the investment of resources in an ongoing administrative proceeding does not create a vested right in a particular procedural outcome. Accepting the commenters' argument would effectively immunize any pending proceeding from procedural improvements, no matter how legally necessary or administratively beneficial. We believe that we must balance the interests of individual IOPOs and HCLs currently in the appeals process against the broader public interest in a constitutionally sound and legally consistent appeals framework.

Comment: A commenter asserted that CMS has not provided an adequate justification to support how the CMS Administrator has the relevant subject expertise and experience with federal regulations concerning appeals, provider audit and reimbursement matters, Medicare cost report issues, and related subjects at or above the level of the contractor hearing officer or the CMS reviewing official. This commenter opined that past CMS Administrator decisions have reflected misreadings of governing statutes, regulations, and Agency guidance in ways that favored CMS at the expense of a fair and neutral application of the law. This commenter further asserted that the current contractor hearing officer has had a successful career at CMS with positions in several offices including the Director of the Division of Hearings and Decisions in CMS's Office of Hearings, where he has successfully mediated over 2,000 Provider Reimbursement Review Board Medicare provider and Medicare Advantage appeals. The commenter also asserted that the current CMS reviewing official serves as the Chief Hearing Officer and leads the CMS Office of Hearings and has over 25 years' experience in administrative litigation and healthcare law, specializing in adjudicating complex appeals, including reimbursement determinations, compliance matters, and contract disputes.

Response: CMS appreciates the commenter's kind and complimentary words about the experience, expertise, and competence of at least one of the hearing officers and one of the CMS reviewing officials. But the commenter's argument obfuscates the nature and purpose of CMS's proposal to explicitly provide for discretionary CMS Administrator's review in this context. CMS has not done so based on a judgment that any particular Administrator has greater or less technical expertise in Medicare cost accounting or provider reimbursement than any particular contractor hearing officer or CMS reviewing official. Instead, CMS has done so because the Administrator has a different perspective and role as a principal officer of the United States responsible for the overall legal and policy direction of CMS and an official with broad oversight responsibility for the Medicare and Medicaid programs, including the legal and policy frameworks that govern appeals. While we appreciate the commenter highlighting the qualifications of the current contractor hearing officer and the CMS reviewing official, we note that the Administrator brings a different but equally relevant set of qualifications to the review function. The Administrator is responsible for overseeing a $1+ trillion federal program encompassing Medicare, Medicaid, and the Children's Health Insurance Program and the Administrator has broad familiarity with the legal, regulatory, and policy frameworks governing all aspects of CMS operations, including provider reimbursement. Additionally, the Administrator is supported by a team of expert legal and policy staff who can provide technical analysis on complex cost report and reimbursement questions such that the Administrator

need not be a specialist in Medicare cost accounting to exercise meaningful oversight of decisions that raise legal or policy questions. The commenter's opinion that past Administrator decisions have misread governing statutes and regulations in ways that favored CMS do not invalidate the authority of the Administrator to conduct a discretionary review. CMS is committed to ensuring that the Administrator's discretionary review and decisions are conducted in a fair, neutral, and legally sound manner, consistent with applicable statutes, regulations, and Agency manuals and guidance.

Comment: A commenter suggested that CMS implement a nondiscretionary right of administrative appeal for disputes above a material financial threshold.

Response: We disagree with the commenter's suggestion which seems to imply that IOPOs and HCLs with large financial stakes in a dispute should have an automatic, non-waivable right to Administrator-level review, rather than being subject to the Administrator's discretionary review. This approach would transform the Administrator's review from a discretionary oversight mechanism into a mandatory appellate tier, adding significant time, delays and resource burdens to the review process. The Administrator's discretionary review is precisely what makes it constitutionally and administratively appropriate since it preserves the Administrator's ability to focus on cases of genuine legal and policy significance rather than serving as a routine appellate body for only cases above a material, or large, dollar threshold. Although we are aware of the current $1,000 dispute threshold for IOPOs and HCLs to seek the administrative review process, any specific ''material'' dollar threshold could be arbitrary, as we believe there is no principled legal basis for concluding that disputes above a certain dollar amount should automatically warrant Administrator review while those below do not. Additionally, a ''material'' financial threshold could create incentives for parties to artificially inflate the claimed value of disputes to trigger a nondiscretionary review right. Under the proposal, IOPOs and HCLs with significant financial amounts in dispute can request the Administrator to review a decision of the contractor hearing officer or the CMS reviewing official.

After careful consideration of the public comments received on our proposed rule, we are finalizing our proposals pertaining to the Administrator's discretionary review of IOPO and HCL appeals at 42 CFR 405.1801, 405.1803, 405.1811(a)(2), 405.1813(e)(1) and (e)(3), 405.1814, 405.1821, 405.1833 and 405.1834(b), (c), (d), (e) and (f). We acknowledge commenters' request for clarity regarding the proposed timelines for the Administrator to review a CMS reviewing official's decision. Based on public comments received requesting clarity of the proposals, we are finalizing, with modifications, our proposals at §§ 405.1811(c)(3), 405.1813(e)(2), 405.1834(a), 405.1834(g)(2)(ii), (g)(2)(iii) and (g)(3) to provide greater clarity to IOPOs and HCLs, and operational feasibility with respect to the timelines of the Administrator's discretionary review.

Specifically, we are modifying § 405.1811(c)(3) to make a correction because we erroneously included text that was part of § 405.1811(c)(2) in our proposed § 405.1811(c)(3) that read ''unless the provider qualifies for a good cause extension under § 405.1813, the date of receipt by the contractor of the provider's hearing request must be no later than 180 days after the date of receipt by the provider of the final contractor or Secretary determination. An IOPO or histocompatibility laboratory is subject to the amount in controversy requirement specified in § 413.420(g).'' However, we did not propose or intend to propose changes to § 405.1811(c)(2). Instead, we intended to propose that § 405.1811(c)(3) specify (similar to our proposal to § 405.1811(a)(2)) that ''With the exception of an IOPO or histocompatibility laboratory, the amount in controversy (as determined in accordance with § 405.1839) must be at least $1,000 but less than $10,000. An IOPO or histocompatibility laboratory is subject to the amount in controversy requirement specified in § 413.420(g).'' With this modification, we are preserving the original regulation text at § 405.1811(c)(3) to specify the amount in controversy requirement for providers that are not IOPOs or histocompatibility laboratories, as well as the amount in controversy requirement for IOPOs and histocompatibility laboratories.

With regard to § 405.1813(e)(2), in this final rule, we are finalizing § 405.1813(e)(2) with a modification for clarity, transparency and efficiency, to specify that the contractor hearing officer(s) must promptly send the contractor hearing decision to the appropriate component of CMS (currently the Center for Medicare), and the CMS reviewing official (currently the CMS Office of Hearings). Although we did not propose that § 405.1813(e)(2) specify that the contractor hearing officer(s) must promptly send the contractor hearing decision to the CMS reviewing official, we believe that in the interest of clarity, transparency and efficiency, and so that all adjudicators are aware, the contractor hearing officer(s) must promptly send the contractor hearing decision to the appropriate component of CMS (currently the Center for Medicare), as well as to and the CMS reviewing official (currently the CMS Office of Hearings).

We are also making a modification to the regulation text we proposed for § 405.1834(a) to correct a typographical discrepancy in the first sentence to include the word 'then' before ''discretionary review'' that we intended to include in the proposed regulation text. With this modification, we are finalizing that § 405.1834(a) will specify that CMS or a provider that is a party to, and dissatisfied with, a final decision by the contractor hearing officer(s), upon submitting a request that meets the requirements of paragraph (c) of this section, is entitled to further administrative review of the decision by a CMS reviewing official, and the decision may be reviewed at the discretion of first a designated CMS reviewing official and then discretionary review by the Administrator. No other individual, entity, or party has the right to the review. The review is conducted first by a designated CMS reviewing official who considers whether the decision of the contractor hearing officer(s) is consistent with the controlling legal authority (as described in § 405.1834(e)(1) of this subpart) and the evidence in the record, and the CMS reviewing official's decision may then be subject to further discretionary review by the Administrator.

In the proposed rule, we proposed that under § 405.1834(g)(2)(ii) the Administrator must issue a Notice advising the parties of his or her intent to review or to decline to review within 30 days of the Administrator's receipt of a request for review from CMS or any party to the CMS reviewing official's decision. In this final rule, we are finalizing § 405.1834(g)(2)(ii) with a modification, for clarity and efficiency, to specify a 45-day timeframe for the Administrator to issue a Notice advising the parties of his or her intent to review or to decline to review a CMS reviewing official's decision, instead of the 30-day timeframe we proposed.

In the proposed rule, we also proposed that under § 405.1834(g)(2)(iii), if the Administrator

issues a Notice to decline review of the reviewing official's decision or if the Administrator does not issue a determination regarding review of the reviewing official's decision within 30 days of the Administrator's receipt of a request to review, the decision of the CMS reviewing official is final. In this final rule, we are finalizing § 405.1834(g)(2)(iii) with a modification, for clarity and efficiency, to specify that if the Administrator declines to review the reviewing official's decision or the Administrator does not issue a determination regarding review of the reviewing official's decision within 45 days of the Administrator's receipt of a request to review, instead of the 30-day timeframe we proposed, the decision of the CMS reviewing official is final in accordance with § 405.1834(f)(1).

Finally, in the proposed rule, we proposed that under § 405.1834(g)(3), within 45 days of the Administrator's receipt of a CMS reviewing official's decision, the Administrator may issue a Notice of Review on his or her own motion, and that if the Administrator does not issue a determination regarding his or her own motion review within 45 days of the Administrator's receipt of a CMS reviewing official's decision, the decision of the CMS reviewing official is final. In this final rule, we are finalizing § 405.1834(g)(3) with a modification, for clarity and efficiency, to specify that in the absence of a request for the Administrator to review under 405.1834(g)(2), the Administrator may issue a Notice of Review on his or her own motion within 45 days of the Administrator's receipt of a CMS reviewing official's decision.

The Notice of Review must be sent to the parties, the contractor, and the appropriate component of CMS. The Notice of Review must contain a brief statement of the issues under review and solicit comments from the parties, contractor, and CMS. If the Administrator does not issue a determination regarding his or her own motion review within 45 days of the Administrator's receipt of a CMS reviewing official's decision, the decision of the CMS reviewing official is final.

(2) Technical and Conforming Changes at § 413.420(g)

Consistent with the proposals in section X.D.4.b.(1). of the preamble of the proposed rule, we proposed conforming revisions to the current regulations at § 413.420(g) for appeals pertaining to IOPOs and HCLs. Specifically, we proposed to revise § 413.420(g) to reflect that if the amount in controversy is $1,000 or more, any IOPO or histocompatibility laboratory that disagrees with a contractor's cost determination is entitled to a contractor hearing, review of the contractor hearing by a CMS reviewing official, and discretionary Administrator Review of a CMS reviewing official decision, in accordance with the procedures set forth in § 405.1801(b)(2) and §§ 405.1811 through 405.1834.

We did not receive comments on these technical and conforming changes at § 413.420(g).

(3) Effective Dates

In the proposed rule, we proposed that these provisions will apply to administrative appeals that were timely filed with a contractor hearing officer on or after the effective date of this rule, under §§ 405.1811 and 405.1834, and/or that are pending before a contractor hearing officer or a CMS reviewing official on the effective date of the rule. With respect to requests for good cause extensions under § 405.1813 (for contractor hearing officer hearings), IOPOs and HCLs that have not filed a timely request for a contractor hearing and that wish to seek an extension of the time limit for filing an appeal based on good cause, have an additional 60 days after the effective date of this rule to seek an extension without meeting the ''reasonable time'' requirements of § 405.1813 (but must meet all other requirements of that section).

Comment: A few commenters suggested a delayed implementation date for this proposal to commence no sooner than fiscal year 2029.

Response: We appreciate the commenters' request for a delayed implementation date to FY 2029 to allow IOPOs and HCLs sufficient time to prepare, however, we do not believe that a delayed implementation date until FY 2029 is warranted because as noted the proposed changes are primarily procedural and clarifying in nature and do not impose new substantive obligations upon IOPOs or HCLs. Additionally, the changes codify existing practice under the Agency's Standing Order 2023–01, such that the affected parties are already operating under a similar framework of what we proposed. We believe that a delayed implementation would prolong the period of regulatory uncertainty that this rulemaking is designed to resolve and ensuring that the regulations explicitly provide that a principal officer has reviewable authority over inferior officer decisions is a reason to have a prompt implementation period, as we proposed in the proposed rule.

After consideration of the public comments we received, we are finalizing this proposal to apply to administrative appeals that were timely filed with a contractor hearing officer on or after the effective date of this rule, under §§ 405.1811 and 405.1834, and/or that are pending before a contractor hearing officer or a CMS reviewing official on the effective date of this rule. With respect to requests for good cause extensions under § 405.1813 (for contractor hearing officer hearings), IOPOs and HCLs that have not filed a timely request for a contractor hearing and that wish to seek an extension of the time limit for filing an appeal based on good cause, have an additional 60 days after the effective date of this rule to seek an extension without meeting the ''reasonable time'' requirements of § 405.1813 (but must meet all other requirements of that section).

5. Technical Corrections and Clarifications of §§ 412.116(c) and 413.404(b)(3)(ii)(A) and (C)

In the proposed rule, we proposed to make several technical corrections or clarifications to the regulatory text, which are unrelated to any of the other proposals in section X.D. of the preamble of the proposed rule.

We proposed to make a technical correction to § 412.116(c), to change ''kidney'' to ''organ.'' This correction should have been made in our FY 2022 IPPS/LTCH PPS final rule, with comment period (86 FR 73468 through 73505), but was overlooked.

We proposed to make a technical correction to § 413.404(b)(3)(ii)(A) to clarify in the definition of a deceased donor SAC that the deceased donor SAC is an average organ acquisition cost that a TH incurs to procure an organ from a deceased donor. The existing regulation omits the phrase ''organ acquisition.'' This proposed language also mirrors the language that defines the living donor SAC.

We proposed to make a technical correction to § 413.404(b)(3)(ii)(C), which inadvertently omitted registry fees from the costs that transplant hospital may use to develop the deceased donor SAC. In the FY 2022 IPPS/LTCH PPS final rule (86 FR73477 and 73478), we included registry fees in the allowable organ acquisition costs used in developing transplant hospital living donor SACs, but inadvertently omitted registry fees from the allowable acquisition costs used to develop the transplant hospital deceased donor SACs. Registry fees would be incurred by transplant hospitals for every potential transplant recipient on their waitlist. Therefore, we proposed to add § 413.404(b)(3)(ii)(C)(*8*), to the allowable costs used to develop the deceased

donor TH SAC, to include registry fees as specified at § 413.402(b)(6).

We did not receive any comments on these proposed technical corrections and are finalizing them as proposed.

E. Adoption of Health Information Technology Standards and Incorporation by Reference

1. Background

As part of the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) both Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges'' proposed rule (2026 CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule) (91 FR 19890), ONC proposed to adopt a set of health information technology (IT) standards in section II.J. (91 FR 20001). In order to accelerate the adoption of standards that are important for HHS efforts to advance electronic prior authorization and other use cases, ONC is finalizing these proposals as part of the FY 2027 IPPS/LTCH PPS final rule. For the purposes of this final rule, ONC has only reviewed and responded to comments on the standards proposed for adoption in section II.J. of the 2026 CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule. Specifically, ONC summarizes and responds to comments related to proposals to:

- Adopt updated versions of certain health IT standards and specifications on behalf of HHS related to the interoperability APIs; and
- Adopt updated versions of standards currently adopted in 45 CFR 170.215 and expire the existing versions on January 1, 2028. ONC also offered an alternative proposal to remove and replace standards in 45 CFR 170.215(j), (k), (m), and (n) with the updated version of the standard upon the effective date of a final rule, without providing for a transition period during which multiple versions of each standard will be available for HHS use.

Comments received related to other proposals from the 2026 CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule are still being reviewed and considered and may be the subject of subsequent final rules related to such proposals in the future.

2. Overview

In the 2026 CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule, ONC proposed to adopt standards and implementation specifications in 45 CFR 170.215 for interoperability APIs and related activities on behalf of HHS under the authority in section 3004 of the PHSA (42 U.S.C. 300jj–14) (91 FR 20001). ONC proposed these standards for adoption by HHS as part of a nationwide health IT infrastructure that supports reducing burden and health care costs and improving patient care. ONC proposed to adopt these standards on behalf of HHS in one location within the CFR for use within other HHS programs. These proposals reflected a unified approach across HHS to adopt standards for interoperability API activities. This approach is intended to increase alignment across HHS and reduce regulatory burden for interested parties subject to program requirements that incorporate these standards.

ONC proposed to adopt updated versions of certain standards that the Secretary adopted in the ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2026 Rates; Changes to the FY 2025 IPPS Rates Due to Court Decision; Requirements for Quality Programs; and Other Policy Changes; Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization'' (FY 2026 IPPS/LTCH PPS) final rule for HHS use (90 FR 36536). As part of the FY 2026 IPPS/LTCH PPS final rule, ONC finalized the ''Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization'' (HTI–4) final rule (90 FR 37162 and 37181). ONC proposed to adopt these updated versions (listed in section X.E.7. of the preamble of this final rule) in 45 CFR 170.215. ONC stated that if the adoption of these proposed standards is finalized, they would be indicated for use by CMS subject to any other requirements that are finalized from the 2026 CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule. In addition to these updated versions, ONC proposed to adopt an additional standard in 45 CFR 170.215(k)(3) that supports the exchange of attachment information for prior authorization transactions. Summaries of the standards that ONC proposed to adopt and subsequently incorporate by reference can be found below in section X.E.9. of the preamble of this final rule.

3. Adoption of Standards and Implementation Specifications

The Health Information Technology for Economic and Clinical Health Act (hereinafter referred to as the ''HITECH Act''), Title XIII of Division A and Title IV of Division B of the ''American Recovery and Reinvestment Act of 2009'' (Pub. L. 111–5), was enacted on February 17, 2009). The HITECH Act amended the Public Health Service Act (PHSA) and created ''Title XXX—Health Information Technology and Quality'' to improve health care quality, safety, and efficiency through the promotion of health IT and exchange of EHI. Subsequently, Title IV of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) amended portions of the HITECH Act by modifying or adding certain provisions to the PHSA relating to health IT.

Section 3001 of the PHSA directs the National Coordinator to perform duties in a manner consistent with the development of a nationwide health IT infrastructure that allows for electronic use and exchange of information.

Section 3004 of the PHSA identifies a process for the adoption of health IT standards, implementation specifications, and certification criteria, and authorizes the Secretary to adopt such standards, implementation specifications, and certification criteria. As specified in section 3004(a)(1) of the PHSA, the Secretary is required, in consultation with representatives of other relevant federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator under section 3001(c) of the PHSA and subsequently determine whether to propose the adoption of any grouping of such standards, implementation specifications, or certification criteria. The Secretary is required to publish all determinations in the **Federal Register**.

Section 3004(b)(3) of the PHSA, which is entitled ''Subsequent Standards Activity,'' provides that the Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published by the Health IT Advisory Committee (HITAC). As noted in the ''2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications'' final rule (80 FR 62602), which appeared in the **Federal Register**

on October 16, 2015, ONC considers this provision in the broader context of the HITECH Act and the Cures Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITAC and endorsed by the National Coordinator, as well as other appropriate and necessary health IT standards, implementation specifications, and certification criteria (80 FR 62606).

Under the authority outlined in section 3004(b)(3) of the PHSA, the Secretary may adopt standards, implementation specifications, and certification criteria as necessary even if those standards have not been recommended and endorsed through the process established for the HITAC under section 3002(b)(2) and (3) of the PHSA. Moreover, while HHS has traditionally adopted standards and implementation specifications at the same time as adopting certification criteria that reference those standards, the Secretary's authority under section 3004(b)(3) of the PHSA is not limited to adopting standards or implementation specifications at the same time certification criteria are adopted.

Finally, the Cures Act amended the PHSA by adding section 3004(c), which specifies that in adopting and implementing standards under section 3004, the Secretary shall give deference to standards published by standards development organizations (SDOs) and voluntary consensus-based standards bodies.

4. Alignment With Federal Advisory Committee Activities

The HITECH Act established two federal advisory committees, the Health IT Policy Committee (hereinafter referred to as the ''HITPC'') and the Health IT Standards Committee (hereinafter referred to as the ''HITSC''). Each committee was responsible for advising the National Coordinator on different aspects of health IT policy, standards, implementation specifications, and certification criteria.

Section 4003(e) of the Cures Act amended section 3002 of the PHSA and replaced the HITPC and HITSC with one committee, the HITAC. After that change, section 3002(a) of the PHSA now establishes that the HITAC advises and recommends to the National Coordinator standards, implementation specifications, and certification criteria relating to the implementation of a health IT infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. The Cures Act specifically directs the HITAC to advise on two areas: (1) a policy framework to advance an interoperable health IT infrastructure (section 3002(b)(1) of the PHSA); and (2) priority target areas for standards, implementation specifications, and certification criteria (section 3002(b)(2) of the PHSA).

For the policy framework, as described in section 3002(b)(1)(A) of the PHSA, the Cures Act tasks the HITAC with providing recommendations to the National Coordinator on a policy framework for adoption by the Secretary consistent with the Federal Health IT Strategic Plan under section 3001(c)(3) of the PHSA. In February of 2018, the HITAC made recommendations to the National Coordinator for the initial policy framework and subsequently published a schedule in the **Federal Register** and an annual report on the work of the HITAC and ONC to implement and evolve that framework.[681] [682] For the priority target areas for standards, implementation specifications, and certification criteria, section 3002(b)(2)(A) of the PHSA identifies that, in general, the HITAC will recommend to the National Coordinator, for purposes of adoption under section 3004 of the PHSA, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. In October 2019, the HITAC finalized recommendations on priority target areas for standards, implementation specifications, and certification criteria.[683]

5. Interoperability Standards Advisory (ISA)

ONC's ISA supports the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the health care industry to address specific interoperability needs.[684] [685] The ISA is updated on an annual basis based on recommendations received from public comments and subject matter expert feedback. This public comment process reflects ongoing dialogue, debate, and consensus among industry and interested parties when more than one standard or implementation specification could be used to address a specific interoperability need.

The ISA includes the implementation specifications finalized in section X.E.7. of the preamble of this final rule. ONC encourages interested parties to review the ISA to better understand key applications for the implementation specifications it is finalizing in this rule.

6. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 (hereinafter referred to as the ''NTTAA'') (Pub. L. 104–113, enacted March 07, 1996; 15 U.S.C. 3701 *et seq.*) and OMB Circular A–119 require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A–119 provide exceptions to electing only standards developed or adopted by voluntary consensus bodies, namely when doing so will be inconsistent with applicable law or otherwise impractical. Agencies have the discretion to decline the use of existing voluntary consensus standards if it is determined that such standards are inconsistent with applicable law or otherwise impractical, and instead use a government-unique standard or other standard. In addition to the consideration of voluntary consensus standards, the OMB Circular A–119 recognizes the contributions of standardization activities that take place outside of the voluntary consensus standards process. Therefore, in instances where use of voluntary consensus standards will be inconsistent with applicable law or otherwise impracticable, other standards should be considered that meet the agency's regulatory, procurement or program needs; deliver favorable technical and economic outcomes; and are widely utilized in the marketplace.

[681] Health Information Technology Advisory Committee. (2018, February 21). HITAC Policy Framework. Retrieved from *https://www.healthit.gov/sites/default/files/page/2019-07/2018-02-21_HITAC_Policy-Framework_FINAL_508-signed.pdf.*

[682] Health Information Technology Advisory Committee. (2020, March 2). Health Information Technology Advisory Committee (HITAC) Annual Report for Fiscal Year 2019. Retrieved from *https://www.healthit.gov/sites/default/files/page/2020-03/HITAC%20Annual%20Report%20for%20FY19_508.pdf.*

[683] Interoperability Standards Priorities Task Force. (2019, October 16). Interoperability Standards Priorities Task Force 2018 Report. Retrieved from *https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf.*

[684] Office of the National Coordinator for Health Information Technology. (n.d.). Interoperability Standards Platform. Retrieved from *https://www.healthit.gov/isp/.*

[685] Office of the National Coordinator for Health Information Technology. (2025, January 30). About the ISA. Retrieved from *https://www.healthit.gov/isp/about-isa.*

7. Proposal To Adopt Standards for Use by HHS

Consistent with sections 3004(b)(3), 3001(b), and 3001(c) of the PHSA, ONC proposed to adopt standards in 45 CFR 170.215(j), (k), (m), and (n) on behalf of the Secretary to support the continued development of a nationwide health IT infrastructure and support ongoing federal alignment of standards for interoperability and health information exchange (91 FR 20002). ONC previously adopted versions of all but one of these standards in the HTI–4 final rule (90 FR 37130). In addition, ONC proposed to adopt an additional standard, the HL7 FHIR® Da Vinci Clinical Data Exchange (CDex) IG [Implementation Guide] in 45 CFR 170.215(k)(3). Specifically, ONC proposed to adopt the following versions of the standards and incorporate them by reference in 45 CFR 170.299(g).

- HL7 FHIR® Da Vinci—Coverage Requirements Discovery IG [Implementation Guide], Version 2.2.1–STU 2.2 (proposed in 45 CFR 170.215(j)(1)(ii)).[686]

ONC previously adopted version 2.0.1–STU 2 of the Coverage Requirements Discovery (CRD) IG in 45 CFR 170.215(j)(1)(i) in the HTI–4 final rule (90 FR 37167). This updated version of the CRD IG includes improvements such as setting clearer expectations for handling failure states, correcting contexts for order-dispatch, clarifying expectations for mandatory hook support, and setting expectations for endpoints and endpoint discovery. This version also includes substantive clarifications, corrections, and enhancements for the Coverage Information FHIR extension, which is a core profile in the IG by which payer systems communicate coverage and prior authorization requirements to provider systems.

- HL7 FHIR® Da Vinci—Documentation Templates and Rules Implementation Guide, Version 2.2.0–STU 2.2 (proposed in 45 CFR 170.215(j)(2)(ii)).[687]

ONC previously adopted version 2.0.1–STU 2 of the Documentation Templates and Rules (DTR) IG in 45 CFR 170.215(j)(2)(i) in the HTI–4 final rule (90 FR 37167). This updated version of the DTR IG includes improvements such as aligning endpoint discovery language with CRD IG requirements, addressing CMS enforcement discretion regarding the use of X12N 278 transaction standard, requiring DTR clients to appropriately manage access to data that is sensitive per policy and regulatory requirements when responding to queries from a DTR application, and streamlining questionnaire retrieval if the CRD workflow is used in combination with the DTR workflow.

- HL7 FHIR® Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.2.1–STU 2.2 (proposed in 45 CFR 170.215(j)(3)(ii)).[688]

ONC previously adopted version 2.0.1–STU 2 of the PAS IG in 45 CFR 170.215(j)(3)(i) in the HTI–4 final rule (90 FR 37167). This updated version of the PAS IG includes improvements such as clarifying how to cancel an entire prior authorization claim instead of cancelling individual items, addressing concerns about required fields that are specified in the license restricted X12N TRN03 guide (which is referenced within the PAS IG), and updating the guide to be compliant with US Core IG STU 3.1.1, 6.0.1, and 7.0.0. This version also provides new guidance regarding how a provider system can query the payer system for a specific prior authorization submission, and new requirements to support the ''rest-hook'' subscription channel by which payer systems can provide updates on prior authorization submissions.

- HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) [Implementation Guide], Version 2.2.0–STU 2.2 (proposed in 45 CFR 170.215(k)(1)(ii)).[689]

ONC previously adopted version 2.0.0–STU 2 of the CARIN IG for Blue Button® in 45 CFR 170.215(k)(1)(i) in the HTI–4 final rule (90 FR 37182). This updated version of the CARIN IG for Blue Button includes improvements such as additional updates to ensure alignment with US Core IG STU 7.0.0 and 6.1.0, updates to certain profiles, updates and refinements to codes identified in the IG, and updates to search parameters.

- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.1.0–STU 2.1 (proposed in 45 CFR 170.215(m)(2)).[690]

ONC previously adopted version 2.0.1–STU 2 of the PDex US Drug Formulary IG in 45 CFR 170.215(m)(1) in the HTI–4 final rule (90 FR 37182). This updated version of the PDex US Drug Formulary IG includes improvements such as updated references to multiple versions of US Core IG, guidance for more granular pharmacy benefits, updates to search parameters, and guidance regarding authentication.

- HL7 FHIR® Da Vinci PDex [Payer Data Exchange] Plan Net Implementation Guide, Version 1.2.0–STU 1.2 (proposed in 45 CFR 170.215(n)(2)).[691]

ONC previously adopted version 1.1.0–STU 1.1 US of the PDex Plan Net IG in 45 CFR 170.215(n)(1) in the HTI–4 final rule (90 FR 37182). This updated version of the PDex Plan Net IG includes improvements such as updates to dependencies to reference multiple versions of the US Core IG, updates to dependencies to reference the HL7 FHIR® Da Vinci—Health Record Exchange (HRex) IG, Version 1.1.0–STU 1.1, updates to search parameters, and the addition of a bulk export operation.

- HL7 FHIR® Da Vinci Clinical Data Exchange (CDex) IG [Implementation Guide], Version 2.1.0–STU 2.1 (proposed in 45 CFR 170.215(k)(3)).[692]

The CDex IG supports requesting and sending attachments for claims and prior authorization transactions, requesting documentation to support payer operations such as claims audits, and exchanging clinical data between referring providers. In section II.H.7. of the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (91 FR 19995), HHS proposed to adopt the CDex IG as the attachment standard for prior authorization transactions under the required HIPAA Administrative Simplification provisions. ONC separately proposed to adopt this standard in 45 CFR 170.215(k)(3) to make it available for use by other programs; for instance, programs that may wish to incorporate this standard into regulations to align with the HIPAA

[686] Health Level Seven International. (2026, March 27). Da Vinci—Coverage Requirements Discovery IG. Retrieved from *https://hl7.org/fhir/us/davinci-crd/2.2.1/en/*.

[687] Health Level Seven International. (2026, March 27). Da Vinci—Documentation Templates and Rules IG. Retrieved from *https://hl7.org/fhir/us/davinci-dtr/2.2.0/en/*.

[688] Health Level Seven International. (2026, March 27). Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide. Retrieved from *https://hl7.org/fhir/us/davinci-pas/2.2.1/en/*.

[689] Health Level Seven International. (2026, March 27). CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®). Retrieved from *https://hl7.org/fhir/us/carin-bb/STU2.2/*.

[690] Health Level Seven International. (2025, February 26). Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide. Retrieved from *https://hl7.org/fhir/us/davinci-drug-formulary/STU2.1/*.

[691] Health Level Seven International. Da Vinci PDex [Payer Data Exchange] Plan Net Implementation Guide. Retrieved from *https://hl7.org/fhir/us/davinci-pdex-plan-net/STU1.2/*.

[692] Health Level Seven International. (2025, February 11). Da Vinci Clinical Data Exchange (CDex) IG. Retrieved from *https://hl7.org/fhir/us/davinci-cdex/STU2.1/*.

Administrative Simplification requirements, if the proposals in section II.H.7. of the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (91 FR 19995) are finalized.

In summary, ONC requested comment in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule on the CFR citations listed in Table 12 (91 FR 20005), and specifically on the proposal to adopt standards in 45 CFR 170.215(j), (k), (m), and (n) on behalf of the Secretary.

We received public comments on these proposals. The following is a summary of the comments received and our responses.

Comment: Many commenters supported the adoption of the proposed implementation guides, including both the proposals to adopt updated versions of implementation guides previously adopted in the HTI–4 final rule and the additional proposal to adopt the CDex IG. Commenters emphasized the importance of moving to updated versions to avoid locking implementers into outdated versions that do not adequately support interoperability. Commenters noted that versions of these standards adopted in prior rulemaking had been superseded by the publication of subsequent versions and agreed with the importance of adopting current standards to optimize provider experience. Commenters generally supported the utilization of contemporary, FHIR-based standards, which can reduce manual and other cumbersome methods of information exchange when implemented consistently and effectively.

Response: We thank commenters for their support.

Comment: Many commenters specifically expressed support for the proposed adoption of version 2.2.1 of the CRD IG, version 2.2.0 of the DTR IG, and version 2.2.1 of the PAS IG for electronic prior authorization. Commenters supported alignment on these versions as a common target for different entities supporting exchange of information to support electronic prior authorization. A commenter stated that the 2.2 versions have matured substantially from the 2.0 versions and reflect lessons learned that will support more effective interoperability. A commenter stated that the latest versions of these guides have matured sufficiently and they are appropriate for adoption in regulatory mandates. Another commenter noted that the IGs have gone through Connectathon testing, HIPAA exception testing, and operational pilots and deployments, and that the proposed versions represent significant updates and refinements to the versions originally recommended for adoption in the 2024 CMS Interoperability Prior Authorization final rule (89 FR 8945).

Response: We thank commenters for their support.

Comment: Several commenters noted that 2.1 versions of the CRD, DTR, and PAS IGs that support electronic prior authorization are currently available but it is unclear whether implementers would be able to use these versions.

Response: While we recognize that these versions have been published, we note that these too have been superseded by newer 2.2.1 and 2.2.0 versions. We did not propose to adopt the 2.1.0 versions of these IGs because we believe those versions are deficient in ways similar to the 2.0.1 versions of these IGs and would complicate nationwide deployment of electronic prior authorization for similar reasons. We note meaningful and significant improvements across CRD, DTR, and PAS IGs in versions 2.2.1 and 2.2.0 over versions 2.1.0 of these IGs, including better order/appointment context for version 2.2.1 of the CRD IG; improved questionnaire package and response behavior in version 2.2.0 of the DTR IG; and better submission, status, and authorization response automation in version 2.2.1 of the PAS IG.

Also, the National Coordinator for Health Information Technology has not approved version 2.1.0 for use in the ONC Health IT Certification Program, which is necessary for health IT developers to voluntarily utilize newer versions of standards adopted in regulation under the Standards Version Advancement Process (45 CFR 170.405). Thus, while implementers may use these versions as part of development cycles, these versions would not meet requirements to use versions of the standards adopted in 45 CFR 170.215, for instance, as part of requirements for the electronic prior authorization certification criteria in 45 CFR 170.315(g)(31) through (33).

Comment: Several commenters expressed support for the adoption of the CDex IG as the standard for prior authorization attachments, stating that this IG provides flexibility for different types of attachments, can support different scenarios, and complements the PAS IG. A commenter supported the adoption of the CDex IG and efforts to encourage its use but did not support its inclusion in health IT certification criteria for electronic prior authorization at this time.

Response: We thank commenters for their support of the proposed adoption of the CDex IG. We note that we did not propose to incorporate the CDex IG as part of any health IT certification criteria at 45 CFR 170.315 in the CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, and we are not finalizing any requirements related to certification criteria in the policies we are finalizing in this final rule. We will consider this comment if we explore future proposals related to incorporation of the CDex IG within certification criteria in the future.

Comment: Several commenters stated that while the CDex IG can play an important role in supporting standardized transmission of clinical information outside of structured data elements, payers should prioritize use of structured data through questionnaires transmitted under the DTR IG and cautioned that widespread use of CDex could simply replicate current workflows using fax. Commenters also noted that production maturity and testing for this IG lag other IGs for electronic prior authorization transactions, for instance with respect to appropriate file sizes, and that deployment should follow implementation of these other IGs.

Response: We appreciate commenters' input on best practices for how the CDex IG should be used as part of electronic prior authorization workflows. While we are finalizing the adoption of the CDex IG in 45 CFR 170.215, we note that HHS has not yet finalized any related proposals to require its use at this time. However, these comments may inform future policies with respect to utilization of this IG. We also appreciate input on the current maturity of this IG. While we believe the IG is sufficiently advanced to warrant adoption at this time, we will continue to monitor the development of improved versions in the future that have undergone additional testing.

Comment: Several commenters noted that version 2.2.0 of the PDex IG has been approved for publication and recommended it be considered for adoption in the final rule if it is finalized prior to publication of the final rule.

Response: We did not propose to adopt version 2.2.0 of the PDex IG, nor has it been published at the time of the publication of this final rule. We will consider this version for adoption in future rulemaking.

Comment: Regarding the proposal to adopt version 2.1.0 of the PDex US Drug Formulary IG, a commenter stated that this proposal appeared to be in tension with the proposal in section II.F.3. of the 2026 CMS Interoperability

Standards and Prior Authorization for Drugs proposed rule (91 FR 19974 through 19975) to remove the formulary requirement for the Provider Access API and Payer-to-Payer API. The commenter stated that the removal of this functionality from these API requirements would mean that development efforts for this updated version of the IG would not impact provider-facing use cases where it would be most important.

Response: We thank the commenter for their feedback. We disagree that the adoption of this standard would conflict with CMS' proposals in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule. We have proposed to adopt the updated version of the PDex US Drug Formulary in order to continue to advance interoperability by using improved versions of standards and believe this is appropriate, regardless of policies that CMS finalizes around how payers are required to use the IG.

Comment: A commenter stated the PlanNet IG does not fully support real-world use cases today. Another commenter identified implementation gaps within the current version, including discrepancies between the IG's requirement for REST-based access and bulk consumption patterns for provide directory data. A commenter stated that there are open implementation questions regarding version 2.2.0 of the CARIN IG for Blue Button, such as inconsistences with the FHIR core specification and limitations around support for exchange with multiple networks.

Response: We appreciate commenters' feedback on potential improvements for these IGs. While we believe these IGs are appropriate for adoption in order to support continued progress on interoperability of provider directory information, ONC and CMS will continue to monitor and encourage efforts to improve these IGs.

Comment: Multiple commenters recommended that specific standard for trial use (STU) versions should be named in a final rule. However, another commenter recommended that HHS should avoid naming IG versions in regulation and should not rely on a moving set of ''unexpired'' guides as a substitute for clear version control.

Response: We agree with the commenters that stated it is important to name specific versions in regulation to ensure that implementers subject to federal regulations are aligned around common versions of standards that enable interoperability between systems. Furthermore, to require regulated entities to use specific versions of a standard, we must adopt the specific published version in regulation and incorporate it by reference.

Comment: Many commenters recommended that CMS and ONC ensure that standards are tested in real-world settings prior to any compliance dates set for conformance to the standards. A commenter recommended that HHS adopt approaches to testing that go beyond conformance testing to a certain version of a standard and advance approaches that test interoperability between real-world implementations using all permissible versions of a standard.

Response: We agree with commenters on the need for thorough testing across the ecosystem. CMS and ONC continue to collaborate with industry to develop testing opportunities. For instance, at the time of this final rule, we have published Inferno test kits [693] for both provider and payers on version 2.2.1 of the CRD IG, and test kits for the 2.2.0 and 2.2.1 versions of the DTR and PAS IGs, respectively, are under development. We also note that other industry opportunities for testing these IGs are available, including HL7 Connectathons, the CMS Health Technology Ecosystem,[694] and other platforms that allow for partner testing regardless of versions. We believe that these initiatives are informing an increasingly robust testing environment that will support implementers. At the same time, we believe it is necessary to adopt version 2.2.1 of the CRD IG, version 2.2.0 of the DTR IG, and version 2.2.1 of the PAS IG to ensure there is clarity about the ability to use these versions and benefit from the significant improvements that have been made over the previously adopted versions.

Final Decision: After consideration of the public comments we received, we are finalizing our proposals to adopt the standards below in 45 CFR 170.215(j), (k), (m), and (n) on behalf of the Secretary. We have updated the citations where we are adopting these standards in regulation based on the policy we proposed as an alternative proposal (91 FR 20003 through 20004) and that we are finalizing below to replace previously adopted versions in 45 CFR 170.215 where applicable.

- HL7 FHIR® Da Vinci—Coverage Requirements Discovery IG [Implementation Guide], Version 2.2.1–STU 2.2 (adopted in 45 CFR 170.215(j)(1)(i)).[695]
- HL7 FHIR® Da Vinci—Documentation Templates and Rules Implementation Guide, Version 2.2.0–STU 2.2 (adopted in 45 CFR 170.215(j)(2)(i)).[696]
- HL7 FHIR® Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.2.1–STU 2.2 (adopted in 45 CFR 170.215(j)(3)(i)).[697]
- HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) [Implementation Guide], Version 2.2.0—STU 2.2 (adopted in 45 CFR 170.215(k)(1)(i)).[698]
- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.1.0—STU 2.1 (adopted in 45 CFR 170.215(m)(1)).[699]
- HL7 FHIR® Da Vinci Payer PDex [Payer Data Exchange] Plan Net Implementation Guide, Version 1.2.0—STU 1.2 (adopted in 45 CFR 170.215(n)(1)).[700]
- HL7 FHIR® Da Vinci Clinical Data Exchange (CDex) IG [Implementation Guide], Version 2.1.0—STU 2.1 (adopted in 45 CFR 170.215(k)(3)(i)).[701]

With respect to the CARIN IG for Blue Button®, we note that the proposed regulatory text for 45 CFR 170.215(k)(1)(ii) in the CMS Interoperability Standards and Prior Authorization for Drugs proposed rule inadvertently specified the proposed version of the IG as 2.1.2, as opposed to the 2.2.0 version named elsewhere throughout the proposed rule. We clarify that we are finalizing the adoption of version 2.2.0 of the CARIN IG for Blue Button® in this final rule.

[693] *See https://inferno.healthit.gov/test-kits/.*

[694] *See https://www.cms.gov/priorities/health-technology-ecosystem/overview.*

[695] Health Level Seven International. (2026, March 27). Da Vinci—Coverage Requirements Discovery IG. Retrieved from *https://hl7.org/fhir/us/davinci-crd/2.2.1/en/.*

[696] Health Level Seven International. (2026, March 27). Da Vinci—Documentation Templates and Rules IG. Retrieved from *https://hl7.org/fhir/us/davinci-dtr/2.2.0/en/.*

[697] Health Level Seven International. (2026, March 27). Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide. Retrieved from *https://hl7.org/fhir/us/davinci-pas/2.2.1/en/.*

[698] Health Level Seven International. (2026, March 27). CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®). Retrieved from *https://hl7.org/fhir/us/carin-bb/STU2.2/.*

[699] Health Level Seven International. (2025, February 26). Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide. Retrieved from *https://hl7.org/fhir/us/davinci-drug-formulary/STU2.1/.*

[700] Health Level Seven International. Da Vinci PDex [Payer Data Exchange] Plan Net Implementation Guide. Retrieved from *https://hl7.org/fhir/us/davinci-pdex-plan-net/STU1.2/.*

[701] Health Level Seven International. (2025, February 11). Da Vinci Clinical Data Exchange (CDex) IG. Retrieved from *https://hl7.org/fhir/us/davinci-cdex/STU2.1/.*

8. Expiration Dates for Certain Versions of Adopted Standards

In the CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, ONC also proposed to add an expiration date of January 1, 2028, to corresponding versions of standards currently in 45 CFR 170.215(j), (k), (m), and (n) if the proposals to adopt newer versions of adopted standards and specifications in 45 CFR 170.215(j), (k), (m), and (n) were finalized (91 FR 20003). ONC proposed this expiration date to provide certified health IT developers and other entities required to use these standards with a transition period during which they may update and deploy health IT conformant with either the existing or updated versions of these standards. ONC stated that after the expiration date, only non-expired versions of the relevant standards in 45 CFR 170.215(j), (k), (m), and (n) would be available for use. ONC stated that it believed that a coordinated transition period that establishes a single expiration date across the relevant IGs in 45 CFR 170.215(j), (k), (m), and (n) would create consistency for industry and facilitate interoperability by ensuring that health IT systems leveraging these standards under different HHS programs use the same baseline standards for the same use cases. In addition, ONC stated that it believed a transition period would allow those health IT developers and other entities required to use these standards flexibility to complete development towards the existing standards in 45 CFR 170.215(j), (k), (m), and (n), and to iterate to newer standards.

However, ONC also stated that it believes that this flexibility may lead to more heterogeneity where some deployed health IT uses one standard and other deployed health IT uses newer versions of those standards, thus complicating shared goals with CMS to facilitate a FHIR-based ecosystem for prior authorization, payer to payer exchange, and patient access to coverage information. Therefore, ONC proposed an alternative approach to updating these standards. Specifically, as an alternative to the proposal above, ONC proposed to remove and replace standards in 45 CFR 170.215(j), (k), (m), and (n) with the standards it proposed upon the effective date of a final rule, without providing for a transition period during which multiple versions of each standard would be available for HHS use (91 FR 20003 through 20004).

ONC understands that both certified health IT developers and other health IT developers wish to have a single, baseline standard across use cases as quickly as practicable for purposes of consistency and interoperability. ONC stated that this alternative proposal could help advance this goal, particularly in areas such as electronic prior authorization. For instance, under this alternative proposal, a certified health IT developer with a Health IT Module certified to the ''provider prior authorization API—documentation templates and rules'' criterion for electronic prior authorization in 45 CFR 170.315(g)(32), and currently using the standard in 45 CFR 170.215(j)(2)(i) (which is the DTR IG, Version 2.0.1–STU 2), would need to use the newer version of the standard to remain certified to the criterion in 45 CFR 170.315(g)(32) as of the effective date of a final rule, which ONC proposed to be the DTR IG, Version 2.2.0–STU 2.2.

In summary, in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (91 FR 20003 through 20005) ONC requested comment on our proposals in the CFR citations listed in Table 12 of the proposed rule, and specifically on the following:

- The proposal to add an expiration date of January 1, 2028, to corresponding standards currently in 45 CFR 170.215(j), (k), (m), and (n) if our proposals to adopt newer versions of these standards are finalized.
- The alternative proposal to remove and replace the standards in 45 CFR 170.215(j), (k), (m), and (n) with the newer versions of the standards, without a transition period for use of multiple versions.

We received public comments on these proposals. The following is a summary of the comments received and our responses.

Comment: Among commenters who addressed these proposals, most supported the proposed expiration date of January 1, 2028 for previously adopted standards, meaning implementers required to use a standard in an applicable section of 170.215 would need to use the proposed updated versions of the standards after this date.

Commenters expressed support for transition periods during which more than one version of an unexpired standard would be available for use. A commenter stated that a defined overlap window between standard versions is important to the safety of a version transition, and that a ''hard cutover'' is unrealistic for managing a transition across a wide range of systems. Another commenter stated that a transition period can help to ensure clinical practices are able to obtain the technical assistance and tools necessary to manage version updates.

Response: We thank commenters for their support of the proposal. We recognize that a transition period that allows for more than one version of a standard can provide implementers at different levels of readiness with needed flexibility, reducing the burden associated with transitions. For this reason, we have pursued approaches to structuring our regulations in a way that can allow for such transition periods. However, we disagree that such transition periods are appropriate in every scenario when moving between two versions of required standards. For instance, allowing implementers to use two versions of the same standard when versions have limited compatibility can have negative consequences such as reduced interoperability that may outweigh the benefits of greater flexibility.

Comment: Several commenters stated that finalizing the proposed expiration date of January 1, 2028 for previously adopted standards would allow payers subject to the requirements in the 2024 CMS Interoperability Standards and Prior Authorization final rule to continue using versions of the IGs that best suit them as they prepare for January 1, 2027 deadlines for establishment of certain payer APIs.

Response: We disagree with the commenters that the proposed expiration date of January 1, 2028 for previously adopted versions would support preparation for the January 1, 2027 compliance date for establishment of certain payer APIs. We note that CMS did not finalize requirements for payer APIs to conform to standards in 45 CFR 170.215(j), (k), (m), and (n), by January 1, 2027 in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule. Rather, in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule, CMS proposed to require conformance with unexpired versions of these standards by October 1, 2027, through cross-references to sections of 45 CFR 170.215(j), (k), (m), and (n) (91 FR 19908). Therefore, as of January 1, 2027, payers would not be required to conform to standards in 45 CFR 170.215(j), (k), (m), and (n) and would not benefit from having multiple standards available at these citations to meet regulatory requirements on that date.

We further note that if CMS finalizes its proposed compliance date for payers of October 1, 2027, under our proposed expiration date of January 1, 2028, payers would only be able to use previously adopted standards in 45 CFR

170.215(j), (k), (m), and (n) for a period of three months until these versions would no longer be available for use. Therefore, we do not believe that the transition period that would be created under our proposal, or lack thereof, would impact the ability of impacted payers to prepare for October 1, 2027 compliance date for payer APIs to conform to standards in 45 CFR 170.215(j), (k), (m), and (n).

Comment: Several commenters recommended delaying the January 1, 2028 date, with some suggesting January 1, 2029 as an alternative. Commenters stated that the proposed date of January 1, 2028 may not align with industry recommendations regarding the development time necessary for exclusive implementation of a new version of a standard from the time the new version appears in a final rule. Commenters noted that, while it was unclear when the proposals in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule would be finalized, it was unlikely that these proposals would be finalized in time for the recommended period to elapse between a final rule and January 1, 2028. Commenters discussed the minimum amount of time that previously adopted versions should be retained from a final rule finalizing a new version of a standard. Commenters suggested time periods including 24 months, 18 months, and 12 months. A commenter stated that the feasibility of an expiration date of January 1, 2028 would depend on the extent to which subsequent versions of the IGs introduce significant changes and that this date should be evaluated in light of such changes.

Response: We appreciate commenters' concerns about the amount of time between finalizing the proposed standards in 45 CFR 170.215(j), (k), (m), and (n) and the proposed January 1, 2028 expiration date for previously adopted versions. We generally agree that the timeframes commenters suggested are reasonable for upgrading to a newly required version. However, because implementers are still working towards initial deployment of solutions at the time of this final rule, we believe it is most appropriate to focus on the timeframe under which regulated entities will first be required to use updated standards in 45 CFR 170.215(j), (k), (m), and (n).

We note that CMS has proposed that impacted payers would be required to ensure payer APIs conform to an unexpired version of the relevant standards in 45 CFR 170.215(j), (k), (m), and (n), by October 1, 2027 (91 FR 19908). If CMS finalizes this proposed requirement, impacted payers would have 15 months from the effective date of this final rule (October 1, 2026) to our primary proposed date of January 1, 2028 for the expiration of previously adopted versions in 45 CFR 170.215(j), (k), (m), and (n), after which APIs would need to come into compliance with updated versions of the standards. Under our alternative proposal to replace previously adopted versions of the standards in in 45 CFR 170.215(j), (k), (m), and (n) with updated versions upon the effective date of a final rule (91 FR 20003), impacted payers would have 12 months between the effective date of this final rule and the date upon which payer APIs would need to conform to the updated standards we are finalizing in this final rule, if CMS' proposed October 1, 2027 compliance date is finalized.

We believe the periods between finalizing the updated versions of the standards in this final rule and the date by which payer APIs must comply with those updated versions provides an appropriate implementation window. This timeframe is also consistent with the periods recommended by some of the commenters under both our primary and alternative proposals. Although the implementation period under our alternative proposal would be three months shorter than the period under our primary proposal of January 1, 2028, if CMS finalizes its proposed compliance date of October 1, 2027, we believe that a 12-month implementation window before the standards are required to be used remains reasonable. We discuss additional benefits associated with adopting our alternative proposal below.

For discussion of timelines for reporting of electronic prior authorization measures in the Promoting Interoperability Program and the MIPS Promoting Interoperability performance category which may impact health IT developers certifying Health IT Modules to electronic prior authorization certification criteria in 170.315(g)(31) through (33) to support customers required to report on these measures in order to become Meaningful EHR Users, we refer readers to additional discussion below.

Finally, we agree with commenters that it is appropriate to consider the degree of change between versions of a standard when establishing a timeline for required use of an updated version of a standard. We believe that the scale of updates reflected in the proposed versions of IGs in 45 CFR 170.215(j), (k), (m), and (n) are consistent with the expected periods between the publication date of this final rule and the finalized and proposed dates by which regulated entities would be required to use these updated versions.

Comment: Several commenters raised concerns with a transition period that allows for the use of more than one version of a standard. Commenters stated that having entities operating on different versions at different times can cause misalignment in capabilities and functionalities between exchange partners, for instance, if a payer migrates to an updated IG version while a health care provider's system is still on the prior version. A commenter noted that stakeholders are currently implementing different versions of the same IGs we have adopted in 45 CFR 170.215(j), (k), (m), and (n), resulting in fragmentation rather than alignment. A commenter stated that any transition period should condition adoption of updated versions on maintaining compatibility with the existing version for the duration of the transition period.

Response: We agree with commenters that providing for a transition period between standards may present risks under certain circumstances. For instance, when there are significant compatibility issues between versions of a standard, enabling regulated entities to use both versions during the same period can create interoperability challenges. In some scenarios, these interoperability challenges may outweigh the benefits of a transition period that provides implementers with more flexibility. We believe this consideration is relevant with respect to the policies in this final rule, as we are aware of significant compatibility issues between the previously adopted 2.0.1 versions of the CRD, DTR, and PAS IGs, and the 2.2.1 versions of the CRD and PAS IGs, and 2.2.0 version of the DTR IG, that we are finalizing in this final rule. We believe challenges arising from these compatibility issues could be ameliorated by establishing only one version of each IG. Specifically, by adopting the proposed versions of the CRD, DTR, and PAS IGs in 170.215(j)(1)–(3) as the only versions that regulated entities can utilize to meet initial conformance requirements under proposed API requirements for impacted payers and certification criteria requirements for health IT developers, respectively. Regarding maintaining compatibility with previous versions during a transition period, we believe it is important to balance the value of maintaining compatibility with the cost to implementers of maintaining support for multiple versions at the same time.

Comment: A commenter stated that the proposed 2.2.1 versions of the CRD

and PAS IGs and 2.2.0 version of the DTR IG were the appropriate versions of the IGs for industry to align around in 2028. The commenter further stated that those entities required to use the IGs should be encouraged to move towards the CRD and PAS 2.2.1 and DTR 2.2.0 versions as soon as possible. Commenters stated that the January 1, 2028 date would provide a stable target for updating to the new versions for health IT developers and payers that are subject to finalized or proposed requirements related to electronic prior authorization. A commenter stated that requirements to conform to previously adopted 2.0.1 versions of the CRD, DTR, and PAS IGs would result in antiquated functionality and would represent a step back from current progress on developing solutions. Commenters also stated that policies must avoid requiring outdated standards or duplicative translation workflows that could move the industry backward, impose undue administrative burden, or require stakeholders to invest in systems that may soon need to be replaced. Commenters urged CMS to designate a clear baseline version as required and then establish a structured approach to retiring previous versions going forward.

Response: We agree with commenters' support for the 2.2.1 versions of the CRD and PAS IGs and the 2.2.0 version of the DTR IG as the target versions implementers should adopt. We recognize the significant work that industry participants in HL7 have done to update these IGs over the past several years to ensure that there is a workable foundation informed by initial experiences with these specifications. We further agree with commenters who believe that 2028 is an appropriate target for stakeholders implementing electronic prior authorization to coalesce around common standards and achieve interoperability at scale across the industry. We further agree with the comments about the importance of establishing a baseline version, as we believe that focusing on a single baseline version can reduce confusion and additional burden for implementers during the initial deployment of health IT systems to meet requirements. We further agree that a structured approach to retiring versions following establishment of this baseline version is important and intend to work with CMS to monitor subsequent versions of these IGs and determine appropriate timelines for adopting these versions in regulation, while aiming to provide transition periods between versions where feasible.

However, we are concerned that maintaining the 2.0.1 versions of the CRD, DTR, and PAS IGs in 45 CFR 170.215 in the period leading up to 2028, as we proposed, does not align with the goal of ensuring that regulated entities deploy CRD and PAS version 2.2.1 and DTR version 2.2.0 by 2028. Keeping the 2.0.1 versions of these standards in the Program during this period, when regulated entities will be developing and beginning to deploy systems that support electronic prior authorization, may divert attention and resources towards outdated and insufficient standards. Instead, we intend to support industry efforts to build and deploy systems that conform to the updated versions of the IGs, which are better suited to support electronic prior authorization. We agree with the comment characterizing the 2.0.1 versions of the CRD, DTR, and PAS IGs as outdated, and we agree that it is important for standards adoption policies to minimize the degree to which implementers develop systems using standards that have limited utility and longevity. We note that the proposed 2.2.1 versions of the CRD and PAS IGs and 2.2.0 version of the DTR IG address prior version ambiguities, making the automation of prior authorizations more dependable with fewer failed transactions and manual follow-ups.

We further believe that it would be beneficial to focus on a single set of versions as a baseline for initial implementation of the CRD, DTR, and PAS IGs across entities required to use these standards. Aligning industry on CRD and PAS 2.2.1, and DTR 2.2.0, across payer and provider IT systems will improve end-to-end interoperability by aligning handoffs between CRD, DTR, and PAS workflows.

Comment: Several commenters stated that the currently adopted 2.0.1 versions of the CRD, DTR, and PAS IGs should be maintained as an option until January 1, 2028 if health care providers are required to utilize health IT certified to electronic prior authorization criteria to report on Electronic Prior Authorization measures in the CMS Promoting Interoperability program and the MIPS Promoting Interoperability performance category during CY 2027. Enabling health IT developers to certify Health IT Modules to these previously adopted versions during CY 2027 would increase the likelihood that developers are able to provide customers with certified products during CY 2027 to meet program requirements. However, commenters stated that if CMS did not finalize proposals to require the use of specific certified health IT for these measures in CY 2027, they recommended moving directly to the proposed versions (CRD and PAS 2.2.1 and DTR 2.2.0), consistent with the alternative proposal in the proposed rule.

Response: We disagree with commenters that it is necessary to maintain the previously adopted 2.0.1 versions of the CRD, DTR, and PAS IGs until January 1, 2028 to help participants meet requirements in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category. We note that in section IX.F. of this final rule CMS has finalized its proposal to make the Electronic Prior Authorization measure in the Medicare Promoting Interoperability Program for eligible hospitals and CAHs a bonus measure in CY 2027, and to require that eligible hospitals and CAHs report the measure in 2028 in order to be a meaningful EHR user. We also note that CMS has made similar proposals in the CY 2027 PFS Proposed Rule to make the Electronic Prior Authorization measure in the MIPS Promoting Interoperability performance category a bonus measure in CY 2027 and a measure that eligible clinicians are required to report in 2028 (91 FR 44180 and 44181). We believe that these CMS final and proposed policies will or would (with respect to proposed policies) provide greater flexibility to health IT developers as they deploy certified health IT to customers.

However, we believe it is important that any flexibility during CY 2027 enables health IT developers to work towards deployment of certified products that will most effectively support interoperability and improve provider experience, and that these goals will be best accomplished through use of the 2.2.1 versions of the CRD and PAS IGs and the 2.2.0 version of the DTR IG. While we hope that CMS' bonus policies will incentivize some participants in these programs and their health IT developers to become early implementers of the technology, we are not seeking to encourage health IT developers to certify Health IT Modules to the 2.0.1 versions of the CRD, DTR, and PAS IGs solely to ensure customers can qualify for bonus points proposed under these programs. While allowing a patchwork of previously adopted 2.0.1 and updated 2.2.1/2.2.0 implementations may provide temporary flexibility for developers, it would almost certainly impede electronic prior authorization capabilities for providers and patients by introducing variations in implementation decisions and requiring

more local interpretations. This, we believe, will hinder plans to scale electronic prior authorization nationwide in 2028 and limit the potential benefits of electronic prior authorization for patients and providers. Therefore, we believe our alternative proposal, under which we would replace previously adopted standards upon the effective date of a final rule, will more effectively support our policy goals by ensuring health IT developers do not focus on certifying Health IT Modules to the criteria in 45 CFR 170.315(g)(31) through (33) using previously adopted versions of the standards.

Comment: A commenter supported our alternative proposal, highlighting the benefits of replacing the current CRD, DTR, and PAS IGs with the proposed versions as of the effective date of a final rule. The commenter stated that this approach would ensure immediate focus on updated versions and consolidated focus around the same IG version, rather than multiple versions being available during a transition period. The commenter further stated that this approach would improve implementation consistency and reduce variation among implementations. Another commenter stated that the proposed versions of the CRD, DTR, and PAS IGs are not compatible with the existing adopted versions and include breaking changes between versions.

Response: We appreciate the support for our alternative proposal and agree with the commenter that this approach would help to enable implementers to consolidate around the same versions of the CRD, DTR, and PAS IGs in 45 CFR 170.215(j)(1) through (3) during the initial rollout of these capabilities. As noted in feedback from many commenters, these IGs have evolved rapidly since the prior versions we adopted, with industry collaborating around improvements to ensure they can be effectively implemented in accordance with the timeframes HHS has put forth in different programs to advance electronic prior authorization.

We also agree that the 2.0.1 versions of CRD, DTR, and PAS IGs that we originally adopted still include significant issues as identified by implementers, which industry has rapidly addressed through the CRD and PAS 2.2.1 and DTR 2.2.0 versions we proposed for adoption. As noted by a number of commenters, there are documented compatibility issues between these versions of the CRD, DTR, and PAS IGs. We note that we also received a comment stating that backwards compatibility between versions would help to mitigate any issues during a transition period. However, we agree with those commenters that pointed to compatibility concerns and we invite interested parties to review change logs related to 2.2.1 and 2.2.0 versions of the CRD, DTR, and PAS IGs to understand technical flaws, inconsistencies, and enhancements that were identified in previous versions.[702] [703] [704] For these reasons, we believe our alternative proposal to replace these versions upon the effective date of the final rule is more appropriate in this case than the more typical provision for a transition period between standards versions.

Comment: Several commenters opposed our alternative proposal to replace previously adopted versions of the proposed standards upon the effective date of a final rule. Commenters stated that the alternative proposal, which would not provide for a transition period, would risk accelerating fragmentation by forcing rapid upgrades across trading partners that may not have similar readiness levels. The commenter stated that this alternative would force version switches and pause or restart implementation, delay Prior Authorization API go-live dates, and negatively impact clinician end-users. A commenter recommended that CMS and ONC establish a predictable and coordinated transition schedule rather than immediately replacing versions. The commenter stated that they believed backward compatibility between the versions of the IG would limit interruptions for users due to use of more than one version of the IGs across trading partners.

Response: While we acknowledge the commenters' concerns, we disagree that our alternative proposal would result in significant disruption to end-users as well as fragmentation across implementations. We believe considerations specific to the current state of implementation for the proposed standards and timelines for requirements to use the standards mitigate these concerns. Though we acknowledge that some regulated entities have started to develop solutions with the adopted versions of the standards, we believe the effects described by the commenters will be mitigated by the fact that regulated entities are still in the process of developing solutions and have additional opportunities to update solutions in accordance with the latest standards.

At the time of this final rule, we believe that regulated entities do not yet have well-established implementations in place using the versions of the standards we previously adopted. With respect to the 2.0.1 versions of the CRD, DTR, and PAS IGs, as of the publication of this final rule, no health IT developers have yet completed certification to the criteria in 45 CFR 170.315(g)(31) through (33) using the 2.0.1 versions of the IGs we previously adopted in 45 CFR 170.215(j)(1) through (3).[705] With respect to impacted payers, commenters have noted that many payers have progressed beyond version 2.0.1 and have begun to implement version 2.1 of the CRD, DTR, and PAS IGs as they work on initial implementation of Prior Authorization APIs. We believe the lack of well-established or deployed implementations at this time using the previously adopted 2.0.1 versions of the CRD, DTR, and PAS IGs in 170.215(j) reduces the potential disruption that would result from finalizing policies that require entities to build to updated versions of the standards.

We also believe the flexibility in finalized and proposed timelines for requiring regulated entities to use the proposed standards will reduce the potential disruption and burden of requiring use of the updated versions of the standards without maintaining previous versions. CMS has proposed a compliance date of October 1, 2027, when impacted payers would be required to ensure APIs conform to a version of the standards in 45 CFR 170.215(j), (k), (m), and (n) (91 FR 19908). Prior to this proposed date, APIs established by impacted payers are not required to conform to any version of these standards. Therefore, if CMS finalizes an October 1, 2027 compliance date, impacted payers would have approximately a year from the effective date of this final rule to the date when their APIs would need to come into compliance with an unexpired version of the standards in 45 CFR 170.215(j), (k), (m), and (n). We believe finalizing our alternative proposal will ensure payers focus development efforts in the months leading up to October 1, 2027, on the latest version of the proposed standards, which would be necessary to remain compliant beyond the January 1, 2028 expiration date we originally proposed. We believe this pathway will

[702] See *https://build.fhir.org/ig/HL7/davinci-crd/en/changes.html.*

[703] See *https://build.fhir.org/ig/HL7/davinci-dtr/en/changehistory.html.*

[704] See *https://build.fhir.org/ig/HL7/davinci-pas/en/changelog.html.*

[705] Information on health IT developers that have completed certification to specific criteria under the ONC Health IT Certification Program can be found at *https://chpl.healthit.gov/.*

ensure that payers do not pursue versions of the standards that would expire shortly after the proposed initial compliance date for payer APIs and become obsolete for those purposes. We also believe this pathway will support improved interoperability and effective implementation during the early rollout of these systems.

With respect to health IT developers, as discussed previously, CMS has finalized or proposed policies in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category to make the Electronic Prior Authorization measures in these programs an optional bonus measure in CY 2027 and required in CY 2028. Under these policies, if remaining proposals are finalized, developers seeking to certify health IT modules to the certification criteria in 45 CFR 170.315(g)(31) through (33) would have until the CY 2028 performance periods for these programs to deploy certified health IT meeting the updated standards before customers are required to report on Electronic Prior Authorization measures in order to become a Meaningful EHR User.

We disagree with the comment that there is backwards compatibility between the versions of the CRD, DTR, and PAS IG that would mitigate interoperability challenges arising from concurrent use of the previously adopted 2.0.1 versions and the updated 2.2.1 versions of the CRD and PAS IGs and 2.2.0 version of the DTR IG. Based on input from other commenters who have raised concerns about compatibility issues, as well as the documented technical flaws, inconsistencies, and enhancements that have been identified between versions,[706] [707] [708] we believe concurrent use would introduce compatibility concerns. We expect standards developers will be able to provide more reliable backwards compatibility between future versions of these IGs, which will reduce the potential challenges associated with providing a transition period between versions.

In light of timelines for required use of these standards and the status of development and deployment activities at the time of the publication of this final rule, we believe finalizing our alternative proposal will not result in significant disruption and will ultimately reduce fragmentation by accelerating regulated entities' ability to coalesce around a common standards baseline. Thus, to better support interoperability and drive consistent movement toward effective implementation of electronic prior authorization and other use cases, we are finalizing our alternative proposal to replace previously adopted versions of standards in 45 CFR 170.215(j), (k), (m), and (n) with the updated versions of the standards we are finalizing upon the effective date of this final rule.

Comment: Several commenters sought further clarification on the meaning of the term ''expire'' with respect to the proposed language. Commenters stated that the definition of these terms was not clear, and the term ''expired'' is also used by HL7 to describe IGs that are available but not actively maintained.

Response: We have used the term ''expire'' for several years with respect to standards adopted in 45 CFR part 170. In the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI–1) final rule, we stated that the term ''expires'' means ''the standard is unavailable for use in the Program, or any other programs that may cite the standard, as of the expiration date'' (89 FR 1214). We appreciate there are other uses of this term with respect to standards development and maintenance. In the context of the regulations in 45 CFR part 170, this term has been used to reflect final policies around transitions between versions of standards and enables ONC to provide clear guidance to implementers about when such a transition will take place without needing to engage in additional notice and comment rulemaking to remove a standard from 45 CFR part 170.

Comment: Commenters urged CMS and ONC to harmonize standards required for programs affecting different entities. Commenters also recommended that CMS and ONC clearly communicate timelines and expectations around transition periods. Commenters urged clarity for industry about what is required at different times. A commenter requested that ONC clarify whether health IT developers seeking certification of their Health IT Modules to certification criteria that reference the proposed versions of the CRD, DTR, and PAS IGs would be required to demonstrate backward compatibility with the payer implementations based on the currently adopted versions of the IGs. A commenter also requested clarification on ONC testing procedures for version 2.2.1 of the PAS IG related to support for multiple versions of US Core.

Response: We appreciate commenters' feedback and share commenters' interest in ensuring alignment between regulatory requirements that impact the same end-users. Through the proposals we are finalizing in this rule, as well as the HTI–4 final rule and the CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, ONC and CMS have sought to ensure standards alignment between different programs under which HHS is advancing electronic prior authorization and other initiatives. Proposals and final policies in these rulemaking actions have aimed to reference a common set of FHIR IGs in 45 CFR 170.215. ONC and CMS will monitor the future development of these IGs and determine when to propose to adopt new versions to ensure that updates to regulatory requirements are updated in concert across programs impacting different implementers that are supporting these activities. We further appreciate the comment regarding communications and will seek to develop additional materials and communications opportunities to reiterate and explain policies finalized in rulemaking.

We clarify that health IT developers seeking certification of their Health IT Modules to certification criteria that reference versions 2.2.0 and 2.2.1 of the CRD, DTR, and PAS IGs will not be required to demonstrate backward compatibility with any version of the IGs preceding the versions established in regulation. Regarding requirements under the ONC Health IT Certification Program, we did not propose any updates to the requirements for the electronic prior authorization certification criteria in 45 CFR 170.315(g)(31) through (33) beyond the proposed standards updates. For further information about testing procedures under the ONC Health IT Certification Program including for version 2.2 of the PAS IG, we invite interested parties to monitor the Certification Program website, paying special attention to the Certification Companion Guides for certification criteria at 45 CFR 170.315(g)(31) through (33) [709] for additional information and educational resources related to the electronic prior authorization certification criteria as part of the Program.

[706] See *https://build.fhir.org/ig/HL7/davinci-crd/en/changes.html.*

[707] See *https://build.fhir.org/ig/HL7/davinci-dtr/en/changehistory.html.*

[708] See *https://build.fhir.org/ig/HL7/davinci-pas/en/changelog.html.*

[709] See Certification Companion Guides for 45 CFR 170.315(g)(31) through (33) at *https://healthit.gov/test-method/provider-prior-authorization-api-coverage-requirements-discovery, https://healthit.gov/test-method/provider-prior-authorization-api-documentation-templates-and-rules,* and *https://healthit.gov/test-method/provider-prior-authorization-api-prior-authorization-support.*

Comment: Several commenters recommended that ONC develop a process to provide notification in advance of an expected version expiration date. Commenters stated that a defined, predictable cadence for updates is necessary for regulated entities to plan implementation cycles and that irregular or ad hoc updates increase uncertainty and costs. A commenter recommended that ONC develop a process by which regulated entities are notified at least 12 months in advance of an expected standards version expiration date, and that a notification process would create transparency and predictability around timelines for advancing to unexpired versions of adopted standards. Several commenters recommended that ONC should base decisions and timelines about adopting new versions on an evaluation of readiness and utilization to ensure that new versions are effectively being used in practice before they are required. A commenter noted that a compliance date of January 1, 2028, overlaps with annual demands on businesses in the fourth quarter, and that entities would prefer compliance dates in the middle of the year.

Response: Generally, we agree with commenters that notification in advance of transitions between versions is important to being able to appropriately plan for updates to systems and allows regulated entities to mitigate potential interoperability challenges and service interruptions. However, several factors compel finalization of our policy to replace the adopted versions of standards at 45 CFR 170.215(j), (k), (m), and (n) with more recent versions without further maintaining the previously adopted versions. For instance, these factors include known deficiencies with versions currently listed at 45 CFR 170.215(j)(1) through (3) and the absence of any Health IT Modules certified to criteria that reference these standards.

ONC and CMS will continue to collaborate with standards development organizations and industry to monitor the development of updated versions of standards that are appropriate for adoption in regulation. We further concur that it is important for HHS to engage in notice and comment rulemaking in a manner that provides implementers with adequate time to effectively deploy updated systems and products subject to regulatory requirements around the use of standards. For instance, we are establishing 2.2.0 and 2.2.1 versions of CRD, DTR, and PAS IGs as the only version of these IGs available for use in certification criteria at 45 CFR 170.315(g)(31) through (33) as of the effective date of this final rule. This is intended to give industry as much time as possible to develop and deploy Health IT Modules conformant with these versions of standards. Regarding evaluating the readiness and utilization of a new version of a standard, we agree that this is an important capability and will continue to work with CMS on such monitoring activities. However, we note that in addition to considering readiness and utilization, we must consider broader timing considerations around introducing new versions of standards to ensure desired versions are introduced through the rulemaking cycle promptly.

We also appreciate commenters' concerns with establishing a January 1 date around standards versions which have compliance implications due to entities' obligations during this time of the year. However, we must balance these considerations with the need to align with other regulatory timelines which are organized around the calendar year that are relevant to these policies. For instance, the performance period for the MIPS Promoting Interoperability performance category and the EHR reporting period for the Promoting Interoperability program are both tied to the calendar year. Contract years for impacted payers, for instance, MA organizations, are also based on the calendar year. Therefore, we believe it is most appropriate to base dates for transition between versions required for compliance in a given period on the calendar year. However, we will continue to consider regulatory approaches that recognize these timing challenges.

Comment: Commenters provided other recommendations with respect to transitions between standards versions. A commenter suggested HHS publish a public crosswalk of breaking changes between versions of a standard to reduce duplicative work by implementers. A commenter noted that management of the transition between versions should clearly articulate compatibility expectations and how long outdated versions should remain available to mitigate uncertainty among end users. A commenter recommended that all documents incorporated by reference are available at a public URL without charge.

Response: We appreciate these suggestions and will consider how we can work in collaboration with standards development organizations on materials that can help implementers understand changes between versions. We also intend to continue to provide information about compatibility expectations when we adopt new versions of required standards. Finally, we note that we continue to seek to ensure the standards we adopt are available free of charge on public websites to the greatest extent possible. We note that all of the standards adopted in this final rule are available in this manner.

Final Decision: After consideration of the public comments received, we are finalizing our alternative proposal to replace previously adopted versions of corresponding standards with the versions we have finalized upon the effective date of this final rule. Specifically, we adopt the following standards at the specified locations and remove the versions currently adopted at those locations:

- HL7 FHIR® Da Vinci—Coverage Requirements Discovery IG [Implementation Guide], Version 2.2.1—STU 2.2 (adopted in 45 CFR 170.215(j)(1)(i)).[710]
- HL7 FHIR® Da Vinci—Documentation Templates and Rules Implementation Guide, Version 2.2.0—STU 2.2 (adopted in 45 CFR 170.215(j)(2)(i)).[711]
- HL7 FHIR® Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.2.1—STU 2.2 (adopted in 45 CFR 170.215(j)(3)(i)).[712]
- HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) [Implementation Guide], Version 2.2.0—STU 2.2 (adopted in 45 CFR 170.215(k)(1)(i)).[713]
- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.1.0—STU 2.1 (adopted in 45 CFR 170.215(m)(1)).[714]
- HL7 FHIR® Da Vinci PDex [Payer Data Exchange] Plan Net Implementation Guide, Version 1.2.0—

[710] Health Level Seven International. (2026, March 27). Da Vinci—Coverage Requirements Discovery IG. Retrieved from *https://hl7.org/fhir/us/davinci-crd/2.2.1/en/*.

[711] Health Level Seven International. (2026, March 27). Da Vinci—Documentation Templates and Rules IG. Retrieved from *https://hl7.org/fhir/us/davinci-dtr/2.2.0/en/*.

[712] Health Level Seven International. (2026, March 27). Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide. Retrieved from *https://hl7.org/fhir/us/davinci-pas/2.2.1/en/*.

[713] Health Level Seven International. (2026, March 27). CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®). Retrieved from *https://hl7.org/fhir/us/carin-bb/STU2.2/*.

[714] Health Level Seven International. (2025, February 26). Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide. Retrieved from *https://hl7.org/fhir/us/davinci-drug-formulary/STU2.1/*.

STU 1.2 (adopted in 45 CFR 170.215(n)(1)).[715]

While we acknowledge commenters' support for our primary proposal to finalize an expiration date of January 1, 2028, for previously adopted versions of standards, we believe that our alternative proposal is the most effective way to address the interoperability and compatibility concerns also raised by commenters. Replacing these standards with the updated versions upon the effective date of the final rule will ensure that entities required to use these standards develop to a common baseline as they initially deploy systems to meet proposed and finalized requirements. By removing previously adopted versions that would soon become obsolete, we are ensuring that regulated entities focus development efforts on versions of the standards that will effectively support interoperability.

We wish to reiterate that in this final rule, CMS is not addressing the compliance dates proposed in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule for payer APIs to conform to standards in 45 CFR 170.215(j), (k), (m), and (n). The updated versions of standards we are finalizing in this final rule would only be required for payer APIs if CMS finalizes these proposals in a future 2026 CMS Interoperability Standards and Prior Authorization for Drugs final rule.

9. Incorporation by Reference

The Office of the Federal Register has established requirements for materials (for example, standards and implementation specifications) that agencies propose to incorporate by reference in the CFR (79 FR 66267, 1 CFR 51.5(b)). Specifically, 1 CFR 51.5(b)(2) requires agencies to discuss, in the preamble of a final rule, the ways that the materials they incorporate by reference are reasonably available to interested parties and how interested parties can obtain the materials; and summarize, in the preamble of the final rule, the material they incorporate by reference.

To make the materials ONC intends to incorporate by reference reasonably available, it provides a URL for the standards and implementation specifications. In many cases, these standards and implementation specifications are directly accessible through the URLs provided. In most of these instances, access to the standard or implementation specification can be gained through no-cost (monetary) participation, subscription, or membership with the applicable SDO or custodial organization. Alternatively, a copy of the standards may be viewed for free at the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW, Washington, DC 20201. Please call (202) 690–7171 in advance to arrange inspection.

The NTTAA and the OMB Circular A–119 require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A–119 provide exceptions to selecting only standards developed or adopted by voluntary consensus standards bodies, namely when doing so will be inconsistent with applicable law or otherwise impractical. As discussed in section X.E.5. of this preamble, ONC has followed the NTTAA and OMB Circular A–119 in adopting standards and implementation specifications. Over the years of adopting standards and implementation specifications for certification, ONC has worked with SDOs, such as HL7, to make the standards it proposed to adopt, and subsequently adopt and incorporate by reference in the **Federal Register**, available to interested parties. As described previously, this includes making the standards and implementation specifications available through no-cost memberships and no-cost subscriptions.

As required by 1 CFR 51.5(b), ONC provides summaries of the standards it is adopting and incorporating by reference in the Code of Federal Regulations. ONC also provides relevant information about these standards and implementation specifications throughout the preamble.

Application Programming Interface Standards—45 CFR 170.215

- *HL7 FHIR® Da Vinci—Coverage Requirements Discovery IG [Implementation Guide], Version 2.2.1—STU 2.2, Generated March 27, 2026.*

URL: *https://hl7.org/fhir/us/davinci-crd/2.2.1/en/.*

This is a direct access link.

Summary: The CRD IG defines a workflow to allow payers to provide information about coverage requirements to health care providers through their provider systems at the time treatment decisions are being made. This will ensure that clinicians and administrative staff have the capability to make informed decisions and meet the requirements of the patient's insurance coverage.

- *HL7 FHIR® Da Vinci—Documentation Templates and Rules Implementation Guide, Version 2.2.0—STU 2.2, Generated March 27, 2026.*

URL: *https://hl7.org/fhir/us/davinci-dtr/2.2.0/en/.*

This is a direct access link.

Summary: The DTR IG provides a mechanism for payers to express their documentation requirements computably in a way that allows clinicians and other EHR users to navigate and quickly specify the needed information in a context-specific way. The guide allows rules to be written in a way that supports automatically extracting existing EHR information for review/confirmation and adjusting the information prompted for based on what data is already known or entered to minimize impact on provider time while expediting subsequent payer interactions.

- *HL7 FHIR® Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.2.1—STU 2.2, Generated March 27, 2026.*

URL: *https://hl7.org/fhir/us/davinci-pas/2.2.1/en/.*

This is a direct access link.

Summary: The PAS IG enables direct submission of prior authorization requests from EHR systems using FHIR. The IG also defines capabilities around the management of prior authorization requests, including checking the status of a previously submitted request, updating a previously submitted request, and canceling a request. Direct submission of prior authorization requests from the EHR can result in faster prior authorization decisions, reducing costs for both providers and payers and improving patient experience.

- *HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) [Implementation Guide], Version 2.2.0—STU 2.2, Generated March 27, 2026.*

URL: *https://hl7.org/fhir/us/carin-bb/STU2.2/.*

This is a direct access link.

Summary: The CARIN IG for Blue Button Framework and Common Payer Consumer Data Set (CPCDS) provides a set of resources that payers can display to consumers via a FHIR API. The CARIN IG for Blue Button was defined by the CARIN Alliance to meet the requirements in the 2020 CMS Interoperability and Patient Access final rule for impacted payers to make available claims and encounter data via Patient Access, Provider Access, and Payer-to-Payer APIs. This IG is

[715] Health Level Seven International. Da Vinci PDex [Payer Data Exchange] Plan Net Implementation Guide. Retrieved from *https://hl7.org/fhir/us/davinci-pdex-plan-net/STU1.2/.*

primarily used to exchange financial (claims and encounter) data, with some limited associated clinical data.

• *HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.1.0—STU 2.1, Generated February 26, 2025.*

URL: *https://hl7.org/fhir/us/davinci-drug-formulary/STU2.1/.*

This is a direct access link.

Summary: The PDex US Drug Formulary IG defines a FHIR interface to a health insurer's drug formulary information for patients/consumers. The primary use cases for this FHIR interface enable consumers, members, and patients to understand the costs and alternatives for drugs that have been prescribed, and to compare their drug costs across different insurance plans.

• *HL7 FHIR® Da Vinci PDex [Payer Data Exchange] Plan Net Implementation Guide, Version 1.2.0—STU 1.2, Generated February 25, 2025.*

URL: *https://hl7.org/fhir/us/davinci-pdex-plan-net/STU1.2/.*

This is a direct access link.

Summary: The PDex Plan Net IG defines a FHIR interface to access information about a health insurer's insurance plans, their associated networks, and the organizations and providers that participate in these networks. Publication of these data through a standard FHIR API will enable third parties to develop applications through which consumers and providers can query the participants in a payer's network that may provide services that address their health care needs.

• *HL7 FHIR® Da Vinci Clinical Data Exchange (CDex) IG [Implementation Guide], Version 2.1.0—STU 2.1, Generated February 11, 2025.*

URL: *https://hl7.org/fhir/us/davinci-cdex/STU2.1/.*

This is a direct access link.

Summary: The CDex IG helps implementers use FHIR-based interactions to exchange specific clinical data between providers and payers (or other providers). This IG documents the Direct Query, Task-Based, and Attachments transaction approaches for requesting and sending information. Key scenarios this IG can support include requesting and sending attachments for claims and prior authorization transactions, requesting documentation to support payer operations such as claims audits, and exchanging clinical data between referring providers.

Final Decision: We did not receive any comments on these proposals and are incorporating by reference the adopted standards we are finalizing in 45 CFR 170.299.

HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Implementation Guide, Version 2.1.0—STU 2.1, also referenced in the amendatory text of this document, was approved for that location in a previously-published final rule.

XI. MedPAC Recommendations and Publicly Available Files

A. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2026 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the policies set forth in this final rule. MedPAC recommendations for the IPPS for FY 2027 are addressed in Appendix B to this final rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's website at *https://www.medpac.gov.*

B. Publicly Available Files

IPPS-related data are available on the internet for public use. The data can be found on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.* We listed the data files available in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19751 through 19753). Commenters interested in discussing any data files used in construction of this final rule should contact Michael Treitel at (410) 786–4552.

XII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

• The need for information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the proposed rule, we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). The following ICRs are listed in the order of appearance within the preamble (see sections II. through XI. of the preamble of this final rule).

B. Collection of Information Requirements

1. ICRs for the Hospital Readmissions Reduction Program

In section V.I. of the preamble of this final rule, we discuss our finalized updates to the Hospital Readmissions Reduction Program. Specifically, in this final rule, we are adopting with modification the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure beginning with an early look for the FY 2028 (applicable period of July 1, 2024 to June 30, 2026) and FY 2029 (applicable period of July 1, 2025 to June 30, 2027) program years. The measure will then be used in the Hospital Readmissions Reduction Program for payment adjustment beginning with the FY 2030 program year (applicable period of July 1, 2026 to June 30, 2028) and subsequent years. Because this measure is calculated using Medicare administrative data (Medicare Fee-for-Service Part A and Part B claims, hospital-submitted Medicare Advantage (MA) claims and MA encounter data) that are already reported to the Medicare program for payment purposes under OMB control number 0938–1197 (expiration date October 31, 2027), and MA Organization-submitted encounter data already collected by CMS under OMB control number 0938–1152 (expiration date July 31, 2027), adopting this measure will not result in any change in information collection burden.

We received no comments on these information collection burden assumptions and therefore are finalizing these assumptions without modification.

2. ICRs for the Hospital Value-Based Purchasing Program

In section V.J. of the preamble of this final rule, we discuss our finalized updates to the Hospital Value-Based Purchasing Program. Specifically, we are modifying the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization, Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization, Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization, Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease Hospitalization, and Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft Surgery measures beginning with the July 1, 2028—June 30, 2030 performance period, associated with the FY 2032 payment determination. The finalized modifications include adding Medicare Advantage beneficiaries into the patient cohorts and modifying the applicable performance period from a 3-year period to a 2-year period.

The five measures we are modifying currently use data that are collected using Medicare Fee-For-Service claims that hospitals are already submitting to the Medicare program for payment purposes under OMB control number 0938–1197 (expiration date October 31, 2027); therefore, there is no additional information collection burden regarding the modification of the applicable performance period. We also assume no change in burden associated with the modification to add Medicare Advantage beneficiaries into the measure cohorts. As finalized, the measure will use Medicare Advantage encounter data already collected by CMS under OMB control number 0938–1152 (expiration date July 31, 2027) to determine cohort inclusion criteria, complications outcomes, and present on admission comorbidities. We discuss the burden associated with the adoption of these measures under the Hospital Inpatient Quality Reporting Program in section XII.B.4.c. of the preamble of this final rule.

We received no comments on these information collection burden assumptions and therefore are finalizing these assumptions without modification.

3. ICRs for the Hospital-Acquired Condition Reduction Program

OMB has currently approved 28,840 hours of burden and approximately $1.5 million under OMB control number 0938–1352 (expiration date February 28, 2029), accounting for information collection burden experienced by 400 subsection (d) hospitals selected for validation each year in the Hospital-Acquired Condition Reduction Program. We did not finalize any new policies or updates for the Hospital-Acquired Condition Reduction Program in this final rule.

4. ICRs for the Hospital Inpatient Quality Reporting Program

a. Background

Data collection for the Hospital Inpatient Quality Reporting Program is associated with OMB control number 0938–1022 (expiration date December 31, 2028), under which OMB has currently approved 1,351,632 hours of burden at a cost of approximately $73.7 million, accounting for information collection burden experienced by approximately 3,050 IPPS hospitals and 1,500 non-IPPS hospitals for the FY 2028 payment determination. In this final rule, we describe the burden changes regarding collection of information, under OMB control number 0938–1022.

For more detailed information on our finalized policies for the Hospital Inpatient Quality Reporting Program, we refer readers to sections IX.B. and IX.C. of the preamble of this final rule. We are adopting three new measures: (1) the Advance Care Planning electronic clinical quality measures (eCQM) beginning with the CY 2028 reporting period/FY 2030 payment determination; (2) the Hospital Harm-Postoperative Venous Thromboembolism (VTE) eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination; and (3) the Excess Days in Acute Care After Hospitalization for Diabetes measure beginning with the July 1, 2025 through June 30, 2027 performance period, associated with the FY 2029 payment determination. We are also adopting five mortality measures for the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination, through the July 1, 2027 through June 30, 2029 performance period, associated with the FY 2031 payment determination: (1) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization measure; (2) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization measure; (3) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization measure; (4) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization measure; and (5) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery measure. We are also modifying three measures beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination: (1) the Excess Days in Acute Care after Hospitalization for AMI measure; (2) the Excess Days in Acute Care after Hospitalization for HF measure; and (3) the Excess Days in Acute Care after Hospitalization for Pneumonia measure. We are additionally removing three self-selected eCQMs beginning with the CY 2028 reporting period/FY 2030 payment determination: (1) the VTE Prophylaxis eCQM; (2) the Intensive Care Unit VTE Prophylaxis eCQM; and (3) Discharged on Antithrombotic Therapy eCQM. Lastly, we are updating the reporting and submission requirements for the Maternal Morbidity Structural measure beginning with the CY 2026 reporting period/FY 2028 payment determination. None of these measure adoptions, removals, or modifications will affect information collection burden.

We are modifying the reporting and submission requirements for eCQMs to require mandatory reporting of the Malnutrition Care Score eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination, and to require mandatory reporting of Hospital Harm eCQMs after two years of self-selected reporting beginning with the CY 2028 reporting period/FY 2030 payment determination. We discuss the impacts on information collection burden associated with these policies later in this section.

Using the most recent data from the BLS for medical records specialists (SOC 29–2072), entitled, the May 2024 Occupational Employment and Wage Estimates, we are finalizing the use of the median hourly wage for medical records specialists for the industry, ''general medical and surgical hospitals,'' which is $27.53.[716] We believe the industry of ''general medical and surgical hospitals'' is more specific to this program compared to other industries under medical records specialists, such as ''office of physicians'' or ''nursing care facilities.'' We calculated the cost of overhead,

[716] U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics: General Medical and Surgical Hospitals, Medical Records Specialists. Accessed December 29, 2025. Available at: *https://www.bls.gov/oes/special-requests/oesm24in4.zip.*

including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($27.53 × 2 = $55.06) to estimate total cost is a reasonably accurate estimation method. Unless otherwise specified, we will calculate cost burden to hospitals using a wage plus benefits estimate of $55.06 per hour throughout the discussion in this section of this rule for the Hospital Inpatient Quality Reporting program. As noted in the FY 2027 IPPS/LTCH PPS proposed rule, although BLS released updated wage rates after the proposed rule appeared in the **Federal Register** and before this final rule will appear in the **Federal Register**, we are maintaining the wage rates used in the proposed rule (91 FR 19754).

In the FY 2026 IPPS/LTCH PPS final rule (90 FR 37192), our burden estimates were based on an assumption of approximately 3,050 IPPS hospitals. For this final rule, based on data from the FY 2026 Hospital Inpatient Quality Reporting Program payment determination, we are maintaining that assumption and estimate that approximately 3,050 IPPS hospitals will report data to the Hospital Inpatient Quality Reporting Program for the CY 2027 reporting period.

b. Information Collection Burden Estimate for the Adoption of Two eCQMs

In sections IX.B.1. and IX.C.3.b. of the preamble of this final rule, we are adopting the Advance Care Planning eCQM and Hospital Harm—Postoperative VTE eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination, respectively, to add to the set of eCQMs from which hospitals may self-select to meet their eCQM reporting requirements. The adoption of these two eCQMs will not affect the information collection burden of submitting eCQMs under the Hospital Inpatient Quality Reporting Program as current policy under OMB control number 0938–1022 requires hospitals to submit data for three self-selected and eight mandatory eCQMs from the eCQM measure set, for a total of 11 eCQMs, for the CY 2028 reporting period/FY 2030 payment determination and subsequent years. In other words, although these new eCQMs will be added to the eCQM measure set, hospitals will not be required to report more than a total of 11 eCQMs for the FY 2030 payment determination and subsequent years. In section IX.C.8.c.(3). of the preamble of this final rule, we discuss the burden associated with modifying eCQM reporting and submission requirements to require mandatory reporting of Hospital Harm eCQMs after two years of self-selected reporting beginning with the CY 2028 reporting period/FY 2030 payment determination.

c. Information Collection Burden Estimate for the Adoption of Six Claims-Based Measures

In sections IX.B.2. and IX.C.3.a. of the preamble of this final rule, we are adopting six claims-based measures. In section IX.C.3.a. of the preamble of this final rule, we are adopting one new claims-based measure: (1) Excess Days in Acute Care After Hospitalization for Diabetes measure beginning with the July 1, 2025 through June 30, 2027 performance period, associated with the FY 2029 payment determination. In section IX.B.2. of the preamble of this final rule, we are adopting five mortality measures beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination, through the July 1, 2027 through June 30, 2029 performance period, associated with the FY 2031 payment determination: (1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following AMI Hospitalization measure; (2) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following HF Hospitalization measure; (3) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization measure; (4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following COPD Hospitalization measure; and (5) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following CABG Surgery measure.

Because these measures are calculated using Medicare Fee-For-Service claims that are already reported to the Medicare program for payment purposes under OMB control number 0938–1197 (expiration date October 31, 2027) and Medicare Advantage encounter data already collected by CMS under OMB control number 0938–1152 (expiration date July 31, 2027) to determine cohort inclusion criteria, complications outcomes, and present on admission comorbidities, adoption of these measures will not result in a change in burden associated with OMB control number 0938–1022.

d. Information Collection Burden Estimate for the Modification of Three Excess Days in Acute Care After Hospitalization Measures

In section IX.C.5. of the preamble of this final rule, we are modifying three measures beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination: (1) the Excess Days in Acute Care after Hospitalization for AMI measure; (2) the Excess Days in Acute Care after Hospitalization for HF measure; and (3) the Excess Days in Acute Care after Hospitalization for Pneumonia measure.

This modification will include adding Medicare Advantage beneficiaries to the current cohort of patients and shortening the performance period from 3 years to 2 years. Because these measures will be calculated using Medicare Fee-For-Service claims that are already reported to the Medicare program for payment purposes under OMB control number 0938–1197 and Medicare Advantage encounter data already collected by CMS under OMB control number 0938–1152 to determine cohort inclusion criteria, complications outcomes, and present on admission comorbidities, modifying these measures will not result in a change in burden associated with OMB control number 0938–1022.

e. Information Collection Burden Estimate for the Removal of Three eCQMs

In section IX.C.4. of the preamble of this final rule, we are removing three eCQMs beginning with the CY 2028 reporting period/FY 2030 payment determination: (1) the VTE Prophylaxis eCQM; (2) the Intensive Care Unit VTE eCQM; and (3) Discharged on Antithrombotic Therapy eCQM. Because reporting these eCQMs is not mandatory, but they are instead available in the Hospital Inpatient Quality Reporting Program eCQM measure set for hospitals to self-select to report, removing these eCQMs will not result in a change in burden associated with OMB control number 0938–1022.

f. Information Collection Burden Estimate for the Modification to the Reporting and Submission Requirements for the Maternal Morbidity Structural Measure

In section IX.C.8.d.(1). of the preamble of this final rule, we are modifying the reporting and submission requirements for the Maternal Morbidity Structural measure beginning with the CY 2026 reporting period/FY 2028 payment determination. We note that in

the FY 2027 IPPS/LTCH PPS proposed rule, we erroneously stated that we were proposing to modify this measure beginning with the CY 2027 reporting period/FY 2029 payment determination (91 FR 19755). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365), we adopted the Maternal Morbidity Structural measure, requiring hospitals to attest ''yes'', ''no'', or ''not applicable'' to one two-part question. The currently approved information collection burden for the Maternal Morbidity Structural measure under OMB control number 0938–1022 is five minutes (0.083 hours) per IPPS hospital annually. We are adding a sub-question to collect the name of the Statewide and/or National Perinatal Quality Improvement Collaborative Program in which the hospital participates. We believe that the currently approved burden of five minutes is adequate for hospitals to both attest to the current two-part question and answer the adopted sub-question and therefore are not finalizing any changes to the currently approved burden estimate.

g. Information Collection Burden Estimate for the Changes to eCQM Reporting and Submission Requirements

In section IX.C.8.c.(2). of the preamble of this final rule, we are modifying the reporting and submission requirements for the Malnutrition Care Score eCQM to require mandatory reporting beginning with the CY 2028 reporting period/FY 2030 payment determination. The Malnutrition Care Score eCQM (previously known as Global Malnutrition Composite Score eCQM) was initially adopted in the FY 2023 IPPS/LTCH PPS final rule into the Hospital Inpatient Quality Reporting Program measure set from which a hospital could self-select beginning with the CY 2024 reporting period/FY 2026 payment determination (87 FR 49239 through 49246).

In section IX.C.8.c.(3). of the preamble of this final rule, we are modifying the reporting and submission requirements for Hospital Harm eCQMs to require mandatory reporting after 2 years of self-selected reporting, beginning with the CY 2028 reporting period/FY 2030 payment determination. In the currently approved eCQM measure set, there are two Hospital Harm eCQMs in the Hospital Inpatient Quality Reporting Program measure set from which a hospital could self-select that have not previously been finalized to become mandatory already: Hospital Harm-Falls with Injury and Hospital Harm-Postoperative Respiratory Failure. Under this policy, these two measures will begin mandatory reporting with the FY 2030 payment determination, given they were adopted in the FY 2025 IPPS/LTCH PPS final rule for self-selection eCQMs beginning with the FY 2028 payment determination (89 FR 69534 through 69545). Additionally, as discussed in section IX.C.3.b. of the preamble of this final rule, we are adopting the Hospital Harm-Postoperative VTE eCQM as a self-selected eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination. This measure will begin mandatory reporting with the FY 2032 payment determination.

Current Hospital Inpatient Quality Reporting Program policy under OMB control number 0938–1022 requires hospitals to submit data for three self-selected and eight mandatory eCQMs, for a total of 11 eCQMs, for the CY 2028 reporting period/FY 2030 payment determination and subsequent years. The currently approved information collection burden per reported eCQM under OMB control number 0938–1022 is 10 minutes (0.167 hours) per hospital per quarter or 40 minutes (0.67 hours) per hospital annually. For the CY 2028 reporting period/FY 2030 payment determination and CY 2029 reporting period/FY 2031 payment determination, we estimate the reporting modifications to the Malnutrition Care Score and two Hospital Harm eCQMs will result in a total increase of 120 minutes (2 hours) per hospital annually (10 minutes/eCQM × 3 eCQMs × 4 quarters) or a total annual burden increase across all 3,050 IPPS hospitals of 6,100 hours (2 hours × 3,050 IPPS hospitals) at a cost of $335,866 (6,100 hours × $55.06). Beginning with the CY 2030 reporting period/FY 2032 payment determination, when the Hospital Harm-Postoperative VTE eCQM becomes a mandatory eCQM, we estimate the reporting modifications will result in a total increase of 160 minutes (2.67 hours) per hospital annually (10 minutes/eCQM × 4 eCQMs × 4 quarters) or a total annual burden increase across all 3,050 IPPS hospitals of 8,133 hours (2.67 hours × 3,050 IPPS hospitals) at a cost of $447,803 (8,133 hours × $55.06).

h. Summary of Information Collection Burden Estimates for the Hospital Inpatient Quality Reporting Program

In summary, under OMB control number 0938–1022 (expiration date December 31, 2028), we estimate that the policies finalized in this final rule will result in an increase in information collection burden of 8,133 hours at a cost of $447,803. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1022. With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.K. of Appendix A of this final rule).

TABLE XII.B-01: SUMMARY OF HOSPITAL INPATIENT QUALITY REPORTING PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2028 AND CY 2029 REPORTING PERIODS

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2028 and CY 2029 Reporting Periods								
Activity	Estimated Time per Record (in minutes)	Number Reporting Quarters per Year	Number of Respondents Reporting	Average Number Records per Respondent per Quarter	Annual Burden (Hours) per Respondent	Finalized Annual Burden (in hours) Across Hospitals	Previously Finalized Annual Burden (in hours) Across Hospitals	Net Difference in Annual Burden Hours
Modification of Malnutrition Care Score eCQM Reporting	10	4	3,050	1	0.67	24,400	22,367	2,033
Modification of Hospital Harm eCQMs Reporting	20	4	3,050	1	1.33	26,433	22,367	4,067
	Total Change in Information Collection Burden Hours: 6,100							
	Total Cost Estimate: Updated Hourly Wage ($55.06) x Change in Burden Hours (6,100) = **$335,866**							

TABLE XII.B-02: SUMMARY OF HOSPITAL INPATIENT QUALITY REPORTING PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2030 REPORTING PERIOD

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2028 and CY 2029 Reporting Periods								
Activity	Estimated Time per Record (in minutes)	Number Reporting Quarters per Year	Number of Respondents Reporting	Average Number Records per Respondent per Quarter	Annual Burden (Hours) per Respondent	Finalized Annual Burden (in hours) Across Hospitals	Previously Finalized Annual Burden (in hours) Across Hospitals	Net Difference in Annual Burden Hours
Modification of Malnutrition Care Score eCQM Reporting	10	4	3,050	1	0.67	24,400	22,367	2,033
Modification of Hospital Harm eCQMs Reporting	30	4	3,050	1	2.0	28,467	22,367	6,100
	Total Change in Information Collection Burden Hours: 8,133							
	Total Cost Estimate: Updated Hourly Wage ($55.06) x Change in Burden Hours (8,133) = **$447,803**							

We received no comments on these information collection burden estimates and therefore are finalizing the burden estimates associated with these provisions without modification.

5. ICRs for the PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program

a. Background

OMB has currently approved a total of 2 hours of burden at a cost of $111 under OMB control number 0938–1175 (expiration date January 31, 2029), accounting for the annual information collection requirements for 11 PCHs for the PCH Quality Reporting Program. In this final rule, we describe the burden changes regarding collection of information under OMB control number 0938–1175 for PCHs.

For more detailed information on our finalized policies for the PCH Quality Reporting Program, we refer readers to sections IX.B. and IX.D. of this final rule. We are adopting two measures with voluntary reporting for the CY 2028 reporting period/FY 2030 program year followed by mandatory reporting beginning with the CY 2029 reporting period/FY 2031 program year: (1) the Advance Care Planning electronic clinical quality measure (eCQM); and (2) the Malnutrition Care Score eCQM. This is a modification from the FY 2027 IPPS/LTCH PPS proposed rule, in which we proposed to adopt both measures with mandatory reporting beginning with the CY 2028 reporting period/FY 2030 program year (91 FR 19564 through 19568 and 91 FR 19605 through 19608). We are also removing the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the CY 2026 reporting period/FY 2028 program year. We discuss the impacts on information collection burden associated with these policies later in this section.

Using the most recent data from the BLS for medical records specialists (SOC 29–2072), entitled, the May 2024 Occupational Employment and Wage Estimates, we are finalizing the use of the median hourly wage for medical records specialists for the industry, ''general medical and surgical hospitals,'' which is $27.53.[717] Because we are estimating the burden specific to PCHs, as previously assumed in the FY 2026 IPPS/LTCH PPS final rule, we believe the industry of ''general medical and surgical hospitals'' is more specific to this program compared to other industries under medical records specialists, such as ''office of physicians'' or ''nursing care facilities'' (90 FR 37194). We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with the FY 2026 IPPS/LTCH PPS final rule and previous years (90 FR 37194). This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($27.53 × 2 = $55.06) to estimate total cost is a reasonably accurate estimation method. Unless otherwise specified, we will calculate cost burden to PCHs using a wage plus benefits estimate of $55.06 per hour throughout the discussion in this section of this rule for the PCH Quality Reporting Program. In order to maintain consistency to the extent possible between proposed and final rules, as noted in the FY 2027 IPPS/LTCH PPS proposed rule, although BLS released updated wage rates after the proposed rule appeared in the **Federal Register** and before this final rule will appear in the **Federal Register**, we are maintaining the wage rates used in the proposed rule (91 FR 19757).

[717] U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics: General Medical and Surgical Hospitals, Medical Records Specialists. Available at: *https://www.bls.gov/oes/special-requests/oesm24in4.zip.*

b. Information Collection Burden Estimate for the Adoption of Two eCQMs

In sections IX.B.1. and IX.D.2.a. of this final rule, we are adopting the Advance Care Planning and Malnutrition Care Score eCQMs, respectively, with voluntary reporting for the CY 2028 reporting period/FY 2030 program year, followed by mandatory reporting beginning with the CY 2029 reporting period/FY 2031 program year. This is a modification from the FY 2027 IPPS/LTCH PPS proposed rule, in which we proposed to adopt both measures with mandatory reporting beginning with the CY 2028 reporting period/FY 2030 program year (91 FR 19564 through 19568 and 91 FR 19605 through 19608). For voluntary reporting in the CY 2028 reporting period/FY 2030 program year, we assume 6 PCHs (50 percent) will report each eCQM. Similar to the currently approved information collection burden estimates for submission of eCQMs for the Hospital Inpatient Quality Reporting Program under OMB control number 0938–1022, we assume a Medical Records Specialist will require 10 minutes (0.167 hours) per eCQM to submit the data required per quarter for each PCH, or 40 minutes (0.67 hours) annually. For both eCQMs in the CY 2028 reporting period/FY 2030 program year, we estimate a total of 80 minutes (1.33 hours) annually per PCH, or 8 hours across 6 PCHs (1.33 hours × 6 PCHs) at a cost of $440 (8 hours × $55.06). For both eCQMs beginning with the CY 2029 reporting period/FY 2031 program year, we estimate an annual burden of 15 hours across all PCHs (1.33

hours × 11 PCHs) at a cost of $826 (15 hours × $55.06).

c. Information Collection Burden Estimate for the Removal of the COVID–19 Vaccination Coverage Among HCP Measure

In section IX.D.3.a. of this final rule, we are removing the COVID–19 Vaccination Coverage among HCP measure beginning with the CY 2026 reporting period/FY 2028 program year. This measure was previously adopted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45428 through 45434), and the associated information collection is approved under OMB control number 0920–1317 [718] (expiration date January 31, 2028).

PCHs have the option to manually enter data directly into the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network web-based application or by uploading a CSV file. CDC estimates that each PCH requires between 40 minutes (0.67 hours) to upload a CSV file and 45 minutes (0.75 hours) monthly to enter the data manually. CDC assumes that manual data entry will be completed by a Microbiologist with a wage rate of $58.60/hour and uploading of a CSV file will be completed by an Information Technologist with a wage rate of $56.50/hour. Therefore, we estimate that this removal will result in a decrease in burden of between 88 hours (0.67 hours × 12 months × 11 PCHs) at a cost of $4,972 (88 hours × $56.50/hour) and 99 hours (0.75 hours × 12 months × 11 PCHs) at a cost of $5,801 (99 hours × $58.60/hour) annually across all 11 PCHs under OMB control number 0920–1317.

d. Summary of Information Collection Burden Estimates for the PCH Quality Reporting Program

In summary, under OMB control number 0938–1175 (expiration date January 31, 2029), we estimate that the policies finalized in this final rule for the PCH Quality Reporting Program will result in an increase in information collection burden of 15 hours and $826. We also estimate that the policies finalized in this final rule for the PCH Quality Reporting Program will result in a decrease in information collection burden between 88 hours at a savings of $4,972 and 99 hours at a savings of $5,801 under OMB control number 0920–1317. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1175. With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.L. of Appendix A of this final rule).

We did not receive any public comments regarding these information collection burden estimates.

TABLE XII.B-03: SUMMARY OF PCH QUALITY REPORTING PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2028 REPORTING PERIOD UNDER OMB CONTROL NUMBER 0938-1175

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1175 for the CY 2028 Reporting Period								
Activity	Estimated Time per Record (in minutes)	Number Reporting Quarters per Year	Number of Respondents Reporting	Average Number Records per Respondent per Quarter	Annual Burden (Hours) per Respondent	Finalized Annual Burden (in hours) Across PCHs	Previously Finalized Annual Burden (in hours) Across PCHs	Net Difference in Annual Burden Hours
Adoption of Advance Care Planning eCQM	10	4	6	1	0.67	4	0	+4
Adoption of Malnutrition Care Score eCQM	10	4	6	1	0.67	4	0	+4
	Total Change in Information Collection Burden Hours: +8							
	Total Cost Estimate: Updated Hourly Wage ($55.06) x Change in Burden Hours (+8) = **$440**							

TABLE XII.B-04: SUMMARY OF PCH QUALITY REPORTING PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2029 REPORTING PERIOD UNDER OMB CONTROL NUMBER 0938-1175

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1175 for the CY 2029 Reporting Period								
Activity	Estimated Time per Record (in minutes)	Number Reporting Quarters per Year	Number of Respondents Reporting	Average Number Records per Respondent per Quarter	Annual Burden (Hours) per Respondent	Finalized Annual Burden (in hours) Across PCHs	Previously Finalized Annual Burden (in hours) Across PCHs	Net Difference in Annual Burden Hours
Adoption of Advance Care Planning eCQM	10	4	11	1	0.67	7	0	+7
Adoption of Malnutrition Care Score eCQM	10	4	11	1	0.67	7	0	+7
	Total Change in Information Collection Burden Hours: +15*							
	Total Cost Estimate: Updated Hourly Wage ($55.06) x Change in Burden Hours (+15) = **$826**							

* Due to rounding, total change in burden differs from the sum of burden for each proposal.

[718] *Available at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202509-0920-004.*

TABLE XII.B-05: SUMMARY OF PCH QUALITY REPORTING PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2026 REPORTING PERIOD UNDER OMB CONTROL NUMBER 0920-1317

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0920-1317 for the CY 2026 Reporting Period								
Activity	Estimated Time per Record (in minutes)	Number Reporting Quarters per Year	Number of Respondents Reporting	Average Number Records per Respondent per Quarter	Annual Burden (Hours) per Respondent	Finalized Annual Burden (in hours) Across PCHs	Previously Finalized Annual Burden (in hours) Across PCHs	Net Difference in Annual Burden Hours
Removal of COVID-19 Vaccination Coverage Among HCP Measure	-45*	12	11	1	-9	0	99	-99
	Total Change in Information Collection Burden Hours: -99*							
	Total Cost Estimate: Updated Hourly Wage ($58.60) x Change in Burden Hours (-99) = **-$5,801**							

*For purposes of this table, we state the maximum possible burden across all PCHs.

6. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

As required by section 1886(m)(5)(A)(i) of the Act, an LTCH that does not meet the requirements of the LTCH QRP for a fiscal year will receive a 2-percentage point reduction to its otherwise applicable annual update for that fiscal year. We estimated that the burden associated with the LTCH QRP is the time and effort associated with complying with the requirements of the LTCH QRP.

In section IX.E.3. of this final rule, we finalized our proposal to remove the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) (HCP COVID–19 Vaccine) measure. We also finalized our proposal, in section IX.E.4 of this final rule, to remove the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID–19 Vaccine) measure. We also finalized our proposal that both measure removals will be effective beginning with the FY 2028 LTCH QRP.

a. ICRs for Removal of the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) Measure Beginning with the FY 2028 LTCH QRP

In section IX.E.3. of this final rule, we finalized our proposal to remove the (HCP COVID–19 Vaccine measure beginning with the FY 2028 LTCH QRP. We note that the CDC would account for the burden associated with the HCP COVID–19 Vaccine measure collection under OMB control number 0920–1317 (expiration 01/31/2028). Currently, the CDC does not estimate burden for COVID–19 vaccination reporting under PRA package OMB control number 0920–1317 due to a waiver under section 321 of the National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660, enacted on November 14, 1986 (NCVIA)).[719] However, CMS is providing an estimate of reduction in burden and cost for LTCHs here. Consistent with the CDC's experience of collecting data using the NHSN, we estimate the removal of this measure will result in a reduction of 1 hour per month to collect data for the HCP COVID–19 Vaccine measure and enter it into NHSN. We believe that this data would be entered by a medical secretary or administrative assistant. However, LTCHs determine the staffing resources necessary.

For the purposes of calculating the costs associated with the collection of information requirements, we obtained median hourly wages from the BLS May 2024 Occupational Employment and Wage Estimates.[720] To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in table XII.B–06.

TABLE XII.B-05: U.S. BUREAU OF LABOR AND STATISTICS' MAY 2024 OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage ($/hr)	Other Indirect Costs and Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Administrative Assistants	43-6013	$21.46	$21.46	$42.92

We estimated that the removal of the HCP COVID–19 measure from the LTCH QRP will result in a reduction of 12 hours per LTCH per year. Using FY 2025 data, we estimated a total of 318 LTCHS annually for a decrease of 3,816 hours (12 hours × 318 LTCHS) for all LTCHs. Given an estimated $42.92 hourly wage for administrative assistants, we estimate a decrease of $515.04 per LTCH (12 hours × $42.92), or a decrease of $163,782.72 for all LTCHs annually ($515.04 × 318 LTCHs). The total revised annual cost increase beginning with the FY 2028 LTCH QRP related to this information collection is summarized in Table XII.B–06.

[719] Section 321 of the NCVIA provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (*https://www.govinfo.gov/content/pkg/USCODE-2023-title42/pdf/USCODE-2023-title42-chap6A-subchapXIX-part1-sec300aa-2.pdf*). Section 321 is not codified in the U.S. Code but can be found in a note *(https://www.govinfo.gov/content/pkg/USCODE-2023-title42/pdf/USCODE-2023-title42-chap6A-subchapXIX-part1-sec300aa-1.pdf*).

[720] U.S. Bureau of Labor Statistics' (BLS) May 2024 Occupational Employment and Wage Estimates. *https://www.bls.gov/oes/special-requests/oesm24nat.zip*

TABLE XII.B-06: ESTIMATED BURDEN ASSOCIATED WITH COLLECTION OF THE HCP COVID-19 VACCINE MEASURE BEGINNING WITH THE FY 2028 LTCH QRP

Requirement	Per LTCH		All LTCHs	
	Change in Annual Burden Hours	Change in Annual Cost	Change in Annual Burden Hours	Change in Annual Cost
Proposed Removal of the HCP COVID-19 Vaccine Measure	-12.00	-$515.04	-3,960	$163,782.72

b. ICRs for Proposed Removal of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning with the FY 2028 LTCH QRP

In section IX.E.4. of this final rule, we finalized our proposal to remove Patient/Resident COVID–19 Vaccine measure, beginning with the FY 2028 LTCH QRP. We believe that data collection would be completed equally by a Registered Nurse (RN) and a Licensed Practical and Licensed Vocational Nurse (LPN/LVN). However, LTCHs determine the staffing resources necessary. In section IX.E.4 of this final rule we also finalize our proposal to remove the item (O0350) from the LCDS, currently approved under OMB control number 0938–1163 (Expiration date: 10/31/2027). The following is a discussion of this information collection.

The net result of removing the related Patient/Resident COVID–19 Vaccine Status measure and the LCDS item used to collect the measure data (O0350. Patient COVID–19 vaccination is up to date) is a decrease of 0.3 minutes or 0.005 hour of clinical staff time. We estimated that the burden and cost for LTCHs for complying with requirements of the FY 2028 LTCH QRP would decrease under our proposal.

For the purposes of calculating the costs associated with the collection of information requirements, we obtained median hourly wages for these staff from the U.S. Bureau of Labor Statistics' (BLS) May 2024 Occupational Employment and Wage Estimates.[721] To account for other indirect costs and fringe benefits, we doubled the hourly wage. These amounts are detailed in Table G3. We established a composite cost estimate using our adjusted wage estimates. The composite estimate of $78.16/hr was calculated by weighting each adjusted hourly wage equally (that is, 50 percent) [($61.80/hr × 0.5) plus ($92.32/hr × 0.5) = $76.57].

TABLE XII.B-07: U.S. BUREAU OF LABOR AND STATISTICS' MAY 2024 OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage ($/hr)	Other Indirect Costs and Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Licensed Practical and Licensed Vocational Nurse (LPN/LVN)	29-2061	$29.97	$29.97	$60.81
Registered Nurse (RN)	29-1141	$45.00	$45.00	$92.32

Using FY 2025 data, we estimated an annual total of 102,590 discharges from 318 LTCHs for an annual decrease of 512.95 hours (102,590 × 0.005 hour) for all LTCHs. Given 0.005 hours at $76.57 per hour, we estimated the total cost will decrease annually by $39,276.58 for all LTCHs ($76.57 × 512.95 hours). For each LTCH, we estimated an annual burden decrease of 1.61 hours (512.95 hours/318 LTCHs) and an annual decreased cost of $123.51. The total estimated annual burden decrease associated with the removal of the Patient/Resident COVID–19 Vaccine Status item (O0350) on discharge beginning with the FY LTCH QRP is summarized in Table XII.B–08.

TABLE XII.B-06: ESTIMATED BURDEN ASSOCIATED WITH COLLECTION OF THE HCP COVID-19 VACCINE MEASURE BEGINNING WITH THE FY 2028 LTCH QRP

Requirement	Per LTCH		All LTCHs	
	Change in Annual Burden Hours	Change in Annual Cost	Change in Annual Burden Hours	Change in Annual Cost
Proposed Removal of the HCP COVID-19 Vaccine Measure	-12.00	-$515.04	-3,960	$163,782.72

We invited public comments on the proposed modification to information collection requirements for LTCH QRP beginning with the FY 2028 LTCH QRP.

We received comments on the proposed modification to information collection requirements for the LTCH QRP, related to the removal of the HCP COVID–19 Vaccine and Patient/Resident COVID–19 Vaccine measures, and have summarized those in sections IX.E.3. and IX.E.4, respectively. After careful consideration of the comments,

[721] U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics. May 2024. *https://www.bls.gov/oes/special-requests/oesm24nat.zip.*

we are finalizing these proposals without modification.

7. ICRs for the Medicare Promoting Interoperability Program

a. Background

OMB has currently approved 30,151 hours of burden at a cost of $1,669,707 under OMB control number 0938–1278 (expiration date March 31, 2029), accounting for information collection burden experienced by approximately 3,150 eligible hospitals and 1,400 Critical Access Hospitals (CAHs) for the electronic health record (EHR) reporting period in CY 2026. The collection of information burden analysis in this final rule focuses on all eligible hospitals and CAHs that could participate in the Medicare Promoting Interoperability Program and report on objectives, measures, and electronic clinical quality measures (eCQMs) under the Medicare Promoting Interoperability Program for the EHR reporting periods in CY 2026 and CY 2027.

For more detailed information on our policies for the Medicare Promoting Interoperability Program, we refer readers to section IX.B. and IX.F. of the preamble of this final rule. For the Medicare Promoting Interoperability Program, we are adopting three new measures: (1) the Advance Care Planning eCQM beginning with the CY 2028 reporting period; (2) the Hospital Harm-Postoperative Venous Thromboembolism (VTE) eCQM beginning with the CY 2028 reporting period; and (3) the Unique Device Identifiers for Implantable Medical Devices measure beginning with the EHR reporting period in CY 2027. Additionally, we are removing two attestations and five measures: (1) the Office of the National Coordinator for Health Information Technology (ONC) Direct Review Attestation beginning with the EHR reporting period in CY 2026; (2) the optional ONC-Authorized Certification Body (ONC–ACB) Surveillance Attestation beginning with the EHR reporting period in CY 2026; (3) the Support Electronic Referral Loops by Sending Health Information measure beginning with the EHR reporting period in CY 2029; (4) the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure beginning with the EHR reporting period in CY 2029; (5) the VTE Prophylaxis eCQM beginning with the CY 2028 reporting period; (6) the Intensive Care Unit VTE Prophylaxis eCQM beginning with the CY 2028 reporting period; and (7) the Discharged on Antithrombotic Therapy eCQM beginning with the CY 2028 reporting period. We are also updating the Electronic Prior Authorization measure by modifying the measure description text, making the measure optional for the EHR reporting period in CY 2027 and required beginning with the EHR reporting period in CY 2028, and modifying the ONC health IT certification criteria eligible hospitals and CAHs must use to attest ''Yes'' beginning with the EHR reporting period in CY 2027.

We are modifying the Malnutrition Care Score eCQM to require mandatory reporting beginning with the CY 2028 reporting period. For those Hospital Harm eCQMs that are not already required to be reported (including any we may propose to adopt in the future), we are also modifying the eCQM reporting and submission requirements for Hospital Harm eCQMs to require mandatory reporting after 2 years of self-selected reporting beginning with the CY 2028 reporting period. We will discuss the impacts on information collection burden associated with these policies later in this section.

We are also revising the definition of CEHRT at 42 CFR 495.4 for the Medicare Promoting Interoperability Program so the definition will be consistent with proposed modifications to ONC health IT certification criteria in the HTI–5 proposed rule. Because the HTI–5 final rule will be issued after this final rule is published in the **Federal Register**, if the ONC health IT certification criteria-related proposals that ONC finalizes in the HTI–5 final rule are different from what was proposed in the HTI–5 proposed rule, we will assess those finalized policies and consider necessary revisions in future rulemaking. There is no information collection burden associated with the finalized revision to the definition of CEHRT.

Using the most recent data from the BLS for medical records specialists (SOC 29–2072), entitled, the May 2024 Occupational Employment and Wage Estimates, we finalized the use of the median hourly wage for medical records specialists for the industry, ''general medical and surgical hospitals,'' which is $27.53.[722] We believe the industry of ''general medical and surgical hospitals'' is more specific to this program compared to other industries under medical records specialists, such as ''office of physicians'' or ''nursing care facilities.'' We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($27.53 × 2 = $55.06) to estimate total cost is a reasonably accurate estimation method. Unless otherwise specified, we will calculate cost burden to hospitals using a wage plus benefits estimate of $55.06 per hour throughout the discussion in this section of this rule for the Medicare Promoting Interoperability Program. As noted in the FY 2027 IPPS/LTCH PPS proposed rule, although BLS released updated wage rates after the proposed rule appeared in the **Federal Register** and before this final rule will appear in the **Federal Register**, we are maintaining the wage rates used in the proposed rule (91 FR 19761).

In the FY 2026 IPPS/LTCH PPS final rule (90 FR 37199), our burden estimates were based on an assumption of 4,550 eligible hospitals and CAHs. For this final rule, based on data from the EHR reporting period in CY 2024, we continue to estimate approximately 3,150 eligible hospitals and 1,400 CAHs will be eligible to report data to the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2027, for a total number of 4,550 respondents.

b. Information Collection Burden for the Adoption of Two eCQMs

In sections IX.B.1. and IX.F.9.b. of the preamble of this final rule, we are adopting two new eCQMs beginning with the CY 2028 reporting period, respectively: (1) the Advance Care Planning eCQM and (2) the Hospital Harm-Postoperative VTE eCQM, to add to the set of eCQMs from which eligible hospitals and CAHs may self-select to meet their eCQM reporting requirements. The adoption of these two eCQMs will not affect the information collection burden of submitting eCQMs under the Medicare Promoting Interoperability Program as currently estimated under OMB control number 0938–1022, which accounts for eligible hospitals and CAHs submitting data for three self-selected and eight mandatory eCQMs, for a total of 11 eCQMs, from the eCQM measure set for the CY 2028 reporting period and subsequent years. In other words, although these two eCQMs will be added to the eCQM measure set, eligible hospitals and CAHs are not currently required to report more than a total of 11 eCQMs for

[722] U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics: General Medical and Surgical Hospitals, Medical Records Specialists. Accessed December 29, 2025. Available at: *https://www.bls.gov/oes/special-requests/oesm24in4.zip.*

the CY 2028 reporting period and subsequent years. However, in section XII.B.7.h, we discuss the burden associated with modifying eCQM reporting and submission requirements to require mandatory reporting for the Malnutrition Care Score and all Hospital Harm eCQMs after two years of self-selected reporting beginning with the CY 2028 reporting period, resulting in eligible hospitals and CAHs being required to report a total of 14 eCQMs for the CY 2028 and CY 2029 reporting periods, and 15 eCQMs beginning with the CY 2030 reporting period.

c. Information Collection Burden Estimate for the Adoption of the Unique Device Identifiers for Implantable Medical Devices Measure

In section IX.F.6. of the preamble of this final rule, we are adopting the Unique Device Identifiers for Implantable Medical Devices measure under the Public Health and Clinical Data Exchange objective beginning with the EHR reporting period in CY 2027. For this attestation-based measure, eligible hospitals and CAHs will be required to report a ''Yes'' response, a ''No'' response, or claim an applicable exclusion for which they are eligible. Like other attestations approved for the Public Health and Clinical Data Exchange objective under OMB control number 0938–1278, we assume eligible hospitals and CAHs require 30 seconds (0.5 minutes) to attest to this measure. Therefore, we estimate a total annual burden increase across all 4,550 eligible hospitals and CAHs of 38 hours (0.0083 hours × 4,550 eligible hospitals and CAHs) at a cost of $2,092 (38 hours × $55.06). As stated in section IX.F.6.b. of the preamble of this final rule, we note that the ONC health IT certification criterion at 45 CFR 170.315(g)(10) can support fulfillment of the measure. Eligible hospitals and CAHs are already required to record and maintain patient-linked implantable device information in their records under 21 CFR 821.30. Additionally, as approved by OMB under control number 0938–1022 for the Hospital Inpatient Quality Reporting Program, in which we account for the information collection burden associated with eCQM reporting and submission for eligible hospitals and CAHs, only the time associated with electronically submitting data to CMS is accounted for in our burden estimates because patient data are already entered into EHRs and health information technology systems as part of clinical practice. Therefore, we assume no additional information collection burden under OMB control number 0938–1278 associated with entry of Unique Device Identifier information into EHRs by eligible hospitals and CAHs.

d. Information Collection Burden Estimate for the Removal of the ONC Direct Review and Optional ONC–ACB Surveillance Attestations

In section IX.F.3. of the preamble of this final rule, we are removing the ONC Direct Review attestation and optional ONC–ACB Surveillance attestation beginning with the EHR reporting period in CY 2026. The information collection burden associated with the ONC Direct Review attestation is currently approved under OMB control number 0938–1278 and assumes each eligible hospital and CAH requires 1 minute (0.0167 hours) at a cost of $1 (0.0167 hours × $55.06) annually to attest ''Yes'' or ''No.'' We therefore estimate a total annual burden decrease across all 4,550 eligible hospitals and CAHs of 76 hours (0.0167 hours × 4,550 eligible hospitals and CAHs) at a savings of $4,185 (76 hours × $55.06). Similarly, we estimate each eligible hospital and CAH that currently elects to submit the optional ONC–ACB Surveillance attestation will experience a decrease in burden of 1 minute (0.0167 hours) at a savings of $1 (0.0167 hours × $55.06) annually. We therefore estimate a total annual burden decrease across all 4,550 eligible hospitals and CAHs of 76 hours (0.0167 hours × 4,550 eligible hospitals and CAHs) at a savings of $4,185 (76 hours × $55.06). We note that although the ONC–ACB Surveillance attestation was finalized in the CY 2017 Quality Payment Program final rule with comment period (81 FR 77019 through 77028), the associated information collection burden has not been accounted for under OMB control number 0938–1278. We will submit a revised Information Collection Request under this OMB control number reflecting the inclusion of this attestation as well as its removal.

e. Information Collection Burden Estimate for the Removal of the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information Measures

In section IX.F.4. of the preamble of this final rule, we are removing the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures, with a modification, beginning with the EHR reporting period in CY 2029. Under OMB control number 0938–1278, eligible hospitals and CAHs are currently required to report using one of three options under the Health Information Exchange objective: (1) the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures; (2) the Health Information Exchange (HIE) Bi-Directional Exchange measure; or (3) the Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) measure. Because eligible hospitals and CAHs will still be required to report either the HIE Bi-Directional Exchange or the Enabling Exchange Under TEFCA measure, we are not finalizing any change to information collection burden associated with this proposal.

f. Information Collection Burden Estimate for the Removal of Three eCQMs

In section IX.F.9.b. of the preamble of this final rule, we are removing three eCQMs beginning with the CY 2028 reporting period: (1) the VTE Prophylaxis eCQM; (2) the Intensive Care Unit VTE Prophylaxis eCQM; and (3) the Discharged on Antithrombotic Therapy eCQM.

The burden associated with eligible hospitals and CAHs submitting eCQMs is currently approved under OMB control number 0938–1022. Because reporting these eCQMs is not mandatory, but they are instead available in the Medicare Promoting Interoperability Program eCQM measure set from which eligible hospitals and CAHs self-select to report, removing these eCQMs will not result in a change in burden associated with OMB control number 0938–1022.

g. Information Collection Burden Estimate for the Updates to the Electronic Prior Authorization Measure

In section IX.F.5. of the preamble of this final rule, we are updating the Electronic Prior Authorization measure beginning with the EHR reporting period in CY 2027. Specifically, we are finalizing that eligible hospitals and CAHs must use technology certified to the criteria at 45 CFR 170.315(g)(31), (32), and (33) to report on the Electronic Prior Authorization measure beginning with the EHR reporting period in CY 2027. We are also modifying the Electronic Prior Authorization measure description such that for at least one medical item or service (excluding drugs) ordered during a hospital encounter that occurs within the EHR reporting period, the prior authorization is requested electronically through a

Prior Authorization API using CEHRT. Because the information collection burden for the Electronic Prior Authorization measure is currently approved under OMB control number 0938–1278 and we are only updating the criteria which eligible hospitals and CAHs will have to meet to attest ''Yes'', we are not finalizing any changes to information collection burden associated with this policy.

In section IX.F.5.d. of the preamble of this final rule, we are making the Electronic Prior Authorization measure optional for the EHR reporting period in CY 2027 and eligible for 10 bonus points. We are also making the Electronic Prior Authorization measure a required measure beginning with the EHR reporting period in CY 2028. Under OMB control number 0938–1278, the currently approved burden estimate for this measure is 0.5 minutes per eligible hospital and CAH. Because we are unable to estimate the number of eligible hospitals and CAHs which may elect not to attest to this measure for the EHR reporting period in CY 2027 as a result of this policy, for burden purposes, we are not finalizing any changes to the currently approved burden estimates.

h. Information Collection Burden Estimate for the Changes to eCQM Reporting and Submission Requirements for CAHs

In section IX.F.9.c. of the preamble of this final rule, we are modifying the reporting and submission requirements for the Malnutrition Care Score eCQM to require mandatory reporting beginning with the CY 2028 reporting period. The Malnutrition Care Score eCQM (previously known as Global Malnutrition Composite Score eCQM) was initially adopted in the FY 2023 IPPS/LTCH PPS final rule into the Medicare Promoting Interoperability Program measure set from which an eligible hospital or CAH could self-select to report beginning with the CY 2024 reporting period (87 FR 49361 through 49364).

In section IX.F.9.c. of the preamble of this final rule, we are modifying the eCQM reporting and submission requirements for all Hospital Harm eCQMs to begin mandatory reporting after two years of self-selected reporting beginning with the CY 2028 reporting period. This policy applies only to Hospital Harm eCQMs that are not already required to be reported, including any Hospital Harm eCQMs we may adopt in future rules. In the currently approved eCQM measure set, there are two Hospital Harm eCQMs in the Medicare Promoting Interoperability Program measure set from which an eligible hospital or CAH could self-select: Hospital Harm-Falls with Injury and Hospital Harm-Postoperative Respiratory Failure. Under this policy, these two measures will begin mandatory reporting with the CY 2028 reporting period, given they were adopted in the FY 2025 IPPS/LTCH PPS final rule as eCQMs that eligible hospitals and CAHs could self-select to report beginning with the CY 2026 reporting period (89 FR 69621 and 69622). Additionally, as discussed in section IX.F.9.b. of the preamble of this final rule, we are adopting the Hospital Harm-Postoperative VTE eCQM as a self-selected eCQM beginning with the CY 2028 reporting period. This measure will begin mandatory reporting with the CY 2030 reporting period.

Currently for the Medicare Promoting Interoperability Program's eCQM reporting requirements, the information collection burden is estimated under OMB control number 0938–1022, and the policy requires eligible hospitals and CAHs to submit data for three self-selected and eight mandatory eCQMs, for a total of 11 eCQMs, for the CY 2028 reporting period and subsequent years. The currently approved information collection burden per reported eCQM under OMB control number 0938–1022 is 10 minutes (0.167 hours) per eligible hospital or CAH per quarter or 40 minutes (0.67 hours) annually. For the CY 2028 and CY 2029 reporting periods, we estimate the modifications to the Malnutrition Care Score and two Hospital Harm eCQMs will result in a total increase of 120 minutes (2 hours) per CAH annually (10 minutes/eCQM × 3 eCQMs × 4 quarters) or a total annual burden increase across all 1,500 CAHs of 3,000 hours (2 hours × 1,500 CAHs) at a cost of $165,180 (3,000 hours × $55.06). Beginning with the CY 2030 reporting period, when the Hospital Harm-Postoperative VTE eCQM will become a mandatory eCQM to report, we estimate the modifications will result in a total increase of 160 minutes (2.67 hours) per CAH annually (10 minutes/eCQM × 4 eCQMs × 4 quarters) or a total annual burden increase across all 1,500 CAHs of 4,000 hours (2.67 hours × 1,500 CAHs) at a cost of $220,240. We refer readers to section XII.B.4.g. of this final rule for discussion of the burden estimates associated with the similar proposals impacting hospitals participating in the Hospital Inpatient Quality Reporting Program. With aligned eCQM reporting requirements between the Medicare Promoting Interoperability Program and the Hospital Inpatient Quality Reporting Program, hospitals need only report eCQMs once for credit in both programs.

i. Summary of Estimates Used To Calculate the Collection of Information Burden

In summary, under OMB control number 0938–1278 (expiration date March 31, 2029), we estimate that the policies in this final rule will result in a decrease in information collection burden of 114 hours at a savings of $6,278. We also estimate that the policies promulgated in this final rule will result in an increase in information collection burden of 4,000 hours at a cost of $220,240 under OMB control number 0938–1022. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1278. With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.N. of Appendix A of this final rule).

TABLE XII.B-10: SUMMARY OF MEDICARE PROMOTING INTEROPERABILITY PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE EHR REPORTING PERIOD IN CY 2026

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1278 for the CY 2026 Reporting Period								
Activity	Estimated Time per Record (in minutes)	Number Reporting Quarters per Year	Number of Respondents Reporting	Average Number Records per Respondent per Quarter	Annual Burden (Hours) per Respondent	Finalized Annual Burden (in hours) Across Hospitals	Previously Finalized Annual Burden (in hours) Across Hospitals	Net Difference in Annual Burden Hours
Removal of ONC Direct Review Attestation	1	1	4,550	1	0.0167	0	76	-76
Removal of ONC-ACB Surveillance Attestation	1	1	4,550	1	0.0167	0	76	-76
	Total Change in Information Collection Burden Hours: -152							
	Total Cost Estimate: Updated Hourly Wage ($55.06) x Change in Burden Hours (-152) = **-$8,370**							

TABLE XII.B-11: SUMMARY OF MEDICARE PROMOTING INTEROPERABILITY PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE EHR REPORTING PERIOD IN CY 2027

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1278 for the CY 2027 Reporting Period								
Activity	Estimated Time per Record (in minutes)	Number Reporting Quarters per Year	Number of Respondents Reporting	Average Number Records per Respondent per Quarter	Annual Burden (Hours) per Respondent	Finalized Annual Burden (in hours) Across Hospitals	Previously Finalized Annual Burden (in hours) Across Hospitals	Net Difference in Annual Burden Hours
Removal of ONC Direct Review Attestation	1	1	4,550	1	0.0167	0	76	-76
Removal of ONC-ACB Surveillance Attestation	1	1	4,550	1	0.0167	0	76	-76
Adoption of Unique Device Identifiers for Implantable Medical Devices Attestation	0.5	1	4,550	1	0.0083	38	0	+38
	Total Change in Information Collection Burden Hours: -114							
	Total Cost Estimate: Updated Hourly Wage ($55.06) x Change in Burden Hours (-114) = **-$6,278**							

TABLE XII.B-12: SUMMARY OF MEDICARE PROMOTING INTEROPERABILITY PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2028 AND CY 2029 REPORTING PERIODS

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2028 and CY 2029 Reporting Periods								
Activity	Estimated Time per Record (in minutes)	Number Reporting Quarters per Year	Number of Respondents Reporting	Average Number Records per Respondent per Quarter	Annual Burden (Hours) per Respondent	Finalized Annual Burden (in hours) Across Hospitals	Previously Finalized Annual Burden (in hours) Across Hospitals	Net Difference in Annual Burden Hours
Modification of Malnutrition Care Score eCQM	10	4	1,500	1	0.67	12,000	11,000	1,000
Modification of Hospital Harm eCQMs	20	4	1,500	1	1.33	13,000	11,000	2,000
	Total Change in Information Collection Burden Hours: 3,000							
	Total Cost Estimate: Updated Hourly Wage ($55.06) x Change in Burden Hours (3,000) = **$165,180**							

TABLE XII.B-12: SUMMARY OF MEDICARE PROMOTING INTEROPERABILITY PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2030 REPORTING PERIOD

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2030 Reporting Period								
Activity	Estimated Time per Record (in minutes)	Number Reporting Quarters per Year	Number of Respondents Reporting	Average Number Records per Respondent per Quarter	Annual Burden (Hours) per Respondent	Finalized Annual Burden (in hours) Across Hospitals	Previously Finalized Annual Burden (in hours) Across Hospitals	Net Difference in Annual Burden Hours
Modification of Malnutrition Care Score eCQM	10	4	1,500	1	0.67	12,000	11,000	1,000
Modification of Hospital Harm eCQMs	30	4	1,500	1	2.00	14,000	11,000	3,000
	Total Change in Information Collection Burden Hours: 4,000							
	Total Cost Estimate: Updated Hourly Wage ($55.06) x Change in Burden Hours (4,000) = **$220,240**							

We received no comments on these information collection burden estimates and therefore are finalizing burden estimates associated with these provisions without modification.

8. ICRs for the Transforming Episode Accountability Model

In section X.A. of the preamble of this final rule, we discuss testing the Transforming Episode Accountability Model (TEAM), finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), and finalize updates to the model under the authority of the CMS Innovation Center. Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. As stated in section 1115A(d)(3) of the Act, chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this final rule for TEAM need not be reviewed by the Office of Management and Budget. However, the anticipated impact of the model's effect is assessed in the Regulatory Impact Analysis (section I.G.11 of Appendix A of this final rule).

We received no comments on the information collection requirements and therefore are finalizing this provision without modification.

9. ICRs for the Comprehensive Care for Joint Replacement Expanded (CJR–X) Model

In section X.C. of the preamble of this final rule, we discuss testing the Comprehensive Care for Joint Replacement Expanded (CJR–X) Model, under the authority of the CMS Innovation Center. Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. As stated in section 1115A(d)(3) of the Act, chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models or expansion of such models under section 1115A of the Act. As a

result, the information collection requirements contained in this final rule for CJR–X need not be reviewed by the Office of Management and Budget. However, the anticipated impact of the model's effect is assessed in the Regulatory Impact Analysis (section I.G.12 of Appendix A of this final rule).

We received no comments on the information collection requirements and therefore are finalizing this provision without modification.

10. ICRs for Acquisition Costs, Reasonable Costs, and Other Cost-Related Policies

In section X.D.3. of the preamble of this final rule, we are finalizing our proposed clarification and codification of cost allocation policies, and in section X.D.4. of the preamble of this final rule, we are finalizing our proposed discretionary Administrator review of CMS reviewing official decisions for IOPOs and HCLs for reimbursement appeals. In section X.D.5. of the preamble of this final rule, we are finalizing our proposed clarifications and technical corrections to regulation text. In section X.D.2. of the preamble of this final rule, we are finalizing our proposals, with certain modifications, pertaining to Medicare's reasonable cost reimbursement policies applicable to all providers. We are also finalizing our provision pertaining to OPO public education to be effective with the effective date of this final rule; however, we are allowing a 1-year delay in enforcement, to account for broad initiatives impacting the OPO and transplant ecosystem in parallel with this rule, and for certain IOPOs to update their public education programs.

In section X.D.1. of the preamble of the proposed rule, we proposed to reconcile non-renal organ acquisition costs for IOPOs and HCLs and to require the contractor to establish, adjust if necessary, and publish interim rates for IOPOs and HCLs, with a 1-year delay, effective for cost reporting periods beginning on or after October 1, 2027. We are finalizing our proposal with modifications in section X.D.1. of the preamble of this final rule to reconcile non-renal organ acquisition costs for IOPOs and HCLs and to provide a 2-year delay, to allow additional time to update the IOPO and HCL Medicare cost report and to provide additional time for IOPOs and HCLs to prepare for these changes. We are finalizing our proposals with modifications to allow more IOPO and HCL involvement in setting and adjusting their SACs and testing rates, respectively, as detailed in section X.D.1. of this final rule. Specifically, we are requiring the IOPO to provide the Medicare contractor its reasonable estimate for each organ SAC based upon its prior year's costs and organ procurement volumes and its reasonable and documented estimate of its projected costs and organ procurement volumes for the subsequent year, for contractor review (to ensure reasonableness) and approval. For HCLs, we are requiring the HCL to provide the Medicare contractor its reasonable estimate of its testing rates based on its prior year costs and its reasonable and documented estimate of its projected testing costs and testing volumes for the subsequent year, for contractor review (to ensure reasonableness) and approval. We are also finalizing our proposals to publish non-renal IOPO SACs and HCL testing rates, and to reconcile non-renal organs, as proposed.

There are no additional data collection requirements for IOPOs and HCLs as a result of our finalized policies in section X.D.1. of the preamble of this final rule, because IOPOs and HCLs already collect the data needed for estimating and adjusting their IOPO SACs and HCL testing rates, and for reconciling non-renal organ acquisition costs for IOPOs and HCLs, in accordance with §§ 413.20 and 413.24. However, we recognize that there will be additional reporting requirements associated with our final policies, as IOPOs and HCLs would have to report which organs procured or tests conducted were for organs sent to military or VA hospitals or to foreign countries.

The methods of determining costs payable under Medicare involve making use of data available from the institution's basis accounts, as usually maintained, to arrive at equitable and proper payment for services. Burden hours for each OPO/HCL are the estimated time required (number of hours) to complete ongoing data gathering and recordkeeping tasks, search existing data resources, review instructions, and complete the OMB number 0938–0102, Form CMS–216–94. Currently there are 94 Medicare certified OPOs/HCLs that file Form CMS–216–94 annually. The current estimated average burden per OPO/HCL is 45 hours (30 hours for recordkeeping and 15 hours for reporting). In the proposed rule, we did not estimate additional recordkeeping burden but estimated an average additional reporting burden of 10 hours per OPO/HCL and an estimated additional cost of $785.40 per OPO/HCL. The most recent median hourly wage data is available from the Bureau of Labor Statistics using their national table (available at *https://www.bls.gov/oes/tables.htm*). We reported in the proposed rule that the 2024 median hourly wage for Category 13–2011 (accounting and audit professionals) is $39.27. We added 100 percent of the median wage to account for fringe benefits and overhead costs, which calculates to $78.54 ($39.27 + $39.27) and multiplied it by 10 hours, to determine the additional annual reporting costs per OPO/HCL to be $785.40 ($78.54 IOPOs × 10 hours). We recognized this average reporting burden varies depending on the OPO/HCL's size and complexity. In the proposed rule, we stated that because there are 94 IOPOs and HCLs, the total reporting burden cost for all IOPOs and HCLs would be $73,828 (94 × $785.40). We invited public comment on the hours estimate as well as the staffing requirements utilized to compile and complete the Medicare cost report. Because we modified our proposed 1-year delay, the estimated reporting burden for our final policies would not occur until FY 2029, for cost reporting periods beginning on or after October 1, 2028.

CMS currently collects data on OMB control number 0938–0102, Form CMS–216–94, and revisions to OMB control number 0938–0102 will be included in a future PRA package notice as required under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). There are no new collection of information requirements resulting from any of our proposals in sections X.D.2., X.D.3., X.D.4., and X.D.5. of the preamble of this final rule.

Comment: Several commenters wrote that our burden estimate underestimated IOPO administrative burden and should be revised. A commenter stated that the $785.40 estimate appeared limited to the incremental time associated with completing the revised Medicare cost reporting requirements and does not account for substantial administrative infrastructure needed to operationalize the proposal. A few commenters stated that they would need to overhaul internal accounting methodologies for non-renal organs, revise cost allocation systems, implement new workflows to track and compare actual costs against contractor-approved SACs, and continuously monitor receivables and payables in anticipation of annual reconciliation, in addition to legal, compliance, finance, reimbursement, and IT costs to implement and maintain compliance with the policies. A commenter added that one IOPO reported devoting 32 hours per month just to reconciliation related activities under the existing renal organ

reimbursement requirements. Other commenters wrote that they would need 2 additional finance FTEs to ensure operational viability under the proposals, or an additional 1000 hours of work to prepare for the changes plus 0.5 FTE for quality assurance moving forward. Several commenters asked CMS to conduct additional stakeholder engagement with OPO financial and reimbursement personnel.

Response: The burden estimate we included was devised pursuant to the Paperwork Reduction Act (PRA) requirements for estimating burden to complete the Medicare cost report. The PRA requires federal agencies, including CMS, to comply with its requirements when we require additional documentation from providers, suppliers, and beneficiaries. Therefore, the burden estimate we provided in the proposed rule was solely related to the additional time an IOPO or HCL would be required to complete a revised Medicare Cost Report. Regarding the commenter who noted time spent on current kidney reconciliation activities, our existing kidney reconciliation process has been unchanged for many years. Without more information from the commenter, we are unable to respond further.

CMS follows standardized definitions, accounting, statistics, and reporting practices that are widely accepted in healthcare and related fields. Changes in these practices and systems are not required in order to determine costs payable under the principles of reimbursement. Essentially the methods of determining costs payable under Medicare involve making use of data available from the institution's basis accounts, as usually maintained, to arrive at equitable and proper payment for services. Regulations at 42 CFR 413.20 and 413.24 require that providers submit acceptable cost reports on an annual basis and maintain sufficient financial records and statistical data, capable of verification by qualified auditors. In addition, the regulations require that providers furnish such information to the contractor, including the provider's working trial balance and audited financial statements, as may be necessary to ensure proper payment by the program, receive program payments, and satisfy program overpayment determinations. Some of these accounting controls should already be in place. These costs are general and administrative costs. We appreciate that IOPOs and HCLs will have to make operational and financial changes to comply with the finalized policies, and as noted previously, have extended the implementation timeframe that we proposed to allow an extra year's delay, with implementation finalized for cost reporting periods beginning on or after October 1, 2028.

We are updating the burden estimate for updating the IOPO/MCR cost report to use the latest BLS median wage data available, and to continue to use 10 hours of burden for IOPOs and HCLs. The 2025 median national hourly wage for Category 13–2011 (accounting and audit professionals) is $40.23. We added 100 percent of the median wage to account for fringe benefits and overhead costs, which calculates to $80.46 ($40.23 + $40.23) per hour. Using this updated wage rate, we estimate the burden to complete the revised IOPO/HCL Medicare cost report to now be $804.60 ($80.46 × 10 hours) per IOPO and HCL or $75,632 (94 IOPOs × $804.60) in total for all IOPOs and HCLs. These updated burden estimates, which are associated with the changes to the IOPO/HCL cost report, already account for additional reporting of organs or tests for organs sent to military or VA hospitals, or to foreign countries. IOPOs and HCLs will have two opportunities to comment on these estimates in a forthcoming PRA package and **Federal Register** notice.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 31, 2026.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, and Reporting and recordkeeping requirements.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, and Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Intergovernmental relations, Medicare, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Healthcare, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and record keeping requirements, Public health, Security.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services amends 42 CFR Chapter IV and the Department of Health and Human Services amends 45 CFR subtitle A, subchapter D as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

§ 405.1801 [Amended]

■ 2. In § 405.1801 paragraph (a) is amended in the definition of Administrator review by removing the reference ''§ 405.1875'' and adding in its place the reference ''§§ 405.1834 and 405.1875''.

■ 3. Section 405.1803 is amended by revising paragraph (d)(1)(ii) to read as follows:

§ 405.1803 Contractor determination and notice of amount of program reimbursement.

* * * * *

(d) * * *

(1) * * *

(ii) A final decision by a CMS reviewing official (as described in § 405.1834(f)(1) of this subpart) or the Administrator (as described in §§ 405.1834 and 405.1875(e)(4) of this subpart) following review of a hearing decision by the contractor, the Board or the CMS reviewing official, as the case may be.

* * * * *

■ 4. Section 405.1811 is amended by revising paragraphs (a)(2) and (c)(3) to read as follows:

§ 405.1811 Right to contractor hearing; contents of, and adding issues to, hearing request.

(a) * * *

(2) With the exception of an IOPO or histocompatibility laboratory, the amount in controversy (as determined in accordance with § 405.1839) must be at least $1,000 but less than $10,000. An IOPO or histocompatibility laboratory is subject to the amount in controversy requirement specified in § 413.420(g).

* * * * *

(c) * * *

(3) With the exception of an IOPO or histocompatibility laboratory, the amount in controversy (as determined in accordance with § 405.1839) must be at least $1,000 but less than $10,000. An IOPO or histocompatibility laboratory is subject to the amount in controversy requirement specified in § 413.420(g).

* * * * *

■ 5. Section 405.1813 is amended by revising paragraphs (e)(1) and (2) and adding paragraph (e)(3) to read as follows:

§ 405.1813 Good cause extension of time limit for requesting a contractor hearing.

* * * * *

(e) * * *

(1) A decision denying an extension request under this section and dismissing the appeal is final and binding on the provider, unless the dismissal decision is—

(i) Reviewed by a CMS reviewing official in accordance with § 405.1834(b)(2)(i) of this subpart;

(ii) Reviewed by the Administrator; or

(iii) Reopened and revised by the contractor hearing officer(s) in accordance with §§ 405.1885 through 405.1889 of this subpart.

(2) The contractor hearing officer(s) promptly sends the decision to the appropriate component of CMS (currently the Center for Medicare) (as specified in § 405.1834(b)(4) of this subpart) and the Reviewing Official (currently the CMS Office of Hearings).

(3) A decision granting an extension request under this section is not subject to immediate review by a CMS reviewing official (as described in § 405.1834(b)(3) of this subpart). Any decision may be examined during—

(i) The course of a CMS reviewing official's review of a final jurisdictional dismissal decision or a final hearing decision by the contractor hearing officer(s) (as described in § 405.1834(b)(2)(i) and (ii) of this subpart); or

(ii) The Administrator's review of a CMS reviewing official decision.

■ 6. Section 405.1814 is amended by revising paragraphs (a)(5), (c)(3), and (d) to read as follows:

§ 405.1814 Contractor hearing officer jurisdiction.

(a) * * *

(5) Final jurisdictional findings and jurisdictional dismissal decisions by the contractor hearing officer(s) are subject to the CMS reviewing official procedure in accordance with paragraph (d) of this section and § 405.1834(b)(2)(i) and (b)(2)(ii) of this subpart, as well as the possibility of review by the Administrator as described in § 405.1834(g).

* * * * *

(c) * * *

(3) A jurisdictional dismissal decision by the contractor hearing officer(s) under paragraph (c)(2) of this section is final and binding on the parties, unless the decision is—

(i) Reviewed by a CMS reviewing official in accordance with § 405.1834 of this subpart;

(ii) Is subsequently reviewed by the Administrator in accordance with § 405.1834 of this subpart; or

(iii) Reopened and revised by the contractor hearing officer(s) in accordance with §§ 405.1885 through 405.1889 of this subpart.

(d) *CMS reviewing official and Administrator review of jurisdictional decisions.* Any finding by the contractor hearing officer as to whether it has jurisdiction to grant a hearing on a specific matter at issue in an appeal is not subject to further administrative review, except as provided in this paragraph. The contractor hearing officer's jurisdictional findings as to specific matters at issue in an appeal may be reviewed solely during the course of the CMS reviewing official's review of one of the contractor hearing officer decisions specified in § 405.1834(b)(2) of this subpart or during the course of the Administrator's review of a CMS reviewing official's decision.

■ 7. Section 405.1821 is amended by revising paragraphs (d)(2) introductory text, (d)(2)(i), and (d)(2)(iii) introductory text to read as follows:

§ 405.1821 Prehearing discovery and other proceedings prior to the contractor hearing.

* * * * *

(d) * * *

(2) *Exception.* To the extent a ruling authorizes discovery or disclosure of a matter for which an objection based on privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the contractor hearing officer(s), that portion of the discovery or disclosure ruling may immediately be reviewed by a CMS reviewing official or the Administrator in accordance with § 405.1834.

(i) Upon notice to the contractor hearing officer that the provider intends to seek immediate review of a ruling, or that the contractor or other affected nonparty intends to suggest that the CMS reviewing official or the Administrator, take own motion review of the ruling, the contractor hearing officer stays all proceedings affected by the ruling.

(iii) If the CMS reviewing official or the Administrator—

* * * * *

■ 8. Section 405.1833 is revised to read as follows:

§ 405.1833 Effect of contractor hearing decision.

(a) A contractor hearing decision issued in accordance with § 405.1831 of this subpart is final and binding on all parties to the contractor hearing and on the contractor, unless the contractor hearing decision is—

(1) Reviewed by a CMS reviewing official or by a CMS reviewing official and then is in turn reviewed by the Administrator in accordance with § 405.1834 of this subpart; or

(2) Reopened and revised by the contractor hearing officer(s) in accordance with §§ 405.1885 through 405.1889 of this subpart.

(b) Final contractor hearing decisions are subject to the provisions of § 405.1803(d) of this subpart.

■ 9. Section 405.1834 is amended by—

■ a. Revising the section heading and paragraphs (a), (b)(1)(ii), (b)(4) introductory text, (b)(4)(ii), (c), (c)(1)(i), (c)(3), (c)(3)(i), (d), (d)(1);

■ b. Adding paragraphs (d)(4) and (d)(5);

■ c. Revising paragraphs (e)(1), (e)(3), (f) introductory text, (f)(1) and (f)(2) introductory text;

■ d. Adding paragraphs (f)(3) and (g).

The revisions and additions read as follows:

§ 405.1834 CMS reviewing official procedure and Administrator review.

(a) *Scope.* CMS or a provider that is a party to, and dissatisfied with, a final decision by the contractor hearing officer(s), upon submitting a request that meets the requirements of paragraph (c) of this section, is entitled to further administrative review of the decision by a CMS reviewing official, and the decision may be reviewed at the discretion of first a designated CMS reviewing official and then

discretionary review by the Administrator. No other individual, entity, or party has the right to the review. The review is conducted first by a designated CMS reviewing official who considers whether the decision of the contractor hearing officer(s) is consistent with the controlling legal authority (as described in § 405.1834(e)(1) of this subpart) and the evidence in the record, and the CMS reviewing official's decision may then be subject to further discretionary review by the Administrator.

(b) * * *

(1) * * *

(ii) The CMS reviewing official exercises this review authority in response to a request from a provider party to the appeal that meets the requirements of paragraph (c) of this section, or in response to a request from CMS, or may exercise his or her discretion to take own motion review.

* * * * *

(4) The contractor hearing officer(s) must promptly send copies of any decision specified in paragraph (b)(2) or (b)(3) of this section or in § 405.1821(d)(2) of this subpart and the underlying contractor hearing officer's administrative record to the appropriate component of CMS (currently the Center for Medicare).

(i) * * *

(ii) The appropriate CMS component examines each contractor hearing officer decision that is reviewable under paragraph (b)(2) or (b)(3) of this section or § 405.1821(d)(2) of this subpart, along with any review requests and any other submissions made by a party or CMS in accordance with the provisions of this section, in order to assist the CMS reviewing official's and the Administrator's exercise of this review authority.

(c) *Request for review by a CMS reviewing official.*

(1) * * *

(i) The date of receipt by the appropriate CMS component of the review request is no later than 60 days after the date of receipt by the provider of the contractor hearing officer decision; and

* * * * *

(3) A request from a party or CMS for immediate review of a contractor hearing officer ruling authorizing discovery or disclosure in accordance with paragraph (b)(3) of this section must—

(i) Be made as soon as practicable after the ruling is made, but in no event later than 5 business days after the date the requesting party or CMS received notice of the ruling; and

* * * * *

(d) *Own motion review of a CMS reviewing official.*

(1) The CMS reviewing official has discretion to take own motion review of a contractor hearing officer decision (regardless in either case of whether the decision was favorable or unfavorable to the provider) or other reviewable action.

* * * * *

(4) If the CMS reviewing official does not notify the parties and the contractor that he or she intends to review the contractor hearing officer decision or other reviewable action within 90 days after the date of the contractor hearing officer's decision, then the Administrator may issue a notice instructing the CMS reviewing official to review the contractor hearing officer decision and issue a decision if the CMS reviewing official fails to do so.

(i) The Administrator promptly provides copies of the notice instructing the CMS reviewing official to review the contractor hearing officer decision to the parties, the contractor, and to the appropriate component of CMS.

(ii) After the CMS reviewing official's receipt of the Administrator's notice (instructing the CMS reviewing official to review the contractor hearing officer decision and issue a decision), the CMS reviewing official must allow the parties a reasonable period to comment on the issues identified by the Administrator for review.

(5) If no party requests review of the contractor hearing decision and the CMS reviewing official does not take review on his or her own motion or at the direction of the Administrator within the time periods specified in this paragraph, the contractor hearing officer decision is final in accordance with § 405.1833 of this subpart.

(e) * * *

(1) In reviewing a contractor hearing officer decision specified in paragraph (b)(2) or (b)(3) of this section, the CMS reviewing official must—

* * * * *

(3) Upon completion of the review of a contractor hearing decision specified in paragraph (b)(2) or (b)(3) of this section, the CMS reviewing official issues a written decision that includes findings of fact and conclusions of law on jurisdictional issues and on the merits of each issue under review over which the CMS reviewing official has jurisdiction and affirms, reverses, or modifies the contractor hearing decision or remands the contractor hearing decision to the contractor hearing officer for further proceedings. A copy of the decision must be sent promptly to each party, to the contractor, and to the appropriate component of CMS (currently the Center for Medicare).

(f) *Effect of a reviewing official's decision, remand, and the possibility of Administrator review.*

(1) A decision of affirmation, reversal, or modification by the CMS reviewing official is final and binding on each party and the contractor, except as set forth in paragraph (g) of this section. The CMS reviewing official's decision may be reopened and revised by the CMS reviewing official in accordance with §§ 405.1885 through 405.1889 of this subpart. Decisions of a CMS reviewing official are subject to the provisions of § 405.1803(d) of this subpart. A decision by a CMS reviewing official remanding an appeal to the contractor hearing officer(s) for further proceedings under paragraph (f)(2) of this section is not a final decision.

(2) A remand to the contractor hearing officer(s) by the CMS reviewing official must do all of the following:

* * * * *

(3) The CMS reviewing official must promptly send copies of the CMS reviewing official decision, along with any other submissions made by a party or CMS in accordance with the provisions of this section, to the appropriate component of CMS (currently the Center for Medicare) and to the Administrator c/o the CMS Office of the Attorney Advisor.

(g) *Administrator review of a CMS reviewing official's decision.*

(1) CMS or any party to a CMS reviewing official decision may request Administrator review of a CMS reviewing official decision in accordance with this section. No other provider, individual, or entity may request review. The Administrator may grant or deny review of a CMS reviewing official decision at his or her discretion. The Administrator may also review any decision of the CMS reviewing official on his or her own motion (regardless of whether the decision was favorable or unfavorable to the provider).

(2) A party or CMS may request that the Administrator review a CMS reviewing official decision within 15 days of their receipt of a final CMS reviewing official decision.

(i) All requests for Administrator review and any other submissions to the Administrator under this paragraph must be sent to the Office of the Attorney Advisor. The request for review must be in writing, attach a copy of the CMS reviewing official decision for which it seeks review, and include a brief description of all of the following:

(A) Those aspects of the CMS reviewing official decision with which the requestor is dissatisfied.

(B) The reasons for the requestor's dissatisfaction.

(C) Any argument or record evidence the requestor believes supports its position.

(D) Any additional, extra-record evidence relied on by the provider, along with a demonstration that such evidence was improperly excluded in proceedings below (as described in § 405.1823 of this subpart).

(ii) The Administrator must issue a Notice advising the parties of his or her intent to review or to decline to review within 45 days of the Administrator's receipt of a request for review from CMS or any party to the CMS reviewing official's decision. That Notice must be promptly sent to the parties, the contractor, and the appropriate component of CMS. A Notice advising the parties of the Administrator's intent to review must contain a brief statement of the issues under review and solicit comments from the parties, the contractor, and CMS. A Notice that the Administrator is declining to review need not set forth the basis for the Administrator's decision to decline review the CMS reviewing official's decision.

(iii) If the Administrator declines to review the reviewing official decision or the Administrator does not issue a determination regarding review of the reviewing official decision within 45 days of the Administrator's receipt of a request to review, the decision of the CMS reviewing official is final in accordance with paragraph (f)(1) of this section.

(3) In the absence of a request for the Administrator to review under 405.1834(g)(2), the Administrator may issue a Notice of Review on his or her own motion within 45 days of the Administrator's receipt of a CMS reviewing official's decision. The Notice of Review must be sent to the parties, the contractor, and the appropriate component of CMS. The Notice of Review must contain a brief statement of the issues under review and solicit comments from the parties, contractor, and CMS. If the Administrator does not issue a determination regarding his or her own motion review within 45 days of the Administrator's receipt of a CMS reviewing official's decision, the decision of the CMS reviewing official is final.

(4) If the Administrator elects to review the CMS reviewing official's decision—

(i) The Administrator will set deadlines for the parties and affected nonparties to submit comments; and

(ii) The Administrator's decision affirming, reversing, or modifying the CMS reviewing official's decision is final and binding on each party and the contractor. A decision remanding an appeal to the CMS reviewing official or contractor hearing officer(s) is not a final decision. Decisions of the Administrator are subject to the provisions of § 405.1803(d) of this subpart.

(5) If the Administrator does not issue a written decision that affirms, reverses, modifies or remands the CMS reviewing official's decision within 60 days of the date of issuance of the Notice of Review, the CMS reviewing official's decision becomes final in accordance with paragraph (f)(1) of this section.

(6) The Administrator may remand the CMS reviewing official's decision to the CMS reviewing official, to the contractor hearing officer, or to the contractor. A remand by the Administrator must do all of the following:

(i) Vacate the CMS reviewing official's or the contractor hearing officer's decision or both decisions as to the specific issues remanded.

(ii) Be governed by the same criteria that apply to remands by the Administrator to the Board under § 405.1875(f)(2) of this subpart and require the entity to which the matter is remanded to take specific actions on remand.

(iii) Result in the CMS reviewing official, contractor hearing officer(s), or contractor taking the actions required on remand and issuing a new decision.

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 10. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 11. Section 412.24 is amended by adding paragraph (g) to read as follows:

§ 412.24 Requirements under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.

* * * * *

(g) *Requirements for submission of electronic clinical quality measures (eCQMs) under the PCHQR Program.* When reporting eCQMs under the PCHQR Program, PCHs must use all of the following:

(1) Health information technology (IT) certified to the ONC Health IT Certification Program certification criteria necessary for eCQM reporting, as adopted and updated at 45 CFR 170.315(c).

(2) Certified health IT described in paragraph (g)(1) to calculate, export, and submit results for the eCQMs available to report under the PCHQR Program.

(3) The eCQM electronic measure specifications for the applicable reporting period available on the Electronic Clinical Quality Improvement Resource Center website at *https://ecqi.healthit.gov/* or another website as designated by CMS.

■ 12. Section 412.87 is amended by revising paragraphs (c) introductory text, (d), and (f) to read as follows:

§ 412.87 Additional payment for new medical services and technologies: General provisions.

* * * * *

(c) *Eligibility criteria for alternative pathway for certain transformative new devices.* For applications submitted for new technology add-on payments for FYs 2021 through 2029, inclusive, CMS provides for additional payments (as specified in § 412.88) beyond the standard DRG payments and outlier payments to a hospital for discharges involving covered inpatient hospital services that are new medical devices, if the following conditions are met:

(1) A new medical device is part of the Food and Drug Administration's (FDA) Breakthrough Devices Program and has received Breakthrough Device designation as of September 30, 2026, and has received marketing authorization as a Breakthrough Device for the indication covered by the Breakthrough Device designation by May 1, 2028.

* * * * *

(d) *Eligibility criteria for alternative pathway for certain antimicrobial products.* For applications submitted for new technology add-on payments for FYs 2021 through 2029, inclusive, CMS provides for additional payments (as specified in § 412.88) beyond the standard DRG payments and outlier payments to a hospital for discharges involving covered inpatient hospital services that are new medical products, if the following conditions are met:

(1)(i) For applications submitted for new technology add-on payments for FYs 2021 through 2029, inclusive, a new medical product is designated by FDA as a Qualified Infectious Disease Product as of September 30, 2026, and has received marketing authorization for the indication covered by the Qualified Infectious Disease Product designation by May 1, 2028; or

(ii) For applications submitted for new technology add-on payments for FYs 2022 through 2029, inclusive, a new medical product is approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and used for the indication

approved under the LPAD pathway by May 1, 2028.

* * * * *

(f) *Announcement of determinations and deadline for consideration of new medical service or technology applications.*

* * * * *

(2) CMS only considers, for add-on payments for a particular fiscal year, an application for which the new medical service or technology has received FDA marketing authorization by May 1 prior to the particular fiscal year.

§ 412.88 [Amended]

■ 13. Section 412.88 is amended in paragraph (a)(2)(ii)(A) introductory text by removing the phrase ''paragraph (a)(2)(ii)(B) of'' and adding in its place the phrase ''paragraphs (a)(2)(ii)(B) and (C) of''.

§ 412.90 [Amended]

■ 14. Section 412.90 paragraph (j) is amended by removing the date ''October 1, 2025'' and adding in its place the date ''January 1, 2027''.

§ 412.101 [Amended]

■ 15. Section 412.101 is amended by—
■ a. In paragraph (b)(2)(i), removing the phrase ''FY 2010 and FY 2026 and subsequent years,'' and adding in its place the phrase ''FY 2010 and the portion of FY 2027 beginning January 1, 2027, and subsequent fiscal years,'';
■ b. In paragraph (b)(2)(iii), removing the phrase ''FY 2025,'' and adding in its place the phrase ''the portion of FY 2027 ending December 31, 2026,'';
■ c. In paragraph (c)(1), removing the phrase ''FY 2010 and FY 2026 and subsequent years,'' and adding in its place the phrase ''FY 2010 and the portion of FY 2027 beginning January 1, 2027, and subsequent fiscal years,''; and
■ d. In paragraph (c)(3) introductory text, removing the phrase ''FY 2019 through FY 2025,'' and adding in its place ''FY 2019 through the portion of FY 2027 ending December 31, 2026,''.

■ 16. Section 412.105 is amended by revising paragraph (f)(1)(i) to read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

* * * * *

(f) * * *

(1) * * *

(i) The resident must be enrolled in an approved teaching program. An approved teaching program is one that meets one of the following requirements, subject to the requirements in § 413.84 of this chapter:

(A) Is approved by one of the national organizations listed in *§ 415.152 of this chapter.*

(B) May count towards certification of the participant in a specialty or subspecialty listed in the current edition of either of the following publications:

(*1*) The Directory of Graduate Medical Education Programs published by the American Medical Association.

(*2*) The Annual Report and Reference Handbook published by the American Board of Medical Specialties.

(C) Is approved by the Accreditation Council for Graduate Medical Education (ACGME), or other organization designated by the Secretary, as a fellowship program in geriatric medicine.

§ 412.108 [Amended]

■ 17. Section 412.108 is amended by—
■ a. In paragraph (a)(1) introductory text, removing the date ''October 1, 2025'' and adding in its place the date ''January 1, 2027''; and
■ b. In paragraph (c)(2)(iii) introductory text, removing the date ''October 1, 2025'' and adding in its place the date ''January 1, 2027''.

§ 412.116 [Amended]

■ 18. Section 412.116 is amended in paragraph (c) by removing the phrase ''for kidney acquisition costs in hospitals with approved kidney transplant programs)'' and adding in its place the phrase ''for organ acquisition costs in hospitals with approved organ transplant programs)''.

■ 19. Section 412.230 is amended by—
■ a. In paragraph (a)(5)(i) removing the phrase ''purposes of the wage index if the pre-reclassified'' and adding in its place the phrase ''purposes of the wage index if, using data described in paragraph (d)(2) of this section, the pre-reclassified'';
■ b. Revising paragraph (c)(1); and
■ c. Adding paragraph (d)(6).

The revision and addition read as follows:

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

* * * * *

(c) * * *

(1) To demonstrate proximity to the area, the hospital must submit evidence from a nationally recognized electronic mapping service of the shortest route from the front entrance of the hospital over improved roads or waterways traveled by ferry boats to the county line of the requested area and the distance of that route.

* * * * *

(d) * * *

(6) *Home area reclassification exception.* The requirements of paragraph (d)(1)(iv) of this section do not apply to a hospital that has been granted redesignation as rural under *§ 412.103* and seeks redesignation under this section to its geographic urban area.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END–STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 20. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 21. Section 413.5 is amended by adding paragraphs (c)(10) through (c)(19) to read as follows:

§ 413.5 Cost reimbursement: General.

* * * * *

(c) * * *

(10) Costs incurred by providers for entertainment, including costs associated with entertainment activities, or that are entertainment in nature, are not allowable costs.

(i) This paragraph (c)(10) includes costs that OPOs incur to engage in public education to increase awareness of organ donation and increase donor registration.

(ii) Non-allowable entertainment costs include, but are not limited to the following:

(A) Tickets, admission fees, or entry to sporting or other events, including national or professional sporting events.

(B) Sponsorship of sporting events, teams or athletes, including race car drivers or motorsports activities.

(C) Sponsorship of floats in large-scale regional and national parades.

(D) Concert, theater, or performing arts events, professional musicians or other entertainers.

(E) Wine tours or alcoholic beverages.

(F) Retreats held at spas or luxury resorts, spa services or treatments.

(G) Golf outings, ski trips, cruises, and similar recreational excursions.

(11) Costs incurred by an OPO to engage in public education within its donation service area (DSA), including public education activities designed to reach a broad audience within its DSA, such as but not limited to, billboards, radio advertisements, and social media campaigns, to increase awareness of organ donation and increase donor registration within its DSA are

allowable if they are reasonable and do not violate paragraph (c)(10) of this section.

(12) De minimis or modest costs incurred by providers for employees for purposes of improving employee morale are allowable costs, provided that such costs do not violate the limitations set forth in 42 CFR 413.9(c).

(13) Costs incurred by providers to furnish alcoholic beverages to anyone are not allowable costs.

(14) Costs incurred by OPOs—

(i) For professional education such as meetings, seminars, and presentations on organ donation to acquire all useable organs from potential donors where continuing education credits are not given and where the attendee is clinical staff, non-clinical staff, or contracted staff including, but not limited to, OPO staff, donor hospital staff, and physicians whose role is essential to the OPO's objectives are allowable costs;

(ii) For OPO-sponsored seminars where continuing education credits are given and where the attendee is a member of on the OPO staff are allowable costs to the extent that they are patient care related, reasonable and necessary; and

(iii) For OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO staff, in accordance with § 413.402(d)(2)(v), are not allowable costs.

(15) Costs incurred by a provider—

(i) For employee travel are generally allowable to the extent that they are patient care related, reasonable and necessary;

(ii) To conduct, or send its employees or staff including contracted employees to, patient care related professional education refresher programs, seminars and workshops that increase the quality of patient care or operating efficiency of the provider, are generally allowable costs to the extent that they are patient care related, reasonable, and necessary;

(iii) For entertainment and vacation travel expenses such as travel on cruises or to resorts or spas, or transportation to entertainment or sporting events, are not allowable costs regardless of whether they are or are not incurred in connection with professional educational seminars or continuing education; and

(iv) Related to the personal use of provider vehicles are not allowable costs.

(16) Costs incurred by providers—

(i) For meals sold to visitors, meals for their employees and staff (including executives and management) and non-personnel (including attending physicians) are not allowable costs;

(ii) For de minimis refreshments provided to attendees at educational events, including attendees of OPO-sponsored seminars (with or without continuing education credits) are allowable costs; and

(iii) For meals for employees and contracted staff, whose role is essential to the provider's objectives, when an employee or contracted staff is required to travel away from their primary work location and an overnight stay is required, such as when completing trainings or education, provided such trainings are patient care related are allowable costs.

(17) Costs incurred by providers for drugs sold to other than patients are not related to patient care and are not allowable costs.

(18) Costs incurred by providers for cost of fines or penalties resulting from Federal, State or local laws are not allowable costs.

(19) Costs incurred by providers for operation of a gift shop are not allowable costs.

* * * * *

■ 22. Section 413.9 is amended by adding paragraphs (b)(3) and (c)(4) to read as follows:

§ 413.9 Cost related to patient care.

* * * * *

(b) * * *

(3) *Prudent buyer.* The prudent buyer is a person, provider type or entity that purchases items or property with caution, good judgment, and a sensible approach, aiming to make a sound, informed decision that minimizes risk and avoids unnecessary financial loss. This person, provider type or entity thoughtfully evaluates the condition, legal, and financial aspects of a purchase, much like a reasonably prudent person would in a similar situation.

(c) * * *

(4) Providers are expected to economize by not paying more than the going price for an item or service and seeking to minimize their costs, so that their actual costs will not exceed what a prudent and cost-conscious buyer would pay for a given item or service. If costs are determined to exceed the level that prudent buyers incur, the excess costs are not reimbursable in the absence of clear evidence that the higher costs were unavoidable.

■ 23. Section 413.24 is amended by revising paragraph (d)(6) and adding paragraph (d)(8) to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(d) * * *

(6) *Preventing duplication of costs: departments and provider-based entities.* In some situations, the main provider in a provider-based complex may purchase services for a provider-based entity or for a department of the provider through a contract for services (for example, a management contract), directly assigning the costs to the provider-based entity or department and reporting the costs directly in the cost center for that entity or department. In any situation in which costs are directly assigned to a cost center, there is a risk of excess cost in that cost center resulting from the directly assigned costs plus a share of overhead improperly allocated to the cost center which duplicates the directly assigned costs. This duplication could result in improper Medicare payment to the provider. Where a provider has purchased services for a provider-based entity or for a provider department, like general service costs of the provider (for example, like costs in the administrative and general cost center) must be separately identified to ensure that they are not improperly allocated to the entity or the department. If the like costs of the main provider cannot be separately identified, the costs of the services purchased through a contract must be reclassified to the main provider and allocated among the main provider's benefiting cost centers.

Example: A provider-based complex is composed of a hospital and a hospital-based rural health clinic (RHC). The hospital furnishes the entirety of its own administrative and general costs internally. The RHC, however, is managed by an independent contractor through a management contract. The management contract provides a full array of administrative and general services, with the exception of patient billing. The hospital directly assigns the costs of the RHC's management contract to the RHC cost center (for example, Form CMS 2552–96, Worksheet A, Line 71). A full allocation of the hospital's administrative and general costs to the RHC cost center would duplicate most of the RHC's administrative and general costs. However, an allocation of the hospital's cost (included in hospital administrative and general costs) of its patient billing function to the RHC would be appropriate. Therefore, the hospital must include the costs of the patient billing function in a separate cost center to be allocated to the benefiting cost centers, including the RHC cost center. The remaining hospital administrative and general costs would be allocated to all cost centers, excluding the RHC cost center. If the

hospital is unable to isolate the costs of the patient billing function, the costs of the RHC's management contract must be reclassified to the hospital administrative and general cost center to be allocated among all cost centers, as appropriate.

(8) *Improper allocation of overhead prohibited.* Providers must not include a statistical cost which does not relate to the allocation of administrative and general expenses when it causes an improper distribution of overhead.

(i) Providers must employ either or both methods described in paragraphs (d)(8)(ii) or (iii) of this section, if needed, to prevent the improper allocation of overhead on the Medicare cost report.

(ii) *Negative Adjustment Method for accumulated cost.* When direct costs are reported in a cost center or department that includes purchased services or supplies, costs other than the purchased service costs may receive an allocation of administrative and general costs, and the purchased service costs that are not to receive administrative and general must be identified and removed.

(A) On the Medicare cost report, in any column using accumulated costs as the statistical basis for allocating costs, providers must identify any cost center that is not to receive an allocation by entering a negative 1 (−1) on the appropriate line in the accumulated cost column, or by entering the total accumulated cost as a negative amount on the appropriate line in the reconciliation column. For those cost centers using accumulated costs that are to receive partial allocation of costs, providers must enter a negative amount for the costs that are to be excluded from the statistic on the appropriate line in the reconciliation column.

(B) Cost centers that are not to receive an allocation must not have entries in both the reconciliation and accumulated cost columns when the accumulated cost statistic is offset to zero.

(C) For those cost centers that are to receive partial allocation of costs for costs other than purchased services, the cost to be excluded from the accumulated cost statistic must be reported as a negative amount on the effected cost center in the reconciliation column. This results in entries in both the reconciliation column and accumulated cost statistic column simultaneously for the same line (cost center).

(iii) *Fragmenting (componentizing): Administrative and General Method.* When a provider chooses to fragment, or componentize administrative and general costs, the provider must fragment (that is, subscript), the administrative and general cost center into 2 or more cost centers using accurate statistics to allocate its costs and ensure that overhead costs are accurately assigned to departments benefiting from the services provided. When creating multiple administrative and general cost centers, a provider must track and allocate overhead expenses based on actual resource consumption.

(iv) *Provider request to change its cost finding method.*

(A) A provider that wishes to change its cost finding method must submit a request to its contractor, in writing, 90 days prior to the end of the cost reporting period to which the provider's request for change applies.

(B) The contractor's determination of a provider's request to change methods will be furnished to the provider in writing and will be binding on the provider as of the date of the contractor's written notice.

(C) When the contractor approves the provider's request to change methods, the provider must use this method for the cost reporting period to which the request applies and for all subsequent cost reporting periods, unless the contractor approves a subsequent request by the provider to change its cost finding methods.

* * * * *

§ 413.65 [Amended]

■ 24. Section 413.65 is amended by:

■ a. In paragraph (e)(3)(iii)(A) removing the phrase ''the facility or organization'' and adding in its place the phrase ''an inpatient or outpatient facility or organization''; and

■ b. In paragraph (e)(3)(iii)(B) removing the phrase ''the facility or organization'' and adding in its place the phrase ''an outpatient facility or organization''.

■ 25. Section 413.75 is amended in paragraph (b) by revising the definitions for ''Approved geriatric program'' and ''Approved medical residency program'' to read as follows:

§ 413.75 Direct GME payments: General requirements.

* * * * *

(b) * * *

* * * * *

Approved geriatric program means, subject to the requirements in § 413.84 of this chapter, a fellowship program of one or more years in length that is approved by one of the national organizations listed in § 415.152 of this chapter under that respective organization's criteria for geriatric fellowship programs.

Approved medical residency program means, subject to the requirements in § 413.84 of this chapter, a program that meets one of the following criteria:

(i) Is approved by one of the national organizations listed in *§ 415.152 of this chapter.*

(ii) May count towards certification of the participant in a specialty or subspecialty listed in the current edition of either of the following publications:

(A) The Directory of Graduate Medical Education Programs published by the American Medical Association, and available from American Medical Association, Department of Directories and Publications, 515 North State Street, Chicago, Illinois 60610.

(B) The Annual Report and Reference Handbook published by the American Board of Medical Specialties, and available from American Board of Medical Specialties, One Rotary Center, Suite 805, Evanston, Illinois 60201.

(iii) Is approved by the Accreditation Council for Graduate Medical Education (ACGME), or other organization designated by the Secretary, as a fellowship program in geriatric medicine.

* * * * *

■ 26. Section 413.79 is amended by revising paragraph (l) to read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(l) For purposes of this section, a new medical residency training program means a program that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995, and in the case of a medical residency training program that receives initial accreditation by the appropriate accrediting body and is still within its 5-year cap building period as of October 1, 2026, or starts training residents on or after October 1, 2026, that meets the following conditions:

(1) Subject to the provisions of paragraphs (l)(2) and (l)(3) of this section, at least 90 percent of the individual residents that participate in the program during the 5-year cap building period (that is, for new urban teaching hospitals, during the first 5 program years of the first new program's existence under paragraph (e)(1) of this section; and for rural hospitals, during the first 5 program years of each new program under paragraph (e)(3) of this section) must not have previous experience training in another program in the same specialty.

(2) For purposes of determining whether a program satisfies the requirement under paragraph (l)(1) of

this section, the count of individual residents excludes an individual—

(i) With previous experience training in another program in the same specialty who enters the program as a first-year resident through the National Resident Matching Program or another binding third-party resident matching program; or

(ii) Who meets the definition of a ''displaced resident'' under paragraph (h)(1)(iii) of this section.

(3) The requirement under paragraph (l)(1) of this section does not apply to a program accredited for 16 or fewer resident positions.

* * * * *

■ 27. Section 413.84 is added to read as follows:

§ 413.84 Prohibition against unlawful discrimination.

(a) An approved medical residency training program, as defined in §§ 412.105(f)(1)(i), 413.75(b), and 415.152 of this chapter, or an approved nursing and allied health education program, as defined in § 413.85 of this chapter, must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits.

(b) An accrediting organization of approved medical residency training programs under §§ 412.105(f)(1)(i), 413.75(b), and 415.152 of this chapter, or of approved nursing and allied health education programs under § 413.85 of this chapter, and any publications cited in the regulations that list specialties or subspecialties of such programs, must not use criteria that discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits.

(c) Approved medical residency training programs and approved nursing and allied health education programs include programs that would be accredited except for the accrediting agency's reliance upon an accreditation standard that requires an entity to—

(1) Discriminate, or promote or encourage discrimination, on the basis of race, color, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits; or

(2) Perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training, regardless of whether the standard provides exceptions or exemptions.

■ 28. Section 413.85 is amended by—

■ a. In paragraph (c), revising the definition of ''Approved educational activities'' introductory text; and

■ b. Revising paragraphs (d)(2) and (e).

The revisions read as follows:

§ 413.85 Cost of approved nursing and allied health education activities.

* * * * *

(c) * * *

Approved educational activities means, subject to the requirements in § 413.84 of this chapter, formally organized or planned programs of study of the type that—

* * * * *

(d) * * *

(2) * * *

(i) Subject to the provisions of paragraphs (d)(2)(ii) and (iii) of this section, the net cost of approved educational activities is determined as follows:

(A) Determine allowable direct costs incurred by the provider for trainee stipends and compensation of faculty employed by the provider.

(B) Subtract from those direct costs the revenues the provider receives from students or on behalf of students enrolled in the program, such as, but not limited to, tuition, student fees, or textbooks purchased for resale.

(C) Allocate indirect costs of the activities as determined under the Medicare cost-finding principles in § 413.24, limited to those costs that the provider itself incurs and that are directly attributable to the operation of the approved educational activities.

(ii) The direct and indirect allowable costs of educational activities do not include patient care costs, costs incurred by a related organization, or costs that constitute a redistribution of costs from an educational institution to a provider or costs that have been or are currently being provided through community support.

* * * * *

(e) *Approved nursing and allied health education programs.* Subject to the requirements in § 413.84 of this chapter, CMS will consider an activity an approved nursing and allied health education program if the program is a planned program of study that is licensed by State law, or if licensing is not required, is accredited by the recognized national professional organization for the particular activity.

* * * * *

■ 29. Section 413.402 is amended by revising paragraph (a) and (d)(2)(v) to read as follows:

§ 413.402 Organ acquisition costs.

(a) *Costs related to organ acquisition.* Costs recognized in *paragraph (b)* of this section are allowable costs incurred in the acquisition of organs intended for transplant, including those organs that are subsequently determined unsuitable for transplant and furnished for research from a living donor or a deceased donor by the hospital, or from a deceased donor by an OPO. Additionally, there are administrative and general costs that may be allowable and included on the cost report for an OPO or a TH. Costs incurred by OPOs for public education within its donation service area in accordance with § 413.5(c)(11) and professional education in accordance with § 413.5(c)(14)(iii) are allowable overhead costs and are included on the cost report for an OPO.

* * * * *

(d) * * *

(2) * * *

(v) Costs associated with and incurred for OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO's staff (as described at *§ 486.326(b)*). Costs incurred by OPOs for public education within their donation service area in accordance with § 413.5(c)(11) and professional education in accordance with § 413.5(c)(14)(iii) are allowable overhead costs.

* * * * *

■ 30. Section 413.404 is amended by—

■ a. In paragraph (b)(3)(ii)(A) removing the phrase ''average cost'' and adding in its place the phrase ''average organ acquisition cost'';

■ b. Adding paragraph (b)(3)(ii)(C)(*8*);

■ c. Revising paragraph (c) introductory text; and

■ d. Adding paragraph (d);

The additions and revision read as follows:

§ 413.404 Standard acquisition charge.

* * * * *

(b) * * *

(3) * * *

(ii) * * *

(C) * * *

(*8*) Registry fees as specified in § 413.402(b)(6) of this subpart.

(c) *Independent OPO SACs, for cost reporting periods beginning before October 1, 2028—*

* * * * *

(d) *Independent OPO organ SACs, for cost reporting periods beginning on or after October 1, 2028—*

(1) *General.* For each organ type, the contractor approves the organ-specific SAC based on submission from the IOPO of an estimate of initial cost reporting year projected costs, divided by the initial cost reporting year projected number of usable deceased donor organs that the IOPO expects to procure. For subsequent cost reporting years, the contractor approves the organ-specific SAC submission from the IOPO based on the prior year's actual, reasonable and necessary costs and the IOPO's reasonable estimate of the costs it expects to incur to procure deceased donor organs during the IOPO's cost reporting period, divided by the subsequent cost reporting year's projected number of usable deceased donor organs the IOPO expects to procure during that cost reporting period.

(i) *Initial year.* For each organ type, the contractor approves the IOPO's initial organ-specific SAC, based on the IOPO's budget information.

(ii) *Subsequent years.* For each organ type, the IOPO must provide the Medicare contractor with its reasonable estimated SAC based upon its prior cost reporting period's costs and organ procurement volumes, and its reasonable and documented estimate of its projected costs and organ procurement volumes for the subsequent cost reporting period, for contractor review to ensure reasonableness, and approval.

(iii) *Relationship to interim payments.* Each organ-specific SAC amount is the organ-specific interim payment the TH or other OPO pays to the IOPO, as set forth in § 413.420(d)(2)(i) and (ii).

(iv) *Costs to develop the IOPO deceased donor SACs.* Costs that may be used to develop the IOPO deceased donor SACs include, but are not limited to the following:

(A) Costs of organs acquired from other THs or OPOs.

(B) Costs of transportation as specified in § 413.402(b)(8).

(C) Surgeons' fees for excising deceased donor organs (limited to $1,250 for kidneys).

(D) Costs of tissue typing services, including those furnished by independent laboratories.

(E) Organ preservation and perfusion costs.

(F) General routine and special care service costs (for example, intensive care unit or critical care unit services related to the donor).

(G) Operating room and other inpatient ancillary service costs.

(v) *SAC adjustments.* Only the contractor may adjust the organ SACs. IOPOs may request that the contractor make an adjustment in accordance with § 413.64(e), or the contractor may initiate an adjustment, in accordance with § 413.64(d)(2) or § 413.64(e), as applicable, but no more than quarterly. The IOPO must provide the Medicare contractor with an estimated adjusted SAC based on its actual cost data and its reasonable and documented estimate of costs through the end of its accounting period, to enable the Medicare contractor to review to ensure reasonableness and approve the adjusted SAC.

(2) *Billing SACs for organs generally.* When an IOPO obtains an organ from another OPO, the receiving IOPO is responsible for paying the procuring OPO's SAC. The receiving IOPO uses its SAC for each organ type, and not the procuring OPO's SAC, when billing the TH receiving the organ.

■ 31. Section 413.420 is amended by—

■ a. Revising the section heading and paragraphs (a), (c) introductory text, (c)(1) introductory text, (c)(1)(ii), (iii), and (iv);

■ b. In paragraph (c)(2), removing the phrase ''IOPO or laboratory'' and adding in its place the phrase ''IOPO or HCL'';

■ c. Revising paragraph (d);

■ d. In paragraph (e)(1) introductory text removing the phrase ''IOPOs and histocompatibility laboratories'' and adding in its place the phrase ''IOPOs and HCLs'';

■ e. In paragraph (e)(1)(i) removing the phrase ''IOPO or laboratory'' and adding in its place the phrase ''IOPO or HCL'';

■ f. In paragraph (e)(2) introductory text removing the phrase ''IOPO or histocompatibility laboratory'' and adding in its place the phrase ''IOPO or HCL'';

■ g. Revising paragraphs (e)(2);

■ h. Adding paragraph (e)(3); and

■ i. Revising paragraph (g).

The revisions and additions read as follows:

§ 413.420 Payment to independent organ procurement organizations (IOPOs) and histocompatibility laboratories (HCLs) for organ acquisition costs.

(a) * * *

(1) Covered services furnished by IOPOs and HCLs in connection with organ acquisition and transplantation are reimbursed under the principles for determining reasonable cost contained in this part as follows:

(i) For kidney acquisition and transplantation services, IOPOs and HCLs are reimbursed under the principles for determining reasonable cost.

(ii) For non-renal organ acquisition and transplantation services furnished for cost reporting periods beginning on or after October 1, 2028, IOPOs and HCLs are reimbursed under the principles for determining reasonable cost.

(2) Services furnished by IOPOs and HCLs, that have an agreement with the Secretary in accordance with paragraph (c) of this section, are paid directly by the TH or OPO using a contractor-approved kidney standard acquisition charge (SAC) (for an IOPO) or contractor-approved kidney rates (for an HCL). Effective for cost reporting periods beginning on or after October 1, 2028, services furnished by IOPOs and HCLs, that have an agreement with the Secretary in accordance with paragraph (c) of this section, are paid directly by the TH or OPO using a contractor-approved non-renal organ SAC (for an IOPO) or contractor-approved non-renal rates (for an HCL). (The reasonable costs of services furnished by IOPOs or HCLs are reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

* * * * *

(c) Agreements with IOPOs and HCLs.

(1) Any IOPO or HCL that wishes to have the cost of its pre-transplant services reimbursed under the Medicare program must file an agreement with CMS under which the IOPO or HCL agrees to do all of the following:

* * * * *

(ii) To permit CMS to designate a contractor to approve the interim reimbursement rate, payable by the THs or OPOs for services provided by the IOPO or HCL, and to determine Medicare's reasonable cost based upon the cost report filed by the IOPO or HCL.

(iii) To provide such budget or cost projection information as may be required for the contractor to approve an initial interim rate.

(iv) To pay to CMS amounts that have been received or are receivable by IOPOs or HCLs from THs and OPOs, and that are determined to be in excess of the reasonable cost of the services provided by the IOPO or HCL.

* * * * *

(d) * * *

(1) THs with approved transplant programs and OPOs pay the IOPO or HCL for their pre-transplantation services on the basis of interim rates approved by the contractor for that IOPO or HCL, as follows:

(i) THs with approved kidney transplant programs and OPOs pay the

IOPO or HCL for their kidney pre-transplantation services, based on interim rates approved by the contractor for that IOPO or HCL.

(ii) THs with approved non-renal transplant programs and OPOs pay the IOPO or HCL for their non-renal organ pre-transplantation services furnished for cost reporting periods beginning on or after October 1, 2028, based on interim rates approved by the contractor for that IOPO or HCL.

(2) The interim rates are contractor approved rates, based on costs associated with procuring an organ for transplantation incurred by an IOPO or HCL, respectively, during its previous fiscal year, and on the IOPO's or HCL's reasonable and documented estimate of its projected costs in its subsequent fiscal year, as follows:

(i) The interim rates for kidneys are a contractor approved kidney SAC or contractor approved rates, based on costs associated with procuring kidneys for transplantation, incurred by an IOPO or HCL, respectively, during its previous fiscal year and on the IOPO's or HCL's reasonable and documented estimate of its projected costs in its subsequent fiscal year. If there is not adequate cost data to determine the initial interim rate, the contractor approves it according to the IOPO's or HCL's estimate of its projected costs for the fiscal year.

(ii) For services furnished for cost reporting periods beginning on or after October 1, 2028, the interim rates for non-renal organs are contractor approved non-renal organ-specific SACs or contractor approved rates, based on costs associated with procuring each specific type of non-renal organ for transplantation incurred by an IOPO or HCL, respectively, during its previous fiscal year and on the IOPO's or HCL's reasonable and documented estimate of its projected costs in its subsequent fiscal year. If there is not adequate cost data to determine the initial interim rates, the contractor approves them according to the IOPO's or HCL's estimate of its projected costs for the fiscal year.

(3) Payments or amounts payable from THs and OPOs based on interim rates specified in paragraph (d)(2)(i) of this section are reconciled directly with the IOPO or HCL after the close of the IOPO's or HCL's fiscal year in accordance with § 413.420(e). For cost reporting periods beginning on or after October 1, 2028, payments or amounts payable from THs and OPOs based on interim rates specified in paragraph (d)(2)(ii) of this section are reconciled directly with the IOPO or HCL after the close of the IOPO's or HCL's fiscal year in accordance with § 413.420(e).

(4) When a contractor approves interim rates for IOPOs and HCLs, it must disseminate those interim rates to all THs, OPOs, and contractors.

(e) * * *

(2) *Audit and adjustment for cost reporting periods beginning before October 1, 2028.* A cost report submitted by an IOPO or histocompatibility laboratory is reviewed by the contractor and a new interim reimbursement rate for kidney acquisition costs for the subsequent fiscal year is approved based upon this review.

(i) *Retroactive adjustment.* A retroactive adjustment of the amounts received or receivable by the IOPO or HCL under the kidney interim rate is made in accordance with § 413.64(f).

(ii) *Lump sum adjustment.* If the determination of reasonable cost reveals an overpayment or underpayment resulting from the kidney interim reimbursement rate received or receivable by the IOPO or HCL from THs and OPOs, a lump sum adjustment is made directly between the contractor and the IOPO or HCL.

(3) *Audit and adjustment for cost reporting periods beginning on or after October 1, 2028.* A cost report submitted by an IOPO or HCL is reviewed by the contractor and new interim reimbursement rates for organ acquisition costs for the subsequent fiscal year are approved by the contractor based upon this review and upon the IOPO's or HCL's reasonable estimate of its costs for organ procurement and testing, respectively, in the subsequent fiscal year.

(i) *Retroactive adjustment.* A retroactive adjustment of the amounts received or receivable by the IOPO or HCL under the organ-specific interim rates is made in accordance with § 413.64(f).

(ii) *Lump sum adjustment.* If the determination of reasonable cost reveals an overpayment or underpayment resulting from the organ-specific interim reimbursement rates received or receivable by the IOPO or HCL from THs and OPOs, an adjustment to the interim rate may be initiated by the contractor or requested by the IOPO or HCL, but no more than quarterly. If a rate adjustment is made, then an IOPO or HCL may request that a lump sum adjustment be made directly between the contractor and the IOPO or HCL.

* * * * *

(g) *Appeals.* If the amount in controversy is $1,000 or more, any IOPO or HCL that disagrees with a contractor's cost determination under this section is entitled to a contractor hearing, review of the contractor hearing officer's decision by a CMS reviewing official, and Administrator Review of a CMS reviewing official's decision, in accordance with the procedures set forth in §§ 405.1801(b)(2) and 405.1811 through 405.1834 of this chapter.

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 32. The authority citation for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395h(h).

■ 33. Section 415.152 is amended in the definition of ''Approved graduate medical education (GME) program'' by revising the introductory text and paragraph (1) to read as follows:

§ 415.152 Definitions.

* * * * *

Approved graduate medical education (GME) program means, subject to the requirements in § 413.84 of this chapter, one of the following:

(1) A residency program approved by the Accreditation Council for Graduate Medical Education, by the American Osteopathic Association, by the Commission on Dental Accreditation of the American Dental Association, or by the Council on Podiatric Medical Education of the American Podiatric Medical Association, or other organization determined by the Secretary.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEMS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 34. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 35. Section 419.66 is amended by revising paragraph (c)(2)(ii) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(c) * * *

(2) * * *

(ii) For devices for which pass-through payment status began on or after January 1, 2020, and on or before January 1, 2029, as an alternative pathway to *paragraph (c)(2)(i)* of this section, a new device is part of the Food and Drug Administration's (FDA's)

Breakthrough Devices Program and has received Breakthrough Device designation as of September 30, 2026, and has received marketing authorization for the indication covered by the Breakthrough Device designation.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 36. The authority citation for part 495 continues to read as follows:

Authority: *42 U.S.C. 1302* and *1395hh.*

■ 37. Section 495.4 is amended in the definition of ''Certified electronic health record technology (CEHRT)'' by revising paragraphs (2)(i) and (2)(ii)(A) in introductory text to read as follows:

§ 495.4 Definitions.

Certified electronic health record technology (CEHRT) * * *

(2) * * *

(i) For 2019 through 2026, at 45 CFR 170.315(a)(12) (family health history) and 45 CFR 170.315(e)(3) (patient health information capture); and

(ii) * * *

(A) For 2019 through 2026, the applicable measure calculation certification criterion at *45 CFR 170.315(g)(1)* or *(2)* for all certification criteria that support a meaningful use objective with a percentage-based measure.

* * * * *

§ 495.40 [Amended]

■ 38. Section 495.40 is amended in paragraph (b)(2)(i)(I) introductory text by removing the phrase ''To engage'' and adding in its place the phrase ''Through CY 2026, to engage''.

PART 512—STANDARD PROVISIONS FOR MANDATORY INNOVATION CENTER MODELS AND SPECIFIC PROVISIONS FOR CERTAIN MODELS

■ 39. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 40. Section 512.505 is amended by—

■ a. Adding definitions for ''APC update factor'' and ''MS–DRG update factor'' in alphabetical order;

■ b. Revising definition for ''Spinal fusion''; and

■ c. Adding definition for ''Updated prospective trend factor'' in alphabetical order.

The additions and revision read as follows:

§ 512.505 Definitions.

* * * * *

APC update factor refers to a component applied to the prospective trend factor to ensure that the APC weights corresponding to the performance year are incorporated into the target price calculations, as set forth in § 512.540(b)(7).

* * * * *

MS–DRG update factor refers to a component applied to the prospective trend factor for episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of the performance year to account for changes in MS–DRG definitions and weights between the first and second fiscal years in the performance year, as set forth in § 512.540(b)(7).

* * * * *

Spinal fusion means any cervical, thoracic, or lumbar spinal fusion procedure paid through either of the following:

(1) The IPPS under—

(i) MS–DRG 402, 426, 427, 428, 429, 430, 447, 448, 450, 451, 471, 472, or 473; and

(ii) On or after October 1, 2026 MS–DRG 523, 524, or 525.

(2) The OPPS under HCPCS codes 22551, 22554, 22612, 22630, or 22633.

* * * * *

Updated prospective trend factor refers to the multiplier incorporated into the preliminary target price to estimate changes in spending patterns between the baseline period and the corresponding calendar year and fiscal year in the performance year, calculated as set forth in § 512.540(b)(7).

* * * * *

■ 41. Section 512.525 is amended by revising paragraph (d)(4)(i) to read as follows:

§ 512.525 Episodes.

(d) * * *

(4) * * *

(i) IPPS discharge under—

(A) MS–DRG 402, 426, 427, 428, 429, 430, 447, 448, 450, 451, 471, 472, or 473; and

(B) On or after October 1, 2026 MS–DRG 523, 524, or 525; or

* * * * *

■ 42. Section 512.537 is amended by adding paragraph (b)(4) to read as follows:

§ 512.537 Determination of the episode.

(b) * * *

(4) The beneficiary is in a CJR–X episode and has a procedure performed at a TEAM participant during the 90-day post-discharge period after a CJR–X anchor hospitalization or CJR–X anchor procedure.

* * * * *

■ 43. Section 512.540 is amended by—

■ a. In paragraph (a)(1)(i) by removing the phrase ''the 24 MS–DRGs'' and adding in its place the phrase ''the MS–DRGs''; and

■ b. Revising paragraphs (b)(6) through (8).

The revisions read as follows:

§ 512.540 Determination of preliminary target prices.

(b) * * *

(6) *Prospective normalization factor.* Based on the episodes in the most recent calendar year of the baseline period for performance year 1 and for the entire baseline period starting in performance year 2, CMS calculates a prospective normalization factor at the MS–DRG/HCPCS region level, which is a multiplier that ensures that the average of the total risk-adjusted benchmark price does not exceed the average of the total non-risk adjusted benchmark price, by doing the following:

(i) CMS applies risk adjustment multipliers, as specified in § 512.545(a)(1) through (3), to the most recent baseline year episodes for performance year 1 and to the entire baseline period episodes starting in performance year 2, to calculate the estimated risk-adjusted target price for all performance year episodes.

(ii) CMS divides the mean of the benchmark price for each episode across all hospitals and regions by the mean of the estimated risk-adjusted benchmark price calculated in § 512.540(b)(6)(i) for the same episode types across all hospitals and regions.

(7) *Prospective and updated trend factors.*

(i) Prospective trend factor. The prospective trend factor for each MS–DRG/HCPCS episode type and region is the average (arithmetic mean) of the multiplier, as calculated in paragraph (b)(7)(i) of this section, for that MS–DRG/HCPCS episode type and region and the national average for that MS–DRG/HCPCS episode type.

(A) CMS calculates a multiplier for each MS–DRG/HCPCS episode type and region which is applied to the most recent calendar year of the applicable baseline period.

(B) The multiplier is calculated using linear regression on the logarithmically transformed average regional spending for each MS–DRG/HCPCS episode type in the baseline years and trend years at both the regional and national level.

(C) CMS exponentiates the coefficient from this regression to calculate the estimated annual change (where an exponentiated coefficient of 1 signifies no change) in average regional spending

for each MS–DRG/HCPCS episode type from year to year.

(D) CMS squares the value in paragraph (C) to calculate the 2-year prospective trend factor.

(ii) *Updated prospective trend factor.* CMS calculates the updated prospective trend factor as the product of all the following factors:

(A) The prospective trend factor specified in paragraph (b)(7)(i) of this section.

(B) The APC update factor as specified in this paragraph (B). CMS calculates an APC update factor, after the corresponding calendar year inputs are published in the CY OPPS/ASC final rule, as the ratio of benchmark prices calculated with APC weights corresponding to the calendar year of the performance year to benchmark prices calculated with APC weights corresponding to the calendar year prior to the performance year.

(C) The MS–DRG update factor as specified in this paragraph (C). CMS calculates an MS–DRG update factor, after the corresponding fiscal year inputs are published in the FY IPPS/LTCH PPS final rule, for episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year as the ratio of benchmark prices calculated with the second fiscal year inputs to benchmark prices calculated with the first fiscal year inputs.

(8) *Communication of preliminary target prices.* CMS communicates the preliminary target prices for each MS–DRG/HCPCS episode type for each region, and the preliminary target prices for each MS–DRG/HCPCS episode type specific to the TEAM participant before the performance year in which they apply. CMS communicates the APC and MS–DRG update factors after the corresponding calendar year and second fiscal year inputs are published with the corresponding calendar year and fiscal year final payment rules.

* * * * *

■ 44. Section 512.545 is amended by—

■ a. Revising paragraphs (d)(1) and(e)(1)(ii);

■ b. Adding paragraph (e)(1)(iii);

■ c. Redesignating paragraph (e) as paragraph (e)(2)(i);

■ d. Adding paragraph (e)(2)(ii); and

■ e. Revising paragraph (f).

The revisions and additions read as follows:

§ 512.545 Determination of reconciliation target prices.

* * * * *

(d)(1) At the time of reconciliation, the preliminary target prices computed under § 512.540 are risk adjusted by applying the applicable beneficiary level and hospital-level risk adjustment factors specific to the beneficiary in the episode, as set forth in paragraphs (a)(1) through (6) of this section.

(2) CMS applies the coefficients estimated with the assigned first fiscal year MS–DRG/HCPCS inputs, as determined in § 512.550(c)(1), for episodes with anchor hospitalizations or anchor procedure end date in the fourth quarter of a performance year.

(e) * * *

(1) * * *

(ii) Episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year are calculated specific to the assigned first and second fiscal year MS–DRG/HCPCS episode type and region combination, as determined in § 512.550(c)(1). The benchmark prices and risk adjustment coefficients are calculated with the assigned first fiscal year MS–DRG/HCPCS inputs and applied to the realized case mix of the second fiscal year MS–DRG/HCPCS.

(iii) As applied, cannot exceed ±5 percent of the prospective normalization factor (as specified in § 512.540(b)(6)).

(2) * * *

(ii) For episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year, the final normalization factor is applied to each assigned first and second fiscal year MS–DRG/HCPCS episode type and region combination.

(f) CMS calculates a multiplier, referred to as the capped retrospective trend factor, for each MS–DRG/HCPCS episode type and region, which is applied during reconciliation to the most recent calendar year of the applicable baseline period.

(1)(i) The retrospective trend factor is calculated as the average regional capped performance year episode spending for each MS–DRG/HCPCS episode type divided by the average regional capped baseline period episode spending for each MS–DRG/HCPCS episode type.

(ii) For episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year, CMS calculates the retrospective trend factor as the average regional capped performance year episode spending specific to the second fiscal year MS–DRG/HCPCS episode type divided by the average regional capped baseline period episode spending calculated with the assigned first fiscal year MS–DRG/HCPCS inputs.

(2) The retrospective trend factor is capped so that the maximum difference cannot exceed ±3 percent of the updated prospective trend factor (as specified in § 512.540(b)(7)).

(3)(i) CMS applies the capped retrospective trend factor to the previously calculated normalized, risk adjusted target prices specific to each region and MS–DRG/HCPCS episode type, as specified in paragraph (e)(2) of this section, to calculate the reconciliation target prices, which are compared to performance year spending at reconciliation, as specified in § 512.550(c).

(ii) For episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year, the capped retrospective trend factor is applied specific to each assigned first and second fiscal year MS–DRG/HCPCS episode type and region combination.

■ 45. Section 512.547 is amended by—

■ a. In paragraph (a)(1)(i), removing the phrase ''CY 2025'' and adding in its place the phrase ''July 1, 2024 through June 30, 2025'';

■ b. In paragraph (a)(1)(ii), removing the phrase ''CY 2025'' and adding in its place the phrase ''July 1, 2023 through June 30, 2025'';

■ c. In paragraph (a)(1)(iii), removing the phrase ''CY 2025'' and adding in its place ''the phrase July 1, 2024 through June 30, 2025'';

■ d. In paragraph (a)(2)(i), removing the phrase ''CY 2025'' and adding in its place the phrase ''July 1, 2025 through June 30, 2026'';

■ e. In paragraph (a)(2)(iv), removing the phrase ''CY 2026'' and adding in its place the phrase ''July 1, 2024 through June 30, 2026'';

■ f. In paragraph (a)(2)(v), removing the phrase ''CY 2025'' and adding in its place the phrase ''July 1, 2025 through June 30, 2026'';

■ g. In paragraph (a)(3) introductory text, removing the phrase ''years 3 through 5:'' and adding in its place the phrase ''year 3:'';

■ h. In paragraph (a)(3)(i), removing the phrase ''CY 2025'' and adding in its place the phrase ''July 1, 2026 through June 30, 2027'';

■ i. In paragraph (a)(3)(ii), removing the phrase ''2026'' and adding in its place the phrase ''2028'';

■ j. In paragraph (a)(3)(iii), removing the phrase ''2026'' and adding in its place the phrase ''2028'';

■ k. In paragraph (a)(3)(iv), removing the phrase ''CY 2026'' and adding in its place the phrase ''July 1, 2025 through June 30, 2027'';

■ l. In paragraph (a)(3)(v), removing the phrase ''CY 2025'' and adding in its place the phrase ''July 1, 2026 through June 30, 2027'';

■ m. In paragraph (a)(3)(vi), removing the phrase ''CY 2027'' and adding in its place the phrase ''January 1, 2028 through December 31, 2028'';
■ n. Adding paragraphs (a)(4) and (5).
The additions read as follows:

§ 512.547 Quality measures, composite quality score, and display of quality measures.

(a) * * *

(4) For performance year 4:

(i) *For all episode categories:* Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356) with a July 1, 2027 through June 30, 2028 CQS baseline period.

(ii) *For all episode categories:* Hospital Harm—Falls with Injury (CMIT ID #1518) with a January 1, 2029 through December 31, 2029 CQS baseline period.

(iii) *For all episode categories:* Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788) with a January 1, 2029 through December 31, 2029 CQS baseline period.

(iv) *For all episode categories:* Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (ISCMR) (CMIT ID #134) with a July 1, 2026 through June 30, 2028 CQS baseline period.

(v) *For LEJR episodes:* Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO–PM) (CMIT ID #1618) with a July 1, 2027 through June 30, 2028 CQS baseline period.

(vi) *For LEJR and Spinal Fusion episodes:* Information Transfer PRO–PM (CMIT ID #1797) with a January 1, 2029 through December 31, 2029 CQS baseline period.

(5) For performance year 5:

(i) *For all episode categories:* Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356) with a July 1, 2028 through June 30, 2029 CQS baseline period.

(ii) *For all episode categories:* Hospital Harm—Falls with Injury (CMIT ID #1518) with a January 1, 2030 through December 31, 2030 CQS baseline period.

(iii) *For all episode categories:* Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788) with a January 1, 2030 through December 31, 2030 CQS baseline period.

(iv) *For all episode categories:* Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (ISCMR) (CMIT ID #134) with a July 1, 2027 through June 30, 2029 CQS baseline period.

(v) *For LEJR episodes:* Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO–PM) (CMIT ID #1618) with a July 1, 2028 through July 30, 2029 CQS baseline period.

(vi) *For LEJR and Spinal Fusion episodes:* Information Transfer PRO–PM (CMIT ID #1797) with a January 1, 2030 through December 31, 2030 CQS baseline period.

■ 46. Section 512.550 is amended by revising paragraph (c) to read as follows:

§ 512.550 Reconciliation process and determination of the reconciliation payment or repayment amount.

* * * * *

(c) * * *

(1) CMS assigns a first fiscal year MS–DRG by identifying diagnosis or procedure codes that change between the first and second fiscal year of the performance year per the fiscal year final payment rule MS–DRG definitions, for each episode with an anchor hospitalization or anchor procedure end date in the fourth quarter of a performance year. The first fiscal year MS–DRG will match the second fiscal year MS–DRG if there are no mapping changes for an initiating MS–DRG.

(i) CMS does not assign mapping changs for episodes with anchor hospitalization or anchor procedure end dates in the first three quarters of a performance year.

(2) CMS cancels an episode with an anchor hospitalization or anchor procedure end date in the fourth quarter of a performance year, in accordance with § 512.537(b), if the assigned first fiscal year MS–DRG is not specified in § 512.525(d).

(3) CMS determines the performance year spending for each episode included in the performance year (other than episodes that have been canceled in accordance with § 512.537(b)) for each MS–DRG/HCPCS episode type using claims data that is available 6 months after the end of the performance year.

(4) CMS calculates and applies the high-cost outlier cap for performance year episode spending by applying the calculation described in § 512.540(b)(4) to performance year episode spending for each MS–DRG/HCPCS episode type.

(5)(i) CMS applies the adjustments specified in § 512.545 to the preliminary target prices computed in accordance with § 512.540 to calculate the reconciliation target prices for each MS–DRG/HCPCS episode type.

(ii) CMS calculates the reconciliation target prices for each assigned first and second fiscal year MS–DRG/HCPCS episode type for episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year.

(6)(i) CMS aggregates the reconciliation target prices computed in accordance with paragraph (c)(3) of this section for all episodes included in the performance year (other than episodes that have been canceled in accordance with § 512.537(b)) for each MS–DRG/HCPCS episode type.

(ii) CMS aggregates the reconciliation target prices for each assigned first and second fiscal year MS–DRG/HCPCS episode type for episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year.

(7)(i) CMS subtracts the performance year spending amount determined under paragraphs (c)(1) and (2) of this section from the reconciliation target price amount determined under paragraph (c)(4) of this section for each MS–DRG/HCPCS episode type.

(i) CMS first subtracts the performance year spending amount from the reconciliation target amount for each assigned first and second fiscal year MS–DRG/HCPCS episode type, then sums values for each MS–DRG/HCPCS episode type for episodes with anchor hospitalization or anchor procedure end dates in the fourth quarter of a performance year.

(8) CMS sums the values calculated under paragraph (c)(5) of this section across all MS–DRG/HCPCS episode types to determine the reconciliation amount.

(9)(i) CMS caps the performance year spending amount for each MS–DRG/HCPCS episode type determined under paragraphs (c)(3) and (4) of this section to equal the reconciliation target price computed in accordance with paragraph (c)(5) of this section for episode categories where the TEAM participant did not meet the low volume threshold of at least 31 episodes during the 3-year baseline period.

(ii) Low volume hospital episodes, including episode categories where CMS caps performance year spending, are included in the CQS, as calculated in § 512.547(b), and stop-loss/stop-gain thresholds, as applied at paragraph (e) of this section.

■ 47. Part 512 is amended by adding subpart F to read as follows:

Subpart F—Comprehensive Care For Joint Replacement Expanded (CJR–X) Model

Sec.

General

512.600 Basis and scope of subpart.

512.605 Definitions.

CJR–X Participation

512.610 Mandatory participation.
512.615 APM options.

Beneficiary Population

512.620 Beneficiary inclusion criteria.
512.622 Beneficiary notification.

Episode of Care

512.625 Scope of episode.
512.630 Determination of the episode.

Quality Measures and Composite Quality Score

512.635 Quality measures, composite quality score, and display of quality measures.

Pricing Methodology

512.640 Determination of preliminary target prices.
512.645 Determination of reconciliation target prices.
512.650 Reconciliation process and determination of the reconciliation payment or repayment amount.
512.652 Treatment of incentive programs or add-on payments under existing Medicare payment systems.
512.655 Proration of payments for services that extend beyond an episode.
512.660 Appeals process.

Data Sharing

512.665 Data sharing with CJR–X participants.

Financial Arrangements and Beneficiary Incentives

512.670 Sharing arrangements.
512.675 Distribution arrangements.
512.680 Downstream distribution arrangements.
512.685 CJR–X beneficiary incentives.
512.690 Application of the CMS-sponsored Model Arrangements and Patient Incentives Safe Harbor.

Medicare Program Waivers

512.695 CJR–X Medicare Program Waivers.

Subpart F—Comprehensive Care For Joint Replacement Expanded (CJR–X) Model

General

§ 512.600 Basis and scope of subpart.

(a) *Basis.* This subpart implements the expansion of the Comprehensive Care for Joint Replacement (CJR) Model under section 1115A(c) of the Act. Except as specifically noted in this subpart, the regulations under this subpart do not affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including the applicability of provisions regarding payment, coverage, and program integrity.

(b) *Scope.* This subpart sets forth the following:

(i) Participation in CJR–X.

(ii) Scope of episodes.

(iii) Pricing methodology.

(iv) Quality measures and quality reporting requirements.

(v) Reconciliation and review processes.

(vi) Data Sharing and other requirements.

(vii) Financial arrangements and beneficiary incentives.

(viii) Medicare program waivers.

(c) *Applicability.* Except as otherwise specified in this subpart, CJR–X participants are subject to the standard provisions for Innovation Center models specified in subpart A of this part 512 and in subpart K of part 403 of this chapter.

§ 512.605 Definitions.

For the purposes of this subpart, the following definitions are applicable unless otherwise stated:

AAPM stands for Advanced Alternative Payment Model.

AAPM option means the advanced alternative payment model option for CJR–X participants that provide their CMS EHR Certification ID and attest to their use of CEHRT in accordance with § 512.615.

ACO means an accountable care organization, as defined at § 425.20 of this chapter.

ACO participant has the meaning set forth in § 425.20 of this chapter.

ACO provider/supplier has the meaning set forth in § 425.20 of this chapter.

Acute care hospital means a provider subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

Age bracket risk adjustment factor means the coefficient of risk associated with a patient's age bracket, calculated as described in § 512.645(a)(1).

Aggregated reconciliation target price means the sum of the reconciliation target prices for all episodes attributed to a CJR–X participant for the applicable performance year.

Alignment payment means a payment from a CJR–X collaborator to a CJR–X participant under a sharing arrangement, for the sole purpose of sharing the CJR–X participant's responsibility for making repayments to Medicare.

Anchor hospitalization means the initial hospital stay upon admission for a lower extremity joint replacement for which the institutional claim is billed through the inpatient prospective payment system (IPPS).

Anchor procedure means a TKA or THA procedure that is permitted and paid for by Medicare when performed in a hospital outpatient department (HOPD) and billed through the Hospital Outpatient Prospective Payment System (OPPS).

APM stands for Alternative Payment Model as defined in § 414.1305 of this chapter.

Baseline episode spending means the total episode spending by all providers and suppliers associated with a given MS–DRG/HCPCS episode type for all hospitals in a given region during the baseline period.

Baseline period means the 3-year historical period CMS uses to construct the preliminary target price and reconciliation target price for a given performance year.

Baseline year means any one of the three years included in the baseline period.

Benchmark price means the average standardized episode spending by all providers and suppliers associated with an MS–DRG/HCPCS episode type for all hospitals in a defined region during the applicable baseline period.

Beneficiary economic risk adjustment factor means the coefficient of risk associated with a patient's economic status, calculated as described in § 512.645(a)(3).

CCN stands for CMS certification number.

CDI stands for *Community Deprivation Index.*

CEHRT means certified electronic health record technology that meets the requirements set forth in § 414.1305 of this chapter.

CJR stands for the Comprehensive Care for Joint Replacement Model, that was the Phase I episode-based payment model test by the Innovation Center from April 2016 to December 2024.

CJR–X stands for the Comprehensive Care for Joint Replacement Expanded Model.

CJR–X activities mean any activity related to promoting accountability for the quality, cost, and overall care for CJR–X beneficiaries and performance in the model, including managing and coordinating care, encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery, or carrying out any other obligation or duty under the model.

CJR–X beneficiary means a beneficiary who meets the beneficiary inclusion criteria in § 512.620.

CJR–X collaborator means an ACO or one of the following Medicare-enrolled individuals or entities that enters into a sharing arrangement:

(1) Skilled Nursing Facility (SNF).

(2) Home Health Agency (HHA).

(3) Long-Term Care Hospital (LTCH).

(4) Inpatient Rehabilitation Facility (IRF).

(5) Physician.
(6) Nonphysician practitioner.
(7) Therapist in private practice.
(8) Comprehensive Outpatient Rehabilitation Facility (CORF).
(9) Provider of outpatient therapy services.
(10) Physician Group Practice (PGP).
(11) Hospital.
(12) Critical Access Hospital (CAH).
(13) Non-Physician Provider Group Practice (NPPGP).
(14) Therapy Group Practice (TGP).

CJR–X data sharing agreement means an agreement between the CJR–X participant and CMS that includes the terms and conditions for any beneficiary-identifiable data shared with the CJR–X participant under § 512.665.

CJR–X HCC count risk adjustment factor means the CJR–X Hierarchical Condition Category count that is a categorical risk adjustment variable that reflects a beneficiary's overall health status during a 180-day lookback period that groups similar diagnoses into one related category and counts the total number of diagnostic categories that apply to the beneficiary.

CJR–X participant means an acute care hospital located in any of the 50 United States, District of Columbia, or U.S. Territories that initiates LEJR episodes and is eligible to be paid under both the IPPS and OPPS, unless it meets an exception in § 512.610(b).

CJR–X payment means a payment made by CMS only to CJR–X participants, or a payment adjustment made only to payments made to CJR–X participants, under the terms of CJR–X that is not applicable to any other providers or suppliers.

CJR–X reconciliation report means the report prepared after each reconciliation that CMS provides to each CJR–X participant notifying the CJR–X participant of the outcome of the reconciliation.

Clinician engagement list means the list of eligible clinicians or MIPS eligible clinicians that participate in CJR–X activities and have a contractual relationship with the CJR–X participant, and who are not listed on the financial arrangements list, as described in § 512.615(c).

CMS Electronic Health Record (EHR) Certification ID means the identification number that represents the combination of Certified Health Information Technology that is owned and used by providers and hospitals to provide care to their patients and is generated by the Certified Health Information Technology Product List.

Collaboration agent means an individual or entity that is not a CJR–X collaborator and that is either of the following:

(1) A member of a PGP, NPPGP, or TGP that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is a CJR–X collaborator.

(2) An ACO participant or ACO provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating, and where the ACO is a CJR–X collaborator.

Composite quality score (CQS) means a score computed for each CJR–X participant to summarize the CJR–X participant's level of quality performance on specified quality measures as described in § 512.635.

CORF stands for comprehensive outpatient rehabilitation facility.

Critical access hospital (CAH) means a hospital designated under subpart F of part 485 of this chapter.

Discount factor means a set percentage included in the preliminary target price and adjusted for quality at reconciliation as described at § 512.645(g).

Distribution arrangement means a financial arrangement between a CJR–X collaborator that is an ACO, PGP, NPPGP, or TGP and a collaboration agent for the sole purpose of distributing some or all of a gainsharing payment received by the ACO, PGP, NPPGP, or TGP.

Distribution payment means a payment from a CJR–X collaborator that is an ACO, PGP, NPPGP, or TGP to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments.

DME stands for durable medical equipment.

Downstream collaboration agent means an individual who is not a CJR–X collaborator or a collaboration agent and who is a member of a PGP, NPPGP, or TGP that has entered into a downstream distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is a collaboration agent.

Downstream distribution arrangement means a financial arrangement between a collaboration agent that is both a PGP, NPPGP, or TGP and an ACO participant and a downstream collaboration agent for the sole purpose of sharing a distribution payment received by the PGP, NPPGP, or TGP.

Downstream participant means an individual or entity that has entered into a written arrangement with a CJR–X participant, CJR–X collaborator, collaboration agent, or downstream collaboration agent under which the downstream participant engages in one or more CJR–X activities.

Dually eligible beneficiary means a beneficiary enrolled in both Medicare and full Medicaid benefits.

EHR stands for electronic health record.

Eligible clinician means a clinician as defined in § 414.1305 of this chapter.

Episode means all Medicare Part A and B items and services described in § 512.625(b) (and excluding the items and services described in § 512.625(c)) that are furnished to a CJR–X beneficiary during the time period that begins on the date of the beneficiary's admission to an anchor hospitalization or the date of the anchor procedure, as described at § 512.630(c), and ends on the 90th day following the date of discharge from the anchor hospitalization or anchor procedure, as described at § 512.630(d).

Episode type means the subset of episodes that are associated with a given MS–DRG/HCPCS, as set forth at § 512.640(a)(1).

Final normalization factor means the mathematical mean of the benchmark price for each MS–DRG/HCPCS episode type and region divided by the mean of the risk-adjusted benchmark price for the same MS–DRG/HCPCS episode type and region.

Financial arrangements list means the list of eligible clinicians or MIPS eligible clinicians that have a financial arrangement with the CJR–X participant, CJR–X collaborator, collaboration agent, and downstream collaboration agent, as described in § 512.615(b).

Gainsharing payment means a payment from a CJR–X participant to a CJR–X collaborator, under a sharing arrangement, composed of only reconciliation payments, internal cost savings, or both.

HCPCS stands for Healthcare Common Procedure Coding System and means the system used to bill for items and services.

HHA means a Medicare-enrolled home health agency.

High-cost outlier cap means the CMS-applied episode spending cap at the 99th percentile of regional spending for a given MS DRG/HCPCS episode type, region, and baseline year.

Hospital means a hospital as defined in section 1886(d)(1)(B) of the Act.

Hospital discharge planning means the standards set forth in § 482.43 of this chapter.

ICD–CM stands for International Classification of Diseases, Clinical Modification.

Inpatient measure composite quality score means the sum of inpatient quality

measure point values capped at 20 points.

Internal cost savings means the measurable, actual, and verifiable cost savings realized by the CJR–X participant resulting from care redesign undertaken by the CJR–X participant in connection with providing items and services to CJR–X beneficiaries within an episode. Internal cost savings does not include savings realized by any individual or entity that is not the CJR–X participant.

IPF stands for inpatient psychiatric facility.

IPPS stands for Inpatient Prospective Payment System, and means the payment system for subsection (d) hospitals as defined in section 1886(d)(1)(B) of the Act.

IRF stands for inpatient rehabilitation facility.

LIS stands for Medicare Part D Low-Income Subsidy.

Lower-extremity joint replacement (LEJR) means any hip, knee, or ankle replacement that is paid under MS–DRG 469, 470, 521, or 522 through the IPPS or HCPCS code 27447 or 27130 through the OPPS.

Low-volume hospital means a hospital identified by CMS as having fewer than 31 LEJR episodes during the applicable baseline period.

LTCH stands for long-term care hospital as defined in section 1861(ccc) of the Act.

Medicare severity diagnosis-related group (MS–DRG) means, for the purposes of this model, the classification of inpatient hospital discharges updated in accordance with § 412.10 of this chapter.

Medicare-dependent, small rural hospital (MDH) means a specific type of hospital that meets the classification criteria specified under § 412.108 of this chapter.

Member of the NPPGP or *NPPGP member* means a nonphysician practitioner or therapist who is an owner or employee of an NPPGP and who has reassigned to the NPPGP his or her right to receive Medicare payment.

Member of the PGP or *PGP member* means a physician, nonphysician practitioner, or therapist who is an owner or employee of the PGP and who has reassigned to the PGP his or her right to receive Medicare payment.

Member of the TGP or *TGP member* means a therapist who is an owner or employee of a TGP and who has reassigned to the TGP his or her right to receive Medicare payment.

MIPS stands for Merit-based Incentive Payment System

MIPS eligible clinician means a clinician as defined in § 414.1305 of this chapter.

Model start date means the start of the Phase II model test on January 1, 2028.

Non-AAPM option means the CJR–X participant's choice to not attest to the use of CEHRT as described in § 512.615.

Nonphysician practitioner means one of the following:

(1) A physician assistant who satisfies the qualifications set forth at § 410.74(a)(2)(i) and (ii) of this chapter.

(2) A nurse practitioner who satisfies the qualifications set forth at § 410.75(b) of this chapter.

(3) A clinical nurse specialist who satisfies the qualifications set forth at § 410.76(b) of this chapter.

(4) A certified registered nurse anesthetist (as defined at § 410.69(b)).

(5) A clinical social worker (as defined at § 410.73(a)).

(6) A registered dietician or nutrition professional (as defined at § 410.134).

NPI stands for National Provider Identifier.

NPPGP stands for non-physician provider group practice and means an entity that is enrolled in Medicare as a group practice, includes at least one owner or employee who is a nonphysician practitioner, does not include a physician owner or employee, and has a valid and active TIN.

Net payment reconciliation amount (NPRA) means the dollar amount calculated in accordance with § 512.650(c).

OIG stands for the Department of Health and Human Services' Office of Inspector General.

OP means an outpatient procedure for which the institutional claim is billed by the hospital through the OPPS.

OPPS stands for the Outpatient Prospective Payment System.

Outpatient composite quality score means the sum of outpatient quality measure points values, capped at 20 points.

Overall composite quality score means the sum of the weighted average of the inpatient measure composite quality score and the outpatient measure composite quality score, capped at 20 points.

PAC stands for post-acute care.

PAC provider is a home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), or long-term care hospital (LTCH), as defined in section 1899B(a)(2) of the Act.

Performance year (PY) means a 12-month period beginning on January 1 and ending on December 31 to align with the calendar year.

Performance year spending means the sum of standardized Medicare claims payments during a performance year for the items and services that are included in the episode in accordance with § 512.625(b), excluding the items and services described in § 512.625(c).

PGP stands for physician group practice.

Physician has the meaning set forth in section 1861(r) of the Act.

Preliminary target price means the CMS-set financial amount provided to the CJR–X participant prior to the start of the performance year, that is subject to adjustment at reconciliation, as set forth at § 512.640.

Prospective normalization factor means the multiplier used by CMS in the preliminary target price calculation to ensure that the average of the total risk-adjusted benchmark price does not exceed the average of the total non-risk adjusted benchmark price, calculated as set forth in § 512.640(b)(6).

Prospective trend factor means the multiplier used by CMS in the preliminary target price calculation to estimate changes in spending patterns between the baseline period and the performance year, calculated as set forth in § 512.640(b)(7).

Provider of outpatient therapy services means an entity that is enrolled in Medicare as a provider of therapy services and furnishes one or more of the following:

(1) Outpatient physical therapy services as defined in § 410.60 of this chapter.

(2) Outpatient occupational therapy services as defined in § 410.59 of this chapter.

(3) Outpatient speech-language pathology services as defined in § 410.62 of this chapter.

Reconciliation payment amount means the amount that CMS may pay to a CJR–X participant after reconciliation as determined in accordance with § 512.650(g).

Reconciliation target price means the target price applied to an episode at reconciliation, as determined in accordance with § 512.645.

Region means one of the nine U.S. census divisions, as defined by the U.S. Census Bureau, with the U.S. territories included in Census Division 9.

Reorganization event means a merger, consolidation, spin-off or other restructuring that results in a new hospital entity under a given CCN.

Repayment amount means the amount that the CJR–X participant may owe to Medicare after reconciliation as determined in accordance with § 512.650(g).

Retrospective trend factor means the multiplier CMS uses in its reconciliation target price calculation to

estimate realized changes in spending patterns during the performance year, calculated as set forth in § 512.645(f).

Rural hospital means an IPPS hospital that meets one of the following criteria:

(1) Is located in a rural area as defined under § 412.64 of this chapter.

(2) Is located in a rural census tract defined under § 412.103(a)(1) of this chapter.

Safety net hospital means a hospital in the top 25th percentile in their region for percentage of Medicare LEJR episodes provided to dually eligible beneficiaries during the applicable baseline period.

Sharing arrangement means a financial arrangement between a CJR–X participant and a CJR–X collaborator for the sole purpose of making gainsharing payments or alignment payments under CJR–X.

SNF stands for skilled nursing facility as defined in section 1819(a) of the Act.

Sole community hospital (SCH) means a hospital that meets the classification criteria specified in § 412.92 of this chapter.

Swing-bed hospital means a hospital that meets the definition specified in § 413.114 of this chapter.

TAA stands for total ankle arthroplasty.

TGP or therapy group practice means an entity that is enrolled in Medicare as a therapy group in private practice, includes at least one owner or employee who is a therapist in private practice, does not include an owner or employee who is a physician or nonphysician practitioner, and has a valid and active TIN.

THA means total hip arthroplasty.

Therapist means one of the following individuals as defined at § 484.4 of this chapter:

(1) Physical therapist.

(2) Occupational therapist.

(3) Speech-language pathologist.

Therapist in private practice means a therapist that—

(1) Complies with the special provisions for physical therapists in private practice in § 410.60(c) of this chapter;

(2) Complies with the special provisions for occupational therapists in private practice in § 410.59(c) of this chapter; or

(3) Complies with the special provisions for speech-language pathologists in private practice in § 410.62(c) of this chapter.

TIN stands for taxpayer identification number.

TKA stands for total knee arthroplasty.

CJR–X Participation

§ 512.610 Mandatory participation.

(a) *General*

(1) CJR–X participants, as defined in § 512.605, must participate in CJR–X, except as specified in paragraph (b) of this section.

(2) CJR–X participants will remain CJR–X participants, unless they no longer meet the definition of CJR–X participant, CMS terminates CJR–X, or the CJR–X participant receives notice of termination from CJR–X in accordance with § 512.610(c).

(b) *Exclusions.* CMS excludes from CJR–X hospitals that meet any of the following criteria:

(1) Is a TEAM participant as defined at § 512.505.

(2) Is located in the State of Maryland.

(c) *CJR–X participant termination from CJR–X.*

(1) CMS may in its sole discretion terminate a CJR–X participant's participation in the model immediately or upon advance notice if CMS determines:

(i) One or more grounds for remedial action described in § 512.160(a) have occurred with respect to the CJR–X participant; or

(ii) The CJR–X participant's continued participation would be inconsistent with the purposes of CJR–X, the requirements of this part, or applicable law.

(2) If a CJR–X participant receives a notification from CMS of termination from CJR–X and wishes to dispute the termination, it must provide a written notice to CMS requesting review of the termination within 10 calendar days of the notice.

(i) CMS has 30 days to respond to the CJR–X participant's request for review.

(ii) If the CJR–X participant fails to provide timely notification to CMS, the termination is deemed final.

(3) Where a participant is terminated from the CJR–X Model, the participant hospital will remain liable for all negative NPRA generated from episodes of care that ended prior to termination.

§ 512.615 CJR–X APM options.

(a) *APM options.* A CJR–X participant may choose either of the following options based on their CEHRT use:

(1) *AAPM option.* A CJR–X participant selects the AAPM option by attesting in a form and manner and by a date specified by CMS to their use of CEHRT, as defined in § 414.1305 of this chapter, on an annual basis prior to the start of each performance year. In addition to submitting an annual CEHRT attestation, the CJR–X participant must:

(i) Provide their CMS electronic health record certification ID in a form and manner and by a date specified by CMS on annual basis prior to the end of each performance year; and

(ii) Retain documentation of their attestation to CEHRT use and provide access to the documentation in accordance with § 512.135.

(2) *Non-AAPM option.* CMS assigns the CJR–X participant to the non-AAPM option if the CJR–X participant does not satisfy the requirements set forth in § 512.615(a)(1).

(b) *Financial arrangements list.* A CJR–X participant with CJR–X collaborators, collaboration agents, or downstream collaboration agents during a performance year must submit to CMS a financial arrangements list in a form and manner and by a date specified by CMS on a quarterly basis for each performance year. The financial arrangements list must include the following:

(1) *CJR–X collaborators.* For each physician, nonphysician practitioner, or therapist who is a CJR–X collaborator during the applicable performance year:

(i) The name, TIN, and NPI of the CJR–X collaborator.

(ii) The start date and, if applicable, end date of the sharing arrangement between the CJR–X participant and the CJR–X collaborator.

(2) *Collaboration agents.* For each physician, nonphysician practitioner, or therapist who is a collaboration agent during the applicable performance year:

(i) The name, TIN, and NPI of the collaboration agent and the name and TIN of the CJR–X collaborator with which the collaboration agent has entered into a distribution arrangement.

(ii) The start date and, if applicable, end date of the distribution arrangement between the CJR–X collaborator and the collaboration agent.

(3) *Downstream collaboration agents.* For each physician, nonphysician practitioner, or therapist who is a downstream collaboration agent during the applicable performance year:

(i) The name, TIN, and NPI of the downstream collaboration agent and the name and TIN of the collaboration agent with which the downstream collaboration agent has entered into a downstream distribution arrangement.

(ii) The start date and, if applicable, end date of the downstream distribution arrangement between the collaboration agent and the downstream collaboration agent.

(c) *Clinician engagement list.* A CJR–X participant must submit to CMS a clinician engagement list in a form and manner and by a date specified by CMS on a quarterly basis during each performance year. The clinician

engagement list must include the following:

(1) For each physician, nonphysician practitioner, or therapist who is not on a CJR–X participant's financial arrangements list during the performance year but who does have a contractual relationship with the CJR–X participant and participates in CJR–X activities during the applicable performance year:

(i) The name, TIN, and NPI of the physician, nonphysician practitioner, or therapist.

(ii) The start date and, if applicable, the end date of the contractual relationship between the physician, nonphysician practitioner, or therapist and the CJR–X participant.

(d) *Attestation to no individuals.* A CJR–X participant with no individuals that meet the criteria specified in paragraphs (b)(1) through (3) of this section for the financial arrangements list or paragraph (c) of this section for the clinician engagement list must attest in a form and manner and by a date specified by CMS that there are no financial arrangements or clinician engagements to report.

(e) *Documentation requirements.* A CJR–X participant that submits a financial arrangements list specified in paragraph (b) of this section or a clinician engagement list specified in paragraph (c) of this section must retain and provide access to the documentation in accordance with § 512.135.

Beneficiary Population

§ 512.620 Beneficiary inclusion criteria.

(a) An individual is a CJR–X beneficiary if, based on a 180-day lookback period that ends on the day prior to an anchor procedure or anchor hospitalization, the individual—

(1) Is enrolled in Medicare Parts A and B;

(2) Has Medicare as their primary payer;

(3) Is not eligible for Medicare on the basis of having end stage renal disease, as described at § 406.13 of this chapter;

(4) Is not enrolled in any managed care plan (for example, Medicare Advantage, health care prepayment plans, or cost-based health maintenance organizations);

(5) Is not covered under a United Mine Workers of America health care plan; and

(6) Is in an episode.

(b) The episode is canceled in accordance with § 512.630(e) if at any time during the episode a beneficiary no longer meets all of the criteria in paragraph (a) of this section.

§ 512.622 Beneficiary notifications.

(a) *CJR–X participant beneficiary notification.*

(1) *Notification to beneficiaries.* Each CJR–X participant must provide written notification to each CJR–X beneficiary of his or her inclusion in the CJR–X Model.

(2) *Timing of notification.* Prior to discharge from either the anchor hospitalization or the anchor procedure, as applicable, the CJR–X participant must provide the CJR–X beneficiary with a beneficiary notification as described in paragraph (a)(4) of this section.

(3) *List of CJR–X beneficiaries who have received a notification.* The CJR–X participant must be able to generate a list of all CJR–X beneficiaries who have received such notification, including the date on which the notification was provided to the CJR–X beneficiary, and provide such list to CMS or its designee upon request.

(4*) Content of notification.* The beneficiary notification must contain all of the following:

(i) A detailed explanation of CJR–X and how it might be expected to affect the CJR–X beneficiary's care.

(ii) That the CJR–X beneficiary retains freedom of choice to choose providers, suppliers, and services.

(iii) Explanation of how the CJR–X beneficiary can access care records and claims data through an available patient portal, if applicable, and how to share access to Blue Button® electronic health information with caregivers.

(iv) Explanation of the type of beneficiary-identifiable claims data the CJR–X participant may receive.

(v) A statement that all existing Medicare beneficiary protections continue to be available to the CJR–X beneficiary. These include the ability to report concerns of substandard care to Quality Improvement Organizations or the 1–800–MEDICARE helpline.

(vi) A list of the CJR–X collaborators with which the CJR–X participant has a sharing arrangement. This requirement may be fulfilled by the CJR–X participant including in the detailed notification a publicly available web address where the CJR–X beneficiary may access the list.

(b) *CJR–X collaborator notice.* The CJR–X participant must require every CJR–X collaborator that furnishes an item or service to a CJR–X beneficiary during an episode to provide written notice, to be developed by CMS, to the CJR–X beneficiary that describes general information on the quality and payment incentives under CJR–X, and the existence of the CJR–X collaborator's sharing arrangement.

(1) The notice must be provided no later than the time at which the CJR–X beneficiary first receives an item or service from the CJR–X collaborator during an episode. In circumstances where, due to the CJR–X beneficiary's condition, it is not feasible to provide notification at such time, the notification must be provided to the CJR–X beneficiary or his or her representative as soon as is reasonably practicable.

(2) The CJR–X collaborator must provide to CMS upon request, a list of all CJR–X beneficiaries who received such a notice, including the date on which the notice was provided to the CJR–X beneficiary.

(c) *Discharge planning notice.* The CJR–X participant must provide the CJR–X beneficiary with a written notice of any potential financial liability associated with non-covered items and services recommended or presented as an option as part of discharge planning, no later than the time that the CJR–X beneficiary discusses a particular post-acute care option or at the time the CJR–X beneficiary is discharged from an anchor procedure or anchor hospitalization, whichever occurs earlier.

(1) If the CJR–X participant knows or should have known that the CJR–X beneficiary is considering or has decided to receive a non-covered post-acute care service or other non-covered associated item or service, the CJR–X participant must notify the CJR–X beneficiary in writing that the item or service would not be covered by Medicare.

(2) If the CJR–X participant is discharging a CJR–X beneficiary to a SNF after an inpatient hospital stay, and the CJR–X beneficiary is being transferred to or is considering a SNF that would not qualify under the SNF 3-day waiver in § 512.695(b), the CJR–X participant must notify the CJR–X beneficiary in accordance with paragraph (b)(1) of this section that the CJR–X beneficiary will be responsible for payment for the items and services furnished by the SNF during that stay, except those items and services that would be covered by Medicare Part B during a non-covered inpatient SNF stay.

(d) *Access to records and retention.* The CJR–X participant must provide access to the list and notice described in paragraphs (a), (b), and (c), of this section to CMS, or its designees, in accordance with § 512.135.

Episode of Care

§ 512.625 Scope of episode.

(a) *Lower extremity joint replacement (LEJR) procedures.* The MS–DRGs and HCPCS codes included in episodes are as follows:

(1) IPPS discharge under MS–DRG 469, 470, 521, or 522.

(2) OPPS claim for HCPCS codes 27130 or 27447.

(b) *Included services.* All Medicare Part A and B items and services are included in the episode, except as specified in paragraph (c) of this section. These items and services include, but are not limited to, the following:

(1) Physicians' services.

(2) Inpatient hospital services (including hospital readmissions).

(3) IPF services.

(4) LTCH services.

(5) IRF services.

(6) SNF services.

(7) HHA services.

(8) Hospital outpatient services.

(9) Outpatient therapy services.

(10) Clinical laboratory services.

(11) DME.

(12) Part B drugs and biologic, except for those excluded under paragraph (c) of this section.

(13) Hospice services.

(14) Part B professional claims dated in the 3 days prior to an anchor hospitalization if a claim for the surgical procedure for the same episode type is not detected as part of the hospitalization because the procedure was performed by the CJR–X participant on an outpatient basis, but the patient was subsequently admitted as an inpatient.

(c) *Excluded services.* The following items, services, and payments are excluded from the episode:

(1) Select items and services considered unrelated to the anchor hospitalization or the anchor procedure for episodes in the baseline period and performance year, including, but not limited to, the following:

(i) Inpatient hospital admissions for MS–DRGs that group to the following categories of diagnoses:

(A) Oncology.

(B) Trauma unrelated to the CJR–X episode.

(C) Organ transplant.

(D) Ventricular shunt.

(ii) Inpatient hospital admissions that fall into the following Major Diagnostic Categories (MDCs):

(A) MDC 02 (Diseases and Disorders of the Eye).

(B) MDC 14 (Pregnancy, Childbirth, and Puerperium).

(C) MDC 15 (Newborns).

(D) MDC 25 (Human Immunodeficiency Virus).

(2) New technology add-on payments, as defined in part 412, subpart F of this chapter for episodes in the baseline period and performance year.

(3) Transitional pass-through payments for medical devices as defined in § 419.66 of this chapter for episodes initiated in the baseline period and performance year.

(4) Hemophilia clotting factors provided in accordance with § 412.115 of this chapter for episodes in the baseline period and performance year.

(5) Part B payments for low-volume drugs, high-cost drugs and biologics, and blood clotting factors for hemophilia for episodes in the baseline period and performance year, billed on outpatient, carrier, and DME claims, defined as—

(i) Drug/biologic HCPCS codes that are billed in fewer than 31 episodes in total across all episodes in CJR–X during the baseline period;

(ii) Drug/biologic HCPCS codes that are billed in at least 31 episodes in the baseline period and have a mean allowed cost of greater than $25,000 per episode in the baseline period; and

(iii) HCPCS codes corresponding to clotting factors for hemophilia patients, identified in the quarterly average sales price file for certain Medicare Part B drugs and biologics as HCPCS codes with clotting factor equal to 1, HCPCS codes for new hemophilia clotting factors not included in the baseline period, and other HCPCS codes identified as hemophilia.

(6) Part B payments for low-volume drugs, high-cost drugs and biologics, and blood clotting factors for hemophilia for episodes initiated in the performance year, billed on outpatient, carrier, and DME claims, defined as—

(i) Drug/biologic HCPCS codes that were not captured in the baseline period and appear in 10 or fewer episodes in the relevant performance year;

(ii) Drug/biologic HCPCS codes that were not included in the baseline period, appear in more than 10 episodes in the relevant performance year, and have a mean cost of greater than $25,000 per episode in the relevant performance year; and

(iii) Drug/biologic HCPCS codes that were not included in the baseline period, appear in more than 10 episodes in the relevant performance year, have a mean cost of $25,000 or less per episode in the relevant performance year, and correspond to a drug/biologic that appears in the baseline period but was assigned a new HCPCS code between the baseline period and the relevant performance year.

(iv) HCPCS codes for new hemophilia clotting factors not included in the baseline period.

(d) *CJR–X exclusions list.* The list of excluded MS–DRGs, MDCs, and HCPCS codes is posted on the CMS website.

(e) *Updating the CJR–X exclusions list.* The list of excluded services is updated through rulemaking to reflect any of the following:

(1) Changes to the MS–DRGs under the IPPS.

(2) Coding changes.

(3) Other issues brought to CMS' attention.

§ 512.630 Determination of the episode.

(a) *Timing of episodes.* Episodes initiated on or after January 1, 2028.

(b) *Episode attribution.* All items and services included in the episode are attributed to the CJR–X participant at which the anchor hospitalization or anchor procedure, as applicable, occurs.

(c) *Episode initiation.* An episode is initiated by—

(1) A beneficiary's admission to a CJR–X participant for an anchor hospitalization that is paid under a MS–DRG specified in § 512.625(a); or

(2) A beneficiary's receipt of an anchor procedure billed under a HCPCS code specified in § 512.625(a). If an anchor hospitalization is initiated on the same day as or within 3 days of an outpatient procedure for the same episode type at the same CJR–X participant, the episode start date will be that of the outpatient procedure rather than the admission date, and an anchor procedure will not be initiated.

(d) *Episode conclusion.*

(1) An episode ends on the 90th day following the date of the anchor procedure or the date of discharge from the anchor hospitalization, as applicable, with the date of the anchor procedure or the date of discharge from the anchor hospitalization being counted as the first day in the 90-day post-discharge period.

(e) *Cancellation of an episode.* The episode is canceled and is not included in the reconciliation calculation as specified in § 512.650 if any of the following occur:

(1) The beneficiary ceases to meet any criterion listed in § 512.620.

(2) The beneficiary dies at any point during the episode.

(3) The episode qualifies for cancellation due to extreme and uncontrollable circumstances. An extreme and uncontrollable circumstance occurs if both of the following criteria are met:

(i) The CJR–X participant has a CCN primary address that—

(A) Is located in an emergency area, as those terms are defined in section

1135(g) of the Act, for which the Secretary has issued a waiver under section 1135; and

(B) Is located in a county, parish, or tribal government designated in a major disaster declaration under the Stafford Act.

(ii) The date of admission to the anchor hospitalization or the date of the anchor procedure is during an emergency period (as defined in section 1135(g) of the Act) or in the 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins.

(4) The beneficiary is in a TEAM episode and receives a LEJR procedure at a CJR–X participant during the 30-day post-discharge period after a TEAM anchor hospitalization or TEAM anchor procedure.

Quality Measures and Composite Quality Score

§ 512.635 Quality measures, composite quality score, and display of quality measures.

(a) *Quality measures.* CMS calculates the quality measures used to evaluate the CJR–X participant's performance using Medicare claims data or patient-reported outcomes data reported under existing CMS quality reporting programs, including but not limited to the Hospital Inpatient Quality Reporting Program and the Hospital Outpatient Quality Reporting Program. The following quality measures are used for public reporting and for determining the CJR–X participant's CQS as described in paragraph (b) of this section:

(1) *For all inpatient episodes:* Hospital-level Risk-Standardized Complication Rate following elective primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (CMIT ID #350).

(2) *For all outpatient episodes:* Hospital Visits within 7 days of Hospital Outpatient Department Surgery (CMIT ID #344, OP–36).

(3) *For all inpatient episodes:* Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS) (CMIT ID #338).

(4) *For all outpatient episodes:* Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Survey (OAS CAHPS) (CMIT #162, OP–46).

(5) *For all inpatient episodes:* Hospital-Level Total Hip and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO–PM) (CMIT ID #1618).

(b) *Calculation of the composite quality score (CQS).* CMS calculates an overall composite quality score during reconciliation, capped at 20 points, for each CJR–X participant for the relevant performance year. The overall composite quality score equals the sum of the inpatient measure composite quality score, as described in paragraph (b)(1) of this section, and the outpatient measure composite quality score, as described in paragraph (b)(2) of this section.

(1) CMS calculates the inpatient measure composite quality score by summing the CJR–X participant's quality performance points for all of the following:

(i) The measure identified in paragraph (a)(1) of this section. This measure is weighted at 50 percent of the inpatient composite quality score.

(ii) The measure identified in paragraph (a)(3) of this section. This measure is weighted at 40 percent of the inpatient composite quality score.

(iii) The measure identified in paragraph (a)(5) of this section. This measure is weighted at 10 percent of the inpatient composite quality score.

(2) CMS calculates the outpatient measure composite quality score by summing the CJR–X participant's quality performance points for all of the following:

(i) The measure identified in paragraphs (a)(2) of this section. This measure is weighted at 50 percent of the outpatient composite quality score.

(ii) The measure identified in paragraphs (a)(4) of this section. This measure is weighted at 40 percent of the outpatient composite quality score.

(iii) The measure identified in paragraph (a)(5) of this section. This measure is weighted at 10 percent of the inpatient composite quality score.

(c) *Quality performance points.* CMS calculates quality performance points for each quality measure based on the CJR–X participant's performance relative to the distribution of performance of all hospitals that are eligible for payment under IPPS and meet the minimum patient case or survey count for that measure.

(1) For the measures described in paragraphs (a)(1) and (a)(2) of this section, CMS assigns the CJR–X participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(i) 10.00 for ≥90th.
(ii) 9.25 for ≥80th and <90th.
(iii) 8.50 for ≥70th and <80th.
(iv) 7.75 for ≥60th and <70th.
(v) 7.00 for ≥50th and <60th.
(vi) 6.25 for ≥40th and <50th.
(vii) 5.50 for ≥30th and <40th.
(viii) 0.00 for <30th.

(2) For the measure described in paragraphs (a)(3) and (a)(4) of this section, CMS assigns the CJR–X participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(i) 8.00 for ≥90th.
(ii) 7.40 for ≥80th and <90th.
(iii) 6.80 for ≥70th and <80th.
(iv) 6.20 for ≥60th and <70th.
(v) 5.60 for ≥50th and <60th.
(vi) 5.00 for ≥40th and <50th.
(vii) 5.40 for ≥30th and <40th.
(viii) 0.00 for <30th.

(3) For the measure described in paragraph (a)(5) of this section, CMS assigns the CJR–X participant's measure value to a performance percentile and then CMS assigns quality performance points based on the following performance percentile scale:

(i) 2.00 for ≥90th.
(ii) 1.85 for ≥80th and <90th.
(iii) 1.70 for ≥70th and <80th.
(iv) 1.55 for ≥60th and <70th.
(v) 1.40 for ≥50th and <60th.
(vi) 1.25 for ≥40th and <50th.
(vii) 1.10 for ≥30th and <40th.
(viii) 0.00 for <30th.

(d) *Exception for hospitals without a measure value.*

(1) If the CJR–X participant is without a measure value that would allow CMS to assign quality performance points for that quality measure, CMS assigns the 50th percentile quality performance points to the CJR–X participant for the individual measure.

(2) A CJR–X participant will not have a measure value for—

(i) The measure described in paragraph (a)(1) of this section, if the CJR–X participant does not meet the minimum 25 patient case count.

(ii) The measure described in paragraph (a)(2) of this section, if the CJR–X participant does not meet the minimum 25 patient case count.

(iii) The measure described in paragraph (a)(3) of this section, if the CJR–X participant does not meet the minimum 100 completed surveys.

(iv) The measure described in paragraph (a)(4) of this section, if the CJR–X participant does not meet the minimum 100 completed surveys.

(v) The measure described in paragraph (a)(5) of this section, if the CJR–X participant does not meet the minimum 25 patient case count.

(e) *Display of quality measures.*

(1) CMS displays quality measure results on the publicly available CMS website that is specific to CJR–X, in a form and manner consistent with other publicly reported measures.

(2) CMS shares quality measures with the CJR–X participant prior to display on the CMS website. Quality measure

performance in performance year 1 will be reported in Calendar Year 2029. Subsequent years will be reported in the year following the performance period.

Pricing Methodology

§ 512.640 Determination of preliminary target prices.

(a) *Preliminary target price application.* CMS establishes preliminary target prices for CJR–X participants for each performance year of the model as follows:

(1) *MS–DRG/HCPCS episode type.* CMS uses the MS–DRGs and, as applicable, HCPCS codes specified in § 512.625(d) when calculating the preliminary target prices for each MS–DRG/HCPCS episode type.

(i) CMS determines a separate preliminary target price for each of the MS–DRGs specified in § 512.625(a)(1).

(ii) Preliminary target prices for MS–DRG 470 include HCPCS 27130 and 27447.

(2) *Applicable time period for preliminary target prices.* CMS calculates preliminary target prices for each MS–DRG/HCPCS episode type and region for each performance year and applies the preliminary target price to each episode based on the episode's date of discharge from the anchor hospitalization or the episode's date of the anchor procedure, as applicable.

(3) *Episodes that begin in one performance year and end in the subsequent performance year.* CMS applies the preliminary target price to the episode based on the date of discharge from the anchor hospitalization or the date of the anchor procedure, as applicable, and reconciles the episode based on the date of discharge from the anchor hospitalization or the date of the anchor procedure.

(4) *Exception for low-volume hospitals.* CJR–X participants with fewer than 31 episodes in the applicable baseline period do not receive preliminary target prices for the upcoming performance year and are not eligible for reconciliation for that performance year.

(b) *Preliminary target price calculation.*

(1) CMS calculates preliminary target prices based on average baseline episode spending for the region where the CJR–X participant is located. The region CMS uses for calculating the preliminary target price corresponds to the U.S. Census Division associated with the primary address of the CCN of the CJR–X participant, and CMS bases the regional episode spending amount on all hospitals within the region, except for those excluded from CJR–X as specified in § 512.610(b).

(2) CMS uses the following baseline periods to determine baseline episode spending:

(i) Performance Year 1: Episodes with anchor hospitalization start dates or anchor procedure dates beginning on or after January 1, 2024 and anchor hospitalization discharge dates or anchor procedure dates between January 1, 2024 and December 31, 2026.

(ii) Performance Year 2 and future performance years: CMS uses the same cadence described in paragraph (i) of this section to roll the baseline period forward a year to construct the baseline period.

(3) CMS calculates the benchmark price as the weighted average of baseline episode spending, applying the following weights:

(i) Baseline episode spending from baseline year 1 is weighted at 17 percent.

(ii) Baseline episode spending from baseline year 2 is weighted at 33 percent.

(iii) Baseline episode spending from baseline year 3 is weighted at 50 percent.

(4) *Exception for high episode spending.* CMS applies a high-cost outlier cap to baseline episode spending at the 99th percentile of regional spending for each of the MS–DRG/HCPCS episode types specified in § 512.640(a)(1) for each baseline year individually.

(5) *Exclusion of incentive programs and add-on payments under existing Medicare payment systems.* CMS excludes certain Medicare incentive programs and add-on payments from baseline episode spending by using, with certain modifications, the CMS Price (Payment) Standardization Detailed Methodology.

(6) *Prospective normalization factor.* Based on the episodes in the baseline period, CMS calculates a prospective normalization factor, at the MS–DRG/HCPCS region level, so that the average of the total risk-adjusted benchmark price does not exceed the average of the total non-risk adjusted benchmark price, by—

(i) Applying risk adjustment multipliers, as specified in § 512.645(a)(1) through (3), to baseline period episodes to calculate the estimated risk-adjusted target price for all performance year episodes; and

(ii) Dividing the mean of the benchmark price for each episode across all hospitals and regions by the mean of the estimated risk-adjusted benchmark price calculated in § 512.640(b)(6)(i) for the same episode types across all hospitals and regions.

(7) *Prospective trend factor.* CMS determines the prospective trend factor for each MS–DRG/HCPCS episode type and region as the average (arithmetic mean) of the multiplier, as calculated in paragraph (7)(i) of this section, for that MS–DRG/HCPCS episode type and region and the national average for that MS–DRG/HCPCS episode type.

(i) CMS calculates a multiplier for each MS–DRG/HCPCS episode type and region and applies that multiplier to the most recent calendar year of the applicable baseline period. CMS calculates the multiplier using linear regression on the logarithmically transformed average regional spending for each MS–DRG/HCPCS episode type in the baseline years at both the regional and national level.

(ii) CMS exponentiates the coefficient from the linear regression (as described in paragraph (7)(i) of this section) to calculate the estimated annual change (where an exponentiated coefficient of 1 signifies no change) in average regional spending for each MS–DRG/HCPCS episode type from year to year.

(8) *Discount factor.* CMS applies a discount factor of 2 percent to the CJR–X participant's preliminary target price.

(9) *Notification of preliminary target prices.* CMS provides written notice, in a form and manner specified by CMS, to the CJR–X participant of its preliminary target prices for each MS–DRG/HCPCS episode type for each region prior to the start of the performance year in which the preliminary target prices apply.

§ 512.645 Determination of reconciliation target prices.

(a) *Risk adjustment factors.* CMS risk adjusts the preliminary target prices calculated in accordance with § 512.640 at the beneficiary level using the following: a CJR–X Hierarchical Condition Category (HCC) count risk adjustment factor, an age bracket risk adjustment factor, a beneficiary economic risk adjustment factor, and the additional factors specified in paragraph (a)(6) of this section, and at the hospital level using a hospital bed size risk adjustment factor and a safety net hospital risk adjustment factor.

(1) The CJR–X HCC count risk adjustment factor uses five variables, representing beneficiaries with zero, one, two, three, or four or more CMS–HCC conditions based on a 180-day lookback period that begins 181 days prior to the anchor hospitalization or anchor procedure and ends on the day prior to the anchor hospitalization or anchor procedure.

(2) The age bracket risk adjustment factor uses four variables, representing beneficiaries in the following age groups as of the first day of the episode:

(i) Less than 65 years.

(ii) 65 to less than 75 years.

(iii) 75 years to less than 85 years.

(iv) 85 years or more.

(3) The beneficiary economic risk adjustment factor uses two variables, representing beneficiaries that, as of the first day of the episode:

(i) Meet one or more of the following economic measures:

(A) National CDI above the 80th percentile.

(B) Eligibility for the low-income subsidy.

(C) Eligibility for full Medicaid benefits.

(ii) Do not meet any of the three economic measures in paragraph (a)(3)(i) of this section.

(4) The hospital bed size risk adjustment factor uses four variables based on the CJR–X participant's characteristics:

(i) 250 beds or fewer.

(ii) 251–500 beds.

(iii) 501–850 beds.

(iv) 851 beds or more.

(5) The safety net hospital risk adjustment factor is based on the CJR–X participant meeting the safety net hospital definition in § 512.605.

(6) Additional beneficiary level risk adjustment factors represent the presence or absence in beneficiaries, based on a 180-day lookback period that ends on the day prior to the anchor hospitalization or anchor procedure, of each of the following conditions:

(i) Ankle procedure or reattachment, partial hip procedure, partial knee arthroplasty, total hip arthroplasty or hip resurfacing procedure, and total knee arthroplasty.

(ii) Disability as the original reason for Medicare enrollment.

(iii) Prior post-acute care use.

(iv) HCC 17: Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic.

(v) HCC 36: Diabetes with Severe Acute Complications.

(vi) HCC 37: Diabetes with Chronic Complications.

(vii) HCC 48: Morbid Obesity.

(viii) HCC 125: Dementia, Severe.

(ix) HCC 126: Dementia, Moderate.

(x) HCC 127: Dementia, Mild or Unspecified.

(xi) HCC 151: Schizophrenia.

(xii) HCC 155: Major Depression, Moderate or Severe, without Psychosis.

(xiii) HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia.

(xiv) HCC 224: Acute on Chronic Heart Failure.

(xv) HCC 225: Acute Heart Failure (Excludes Acute on Chronic).

(xvi) HCC 226: Heart Failure, Except End-Stage and Acute.

(xvii) HCC 238: Specified Heart Arrhythmias.

(xviii) HCC 253: Hemiplegia/Hemiparesis.

(xix) HCC 267: Deep Vein Thrombosis and Pulmonary Embolism.

(xx) HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders.

(xxi) HCC 326: Chronic Kidney Disease, Stage 5.

(xxii) HCC 327: Chronic Kidney Disease, Severe (Stage 4).

(xxiii) HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle.

(xxiv) HCC402: Hip Fracture/Dislocation.

(b) *Timing and data used for risk adjustment.* CMS uses 3 years of baseline period data, as described under § 512.640(b)(2)(i) and (ii), to compute all risk adjustment factors prior to the start of the performance year through a linear regression analysis.

(c) *Risk adjustment coefficients.* CMS produces exponentiated coefficients through the annual linear regression analysis to determine the anticipated marginal effect of each risk adjustment factor on episode costs. CMS transforms, or exponentiates, these coefficients, and the resulting coefficients are the beneficiary and hospital-level risk adjustment factors, specified in paragraphs (a)(1) through (6) of this section, that CMS uses during reconciliation for the subsequent performance year.

(d) *Applying risk adjustment at reconciliation.* At the time of reconciliation, CMS risk adjusts the preliminary target prices calculated under § 512.640 by applying the applicable beneficiary level and hospital-level risk adjustment factors specific to the beneficiary in the episode, as set forth in paragraphs (a)(1) through (6) of this section.

(e) *Normalization factor update.* CMS normalizes the risk-adjusted preliminary target prices at reconciliation so that the average of the total risk-adjusted preliminary target price does not exceed the average of the total non-risk adjusted preliminary target price.

(1) The final normalization factor at reconciliation—

(i) Is the mean benchmark price for each MS–DRG/HCPCS episode type and region divided by the mean risk-adjusted benchmark price for the same MS–DRG/HCPCS episode type and region.

(ii) As applied, cannot exceed +/− 5 percent of the prospective normalization factor (as specified in § 512.640(b)(6)).

(2) CMS applies the final normalization factor to the previously calculated, beneficiary-level, risk-adjusted preliminary target prices specific to each region and MS–DRG/HCPCS episode type.

(f) *Trend factor update.* CMS calculates a multiplier for each MS–DRG/HCPCS episode type and region and applies the multiplier at reconciliation to the most recent calendar year of the applicable baseline period. CMS calculates the multiplier as the average regional capped performance year episode spending for each MS–DRG/HCPCS episode type divided by the average regional capped baseline period episode spending for each MS–DRG/HCPCS episode type.

(1) CMS caps the retrospective trend factor so that the maximum difference cannot exceed ±3 percent of the prospective trend factor (as specified in § 512.640(b)(7)).

(2) CMS applies the capped retrospective trend factor to the previously calculated normalized, risk adjusted preliminary target prices specific to each region and MS–DRG/HCPCS episode type, as specified in paragraph (e)(2) of this section.

(g) *Payment system changes.* CMS revises preliminary target prices, as calculated under § 512.640, when determining reconciliation target prices to account for calendar year and fiscal year payment rule updates that occur after preliminary target prices are determined.

(h) *Quality adjustment to discount factor.* CMS calculates a composite quality score as specified at § 512.635(b) and adjusts the discount factor specified at § 512.640(b)(8) to calculate the reconciliation target prices, which are compared to performance year spending at reconciliation, as specified in § 512.650(c) as follows:

(1) A CJR–X participant with excellent composite quality scores, defined as composite quality scores greater than or equal to 17.1, receives a 0.0 discount factor.

(2) A CJR–X participant with good composite quality scores, defined as composite quality scores greater than or equal to 12.1 and less than or equal to 17.0, receives a 1.0 discount factor.

(3) A CJR–X participant with acceptable composite quality scores, defined as composite quality scores greater than or equal to 6.1 and less than or equal to 12.0, receives a 2.0 discount factor.

(4) A CJR–X participant with below acceptable composite quality scores, defined as composite quality scores less than or equal to 6.0, receives a 2.0 discount factor and are ineligible to receive a reconciliation payment, as specified in § 512.650(d).

§ 512.650 Reconciliation process and determination of the reconciliation payment or repayment amount.

(a) *General.* Providers and suppliers furnishing items and services included in the episode bill for such items and services in accordance with existing Medicare rules.

(b) *Reconciliation process.*

(1) Six months after the end of each performance year, CMS performs a reconciliation calculation to establish a reconciliation payment or repayment amount for each CJR–X participant in the applicable performance year as described in paragraph (c) of this section.

(2) For CJR–X participants that experience a reorganization event in which one or more hospitals reorganize under the CCN of a CJR–X participant, CMS performs both of the following:

(i) Separate reconciliation calculations for each predecessor CJR–X participant for episodes where the anchor hospitalization admission or the anchor procedure occurred before the effective date of the reorganization event.

(ii) Reconciliation calculations for each new or surviving CJR–X participant for episodes where the anchor hospitalization admission or anchor procedure occurred on or after the effective date of the reorganization event.

(c) *Calculation of the Net Payment Reconciliation Amount (NPRA).* CMS compares the reconciliation target prices described in § 512.645 and the CJR–X participant's performance year spending to establish an NPRA for the CJR–X participant for each performance year as follows:

(1) CMS determines the performance year spending for each episode included in the performance year (other than episodes that have been canceled in accordance with § 512.630(b)) for each MS–DRG/HCPCS episode type using claims data that is available 6 months after the end of the performance year.

(2) CMS calculates and applies the high-cost outlier cap for performance year episode spending by applying the calculation described in § 512.640(b)(4) to performance year episode spending for each MS–DRG/HCPCS episode type.

(3) CMS applies the adjustments specified in § 512.645 to the preliminary target prices calculated in accordance with § 512.640 to determine the reconciliation target prices for each MS–DRG/HCPCS episode type.

(4) CMS aggregates the reconciliation target prices determined in accordance with paragraph (c)(3) of this section for all episodes included in the performance year (other than episodes that have been canceled in accordance with § 512.630(b)).

(5) CMS aggregates the adjusted performance year spending amounts determined in paragraphs (c)(1) through (2) of this section and subtracts the resulting amount from the aggregated reconciliation target price amount determined in paragraphs (c)(3) through (4) of this section.

(6) CMS applies stop-loss and stop-gain limits to the amount calculated in paragraph (c)(5) of this section as follows:

(i) *Limitation on loss.* For CJR–X participants, except as provided in paragraph (d)(3) of this section, the repayment amount for a performance year cannot exceed 20 percent of the aggregated reconciliation target price amount calculated in paragraph (c)(4) of this section for the performance year. The post-episode spending calculation amount in paragraph (c)(7) of this section is not subject to the limitation on loss.

(ii) *Limitation on gain.* For CJR–X participants, the reconciliation payment amount for a performance year cannot exceed 20 percent of the aggregated reconciliation target price amount calculated in paragraph (c)(4) of this section for the performance year. The post-episode spending amount calculated in paragraph (c)(7) of this section is not subject to the limitation on gain.

(iii) *Additional limitation on loss for certain hospitals.* The repayment amount for the following types of CJR–X participants as defined at § 512.605, cannot exceed 5 percent of the aggregated reconciliation target price amount calculated in paragraph (c)(4) of this section:

(A) Medicare-dependent, small rural hospital (MDH).

(B) Rural hospital.

(C) Safety net hospital.

(D) Sole community hospital (SCH).

(7) CMS calculates the post-episode spending amount. If the average post-episode spending amount for a CJR–X participant in the performance year being reconciled is greater than 3 standard deviations above the regional average post-episode spending amount for the performance year, then the post-episode spending amount that exceeds 3 standard deviations above the regional average post-episode spending amount for the performance year is subtracted from the NPRA for that performance year.

(d) *Reconciliation payment amount or repayment amount.*

(1) Excluding CJR–X participants that receive a below acceptable composite quality score, as specified in § 512.645(h), if the amount calculated in paragraph (c) of this section is positive, CMS pays the CJR–X participant a reconciliation payment equal to the amount described in paragraph (c) of this section.

(2) If the amount calculated in paragraph (c) of this section is negative, the CJR–X participant for the applicable performance year must pay to CMS a repayment equal to the amount described in paragraph (c) of this section.

(e) *CJR–X reconciliation report.* CMS issues each CJR–X participant a CJR–X reconciliation report for the performance year. Each CJR–X reconciliation report contains the following:

(1) The total performance year spending for the CJR–X participant.

(2) The CJR–X participant's reconciliation target prices.

(3) The CJR–X participant's reconciliation amount.

(4) The CJR–X participant's composite quality score calculated in accordance with § 512.635(b).

(5) The CJR–X participant's quality-adjusted reconciliation amount.

(6) The stop-loss and stop-gain limits that apply to the CJR–X participant.

(7) The CJR–X participant's NPRA.

(8) The CJR–X participant's post-episode spending amount, if applicable.

(9) The reconciliation payment amount or repayment amount for the performance year, if applicable.

§ 512.652 Treatment of incentive programs or add-on payments under existing Medicare payment systems.

(a) The CJR–X Model does not replace any existing Medicare incentive programs or add-on payments. The CJR–X payments are independent of, and do not affect, any incentive programs or add-on payments under existing Medicare payment systems.

§ 512.655 Proration of payments for items and services that extend beyond an episode.

(a) *General.* CMS prorates items and services included in the episode that extend beyond the episode so that only those portions of the items and services that were furnished during the episode are included in the calculation of the actual episode payments.

(b) *Proration of items and services.* CMS prorates payments for items and

services that extend beyond the episode for the purposes of calculating both baseline episode spending and performance year spending using the following methodology:

(1) *Non-IPPS inpatient items and services.* Non-IPPS inpatient items and services that extend beyond the end of the episode are prorated according to the percentage of the actual length of stay (in days) that falls within the episode.

(2) *Home health agency items and services.* Home health agency items and services paid under the Medicare prospective payment system in accordance with part 484, subpart E of this chapter that extend beyond the episode are prorated according to the percentage of days, starting with the first billable service date and through and including the last billable service date, that occur during the episode.

(3) *IPPS items and services.* IPPS items and services that extend beyond the end of the episode are prorated according to the MS–DRG geometric mean length of stay, using the following methodology:

(i) The first day of the IPPS stay is counted as 2 days.

(ii) If the actual length of stay that occurred during the episode is equal to or greater than the MS–DRG geometric mean, the full MS–DRG payment is allocated to the episode.

(iii) If the actual length of stay that occurred during the episode is less than the MS–DRG geometric mean length of stay, the MS–DRG payment amount is allocated to the episode based on the number of inpatient days that fall within the episode.

(4) If the full amount of the payment is not allocated to the episode, any remainder amount is allocated to the post-episode spending calculation (defined in § 512.650(c)(7)).

§ 512.660 Appeals process.

(a) *General.* Subject to the limitations on review in § 512.170, the CJR–X participant may submit a notice of calculation error for one or more calculations involving a matter related to payment, reconciliation payment amounts, repayment amounts, the use of quality measure results in determining the composite quality score, or the application of the composite quality score during reconciliation.

(b) *Requirements.*

(1) If the CJR–X participant identifies a calculation error as described in paragraph (a) of this section, the CJR–X participant must submit written notice of the error, in a form and manner specified by CMS, within 30 days of the issuance of the reconciliation report.

(2) If the CJR–X participant does not provide timely written notice of calculation error, CMS deems the CJR–X reconciliation report to be final 30 days after it is issued and proceeds with the payment or repayment processes as applicable.

(3) Only CJR–X participants may use this calculation error process.

(c) *Process.*

(1) If CMS determines the timely error notice meets the requirements of this section and contains sufficient information to substantiate the request, CMS issues an initial determination in writing within 30 days of receipt to either confirm that there was an error in the calculation or verify that the calculation is correct.

(2) CMS reserves the right to extend the time for providing its initial final determination upon written notice to the CJR–X participant.

(3) If the request is not compliant with the requirements of this section or requires additional information—

(i) CMS contacts the CJR–X participant to request additional information in a form and manner as specified by CMS;

(ii) The CJR–X participant must respond within 10 days of CMS' request for additional information in a form and manner as specified by CMS; and

(iii) If a CJR–X participant does not respond in accordance with paragraph (c)(3)(ii) of this section, then the reconciliation report is deemed final.

(d) *Reconsideration request.* A CJR–X participant who wishes to dispute an initial determination made in accordance with paragraph (c) of this section may invoke the reconsideration review process under § 512.190.

Data Sharing

§ 512.665 Data sharing with CJR–X participants.

(a) *General.* CMS shares certain beneficiary-identifiable data as described in paragraphs (b), (c), and (e) of this section and certain regional aggregate data as described in paragraph (d) of this section with CJR–X participants regarding CJR–X beneficiaries and performance under the model, consistent with applicable law.

(b) *Beneficiary-identifiable claims data.* CMS shares beneficiary-identifiable claims data with CJR–X participants as follows:

(1) CMS makes available certain beneficiary-identifiable claims data described in paragraph (5) of this section for CJR–X participants to request for purposes of conducting health care operations work that falls within paragraph (1) or (2) of the definition of health care operations at 45 CFR 164.501 regarding their CJR–X beneficiaries.

(2) A CJR–X participant that wishes to receive beneficiary-identifiable claims data for its CJR–X beneficiaries must:

(i) Submit a formal request for the data on an annual basis in a manner and form and by a date specified by CMS, indicating their selection of summary beneficiary-identifiable data, raw beneficiary-identifiable data, or both, and attest that—

(A) The CJR–X participant is requesting claims data of CJR–X beneficiaries who would be in an episode during the baseline period or performance year, as a HIPAA covered entity.

(B) The CJR–X participant's request reflects the minimum data necessary, as set forth in paragraph (c) of this section, for the CJR–X participant to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

(C) The CJR–X participant's use of claims data will be limited to developing processes and engaging in appropriate activities related to coordinating care, improving the quality and efficiency of care, and conducting population-based activities relating to improving health or reducing health care costs that are applied uniformly to all CJR–X beneficiaries, in an episode during the baseline period or performance year, and that these data will not be used to reduce, limit or restrict care for specific Medicare beneficiaries.

(ii) Sign and submit a CJR–X data sharing agreement, as defined in § 512.605, with CMS as set forth in paragraph (e) of this section.

(3) CMS shares this beneficiary-identifiable claims data with a CJR–X participant in accordance with applicable privacy and security laws and established privacy and security protections.

(4) CMS omits from the beneficiary-identifiable claims data any information that is subject to the regulations in 42 CFR part 2 governing the confidentiality of substance use disorder patient records.

(5) The beneficiary-identifiable claims data will include, when available, the following:

(i) Unrefined (raw) Medicare Parts A and B beneficiary-identifiable claims data for CJR–X beneficiaries in an episode during the 3-year baseline period and performance year.

(ii) Summarized (summary) Medicare Parts A and B beneficiary-identifiable claims data for CJR–X beneficiaries in

an episode during the 3-year baseline period and applicable performance year.

(6) CMS makes available the beneficiary-identifiable claims data for retrieval by CJR–X participants at the following frequency:

(i) Annually, at least one month prior to every performance year for baseline period data, based on the baseline periods described in § 512.640(b)(2).

(ii) As frequently as monthly during the performance year and for up to 6 months after the performance year for performance year data.

(c) *Minimum necessary data.* The CJR–X participant must limit its request for beneficiary-identifiable data under paragraph (b) of this section to the minimum necessary Parts A and B data elements which may include, but are not limited to the following:

(1) Medicare beneficiary identifier (ID).

(2) Procedure code.

(3) Sex.

(4) Diagnosis code.

(5) Claim ID.

(6) The from and through dates of service.

(7) The provider or supplier ID.

(8) The claim payment type.

(9) Date of birth and death, if applicable.

(10) Tax identification number.

(11) National provider identifier.

(d) *Regional aggregate data.*

(1) CMS shares regional aggregate data for the 3-year baseline period and relevant performance year with CJR–X participants as follows.

(i) CMS shares 3-year baseline period regional aggregate data annually at least 1 month before the relevant performance year, based on the baseline periods described in § 512.640(b)(2).

(ii) CMS shares performance year regional aggregate data as frequently as a monthly basis during the applicable performance year and for up to 6 months after the relevant performance year.

(2) Regional aggregate data will—

(i) Be aggregated based on all Parts A and B claims associated with episodes in CJR–X for the U.S. Census Division in which the CJR–X participant is located;

(ii) Summarize average episode spending for episodes in CJR–X in the U.S. Census Division in which the CJR–X participant is located; and

(iii) Be de-identified in accordance with 45 CFR 164.514(b).

(e) *CJR–X data sharing agreement.*

(1) A CJR–X participant who wishes to retrieve the beneficiary-identifiable data specified in paragraph (b) of this section, must complete and submit, on at least an annual basis, a signed CJR–X data sharing agreement, as defined in § 512.605, to be provided in a form and manner and by a date specified by CMS, under which the CJR–X participant agrees:

(i) To comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA Privacy Rule (45 CFR part 160 and subparts A and E of part 164), HIPAA Breach Notification Rule (45 CFR subpart D of part 164) and the requirements of the CJR–X set forth in this part.

(ii) To comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the CJR–X data sharing agreement.

(iii) To contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the CJR–X participant to the same terms and conditions to which the CJR–X participant is itself bound in its CJR–X data sharing agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data retrieved by the CJR–X participant under the CJR–X.

(iv) That if the CJR–X participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may deem the CJR–X participant ineligible to retrieve beneficiary-identifiable data under paragraph (b) of this section for any amount of time, and the CJR–X participant may be subject to additional sanctions and penalties available under the law.

(2) A CJR–X participant must comply with all applicable laws and the terms of the CJR–X data sharing agreement in order to retrieve the beneficiary-identifiable data.

Financial Arrangements and Beneficiary Incentives

§ 512.670 Sharing arrangements.

(a) *General.*

(1) A CJR–X participant may enter into a sharing arrangement with a CJR–X collaborator to make a gainsharing payment, or to receive an alignment payment, or both. A CJR–X participant must not make a gainsharing payment to a CJR–X collaborator, or receive an alignment payment from a CJR–X collaborator, except in accordance with a sharing arrangement.

(2) A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) CJR–X participants must develop, maintain, and use a set of written policies for selecting individuals and entities to be CJR–X collaborators.

(i) These policies must contain criteria related to, and inclusive of, the quality of care delivered by the potential CJR–X collaborator and the provision of CJR–X activities.

(ii) The selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, collaboration agent, or downstream collaboration agent.

(iii) A selection criterion that considers whether a potential CJR–X collaborator has performed a reasonable minimum number of services that would qualify as CJR–X activities, as determined by the CJR–X participant, will be deemed not to violate the volume or value standard if the purpose of the criterion is to ensure the quality of care furnished to CJR–X beneficiaries.

(4) If a CJR–X participant enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of CJR–X.

(b) *Requirements.*

(1) A sharing arrangement must be in writing and signed by the parties, and entered into before care is furnished to CJR–X beneficiaries under the sharing arrangement.

(2) Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

(3) The sharing arrangement must require the CJR–X collaborator and its employees, contractors (including collaboration agents), and subcontractors (including downstream collaboration agents) to comply with all of the following:

(i) The applicable provisions of this part 512 (including requirements regarding beneficiary notifications in § 512.622, access to records in § 512.135(b), record retention in § 512.135(c), and participation in any evaluation, monitoring, compliance in § 512.130, and enforcement activities performed by CMS or its designees in § 512.160).

(ii) All applicable Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement.

(iii) All other applicable laws and regulations.

(4) The sharing arrangement must require the CJR–X collaborator to have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of CJR–X that apply to its role as a CJR–X collaborator, including any distribution arrangements.

(5) The sharing arrangement must not potentially or actually negatively impact beneficiary access, beneficiary freedom of choice, or quality of care.

(6) The board or other governing body of the CJR–X participant must have responsibility for overseeing the CJR–X participant's participation in CJR–X, its arrangements with CJR–X collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the CJR–X Model.

(7) The specifics of the agreement must be documented in writing and must be made available to CMS upon request (as outlined in § 512.150).

(8) The sharing arrangement must specify the following:

(i) The purpose and scope of the sharing arrangement.

(ii) The obligations of the parties, including specified CJR–X activities and other services, to be performed by the parties under the sharing arrangement.

(iii) The date range for which the sharing arrangement is effective.

(iv) The financial or economic terms for payment, including the following:

(A) Eligibility criteria for a gainsharing payment.

(B) Eligibility criteria for an alignment payment.

(C) Frequency of gainsharing or alignment payments.

(D) Methodology and accounting formula for determining the amount of a gainsharing payment or alignment payment.

(9) The sharing arrangement must not do either of the following:

(i) Induce the CJR–X participant, CJR–X collaborator, or any employees, contractors, or subcontractors of the CJR–X participant or CJR–X collaborator to reduce or limit medically necessary services to any Medicare beneficiary.

(ii) Restrict the ability of a CJR–X collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

(c) *Gainsharing payment, alignment payment, and internal cost savings conditions and restrictions.*

(1) Gainsharing payments, if any, must—

(i) Be derived solely from reconciliation payment amounts, or internal cost savings, or both;

(ii) Be distributed on an annual basis (not more than once per calendar year);

(iii) Not be a loan, advance payment, or payment for referrals or other business; and

(iv) Be clearly identified as a gainsharing payment at the time it is paid.

(2) Gainsharing payment eligibility-

(i) To be eligible to receive a gainsharing payment, a CJR–X collaborator must meet quality of care criteria for the performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment. The quality of care criteria must be established by the CJR–X participant and directly relate to the episode.

(ii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR–X collaborator other than ACO, PGP, NPPGP, or TGP, must have directly furnished a billable item or service to a CJR–X beneficiary during an episode that was attributed to the same performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment.

(iii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR–X collaborator that is a PGP, NPPGP, or TGP, must meet the following criteria:

(A) The PGP, NPPGP, or TGP, must have billed for an item or service that was rendered by one or more PGP member, NPPGP member, or TGP member, respectively to a CJR–X beneficiary during an episode that was attributed to the same performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment.

(B) The PGP, NPPGP, or TGP, must have contributed to CJR–X activities and been clinically involved in the care of CJR–X beneficiaries during the same performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment. A non-exhaustive list of examples where a PGP, NPPGP, or TGP might have been clinically involved in the care of CJR–X beneficiaries includes—

(*1*) Providing care coordination services to CJR–X beneficiaries during or after inpatient admission;

(*2*) Engaging with a CJR–X participant in care redesign strategies, and performing a role in implementing such strategies, that are designed to improve the quality of care for episodes and reduce episode spending; or

(*3*) In coordination with other providers and suppliers (such as PGP members, NPPGP members, or TGP members the CJR–X participant; and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR–X beneficiaries.

(iv) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR–X collaborator that is an ACO must meet the following criteria:

(A) The ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was rendered to a CJR–X beneficiary during an episode that was attributed to the same performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment; and

(B) The ACO must have contributed to CJR–X activities and been clinically involved in the care of CJR–X beneficiaries during the performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment. A non-exhaustive list of ways in which an ACO might have been clinically involved in the care of CJR–X beneficiaries could include—

(*1*) Providing care coordination services to CJR–X beneficiaries during or after inpatient admission;

(*2*) Engaging with a CJR–X participant in care redesign strategies and performing a role in implementing such strategies that are designed to improve the quality of care and reduce spending for episodes; or

(*3*) In coordination with providers and suppliers (such as ACO participants, ACO providers/suppliers, the CJR–X participant, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR–X beneficiaries.

(3) The methodology for accruing, calculating, and verifying internal cost

savings will be determined by the CJR–X participant. The methodology—

(i) Must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(ii) Used to calculate internal cost savings that reflect the actual, internal cost savings achieved by the CJR–X participant through the documented implementation of CJR–X activities identified by the CJR–X participant and must exclude—

(A) Any savings realized by any individual or entity that is not the CJR–X participant; and

(B) ''Paper'' savings from accounting conventions or past investment in fixed costs.

(4) The amount of any gainsharing payments must be determined in accordance with a methodology that is based solely on quality of care and the provision of CJR–X activities. The methodology may take into account the amount of CJR–X activities provided by a CJR–X collaborator relative to other CJR–X collaborators.

(5) For a performance year, the aggregate amount of all gainsharing payments that are derived from reconciliation payment amounts must not exceed the amount of that year's reconciliation payment amount.

(6) No entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, collaboration agent, or downstream collaboration agent.

(7) A CJR–X participant must not make a gainsharing payment to a CJR–X collaborator if CMS has notified the CJR–X participant that such CJR–X collaborator is subject to any action by CMS, HHS or any other governmental entity, or its designees, for noncompliance with this part or the fraud and abuse laws, for the provision of substandard care to CJR–X beneficiaries or other integrity problems, or for any other program integrity problems or noncompliance with any other laws or regulations.

(8) The sharing arrangement must require the CJR–X participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation payment amount or was based on the submission of false or fraudulent data.

(9) Alignment payments from a CJR–X collaborator to a CJR–X participant may be made at any interval that is agreed upon by both parties, and must not be—

(i) Issued, distributed, or paid prior to the calculation by CMS of a repayment amount;

(ii) Loans, advance payments, or payments for referrals or other business; or

(iii) Assessed by a CJR–X participant in the absence of a repayment amount.

(10) The CJR–X participant must not receive any amounts under a sharing arrangement from a CJR–X collaborator that are not alignment payments.

(11) For a performance year, the aggregate amount of all alignment payments received by the CJR–X participant must not exceed 50 percent of the CJR–X participant's repayment amount.

(12) The aggregate amount of all alignment payments from a CJR–X collaborator to the CJR–X participant may not be greater than with respect to a CJR–X collaborator—

(i) Other than an ACO, 25 percent of the CJR–X participant's repayment amount; or

(ii) That is an ACO, 50 percent of the CJR–X participant's repayment amount.

(13) The amount of any alignment payments must be determined in accordance with a methodology that does not directly account for the volume or value of past or anticipated referrals or business otherwise generated by, between or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, collaboration agent, or downstream collaboration agent.

(14) All gainsharing payments and any alignment payments must be administered by the CJR–X participant in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(15) All gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(d) *Documentation requirements.*

(1) CJR–X participants must—

(i) Document the sharing arrangement contemporaneously with the establishment of the arrangement;

(ii) Post (and update on at least a quarterly basis) on a publicly available web page on the CJR–X participant's website the following:

(A) Accurate lists of all current CJR–X collaborators, including the CJR–X collaborators' names and addresses as well as accurate historical lists of all CJR–X collaborators.

(B) Written policies for selecting individuals and entities to be CJR–X collaborators as required by § 512.670(a)(3).

(iii) Maintain, and require each CJR–X collaborator to maintain, contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes all of the following, at a minimum:

(A) Nature of the payment (gainsharing payment or alignment payment).

(B) Identity of the parties making and receiving the payment.

(C) Date of the payment.

(D) Amount of the payment.

(E) Date and amount of any recoupment of all or a portion of a CJR–X collaborator's gainsharing payment.

(F) Explanation for each recoupment, such as whether the CJR–X collaborator received a gainsharing payment that contained funds derived from a CMS overpayment of a reconciliation payment or was based on the submission of false or fraudulent data.

(2) The CJR–X participant must keep records of all of the following:

(i) A process for determining and verifying its potential and current CJR–X collaborators' eligibility to participate in Medicare.

(ii) A plan to track internal cost savings.

(iii) Information on the accounting systems used to track internal cost savings.

(iv) A description of current health information technology, including systems to track reconciliation payment amounts, repayment amounts, and internal cost savings.

(v) A plan to track gainsharing payments and alignment payments.

(3) The CJR–X participant must retain and provide access to, and require each CJR–X collaborator to retain and provide access to, the required documentation in accordance with § 512.135.

§ 512.675 Distribution arrangements.

(a) *General.*

(1) An ACO, PGP, NPPGP, or TGP, that is a CJR–X collaborator and has entered into a sharing arrangement with a CJR–X participant may distribute all or a portion of any gainsharing payment it receives from the CJR–X participant only in accordance with a distribution arrangement.

(2) All distribution arrangements must comply with the provisions of this

section and all other applicable laws and regulations, including the fraud and abuse laws.

(b) *Requirements.*

(1) All distribution arrangements must be in writing and signed by the parties, contain the effective date of the agreement, and be entered into before care is furnished to CJR–X beneficiaries under the distribution arrangement.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any distribution payments from an ACO, from an NPPGP to an NPPGP member, or from a TGP to a TGP member, must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR–X activities and that may take into account the amount of such CJR–X activities provided by a collaboration agent relative to other collaboration agents.

(6) The amount of any distribution payments from a PGP must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR–X activities and that may take into account the amount of such CJR–X activities provided by a collaboration agent relative to other collaboration agents.

(7) A collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to a CJR–X beneficiary during an episode that was attributed to the same performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment amount that comprises the gainsharing payment being distributed.

(8) With respect to the distribution of any gainsharing payment received by an ACO, PGP, NPPGP, or TGP, the total amount of all distribution payments for a performance year must not exceed the amount of the gainsharing payment received by the CJR–X collaborator from the CJR–X participant for the same performance year.

(9) All distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(10) The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(11) The distribution arrangement must not do either of the following:

(i) Induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary.

(ii) Reward the provision of items and services that are medically unnecessary.

(12) The CJR–X collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.135, including all of the following:

(i) The relevant written agreements.

(ii) The date and amount of any distribution payment(s).

(iii) The identity of each collaboration agent that received a distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any distribution payment.

(13) The CJR–X collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same CJR–X participant.

(14) The CJR–X collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.135.

§ 512.680 Downstream distribution arrangements.

(a) *General.*

(1) An ACO participant that is a PGP, NPPGP, or TGP and that has entered into a distribution arrangement with a CJR–X collaborator that is an ACO, may distribute all or a portion of any distribution payment it receives from the CJR–X collaborator only in accordance with a downstream distribution arrangement.

(2) All downstream distribution arrangements must comply with the provisions of this section and all applicable laws and regulations, including the fraud and abuse laws.

(b) *Requirements.*

(1) All downstream distribution arrangements must be in writing and signed by the parties, contain the effective date of the agreement, and be entered into before care is furnished to CJR–X beneficiaries under the downstream distribution arrangement.

(2) Participation in a downstream distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the CJR–X participant, any CJR–X collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a CJR–X participant, CJR–X collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any downstream distribution payments from an NPPGP to an NPPGP member or from a TGP to a TGP member must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR–X activities and that may take into account the amount of such CJR–X activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(6) The amount of any downstream distribution payments from a PGP must be determined in accordance with a methodology that is solely based on quality of care and the provision of CJR–X activities and that may take into account the amount of such CJR–X activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(7) A downstream collaboration agent is eligible to receive a downstream distribution payment only if the downstream collaboration agent furnished an item or service to a CJR–X beneficiary during an episode that is attributed to the same performance year for which the CJR–X participant accrued the internal cost savings or earned the reconciliation payment amount that comprises the gainsharing payment from which the ACO made the distribution payment to the PGP, NPPGP, or TGP that is an ACO participant.

(8) The total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the amount of the distribution payment received by the PGP, NPPGP, or TGP from the ACO.

(9) All downstream distribution payments must be made by check,

electronic funds transfer, or another traceable cash transaction.

(10) The downstream collaboration agent must retain his or her ability to make decisions in the best interests of the beneficiary, including the selection of devices, supplies, and treatments.

(11) The downstream distribution arrangement must not do either of the following:

(i) Induce the downstream collaboration agent to reduce or limit medically necessary services to any Medicare beneficiary.

(ii) Reward the provision of items and services that are medically unnecessary.

(12) The PGP, NPPGP, or TGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 512.135, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any downstream distribution payment.

(iii) The identity of each downstream collaboration agent that received a downstream distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

(13) The PGP, NPPGP, or TGP may not enter into a downstream distribution arrangement with any PGP member, NPPGP member, or TGP member who has—

(i) A sharing arrangement with a CJR–X participant.

(ii) A distribution arrangement with the ACO that the PGP, NPPGP, or TGP is a participant in.

(14) The PGP, NPPGP, or TGP must retain and provide access to, and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 512.135.

§ 512.685 CJR–X beneficiary incentives.

(a) *General.* CJR–X participants may choose to provide in-kind patient engagement incentives including but not limited to items of technology to CJR–X beneficiaries in an episode, subject to the following conditions:

(1) The incentive must be provided directly by the CJR–X participant or by an agent of the CJR–X participant under the CJR–X participant's direction and control to the CJR–X beneficiary during an episode.

(2) The item or service provided must be reasonably connected to medical care provided to a CJR–X beneficiary during an episode.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as listed in paragraph (c) of this section, for a CJR–X beneficiary in an episode by engaging the CJR–X beneficiary in better managing his or her own health.

(4) The item or service must not be tied to the receipt of items or services outside the episode.

(5) The item or service must not be tied to the receipt of items or services from a particular provider or supplier.

(6) The availability of the items or services must not be advertised or promoted, except that a CJR–X beneficiary may be made aware of the availability of the items or services at the time the CJR–X beneficiary could reasonably benefit from them.

(7) The cost of the items or services must not be shifted to any federal health care program, as defined at section 1128B(f) of the Act.

(b) *Technology provided to a CJR–X beneficiary.* CJR–X beneficiary engagement incentives involving technology are subject to the following additional conditions:

(1) Items or services involving technology provided to a CJR–X beneficiary may not exceed $1,000 in retail value for any one CJR–X beneficiary during any one episode.

(2) Items or services involving technology provided to a CJR–X beneficiary must be the minimum necessary to advance a clinical goal, as listed in paragraph (c) of this section, for a beneficiary in an episode.

(3) Items of technology exceeding $75 in retail value must—

(i) Remain the property of the CJR–X participant; and

(ii) Be retrieved from the CJR–X beneficiary at the end of the episode, with documentation of the ultimate date of retrieval. The CJR–X participant must document all retrieval attempts. In cases when the item of technology is not able to be retrieved, the CJR–X participant must determine why the item was not retrievable. If it was determined that the item was misappropriated (if it were sold, for example), the CJR–X participant must take steps to prevent future beneficiary incentives for that CJR–X beneficiary. Following this process, documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

(c) *Clinical goals of CJR–X.* The following are the clinical goals of CJR–X, which may be advanced through CJR–X beneficiary incentives:

(1) Beneficiary adherence to drug regimens.

(2) Beneficiary adherence to a care plan.

(3) Reduction of readmissions and complications following an episode.

(4) Management of chronic diseases and conditions that may be affected by the CJR–X procedure.

(d) *Documentation of CJR–X beneficiary incentives.*

(1) CJR–X participants must maintain documentation of items and services furnished as beneficiary incentives that exceed $25 in retail value.

(2) The documentation must be established contemporaneously with the provision of the items and services with a record established and maintained to include at least the following:

(i) The date the incentive is provided.

(ii) The identity of the CJR–X beneficiary to whom the item or service was provided.

(3) The documentation regarding items of technology exceeding $75 in retail value must also include contemporaneous documentation of any attempt to retrieve technology at the end of an episode, or why the items were not retrievable, as described in paragraph (b)(3) of this section.

(4) The CJR–X participant must retain and provide access to the required documentation in accordance with § 512.135.

§ 512.690 Application of the CMS-sponsored Model Arrangements and Patient Incentives Safe Harbor.

(a) *Application of the CMS-sponsored model arrangements safe harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)(1)) is available to protect remuneration furnished in CJR–X in the form of the sharing arrangement's gainsharing payments and alignment payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and § 512.670, in the form of the distribution arrangement's distribution payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and § 512.675, and in the form of the downstream distribution arrangement's distribution payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and § 512.680.

(b) *Application of the CMS-sponsored model patient incentives safe harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect CJR–X beneficiary incentives that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and 512.685.

Medicare Program Waivers

§ 512.695 CJR–X Medicare Program Waivers.

(a) *Waiver of certain telehealth requirements.*

(1) *Waiver of the geographic site requirements.* Except for the geographic site requirements for a face-to-face encounter for home health certification, CMS waives the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act for episodes being tested in CJR–X solely for services that—

(i) May be furnished via telehealth under existing Medicare program requirements; and

(ii) Are included in the episode in accordance with § 512.625(e).

(2) *Waiver of the originating site requirements.* Except for the originating site requirements for a face-to-face encounter for home health certification, CMS waives the originating site requirements under section 1834(m)(4)(C)(ii)(I) through (X) of the Act for episodes to permit a telehealth visit to originate in the beneficiary's home or place of residence solely for services that—

(i) May be furnished via telehealth under existing Medicare program requirements; and

(ii) Are included in the episode in accordance with § 512.625(e).

(3) *Waiver of selected payment provisions.*

(i) CMS waives the payment requirements under section 1834(m)(2)(B) of the Act so that the facility fee normally paid by Medicare to an originating site for a telehealth service is not paid if the service originated in the beneficiary's home or place of residence.

(ii) CMS waives the payment requirements under section 1834(m)(2)(A) of the Act to allow the distant site payment for telehealth home visit HCPCS codes unique to CJR–X.

(4) *Other requirements.* All other requirements for Medicare coverage and payment of telehealth services continue to apply, including the list of specific services approved to be furnished by telehealth.

(b) *Waiver of the SNF 3-day rule.*

(1) *Episodes initiated by an anchor hospitalization.* CMS waives the SNF 3-day rule for coverage of a SNF stay within 30 days of the date of discharge from the anchor hospitalization for a beneficiary who is a CJR–X beneficiary on the date of discharge from the anchor hospitalization if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR–X beneficiary's admission to the SNF.

(2) *Episodes initiated by an anchor procedure.* CMS waives the SNF 3-day rule for coverage of a SNF stay within 30 days of the date of service of the anchor procedure for a beneficiary who is a CJR–X beneficiary on the date of service of the anchor procedure if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR–X beneficiary's admission to the SNF.

(3) *Determination of qualified SNFs.* CMS determines the qualified SNFs for each calendar quarter based on a review of the most recent rolling 12 months of overall star ratings on the Five-Star Quality Rating System for SNFs on the Nursing Home Compare website.

(i) Qualified SNFs are rated an overall of 3 stars or better for at least 7 of the 12 months.

(ii) Qualified SNFs include providers furnishing SNF services under swing bed agreements, which will not be subject to the star ratings requirement.

(4) *Posting of qualified SNFs.* CMS posts to the CMS website the list of qualified SNFs in advance of the calendar quarter.

(5) *Financial liability for non-covered SNF services.* If CMS determines that the waiver requirements specified in paragraph (b) of this section were not met, the following apply:

(i) CMS makes no payment to a SNF for SNF services if the SNF admits a CJR–X beneficiary who has not had a qualifying anchor hospitalization or anchor procedure.

(ii) In the event that CMS makes no payment for SNF services furnished by a SNF as a result of paragraph (b)(5)(i) of this section, the beneficiary protections specified in paragraph (b)(5)(iii) of this section apply, unless the CJR–X participant has provided the beneficiary with a discharge planning notice in accordance with § 512.622(c).

(iii) If the CJR–X participant does not provide the beneficiary with a discharge planning notice in accordance with § 512.622(c)—

(A) The SNF must not charge the beneficiary for the expenses incurred for such services;

(B) The SNF must return to the beneficiary any monies collected for such services; and

(C) The CJR–X participant is financially liable for the expenses incurred for such services.

(4) If the CJR–X participant provided a discharge planning notice to the beneficiary in accordance with § 512.622(c), then normal SNF coverage requirements apply and the beneficiary may be financially liable for non-covered SNF services.

(6) *Other requirements.* All other Medicare rules for coverage and payment of Part A-covered services continue to apply except as otherwise waived in this part.

(c) *Waiver of direct supervision requirement for certain post-discharge home visits.*

(1) *General.* CMS waives the requirement in § 410.26(b)(5) of this chapter that services and supplies furnished incident to a physician's service must be furnished under the direct supervision of the physician (or other practitioner) to permit home visits as specified in this section. The services furnished under this waiver are not considered to be ''hospital services,'' even when furnished by the clinical staff of the hospital.

(2) *General supervision of qualified personnel.* The waiver of the direct supervision requirement in § 410.26(b)(5) of this chapter applies only in the following circumstances:

(i) The home visit is furnished during the episode to a CJR–X beneficiary who has been discharged from an anchor hospitalization or anchor procedure.

(ii) The home visit is furnished at the CJR–X beneficiary's home or place of residence.

(iii) The CJR–X beneficiary does not qualify for home health services under sections 1835(a) and 1814(a) of the Act at the time of any such home visit.

(iv) The visit is furnished by clinical staff under the general supervision of a physician or non-physician practitioner. Clinical staff are individuals who work under the supervision of a physician or other qualified health care professional, and who are allowed by law, regulation, and facility policy to perform or assist in the performance of a specific professional service, but do not individually report that professional service.

(v) No more than 9 visits are furnished to the CJR–X beneficiary during the episode.

(3) *Payment.* Up to 9 post-discharge home visits per CJR–X episode may be billed under Part B by the physician or nonphysician practitioner or by the CJR–X participant to which the supervising physician has reassigned his or her billing rights.

(4) *Other requirements.* All other Medicare rules for coverage and payment of services incident to a physician's service continue to apply.

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 48. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C 300jj–14; 5 U.S.C. 552.

■ 49. Section 170.215 is amended by revising paragraphs (j), (k), (m), and (n) to read as follows:

§ 170.215 Application Programming Interface Standards.

* * * * *

(j) *Prior authorization*—(1) *Coverage requirements discovery*—(i) *Implementation specification.* HL7 FHIR® Da Vinci—Coverage Requirements Discovery IG [Implementation Guide], Version 2.2.1–STU 2.2 (incorporated by reference in § 170.299).

(ii) [Reserved]

(2) *Prior authorization documentation*—(i) *Implementation specification.* HL7 FHIR® Da Vinci—Documentation Templates and Rules Implementation Guide, Version 2.2.0–STU 2.2 (incorporated by reference in § 170.299).

(ii) [Reserved]

(3) *Prior authorization submission*—(i) *Implementation specification.* HL7 FHIR® Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.2.1–STU 2.2 (incorporated by reference in § 170.299).

(ii) [Reserved]

(k) *Payer data exchange*—(1) *Blue button*—(i) *Implementation specification.* HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) [Implementation Guide], Version 2.2.0–STU 2.2 (incorporated by reference in § 170.299).

(ii) [Reserved]

(2) *Payer data exchange*—(i) *Implementation specification.* HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Implementation Guide, Version 2.1.0–STU 2.1 (incorporated by reference in § 170.299).

(ii) [Reserved]

(3) *Clinical data exchange*—(i) *Implementation specification.* HL7 FHIR® Da Vinci Clinical Data Exchange (CDex) IG [Implementation Guide], Version 2.1.0–STU 2.1 (incorporated by reference in § 170.299).

* * * * *

(m) *Drug formulary*—(1) *Implementation specification.* HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.1.0–STU 2.1 (incorporated by reference in § 170.299).

(2) [Reserved]

(n) *Directory information*—(1) *Implementation specification.* HL7 FHIR® Da Vinci PDex [Payer Data Exchange] Plan Net Implementation Guide, Version 1.2.0–STU 1.2 (incorporated by reference in § 170.299).

(2) [Reserved]

■ 50. Section 170.299 is amended by revising paragraphs (g)(41) through (44), (46) and (47), and adding paragraph (50) to read as follows:

§ 170.299 Incorporation by reference.

* * * * *

(g) * * *

(41) HL7 FHIR® Da Vinci—Coverage Requirements Discovery IG [Implementation Guide], Version 2.2.1–STU 2.2, Generated March 27, 2026; IBR approved for § 170.215(j).

(42) HL7 FHIR® Da Vinci—Documentation Templates and Rules Implementation Guide, Version 2.2.0–STU 2.2, Generated March 27, 2026; IBR approved for § 170.215(j).

(43) HL7 FHIR® Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.2.1–STU 2.2, Generated March 27, 2026; IBR approved for § 170.215(j).

(44) HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) [Implementation Guide], Version 2.2.0–STU 2.2, Generated March 27, 2026; IBR approved for § 170.215(k).

* * * * *

(46) HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.1.0–STU 2.1, Generated February 26, 2025; IBR approved for § 170.215(m).

(47) HL7 FHIR® Da Vinci PDex [Payer Data Exchange] Plan Net Implementation Guide, Version 1.2.0–STU 1.2, Generated February 25, 2025; IBR approved for § 170.215(n).

* * * * *

(50) HL7 FHIR® Da Vinci Clinical Data Exchange (CDex) IG [Implementation Guide], Version 2.1.0–STU 2.1, Generated February 11, 2025; IBR approved for § 170.215(k).

* * * * *

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning On or After October 1, 2026, and Payment Rates for LTCHs Effective for Discharges Occurring On or After October 1, 2026

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2027 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2027. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this final rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that would be effective for cost reporting periods beginning on or after October 1, 2026. In addition, we are setting forth a description of the methods and data we used to determine the LTCH PPS standard Federal payment rate that would be applicable to Medicare LTCHs for FY 2027.

In general, except for SCHs and MDHs, for FY 2027, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment:

- The Federal national rate (including, as discussed in section IV.E. of the preamble of this final rule, uncompensated care payments under section 1886(r)(2) of the Act).
- The updated hospital-specific rate based on FY 1982 costs per discharge.
- The updated hospital-specific rate based on FY 1987 costs per discharge.
- The updated hospital-specific rate based on FY 1996 costs per discharge.
- The updated hospital-specific rate based on FY 2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically were paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section

5003(a)(1) of Public Law 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor. Section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 extended the MDH program through FY 2025. As discussed in section V.F. of the preamble of this final rule, section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75) extended the MDH program for FY 2027 discharges occurring before January 1, 2027. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2027. We refer readers to section V.F. of the preamble of this final rule for further discussion of the MDH program.

As discussed in section V.B.2. of the preamble of this final rule, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. In general, Puerto Rico hospitals are paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update. Accordingly, our discussion later in this section does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum of this final rule, we are making changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2027. In section III. of this Addendum of this final rule, we discuss our policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2027. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2027. In section V. of this Addendum, we discuss policy changes for determining the LTCH PPS standard Federal rate for LTCHs paid under the LTCH PPS for FY 2027. The tables to which we refer in the preamble of this final rule are listed in section VI. of this Addendum and are available via the internet on the CMS website.

II. Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2027

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. In this section, we discuss the factors we are using for determining the prospective payment rates for FY 2027.

In summary, the standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the internet on the CMS website) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2027, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount.

We refer readers to section VI.B. of the preamble of this final rule for a complete discussion on the FY 2027 inpatient hospital update. The table that follows shows these four scenarios:

FY 2027 APPLICABLE PERCENTAGE INCREASE FOR THE IPPS				
FY 2027	**Hospital Submitted Quality Data and is a Meaningful EHR User**	**Hospital Submitted Quality Data and is NOT a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User**
Market Basket Rate-of-Increase	3.2	3.2	3.2	3.2
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	-0.8	-0.8
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.4	0.0	-2.4
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.9	-0.9	-0.9	-0.9
Applicable Percentage Increase Applied to Standardized Amount	**2.3**	**-0.1**	**1.5**	**-0.9**

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico. In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users for FY 2027 and subsequent fiscal years is adjusted by the adjustment for failure to be a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act. The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to the standardized amount to ensure budget neutrality for the permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, as discussed in section II.D.2.c. of the preamble of this final rule, consistent with our current methodology for implementing DRG recalibration and

reclassification budget neutrality under section 1886(d)(4)(C)(iii) of the Act.

- An adjustment to ensure the wage index and labor-related share changes (depending on the fiscal year) are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act (as discussed in the FY 2006 IPPS final rule (70 FR 47395) and the FY 2010 IPPS final rule (74 FR 44005)). We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2026 budget neutrality factor and applying a revised factor.
- An adjustment to the standardized amount to implement in a budget neutral manner the wage index cap policy (as described in section III.G.5 of the preamble of this final rule).
- Using our authority under section 1886(d)(5)(I)(i) of the Act, an adjustment to the standardized amount to implement in a budget neutral manner the transition for the discontinuation of the low wage index hospital policy (as described in section III.F.6 of the preamble of this final rule).
- An adjustment to remove the FY 2026 outlier offset and apply an offset for FY 2027, as provided for in section 1886(d)(3)(B) of the Act.

We note, in section VI.N. of the preamble of this final rule, we discuss the Rural Community Hospital Demonstration (RCHD) program. In past years, we made an adjustment to ensure the effects of the RCHD program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. As discussed in that section, as we are not yet able to finalize the FY 2027 estimated costs of the demonstration at this time, we did not propose to apply a budget neutrality offset in the FY 2027 IPPS/LTCH PPS proposed rule. Rather, we are finalizing as proposed to apply budget neutrality offsets for both FY 2027 and FY 2028 to the national IPPS rates in the FY 2028 IPPS/LTCH PPS rulemaking. We would also incorporate any statutory change that might affect the methodology for determining hospital costs either with or without the demonstration. We refer the reader to section VI.N. of the preamble of this final rule for complete details.

For FY 2027, consistent with current law, we are applying the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we are applying a uniform, national budget neutrality adjustment to the FY 2027 wage index for the rural floor.

For FY 2027, we are continuing to not remove the Stem Cell Acquisition Budget Neutrality Factor from the prior year's standardized amount and to not apply a new factor. If we removed the prior year's adjustment, we would not satisfy budget neutrality. We believe this approach ensures the effects of the reasonable cost-based payment for allogeneic hematopoietic stem cell acquisition costs under section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) are budget neutral as required under section 108 of Public Law 116–94. For a discussion of Stem Cell Acquisition Budget Neutrality Factor, we refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 59032 and 59033).

A. Calculation of the Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983, interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2027, we are continuing to use the national labor-related and nonlabor-related shares (which are based on the 2023-based hospital IPPS market basket) that were used in FY 2026. Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2027, as discussed in section III.H. of the preamble of this final rule, as proposed, we are finalizing to use a labor-related share of 66.0 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, as proposed, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this final rule and are available via the internet on the CMS website.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage increase. Accordingly, we are calculating the FY 2027 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, we are using the 2023-based IPPS operating and capital market baskets for FY 2027. As discussed in section VI.B. of the preamble of this final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are reducing the FY 2027 applicable percentage increase (which for this final rule is based on IGI's second quarter 2026 forecast of the 2023-based IPPS market basket) by the productivity adjustment, as discussed elsewhere in this final rule.

Based on IGI's second quarter 2026 forecast of the IPPS hospital market basket percentage increase (as discussed in appendix B of this final rule), the forecast of the hospital market basket percentage increase for FY 2027 for this final rule is 3.2 percent and the forecast of the productivity adjustment for FY 2027 for this final rule is 0.9 percentage point. As discussed earlier, for FY 2027, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that can be applied to the standardized amount. We refer readers to section VI.B. of the preamble of this final rule for a complete discussion on the FY 2027 inpatient hospital update to the standardized amount. We also refer readers to the previous table for the four possible applicable percentage increases that would be applied to update the national standardized amounts. The standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the internet on the CMS website reflect these differential amounts.

Although the update factors for FY 2027 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2027 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal Register** for public comment. Our recommendation on the FY 2027 update factors is set forth in appendix B of this final rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the FY 2027 standardized amount is as follows:

• To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we applied the following inclusion and exclusion criteria: include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); exclude CAHs and Rural Emergency Hospitals (REHs) at the time of this final rule (we finalized to remove REHs in the calculation of the standardized amount in the FY 2025 IPPS/LTCH final rule (89 FR 69941–69942); exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS excluded-cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.

• As in the past, we are adjusting the FY 2027 standardized amount to remove the effects of the FY 2027 geographic reclassifications and outlier payments before applying the FY 2027 updates. We then applied budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on FY 2027 payment policies.

• We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

• Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).

• Consistent with our methodology established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57277), in order to further ensure that we capture only FFS claims, we are excluding claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We are removing organ acquisition charges, except for cases that group to MS–DRG 018, from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS. Revenue centers 081X–089X are typically excluded from ratesetting, however, we are not removing revenue center 891 charges from MS–DRG 018 claims during ratesetting because those revenue 891 charges were included in the relative weight calculation for MS–DRG 018, which is consistent with the policy finalized in the FY 2021 final rule (85 FR 58600). We note that a new MedPAR variable for revenue code 891 charges was introduced in April 2020.

• For FY 2027, we are continuing to remove allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842).

• Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, consistent with the approach we have taken in prior years, for FY 2027, we are applying a proxy based on the prior fiscal year hospital readmissions payment adjustment and a proxy based on the prior fiscal year hospital VBP payment adjustment on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). Under this policy for FY 2027, we used the final FY 2026 readmissions adjustment factors from Table 15 of the FY 2026 IPPS/LTCH PPS final rule and the final FY 2026 hospital VBP adjustment factors from Table 16B of the FY 2026 IPPS/LTCH PPS final rule. These proxy factors are applied on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum. We refer the reader to section V.K. of the preamble of this final rule for a complete discussion on the Hospital Readmissions Reduction Program and section V.L. of the preamble of this final rule for a complete discussion on the Hospital VBP Program.

• The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, is available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

Consistent with prior fiscal years, we are including the estimated empirically justified Medicare DSH payments that would be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we considered estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

We also are including the estimated supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

• When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.G. of the preamble to this final rule and later in this section, we are continuing to use the FY 2014 finalized methodology under which we take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are including estimated uncompensated care payments in this comparison.

As discussed elsewhere in this final rule, section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75) extended the MDH program for FY 2027 discharges occurring before January 1, 2027. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2027. In the proposed rule we stated that approximately 80 hospitals would receive additional payments under the MDH program for the first quarter of FY 2027. Given the limited magnitude, we proposed not to include this extension in the total payments for budget neutrality. Therefore, for purposes of the proposed rule's calculations, we computed payments under the Federal national rate (not including 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate as applicable) for the total payments for these hospitals in the budget neutrality calculations discussed in this same section in the proposed rule and we accounted for uncompensated care payments in the computation of total payments under the Federal rate. We did not receive any comments on this proposal. We are finalizing as proposed not to include this extension in the total payments for budget neutrality. Therefore, as stated previously, for this final rule, we computed payments under the Federal national rate (not including 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate as applicable) for the total payments for these hospitals in the budget neutrality calculations discussed in this section and we accounted for uncompensated care payments in the computation of total payments under the Federal rate.

• As proposed, we included an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2027. Similar to FY 2026, we are including this adjustment based on data on the prior year's performance. Payments for hospitals would be estimated based on the applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2027.

• In our determination of all budget neutrality factors described in section II.A.4. of this Addendum, we used transfer-adjusted discharges.

We note, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49414 through 49415), we finalized a change to the ordering of the budget neutrality factors in the calculation so that the RCH Demonstration budget neutrality factor (if applicable to the fiscal year) is applied after all wage index and other budget neutrality factors. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion.

a. Reclassification and Recalibration of MS–DRG Relative Weights Before Cap

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.D. of the preamble of this final rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For this FY 2027 final rule, as we proposed, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2025 discharge data to simulate payments and compared the following:

• Aggregate payments using the FY 2026 labor-related share percentages, the FY 2026 relative weights, and the FY 2026 pre-reclassified wage data, and applied the proxy hospital readmissions payment adjustments and proxy hospital VBP payment adjustments (as described previously); and

• Aggregate payments using the FY 2026 labor-related share percentages, the FY 2027 relative weights before applying the 10-percent cap, and the FY 2026 pre-reclassified wage data, and applied the same proxy hospital readmissions payment adjustments and proxy hospital VBP payment adjustments applied previously.

Because this payment simulation uses the FY 2027 relative weights (before applying the 10-percent cap), consistent with our policy in section V.I. of the preamble to this final rule, we are applying the adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. We note that because the simulations of payments for all of the budget neutrality factors discussed in this section also use the FY 2027 relative weights, we are applying the adjustor for certain MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell and other immunotherapies) cases in all simulations of payments for the budget neutrality factors discussed later in this section. We refer the reader to section V.I. of the preamble of this final rule for a complete discussion on the adjustor for certain cases that group to MS–DRG 018 and to section II.D.2.b. of the preamble of this final rule, for a complete discussion of the adjustment to the FY 2027 relative weights to account for certain cases that group to MS–DRG 018.

Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we are applying the MS–DRG reclassification and recalibration budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2026. Please see the table later in this section setting forth each of the FY 2027 budget neutrality factors.

b. Budget Neutrality Adjustment for Reclassification and Recalibration of MS–DRG Relative Weights With Cap

As discussed in section II.D.2.c. of the preamble of this final rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48897 through 48900), we finalized a permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. As also discussed in section II.D.2.c. of the preamble of this final rule, and consistent with our current methodology for implementing budget neutrality for MS–DRG reclassification and recalibration of the relative weights under section 1886(d)(4)(C)(iii) of the Act, we apply a budget neutrality adjustment to the standardized amount for all hospitals so that this 10-percent cap on relative weight reductions does not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied this cap. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion.

To calculate this budget neutrality adjustment factor for FY 2027, we used FY 2025 discharge data to simulate payments and compared the following:

• Aggregate payments using the FY 2026 labor-related share percentages, the FY 2027 relative weights before applying the 10-percent cap, and the FY 2026 pre-reclassified wage data, and applied the proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments (as described previously); and

• Aggregate payments using the FY 2026 labor-related share percentages, the FY 2027 relative weights after applying the 10-percent cap, and the FY 2026 pre-reclassified wage data, and applied the same proxy FY 2027 hospital readmissions payment adjustments and proxy FY 2027 hospital VBP payment adjustments applied previously.

Because this payment simulation uses the FY 2027 relative weights, consistent with the proposal finalized in section V.I. of the preamble to this final rule and our historical policy, and as discussed in the preceding section, we applied the adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments.

In addition, we applied the MS–DRG reclassification and recalibration budget neutrality adjustment factor before the cap

(derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2026 to FY 2027. Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we are applying this budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2026. Please see the table later in this section setting forth each of the FY 2027 budget neutrality factors.

c. Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index, or budget neutral.

Section 1886(d)(3)(E)(i) of the Act directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs that are attributable to wages and wage-related costs of the diagnosis related group (DRG) prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. In the FY 2026 IPPS/LTCH PPS final rule (90 FR 36869 through 36873), we finalized a labor-related share of 66.0 percent for discharges occurring on or after October 1, 2025. For FY 2027, we are continuing to use a labor-related share of 66.0 percent for discharges occurring on or after October 1, 2026. Section 1886(d)(3)(E)(ii) of the Act provides that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share results in a higher payment. (We refer the reader to section III.H of the preamble of this final rule for a complete discussion about the labor-related share).

As discussed in section III.H of the preamble of this final rule, for FY 2027, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2027, we are applying the wage index to a labor-related share of 66.0 percent of the national standardized amount.

Section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act (among other provisions) had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent.

Section 1886(d)(3)(E)(i) of the Act provides for the collection of data at least every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, to construct an occupational mix adjustment to the wage index. Consistent with current policy, for FY 2027, we are adjusting 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.D of the preamble of this final rule.

To compute a budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2025 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2027 relative weights and the FY 2026 pre-reclassified wage indexes, applied the FY 2026 labor-related share of 66.0 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the proxy hospital readmissions payment adjustment and the proxy hospital VBP payment adjustment (as described previously).
- Aggregate payments using the FY 2027 relative weights and the FY 2027 pre-reclassified wage indexes, applied the labor-related share for FY 2027 of 66.0 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same proxy FY 2027 hospital readmissions payment adjustments and proxy FY 2027 hospital VBP payment adjustments applied previously.

In addition, we applied the MS–DRG reclassification and recalibration budget neutrality adjustment factor before the cap (derived in the first step) and the 10-percent cap on relative weight reductions adjustment factor (derived from the second step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2026 to FY 2027. Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount for changes to the wage index. Please see the table later in this section for a summary of the FY 2027 budget neutrality factors.

d. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note, in the FY 2024 IPPS/LTCH final rule (88 FR 58971 through 58977), we finalized a policy beginning with FY 2025 to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and only exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with the previous policy, beginning with FY 2024, we include the data of all § 412.103 hospitals (including those that have an MGCRB reclassification) in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

We refer the reader to the FY 2015 IPPS final rule (79 FR 50371 and 50372) for a complete discussion regarding the requirement of section 1886(d)(8)(C)(iii) of the Act. We further note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) of the Act shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the budget neutrality adjustment factor for FY 2027, we used FY 2025 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2027 labor-related share percentage, the FY 2027 relative weights, and the FY 2027 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments (as described previously).
- Aggregate payments using the FY 2027 labor-related share percentage, the FY 2027 relative weights, and the FY 2027 wage data after such reclassifications, and applied the same proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments applied previously.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this final rule, which is available via the internet on the CMS website. This table reflects reclassification crosswalks for FY 2027 and applies the policies explained in section III of the preamble of this final rule. Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount to ensure that the effects of these provisions are budget neutral, consistent with the statute. Please see the table later in this section for a summary of the FY 2027 budget neutrality factors.

The FY 2027 budget neutrality adjustment factor was applied to the standardized

amount after removing the effects of the FY 2026 budget neutrality adjustment factor. We note that the FY 2027 budget neutrality adjustment reflects FY 2027 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this final rule.

e. Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) are equal to the aggregate prospective payments that would have been made in the absence of this provision. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G of the preamble of this final rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor is a national adjustment to the wage index.

In fiscal years in which there are no hospitals in rural Puerto Rico with wage data, similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), we calculate a national rural Puerto Rico wage index. In such years, our calculation of the national rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we use the unweighted average of the wage indexes from all urban areas that are contiguous to (share a border with) the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Based on the current labor market area delineations used for the wage index, all Puerto Rico urban areas are contiguous to a rural area. Therefore, the national rural Puerto Rico wage index is calculated based on the average of the FY 2027 wage indexes for the following urban areas: Aguadilla, PR (CBSA 10380); Arecibo, PR (CBSA 11640), Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660); and San Juan-Bayamon-Caguas, PR (CBSA 41980).

We note, in the FY 2024 IPPS/LTCH final rule (88 FR 58971–77), we finalized a policy beginning with FY 2025 to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations and to only exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with the previous policy, beginning with FY 2024, we include the data of all § 412.103 hospitals (including those that have an MGCRB reclassification) in the calculation of the rural floor.

To calculate the national rural floor budget neutrality adjustment factor, we used FY 2025 discharge data to simulate payments, and the post-reclassified national wage indexes and compared the following:

- National simulated payments without the rural floor.
- National simulated payments with the rural floor.

Based on this comparison, we determined a national rural floor budget neutrality adjustment factor. The national adjustment was applied to the national wage indexes to produce rural floor budget neutral wage indexes. Please see the table later in this section for a summary of the FY 2027 budget neutrality factors.

As further discussed in section III.G.2 of this final rule, section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), enacted on March 11, 2021, amended section 1886(d)(3)(E)(i) of the Act (42 U.S.C. 1395ww(d)(3)(E)(i)) and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index (or imputed floor) for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Unlike the imputed floor that was in effect from FY 2005 through FY 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Specifically, section 9831(b) of Public Law 117–2 amends section 1886(d)(3)(E)(i) of the Act to exclude the imputed floor from the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act. In the past, we budget neutralized the estimated increase in payments each year resulting from the imputed floor that was in effect from FY 2005 through FY 2018. For FY 2022 and subsequent years, in applying the imputed floor required under section 1886(d)(3)(E)(iv) of the Act, we are applying the imputed floor after the application of the rural floor and would apply no reductions to the standardized amount or to the wage index to fund the increase in payments to hospitals in all-urban States resulting from the application of the imputed floor. We refer the reader to section III.G.2 of the preamble of this final rule for a complete discussion regarding the imputed floor.

f. Permanent Cap Policy for Wage Index—Budget Neutrality Adjustment

As noted previously, in section III.G.6 of the preamble to this final rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021) we finalized a policy to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. We also finalized the application of this permanent cap policy in a budget neutral manner through an adjustment to the standardized amount to ensure that estimated aggregate payments under our wage index cap policy for hospitals that will have a decrease in their wage indexes for the upcoming fiscal year of more than 5 percent will equal what estimated aggregate payments would have been without the permanent cap policy.

To calculate a wage index cap budget neutrality adjustment factor for FY 2027, we used FY 2025 discharge data to simulate payments and compared the following:

- Aggregate payments without the 5-percent cap using the FY 2027 labor-related share percentages and the FY 2027 relative weights, and applied the proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments (as described previously).
- Aggregate payments with the 5-percent cap using the FY 2027 labor-related share percentages and the FY 2027 relative weights, and applied the same proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments applied previously.

g. Continued Transition for the Discontinuation of the Low Wage Index Hospital Policy Budget Neutrality Factor

In the FY 2025 interim final action with comment period (IFC) (89 FR 80405 through 80421), we recalculated the FY 2025 IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. We also removed the low wage index budget neutrality factor from the FY 2025 standardized amounts. For FY 2026 and subsequent fiscal years, consistent with the FY 2025 IFC, after considering the D.C. Circuit's decision in *Bridgeport Hospital* v. *Becerra,* we discontinued the low wage index hospital policy and the application of the low wage index budget neutrality factor to the standardized amounts.

For FY 2025 and FY 2026, consistent with our past practice to establish temporary transition policies to mitigate short-term instability and payment fluctuations, we established transition policies for hospitals significantly impacted by the discontinuation of the low wage index hospital policy using our authority under section 1886(d)(5)(I) of the Act. The transitional payment exception for FY 2025 for those hospitals was equal to the additional FY 2025 amount a hospital would have been paid under the IPPS if its FY 2025 wage index were equal to 95 percent of its FY 2024 wage index. The transitional payment exception for FY 2026 was equal to the additional FY 2026 amount the hospital would be paid under the IPPS if its FY 2026 wage index were equal to 90.25 percent of its FY 2024 wage index.[723] For FY 2025, we opted not to budget neutralize the interim transition policy given the timing of the *Bridgeport Hospital* v. *Becerra* decision. However, for FY 2026, we finalized a payment transition with a budget neutrality adjustment through notice-and-comment rulemaking for hospitals facing significant reductions over two years that would not be sufficiently mitigated by the wage index cap policy at 42 CFR 412.64(h)(7). We refer readers to the FY 2025 IFC (89 FR 80405 through 80421) and to the FY 2026 IPPS/LTCH PPS Final Rule (90 FR 36855 through 36857) for a full discussion of these transitional payment policies.

Some hospitals that previously benefitted from the low wage index hospital policy would continue to experience decreases of approximately 5 percent or more per year from their FY 2024 wage index (with the low wage index hospital policy applied). Therefore, we are finalizing as proposed to extend the transitional exception to the calculation payments for FY 2027 for these hospitals in the same manner as we did for the FY 2026 wage index. As noted previously, in section III.G.6 of the preamble to this final rule, for FY 2027 we are finalizing as proposed to use our authority under section 1886(d)(5)(I)(i) of the Act twice. First, we are adopting a narrow

[723] 90.25 percent = 95 percent for FY 2025 * 95 percent for FY 2026. This can also be expressed as .95 − 2.

transitional exception to the calculation of FY 2027 IPPS payments for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy. Second, we are exercising our authority again to do so in a budget neutral manner. To calculate the transition wage index budget neutrality adjustment factor for FY 2027, we used FY 2025 discharge data to simulate payments and compared the following:

- Aggregate payments without the transition for the discontinuation of the low wage index hospital policy, the 5-percent cap using the FY 2027 labor-related share percentages, the FY 2027 relative weights, and applied the proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments (as described previously).
- Aggregate payments with the transition for the discontinuation of the low wage index hospital policy, the 5-percent cap using the FY 2027 labor-related share percentages the FY 2027 relative weights, and applied the same proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments applied previously.

This FY 2027 budget neutrality adjustment factor was applied to the standardized amount.

We note, Table 2 associated with this final rule contains the wage index by provider before and after applying the 5 percent cap and the transition for the discontinuation of the low wage index hospital policy.

The following table is a summary of the FY 2027 budget neutrality factors, as discussed in the previous sections.

SUMMARY OF FY 2027 BUDGET NEUTRALITY FACTORS	
MS-DRG Reclassification and Recalibration Budget Neutrality Factor	0.998748
Cap Policy MS-DRG Weights Budget Neutrality Factor	0.999730
Wage Index Budget Neutrality Factor	1.000312
Reclassification Budget Neutrality Factor	0.949363
*Rural Floor Budget Neutrality Factor	0.973492
Cap Policy Wage Index Budget Neutrality Factor	0.999379
Continued Transition for the Discontinuation of the Low Wage Index Hospital Policy Budget Neutrality Factor	0.999777

*The rural floor budget neutrality factor is applied to the national wage indexes while the rest of the budget neutrality adjustments are applied to the standardized amounts.

h. Request for Information on Potential IPPS Payment Adjustments for Changes in Coding and Classification

Section 1886(d)(4) of the Act requires that the Secretary establish a classification of inpatient hospital discharges by DRG and a methodology for classifying specific hospital discharges within these DRGs. For each DRG, it also requires the Secretary to assign an appropriate weighting factor (*i.e.* DRG relative weight) which reflects the relative hospital resources used with respect to discharges classified within that DRG compared to discharges classified within other DRGs. It also requires the Secretary to adjust the classifications and DRG relative weights to reflect changes in treatment patterns, technology, and other factors which may change the relative use of hospital resources. Section 1886(d)(4)(C)(iii) of the Act specifically requires that these adjustments be made in a budget neutral manner. Furthermore, under section 1886(d)(3)(A)(vi) of the Act, insofar as the Secretary determines that these adjustments did (or are likely to) result in a change in aggregate payments that are a result of changes in the coding or classification of discharges that do not reflect real changes in case mix, the Secretary may adjust payments so as to eliminate the effect of such coding or classification changes.

In the recent 2026 Annual Report of the Boards of Trustees of the Federal Hospital Insurance Trust Fund,[724] it was projected that the increase in real case mix was expected to slow to 0.5 percent annually in fiscal years 2027 through 2035. This projected growth in real case mix is a result of an assumed continuation of the current trend toward treating less complicated cases in outpatient settings, ongoing changes in DRG coding, and the overall impact of new technology. In light of the projected 0.5 percent growth in real case mix, we are seeking public input to inform potential future rulemaking on the establishment of a reasonable maximum default threshold for the annual increase in real case-mix growth. Case mix growth beyond that maximum threshold could be considered a change due to coding and classification and could trigger a proposal for a prospective IPPS payment adjustment under section 1886(d)(3)(A)(vi) of the Act. As an illustrative example, if the projection of real case-mix growth was 0.5 percent for a given year we could establish a maximum default threshold of double that amount (*i.e.* 1.0 percent = 2 times 0.5 percent.) If subsequently the actual case mix growth for that year were to be 1.7 percent we could then propose to prospectively reduce payments by 0.7 percent (= the 1.7 percent actual case mix growth for that year minus the 1.0 percent maximum threshold established for that year.)

We also seek public input on alternative approaches, data sources, and methodologies to ensure that changes in aggregate payments do not inappropriately reflect changes in coding or classification consistent with section 1886(d)(3)(A)(vi) of the Act. Suggestions on alternative approaches, data sources, and methodologies can be sent to *DAC@cms.hhs.gov*.

i. Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2027 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the percent target by dividing the total projected operating outlier payments by the total projected operating DRG payments plus projected operating outlier payments. As discussed in the next section, for FY 2027, we are incorporating an estimate of the impact of outlier reconciliation when setting the outlier threshold. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated total of outlier payments as a proportion of total DRG payments. More information on outlier payments may be

[724] *https://www.cms.gov/oact/tr/2026.*

found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.html.*

(1) Methodology To Incorporate an Estimate of the Impact of Outlier Reconciliation in the FY 2027 Outlier Fixed-Loss Cost Threshold

The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement will be based on operating and capital cost-to-charge ratios (CCRs) calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. Instructions for outlier reconciliation are in section 20.1.2.5 of chapter 3 of the Claims Processing Manual (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*). The original instructions issued in July 2003 [725] instruct MACs to identify for CMS any instances where: (1) a hospital's actual operating CCR for the cost reporting period fluctuates plus or minus 10 percentage points or more compared to the interim operating CCR used to calculate outlier payments when a bill is processed; and (2) the total operating and capital outlier payments for the hospital exceeded $500,000 for that cost reporting period. Cost reports that meet these criteria will have the hospital's outlier payments reconciled at the time of cost report final settlement if approved by the CMS Central Office. For the remainder of this discussion, we refer to these criteria as the original criteria for outlier reconciliation (or the original criteria).

On March 28, 2024, we issued Change Request (CR) 13566, which is available at *https://www.cms.gov/medicare/regulations-guidance/transmittals/2024-transmittals/r12594cp.* CR 13566 provided additional instructions to MACs for cost reports beginning on or after October 1, 2024 that expand the criteria for identifying cost reports MACs are to refer to CMS for approval of outlier reconciliation. On September 22, 2025, we issued Change Request (CR) 14233, which is available at *https://www.cms.gov/medicare/regulations-guidance/transmittals/2025-transmittals/r13428cp,* which delayed the implementation of CR 13566 to cost reports beginning on or after October 1, 2025. As discussed in the FY 2025 IPPS/LTCH final rule, we anticipate that MACs will identify more cost reports to refer to CMS for outlier reconciliation approval. Specifically, CR 14233 instructs for cost reports beginning on or after October 1, 2025, MACs shall identify for CMS any instances where: (1) the actual operating CCR is found to be plus or minus 20 percent or more from the operating CCR used during that time period to make outlier payments, and (2) the total operating and capital outlier payments for the hospital exceeded $500,000 for that cost reporting period. For the remainder of this discussion, we refer to these criteria as the new criteria for outlier reconciliation (or the new criteria). These new criteria for identifying hospital cost reports that MACs identify for outlier reconciliation approval are in addition to the original criteria for reconciliation described previously. That is, under the new criteria, MACs identify hospitals for outlier reconciliation approval that would not have met the original criteria. In addition, CR 14233 instructs that for cost reporting periods that begin on or after October 1, 2025, a hospital in its first cost reporting period will be referred for reconciliation of outlier payments at the time of cost report final settlement. As such, new hospitals will be referred for outlier reconciliation approval regardless of the change to the operating CCR and no matter the amount of outlier payments during the cost reporting period. If we determine that a hospital's outlier payments should be reconciled, we reconcile both operating and capital outlier payments. We refer readers to section 20.1.2.5 of Chapter 3 of the Medicare Claims Processing Manual for complete instructions regarding outlier reconciliation, including the update to the outlier reconciliation criteria provided in CR 14233. (Refer to the FY 2025 IPPS/LTCH PS final rule for additional information (89 FR 69950).)

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42635), we finalized a methodology to incorporate outlier reconciliation in the FY 2020 outlier fixed loss cost threshold. As discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19592), we stated that rather than trying to predict which claims and/or hospitals may be subject to outlier reconciliation, we believe a methodology that incorporates an estimate of outlier reconciliation dollars based on actual outlier reconciliation amounts reported in historical cost reports would be a more feasible approach and provide a better estimate and predictor of outlier reconciliation for the upcoming fiscal year. We also stated that we believe the methodology addresses stakeholder's concerns on the impact of outlier reconciliation on the modeling of the outlier threshold. (For a detailed discussion of additional background regarding outlier reconciliation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule.)

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69949 through 69955), we finalized changes to our methodology to incorporate an estimate of outlier reconciliation in the FY 2025 outlier fixed loss cost threshold to reflect the estimated reconciled outlier payments under the new criteria (described previously). (We note, when we finalized these changes to the methodology beginning with FY 2025, CR 13566 was in place making the new criteria in effect for cost reports beginning on or after October 1, 2024.) In that final rule, we provided step by step details under our methodology to incorporate a projection of outlier payment reconciliations for the FY 2025 outlier threshold calculation. We refer the reader to the FY 2025 IPPS/LTCH final rule for complete details (89 FR 69950 through 69955).

(a) Incorporating a Projection of Outlier Reconciliations for the FY 2027 Outlier Threshold Calculation

Under our methodology for incorporating a projection of outlier reconciliation for the outlier threshold calculation, for each year, we typically advance the historical data used by 1 year, using cost report data that is on a 6-year lag, which is typically the most recent and complete available data to project the estimate of outlier reconciliation. Accordingly, for FY 2025 we used FY 2019 cost report data. Because at that time, the new criteria were not effective until FY 2025 cost reports, to estimate outlier reconciliation dollars under the new criteria, we applied the new criteria to FY 2019 cost reports as if they had been in place at the time of final cost report settlement. (As noted previously, when we finalized these changes to the methodology beginning with FY 2025, CR 13566 was in place making the new criteria in effect for cost reports beginning on or after October 1, 2024.) In FY 2026, we evaluated the FY 2020 cost report data under our methodology as established in FY 2020 and modified in the FY 2025 IPPS/LTCH PPS final rule. As discussed in the FY 2026 IPPS/LTCH PPS final rule, based on our evaluation of the data, for purposes of incorporating an estimate of outlier reconciliation in the outlier fixed-loss cost threshold calculation for FY 2026, we held the data constant and used the percentage of total operating outlier reconciliation dollars to total Federal operating payments from the FY 2025 IPPS/LTCH PPS final rule, which was based on FY 2019 cost reports and PSF data.

For FY 2027, we evaluated the use of the FY 2021 cost report data under our methodology as established in FY 2020 and modified in the FY 2025 IPPS/LTCH PPS final rule, to incorporate a projection of operating outlier reconciliations for the FY 2027 outlier threshold calculation (that is, the FY 2020 methodology as modified in FY 2025 to reflect additional cost reports that would be identified for outlier reconciliation approval under the new criteria in CR 14233). Specifically, for FY 2027 we evaluated using the same steps finalized in the FY 2025 IPPS/LTCH PPS final rule.

Specifically, we calculated a projection of outlier reconciliation using cost report data from FY 2021 hospital cost reports in the December 2025 HCRIS extract that were reconciled using the original criteria for referral for outlier reconciliation approval. In addition, in calculating this estimate, we used data from the Provider Specific File (PSF) and the cost report data to identify the FY 2021 cost reports that would have met the new criteria if those criteria had been in effect. This allows us to account for the additional hospital cost reports that would be referred for outlier reconciliation approval as a result of the new criteria under our methodology. For purposes of this estimate, we used the latest quarterly PSF update (December 2025 for the proposed rule).

As explained previously, our 5-step methodology to incorporate a projection of outlier payment reconciliations for the outlier threshold calculation is described in detail in the FY 2025 IPPS/LTCH final rule (see 89 FR 69950 through 69952). The 5 steps can be summarized as follows:

[724] Change Request 2785 (Transmittal A–03–058; July 3, 2003) found at *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/a03058.pdf.*

Step 1: Identify hospital cost reports that meet the original criteria (Step 1a) or the new criteria (Step 1b).

Step 2: Determine the aggregate amount of operating outlier reconciliation dollars (under both the original criteria (Step 2a) and the new criteria (Steps 2b)).

Step 3: Calculate the aggregate amount of total Federal operating payments across all applicable hospitals using the cost report data.

Step 4: Determine the percentage of total operating outlier reconciliation dollars to total Federal operating payments for the cost report data year.

Step 5: Adjust the outlier target using the percentage from Step 4.

With regard to incorporating outlier reconciliation in the FY 2027 outlier fixed-loss cost threshold, we evaluated the use of the most recent available data (as described previously) using the 5-step methodology as set forth in the FY 2025 IPPS/LTCH PPS final rule. As we explain in greater detail in the discussion that follows, similar to FY 2026, we found that using the most recent available data under our 5-step methodology appears to produce anomalous results that may not provide an appropriate estimate and predictor of outlier reconciliation for the upcoming fiscal year. (We note, for the hospitals identified in Step 1b (hospitals that would be referred for outlier reconciliation under the new criteria), for the proposed rule we posted a public use file that includes the operating CCR calculated from the FY 2021 cost report in the most recent publicly available quarterly HCRIS extract (the December 2025 HCRIS for the proposed rule), the weighted operating CCR used for claim payment during the FY 2021 cost reporting period from the latest quarterly PSF update (December 2025 for the proposed rule), and the supplemental data from the MACs and operating outlier payment reported on the FY 2021 cost report.)

Step 4 of the methodology divides the aggregate amount from Step 2 [726] (operating outlier reconciliation dollars under both the original criteria and the new criteria or total reconciled dollars) by the amount from Step 3 [727] (total Federal operating payments across all applicable hospitals using the cost report data) and multiplies the resulting amount by 100 to produce the percentage of total operating outlier reconciliation dollars to total Federal operating payments (89 FR 69952). As discussed in previous proposed and final rules, when the percentage of total operating outlier reconciliation dollars to total Federal operating payments in Step 4 rounds to a negative value, the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. When the percentage of total operating outlier reconciliation dollars to total Federal operating payments in Step 4 rounds to a positive value, the effect is an increase to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars.

Using the most recent available data for the proposed rule (as described previously), the ratio calculated under Step 4 of the methodology was 0.000000 percent (($457,535/$82,060,762,488) × 100), which, when rounded to the second digit, was +0.0 percent (we note, in the proposed rule we inadvertently listed the denominator as $77,326,439,126 instead of $82,060,762,488. The ratio under step was still 0.0 percent as described). We stated that under Step 5 of the methodology, this percentage amount would be used to adjust the outlier target for FY 2027. This would have meant that for FY 2027, we would have incorporated a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.1 percent [5.1 percent − (0.0 percent)]. This 0.0 percentage was being driven by the numerator in Step 4 (that is, the total reconciled dollars or the aggregate operating outlier reconciliation dollars under both the original criteria and the new criteria).

As stated in the proposed rule, typically, the total reconciled dollars in Step 2 (the numerator of Step 4) is a negative amount reflecting that overall, providers would owe the Medicare program money at the time of outlier reconciliation, which then produces a negative percentage of operating outlier reconciliation dollars to total Federal operating payments in Step 4. Using the most recent available data available at the time of the proposed rule (described previously), the total reconciled dollars in Step 2 (the numerator of Step 4) which is the aggregate operating outlier reconciliation dollars under both the original criteria and the new criteria resulted in a small negative amount owed by providers to CMS $457,535 (we note, in the proposed rule we inadvertently stated that the total reconciled dollars was a small positive amount of $457,535 owed by CMS to providers instead of a negative amount). When Step 2 is divided by the aggregate amount of total Federal operating payments across all applicable hospitals using the cost report data in Step 3 ($82,060,762,488; the denominator in Step 4), this resulted in no adjustment to the proposed threshold (0.0 percent).

As mentioned previously, since FY 2020 we have incorporated outlier reconciliation into the outlier fixed loss cost threshold calculation. For the outlier fixed loss cost threshold calculation for FYs 2020 through 2025, the percentage of operating outlier reconciliation dollars to total Federal operating payments from Step 4 has resulted in a negative value (having the effect of a decrease to the outlier threshold). Similar to the evaluation of FY 2020 cost report data for FY 2026, using the FY 2021 cost report data and PSF values described previously under our methodology would result in a percentage of operating outlier reconciliation dollars to total Federal operating payments that is inconsistent with the prior historical data. Similar to the evaluation of the FY 2020 cost report data for FY 2026, compared to the historical data used to calculate the estimate of outlier reconciliation for FYs 2020–2025, we stated in the proposed rule that we believe 0.0 percent may be an anomaly and may not be an accurate predictor of outlier reconciliations for FY 2027 to use as an estimate of outlier reconciliation dollars for incorporating the effect of outlier reconciliation in the FY 2027 outlier fixed-loss cost threshold. Therefore, rather than use the percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 based on the latest available data (as described previously), for purposes of incorporating an estimate of outlier reconciliation into the outlier fixed-loss cost threshold calculation for FY 2027, we proposed to hold the data constant and to use the percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 from the FY 2025 IPPS/LTCH PPS final rule which is based on FY 2019 cost reports and PSF data. As discussed in that final rule (89 FR 69952), the ratio was a negative 0.041994 percent ((−$36,439,127/$86,772,005,692) × 100), which, when rounded to the second digit, is −0.04 percent. Given the anomaly in the most recent available data described earlier, we stated in the proposed rule that we believe that this is the best available data to estimate and predict outlier reconciliations for FY 2027 to use to incorporate the effect of outlier reconciliation in the FY 2027 outlier fixed-loss cost threshold. This percentage amount was then used to adjust the proposed outlier target for FY 2027 as determined in Step 5. (For complete details on the calculation, refer to the FY 2025 IPPS/LTCH final rule (89 FR 69950 through 69952).)

Under Step 5 of our methodology, because the outlier reconciliation dollars are only available on the cost reports, and not in the Medicare claims data in the MedPAR file used to model the outlier threshold, we proposed to target 5.1 percent minus the percentage determined under Step 4 in determining the outlier threshold. Consistent with the FY 2025 IPPS/LTCH PPS final rule, to incorporate a projection of outlier reconciliation dollars, we proposed to target an outlier threshold at an amount higher than 5.1 percent for outlier payments for FY 2027. Therefore, for FY 2027, we proposed to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.14 percent [5.1 percent − (−0.04 percent)]. As explained earlier, when the aggregate amount of outlier reconciliation as a percent of total operating payments rounds to a negative percent, the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2). of the Addendum to the proposed rule, we provided the FY 2027 proposed outlier threshold as calculated for the proposed rule both with and without

[726] Step 2, the numerator of step 4, is the aggregate amount of operating outlier reconciliation dollars under both the original criteria and the new criteria which is the sum of the amounts from Steps 2a and 2b. (89 FR 69951 through 69952).

[727] Step 3, the denominator of step 4, is the aggregate amount of total Federal operating payments across all applicable hospitals using the cost report data (*i.e.,* FY 2021 cost reports for FY 2027). The total Federal operating payments consist of the Federal payments (Worksheet E, Part A, Line 1.01 and Line 1.02, plus Line 1.03 and Line 1.04), outlier payments (Worksheet E, Part A, Lines 2.02, 2.03, and 2.04), and the outlier reconciliation amounts from Steps 2a and 2b. (89 FR 69952).

including this percentage estimate of operating outlier reconciliation.

Consistent with the approach taken in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19593), we would continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount. Therefore, the proposed operating outlier offset to the standardized amount was 0.949 (1 − 0.051).

We noted in the proposed rule that, for the FY 2027 final rule, consistent with our historical practice, we planned to evaluate the updated data available at the time of the development of that final rule (such as the March 2026 HCRIS extract of the FY 2021 cost report). We stated that we would evaluate the use of that updated data in the methodology to assess whether that data still shows an anomaly such that it would not be appropriate to use in calculating the projection of outlier reconciliation dollars for FY 2027 and, depending on the results of this evaluation, we stated that we may consider use of that data for purposes of projecting an estimate of outlier reconciliation dollars and incorporating that estimate into the modeling for the fixed loss cost outlier threshold for FY 2027. We invited public comment on our proposed methodology for projecting an estimate of outlier reconciliation and incorporating that estimate into the modeling for the fixed loss cost outlier threshold for FY 2027.

Comment: We received a comment supporting our proposal to hold the data constant from the FY 2025 IPPS/LTCH PPS final rule. The commenter also requested that CMS release information on the outlier reconciliation process and data showing the amounts recovered so that it can evaluate the impact of the reconciliation process on the outlier threshold.

Response: We appreciate the commenter's support. We note that the quarterly HCRIS data contains the information the commenter is requesting and is published as a public use file available at *http://www.cms.gov/research-statistics-data-and-systems/downloadable-public-use-files/cost-reports/cost-reports-by-fiscal-year*. For the annual proposed rule we use the December HCRIS and for the annual final rule we use the March HCRIS. Quarterly updates of HCRIS are generally available by the end of the month following the quarterly cutoff date. For example, the December 2025 HCRIS update used in the FY 2027 proposed rule would generally become available towards the end of January 2026. This final rule discusses the impact of incorporating the reconciliation amounts from March 2026 HCRIS reports.

Also, as stated above, for the hospitals identified in Step 1b, we posted a public use file that includes the operating CCR calculated from the FY 2021 cost report in the most recent publicly available quarterly HCRIS extract (the December 2025 HCRIS for the proposed rule), the weighted operating CCR used for claim payment during the FY 2021 cost reporting period from the latest quarterly PSF update (December 2025 for the proposed rule), supplemental data from the MACs and capital outlier payments reported on the FY 2021 cost report.

For this final rule, we evaluated the updated data available at the time of the development of this final rule (specifically, the March 2026 HCRIS extract of the FY 2021 cost report). Using the most recent available data available at the time of this final rule (described previously), the total reconciled dollars in Step 2 (the numerator of Step 4) which is the aggregate operating outlier reconciliation dollars under both the original criteria and the new criteria resulted in a small positive amount owed by CMS to providers of $1,951,291. We note, in the proposed rule, the total reconciled dollars in Step 2 resulted in a small negative amount owed by providers to CMS.

When Step 2 is divided by the aggregate amount of total Federal operating payments across all applicable hospitals using the cost report data in Step 3 ($82,077,743,603; the denominator in Step 4), this results in no adjustment to the threshold (0.0 percent). We note, in the proposed rule, the total reconciled dollars in Step 2 resulted in a small negative amount owed by providers to CMS. As noted above, when Step 2 was divided by the aggregate amount of total Federal operating payments across all applicable hospitals using the cost report data in Step 3 (the denominator in Step 4), the result was the same in the proposed and final rule with no adjustment to the threshold (0.0 percent).

As discussed earlier, typically, the total reconciled dollars in Step 2 (the numerator of Step 4) is a negative amount reflecting that overall, providers would owe the Medicare program money at the time of outlier reconciliation, which then produces a negative percentage of operating outlier reconciliation dollars to total Federal operating payments in Step 4. Using the most recent available data for this final rule (described previously), the total reconciled dollars in Step 2 (the numerator of Step 4) is a small positive amount reflecting that overall, CMS would owe providers money at the time of outlier reconciliation, which, when rounded to the second digit, is +0.0 percent. Similar to the proposed rule, for this final rule, we believe this small positive value may be an anomaly and may not be an accurate predictor of outlier reconciliations for FY 2027 to use as an estimate of outlier reconciliation dollars for incorporating the effect of outlier reconciliation in the FY 2027 outlier fixed-loss cost threshold.

After considering the comments received and based on our evaluation using the updated data available at the time of the development of this final rule which continues to show that that data may be an anomaly, we are finalizing as proposed. Specifically, for purposes of incorporating an estimate of outlier reconciliation into the outlier fixed-loss cost threshold calculation for FY 2027, we are holding the data constant and using the percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 from the FY 2025 IPPS/LTCH PPS final rule which is based on FY 2019 cost reports and PSF data.

As discussed in that final rule (89 FR 69952), the ratio was a negative 0.041994 percent ((−$36,439,127/$86,772,005,692) × 100), which, when rounded to the second digit, is −0.04 percent. Given the anomaly in the most recent available data described earlier, we continue to believe that this is the best available data to estimate and predict outlier reconciliations for FY 2027 to use to incorporate the effect of outlier reconciliation in the FY 2027 outlier fixed-loss cost threshold. We are using this percentage to adjust the outlier target for FY 2027 as determined in Step 5. (For complete details on the calculation, refer to the FY 2025 IPPS/LTCH final rule (89 FR 69950 through 69952).)

Under Step 5 of our methodology, because the outlier reconciliation dollars are only available on the cost reports, and not in the Medicare claims data in the MedPAR file used to model the outlier threshold, we are finalizing to target 5.1 percent minus the percentage determined under Step 4 in determining the outlier threshold. Consistent with the FY 2025 IPPS/LTCH PPS final rule, to incorporate a projection of outlier reconciliation dollars, we are targeting an outlier threshold at an amount higher than 5.1 percent for outlier payments for FY 2027. Therefore, for FY 2027, we are incorporating a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.14 percent [5.1 percent − (−0.04 percent)]. As explained earlier, when the aggregate amount of outlier reconciliation as a percent of total operating payments rounds to a negative percent, the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2). of this Addendum, we provide the FY 2027 outlier threshold as calculated for this final rule both with and without including this percentage estimate of operating outlier reconciliation.

Consistent with the approach taken in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19593), we would continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount. Therefore, the final operating outlier offset to the standardized amount is 0.949 (1 − 0.051).

(b) Adjustment To Account for Capital Outlier Reconciliation Payments in the Projected Proportion of Capital IPPS Payments Paid as Outliers in Determining the FY 2027 Capital Federal Rate

We establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital related costs (58 FR 46348). Similar to the calculation of the adjustment to the standardized amount to account for the projected proportion of operating payments paid as outlier payments, as discussed in greater detail in section III.A.2. of this Addendum, we proposed to reduce the FY 2027 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement would be based on operating and capital CCRs calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is

settled. As such, any reconciliation also applies to capital outlier payments.

Under our methodology for incorporating an adjustment to account for capital outlier reconciliation payments in the projected proportion of capital IPPS payments paid as outliers in determining the FY 2027 capital Federal rate, each year, we typically advance the historical data used by 1 year and use cost report data that is on a six year lag, which is typically the most recent and complete available data to project the estimate of outlier reconciliation. Accordingly, for FY 2025 we used FY 2019 cost report data. Because at that time, the new criteria were not effective until FY 2025 cost reports, to estimate outlier reconciliation dollars under the new criteria, we applied the new criteria to FY 2019 cost reports as if they had been in place at the time of final cost report settlement. (As noted previously, when we finalized these methodology changes beginning with FY 2025, CR 13566 was in place making the new criteria in effect for cost reports beginning on or after October 1, 2024.) In FY 2026, we evaluated the FY 2020 cost report data under our methodology as established in FY 2020 and modified in the FY 2025 IPPS/LTCH PPS final rule. As discussed in the FY 2026 IPPS/LTCH PPS final rule, based on our evaluation of the data, for purposes of incorporating an adjustment to account for capital outlier reconciliation payments in the projected proportion of capital IPPS payments paid as outliers in determining the FY 2026 capital Federal rate, we held the data constant and used the percentage of total capital outlier reconciliation dollars to total capital Federal payments from the FY 2025 IPPS/LTCH PPS final rule, which was based on FY 2019 cost reports and PSF data.

For FY 2027, we evaluated the use of the FY 2021 cost report data under the methodology we used for FY 2025 to incorporate an adjustment to the FY 2027 capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers (that is, the FY 2020 methodology as modified in FY 2025 to reflect additional cost reports that would be identified for reconciliation under the new criteria in CR 14233). Specifically, we calculated an estimate of outlier reconciliation using cost report data from FY 2021 hospital cost reports in the December 2025 HCRIS extract that were reconciled using the original criteria for referral for outlier reconciliation. Similarly, in calculating this estimate, we used data from the Provider Specific File (PSF) and the cost report data to identify the FY 2021 cost reports that would have met the new criteria if those criteria had been in effect. This allowed us to account for the additional hospital cost reports that would be referred for outlier reconciliation approval as a result of the new criteria under our methodology. For purposes of the estimate, we used the latest quarterly PSF update (December 2025) for the proposed rule.

As previously explained, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 699540 through 69955), we finalized changes to our methodology to incorporate an estimate of outlier reconciliation in the FY 2025 outlier fixed loss cost threshold to reflect the estimated reconciled outlier payments under the new criteria in CR 13566 (described previously). In that final rule, we provided step by step details under our methodology to incorporate a projection of outlier payment reconciliations for the FY 2025 outlier threshold calculation. (For complete details on our 5-step methodology to incorporate an adjustment to the capital outlier adjustment factor, we refer readers to the FY 2025 IPPS/LTCH final rule (89 FR 69953 through 69955).) The 5 steps can be summarized as follows:

Step 1: Identify hospital cost reports that meet the original criteria (Step 1a) or the new criteria (Step 1b).

Step 2: Determine the aggregate amount of capital outlier reconciliation dollars (under both the original criteria (Step 2a) and the new criteria (Steps 2b)).

Step 3: Calculate the aggregate amount of total capital Federal payments across all applicable hospitals using the cost report data.

Step 4: Determine the percentage of total capital outlier reconciliation dollars to total capital Federal payments for the cost report data year.

Step 5: Adjust the capital outlier adjustment factor using the percentage from Step 4.

Under this methodology, because the outlier reconciliation dollars are only available on the cost reports, and not in the specific Medicare claims data in the MedPAR file used to estimate outlier payments, in Step 5 the estimate of capital outlier payments are determined by adding the percentage determined in Step 4 to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. (We note that this percentage is added for capital outlier payments but subtracted in the analogous step for operating outlier payments. We have a unified outlier payment methodology that uses a shared threshold to identify outlier cases for both operating and capital payments. The difference stems from the fact that operating outlier payments are determined by first setting a ''target'' percentage of operating outlier payments relative to aggregate operating payments which produces the outlier threshold. Once the shared threshold is set, it is used to estimate the percentage of capital outlier payments to total capital payments based on that threshold. Because the threshold is already set based on the operating target, rather than adjusting the threshold (or operating target), we adjust the percentage of capital outlier to total capital payments to account for the estimated effect of capital outlier reconciliation payments. This percentage is adjusted by adding the capital outlier reconciliation percentage from Step 4 to the estimate of the percentage of capital outlier payments to total capital payments based on the shared threshold.)

As discussed in previous proposed and final rules, when the aggregate capital outlier reconciliation dollars in Step 2 is negative, the estimate of capital outlier payments under our methodology would be lower than the percentage of capital outlier payments otherwise determined using the shared outlier threshold. Under Step 5 this would be a relatively smaller outlier budget neutrality adjustment factor which would have the effect of an increase to the capital Federal rate. When the aggregate capital outlier reconciliation dollars from Step 2 are positive, the estimate of capital outlier payments under our methodology would be higher than the percentage of capital outlier payments otherwise determined using the shared outlier threshold. Under Step 5 this would be a relatively larger outlier budget neutrality adjustment factor which would have the effect of a decrease to the capital Federal rate.

With regard to incorporating an adjustment to account for capital outlier reconciliation payments in the projected proportion of capital IPPS payments paid as outliers, we evaluated the use of the most recent available data (as described previously) using the 5-step methodology as set forth in the FY 2025 IPPS/LTCH PPS final rule. (We note, for the hospitals identified in Step 1b (hospitals that would be referred for outlier reconciliation approval under the new criteria), for the proposed rule we posted a public use file that included the capital CCR calculated from the FY 2021 cost report in the most recent publicly available quarterly HCRIS extract (the December 2025 HCRIS for the proposed rule), the weighted capital CCR used for claim payment during the FY 2021 cost reporting period from the latest quarterly PSF update (December 2025 for the proposed rule), and the supplemental data from the MACs and capital outlier payment reported on the FY 2021 cost report.)

Step 4 of the methodology divides the aggregate amount from Step 2 [4] (capital outlier reconciliation dollars under both the original criteria and the new criteria or total reconciled dollars) by the amount from Step 3 [5] (total Federal capital payments across all applicable hospitals using the cost report data) and multiplies the resulting amount by 100 to produce the percentage of total capital outlier reconciliation dollars to total capital Federal payments (89 FR 69955). Under the methodology, in Step 5 this amount is added to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold (as explained previously).

For the proposed rule, the estimated percentage of FY 2027 capital outlier payments otherwise determined using the shared outlier threshold was 3.60 percent (estimated capital outlier payments of

[4] Step 2, the numerator of step 4, is the aggregate amount of capital outlier reconciliation dollars under both the original criteria and the new criteria which is the sum of the amounts from Steps 2a and 2b. (89 FR 69954 through 69955).

[5] Step 3, the denominator of step 4, is the aggregate amount of total capital Federal payments across all applicable hospitals using the cost report data. The total capital Federal payments consist of the capital DRG payments, capital outlier payments, capital indirect medical education (IME) Payments, capital disproportionate share hospital (DSH) payments (Worksheet E, Part A, Line 50, Column 1) and the capital outlier reconciliation amounts from Steps 2a and 2b. (89 FR 69955).

$264,774,667 divided by (estimated capital outlier payments of $264,774,667 plus the estimated total capital Federal payment of $7,080,040,076)). Using the most recent available data at the time of the proposed rule, the total in Step 2 was $4,597,730, which was a negative amount. The percentage calculated in Step 4 was a negative 0.065891 percent (($4,597,730/$6,977,699,344) × 100), which, when rounded to the second digit, was −0.07 percent (we note, in the proposed rule, we inadvertently listed the denominator as $6,979,384,161 instead of $6,977,699,344 and listed the percentage in step 4 as 0.065876 instead of 0.065891; this update to the denominator and percentage in step 4 does not change the percentage in Step 5). Under Step 5 of the methodology, this percentage amount would be used to adjust the estimate of capital outlier payments for FY 2027. This would mean that for the FY 2027 proposed rule we would have decreased the estimated percentage of FY 2027 aggregate capital outlier payments by 0.07 percent. This negative 0.07 percentage point was being driven by the numerator in Step 4 (that is, the total reconciled dollars or the aggregate capital outlier reconciliation dollars under both the original criteria and the new criteria).

The total reconciled dollars in Step 2 (the numerator of Step 4) was a negative amount reflecting that overall, providers would owe the Medicare program money at the time of outlier reconciliation, which then produces a negative percentage of capital outlier reconciliation dollars to total Federal capital payments in Step 4. This is consistent with the trends in the historical data.

However, we stated in the proposed rule that, as discussed earlier, using the FY 2021 cost report data and PSF values under our methodology for incorporating a projection of operating outlier reconciliations for the outlier threshold calculation would result in a percentage of operating outlier reconciliation dollars to total Federal operating payments that is inconsistent with the historical data. As previously discussed, compared to the historical data used to calculate the estimate of outlier reconciliation for FYs 2020–2025, we stated that we believe that 0.0 percent may be an anomaly and may not be an accurate predictor of outlier reconciliations for FY 2027 to use as an estimate of outlier reconciliation dollars for incorporating the effect of outlier reconciliation in the FY 2027 outlier fixed-loss cost threshold. Therefore, for purposes of incorporating an estimate of outlier reconciliation into the outlier fixed-loss cost threshold calculation for FY 2027, we proposed to hold the data constant and to use the percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 from the FY 2025 IPPS/LTCH PPS final rule which is based on FY 2019 cost reports and PSF data rather than use the percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 based on the latest available data. For this reason, to ensure the use of consistent data for incorporating a projection of operating and capital outlier reconciliations, for purposes of incorporating an adjustment to the capital standard Federal rate for FY 2027, we proposed to also hold the data constant and to use the percentage of total capital outlier reconciliation dollars to total capital Federal payments from Step 4 from the FY 2025 IPPS/LTCH PPS final rule which is based on FY 2019 cost reports and PSF data rather than use the percentage of total capital outlier reconciliation dollars to total capital Federal payments from Step 4 based on the latest available data. We stated that we believe aligning the projection of operating and capital outlier reconciliations based on data from the same period (2019 cost reports) is a consistent and methodologically sound approach for ensuring comparability across calculations and minimizes possible distortions that could result from using data from different reporting periods.

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69955), based on FY 2019 cost reports and PSF data, the ratio was a negative 0.028042 percent ((−$2,181,440/$7,779,306,800) × 100), which, when rounded to the second digit, is −0.03 percent. Accordingly, for the proposed rule, taking into account projected capital outlier reconciliation under our methodology would decrease the estimated percentage of FY 2027 aggregate capital outlier payments by 0.03 percent. This percentage amount was used to adjust the proposed estimated percentage of FY 2027 aggregate capital outlier payments under Step 5 of the methodology. (For complete details on the calculation, refer to the FY 2025 IPPS/LTCH final rule (89 FR 69953 through 69955).)

As discussed in section III.A.2. of the Addendum of the proposed rule, we incorporated the capital outlier reconciliation dollars from Step 5 when applying the outlier adjustment factor in determining the proposed capital Federal rate based on the estimated percentage of capital outlier payments to total capital Federal rate payments for FY 2027.

We noted in the proposed rule, for the FY 2027 final rule, consistent with our historical practice, we plan to evaluate the updated data available at the time of the development of that final rule (such as the March 2026 HCRIS extract of the FY 2021 cost report). We stated that we would evaluate the use of that updated data in the methodology to assess whether that data still shows an anomaly such that it would not be appropriate to use in calculating the projection of outlier reconciliation dollars for FY 2027 and, depending on the results of this evaluation, may consider use of that data for purposes of projecting an estimate of outlier reconciliation dollars and incorporating an adjustment to the FY 2027 capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers. We invited public comment on our proposed methodology for incorporating an adjustment to account for capital outlier reconciliation payments in the projected proportion of capital IPPS payments paid as outliers in determining the FY 2027 capital Federal rate.

Comment: As previously mentioned, we received a comment supporting our proposal to hold the data constant from the FY 2025 IPPS/LTCH PPS final rule. The commenter also requested that CMS release information on the outlier reconciliation process and data showing the amounts recovered so that it can evaluate the impact of the reconciliation process on the outlier threshold.

Response: We appreciate the support for the proposal to hold constant the outlier reconciliation estimate. With regard to the comment requesting that CMS release information on the outlier reconciliation process and data showing the amounts recovered so that it can evaluate the impact of the reconciliation process on the outlier threshold, we refer the reader to our response discussed above.

For this final rule, we evaluated the updated data available at the time of the development of this final rule (specifically, the March 2026 HCRIS extract of the FY 2021 cost report). Using the most recent available data for this final rule, similar to the proposed rule, the total in Step 2 is $4,599,561, which is a negative amount. The percentage calculated in Step 4 is a negative 0.065906 percent (($4,599,561/$6,978,870,688) × 100), which, when rounded to the second digit, is −0.07 percent. Under Step 5 of the methodology, this percentage amount would be used to adjust the estimate of capital outlier payments for FY 2027. This would mean that for this FY 2027 final rule we would decrease the estimated percentage of FY 2027 aggregate capital outlier payments by 0.07 percent. This negative 0.07 percentage point is being driven by the numerator in Step 4 (that is, the total reconciled dollars or the aggregate capital outlier reconciliation dollars under both the original criteria and the new criteria).

After considering the comments received and based on our evaluation using the updated data available at the time of the development of this final rule, we are finalizing as proposed. Specifically, to ensure the use of consistent data for incorporating a projection of operating and capital outlier reconciliations, for purposes of incorporating an adjustment to the capital standard Federal rate for FY 2027, we are finalizing as proposed to also hold the data constant and to use the percentage of total capital outlier reconciliation dollars to total capital Federal payments from Step 4 from the FY 2025 IPPS/LTCH PPS final rule which is based on FY 2019 cost reports and PSF data rather than use the percentage of total capital outlier reconciliation dollars to total capital Federal payments from Step 4 based on the latest available data. As discussed in the proposed rule, we believe aligning the projection of operating and capital outlier reconciliations based on data from the same period (2019 cost reports) is a consistent and methodologically sound approach for ensuring comparability across calculations and minimizes possible distortions that could result from using data from different reporting periods.

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69955), based on FY 2019 cost reports and PSF data, the ratio was a negative 0.028042 percent ((−$2,181,440/$7,779,306,800) × 100), which, when rounded to the second digit, is −0.03

percent. Accordingly, for this final rule, taking into account projected capital outlier reconciliation under our methodology would decrease the estimated percentage of FY 2027 aggregate capital outlier payments by 0.03 percent. This percentage amount is being used to adjust the estimated percentage of FY 2027 aggregate capital outlier payments under Step 5 of the methodology. (For complete details on the calculation, refer to the FY 2025 IPPS/LTCH final rule (89 FR 69953 through 69955).)

As discussed in section III.A.2. of the Addendum of this final rule, we incorporated the capital outlier reconciliation dollars from Step 5 when applying the outlier adjustment factor in determining the capital Federal rate based on the estimated percentage of capital outlier payments to total capital Federal rate payments for FY 2027.

(2) FY 2027 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a detailed discussion of the changes.

As we have done in the past, to calculate the FY 2027 outlier threshold, we simulated payments by applying FY 2027 payment rates and policies using cases from the FY 2025 MedPAR file. As noted in section II.C. of this Addendum, we specify the formula used for actual claim payment which is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the Provider-Specific File (PSF) while CMS uses an adjusted CCR (as described later in this section) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

In order to determine the FY 2027 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2025 to FY 2027. Consistent with the FY 2020 IPPS/LTCH PPS final rule (84 FR 42626 and 42627), we are using the following methodology to calculate the charge inflation factor for FY 2027:

- Include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); include CAHs and REHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS-excluded cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- Include providers that are in both periods of charge data that are used to calculate the 1-year average annual rate of-change in charges per case. We note this is consistent with the methodology used since FY 2014.
- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- In order to ensure that we capture only FFS claims, we included claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- In order to further ensure that we capture only FFS claims, we excluded claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS. As noted previously, we removed allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842).
- Because this payment simulation uses the FY 2027 relative weights, consistent with our policy discussed in section IV.I. of the preamble to this final rule, we applied the adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments.

Our general methodology to inflate the charges computes the 1-year average annual rate-of-change in charges per case which is then applied twice to inflate the charges on the MedPAR claims by 2 years since we typically use claims data for the fiscal year that is 2 years prior to the upcoming fiscal year.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42627), we modified our charge inflation methodology. We stated that we believe balancing our preference to use the latest available data from the MedPAR files and stakeholders' concerns about being able to use publicly available MedPAR files to review the charge inflation factor can be achieved by modifying our methodology to use the publicly available Federal fiscal year period (that is, for FY 2020, we used the charge data from Federal fiscal years 2017 and 2018), rather than the most recent data available to CMS which, under our prior methodology, was based on calendar year data. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for a complete discussion regarding this change.

For the same reasons discussed in that rulemaking, for FY 2027, we proposed to use the same methodology as FY 2020 to determine the charge inflation factor. That is, for FY 2027, we proposed to use the MedPAR files for the two most recent available Federal fiscal year time periods to calculate the charge inflation factor, as we did for FY 2020. Specifically, for the proposed rule we used the December 2024 MedPAR file of FY 2024 (October 1, 2023, to September 30, 2024) charge data (released for the FY 2026 IPPS/LTCH PPS proposed rule) and the December 2025 MedPAR file of FY 2025 (October 1, 2024, to September 30, 2025) charge data (released for the FY 2027 IPPS/LTCH PPS proposed rule) to compute the proposed charge inflation factor. We proposed that for the FY 2027 final rule, we would use more recently updated data, that is the MedPAR files from March 2025 for the FY 2024 time period and March 2026 for the FY 2025 time period.

For FY 2027, under this proposed methodology, to compute the 1-year average annual rate-of-change in charges per case, we compared the average covered charge per case of $90,776.90 ($623,467,062,919/6,868,125) from October 1, 2023, through September 30, 2024, to the average covered charge per case of $97,412.36 ($677,169,023,175/6,951,572) from October 1, 2024, through September 30, 2025. This rate-of-change was 7.310 percent (1.07310) or 15.154 percent (1.15154) over 2 years. The billed charges are obtained from the claims from the MedPAR file and inflated by the inflation factor specified previously.

As we have done in the past, in the FY 2027 IPPS/LTCH PPS proposed rule, we proposed to establish the FY 2027 outlier threshold using hospital CCRs from the December 2025 update to the Provider-Specific File (PSF), the most recent available data at the time of the development of the proposed rule. We proposed to apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We do not apply the adjustment factors described later in this section to hospitals assigned the statewide average CCR. For FY 2027, we proposed to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained later in this section). We also proposed that, if more recent data become available, we would use that data to calculate the final FY 2027 outlier threshold.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted

operating and capital CCR from the same period of the prior year. Therefore, as we have done in the past, we proposed to adjust the CCRs from the December 2025 update of the PSF by comparing the percentage change in the national average case weighted operating CCR and capital CCR from the December 2024 update of the PSF to the national average case weighted operating CCR and capital CCR from the December 2025 update of the PSF. We note that, in the proposed rule, we used total transfer-adjusted cases from FY 2025 to determine the national average case weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology, for the proposed rule, we calculated a December 2024 operating national average case-weighted CCR of 0.24059 and a December 2025 operating national average case-weighted CCR of 0.235176.We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2024 operating national average case-weighted CCR from the December 2025 operating national average case-weighted CCR and then dividing the result by the December 2024 national operating average case-weighted CCR. This resulted in a proposed one-year national operating CCR adjustment factor of 0.977497.

We used this same proposed methodology to adjust the capital CCRs. Specifically, we calculated a December 2024 capital national average case-weighted CCR of 0.01644 and a December 2025 capital national average case-weighted CCR of 0.015639. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2024 capital national average case-weighted CCR from the December 2025 capital national average case-weighted CCR and then dividing the result by the December 2024 capital national average case-weighted CCR. This resulted in a proposed one-year national capital CCR adjustment factor of 0.951277.

For purposes of estimating the proposed outlier threshold for FY 2027, we used a wage index that reflects the policies discussed in the proposed rule. This includes the following:

- The proposed rural and imputed floor adjustments.
- The proposed State frontier floor adjustments in accordance with section 10324(a) of the Affordable Care Act, Public Law 111–148.
- The proposed out-migration adjustment as added by section 505 of Public Law 108–173.
- Our policy (described in section III.F.5 of the preamble of this final rule) to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline.
- The proposed continuation of the transition for the discontinuation of the low wage index hospital policy (as described in section III.F.6 of the preamble of this final rule).

If we did not take the aforementioned into account, our estimate of total FY 2027 payments would be too low, and, as a result, the proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments (which includes outlier reconciliation).

As described in sections V.K. and V.L., respectively, of the preamble of this final rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the proposed outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we proposed to exclude the estimated hospital VBP payment adjustments and the estimated hospital readmissions payment adjustments from the calculation of the proposed outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2027, we proposed to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally.

Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2027, we proposed to include estimated FY 2027 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we proposed to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

In addition, consistent with the methodology finalized in the FY 2023 final rule, we proposed to include the estimated supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals in the computation of the FY 2027 proposed outlier fixed-loss cost threshold. Specifically, we proposed to use the estimated per-discharge supplemental payments to hospitals eligible for the supplemental payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we proposed to incorporate an estimate of FY 2027 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for the FY 2027 proposed rule, we proposed to hold the data constant and to use the FY 2025 final rule percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 from the FY 2025 IPPS/LTCH PPS final rule which is based on FY 2019 cost reports and PSF data. As discussed in the FY 2025 IPPS/LTCH PPS final rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) was a negative 0.041994 percent, which, when rounded to the second digit, is -0.04 percent. Therefore, for FY 2027, we proposed to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.14 percent [5.1 percent $-(-.04$ percent)]. Under this proposed approach, we determined a proposed threshold of $51,704 and calculated total outlier payments of $4,642,138,720 total operating Federal payments of $90,312,360,835. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.14 percent target, which reflected our proposal to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). We note that, if calculated without applying our proposed methodology for incorporating an estimate of outlier reconciliation in the determination of

the outlier threshold, the proposed threshold would be $52,096. We proposed an outlier fixed-loss cost threshold for FY 2027 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and any add-on payments for new technology, plus $51,704.

Comment: Commenters expressed concern about the proposed increase in the high-cost outlier threshold, noting that the fixed-loss threshold will have nearly doubled since FY 2020 compared to only a 15 percent increase over the prior decade. Commenters requested that CMS carefully analyze its methodology to determine why the model for projecting outlier payments in FY 2027 is resulting in a significant increase to the fixed-loss amount.

Several commenters argued that the proposed FY 2027 outlier threshold relies too heavily on recent charge growth, resulting in a substantial increase in the threshold that hospitals may be unable to absorb given continued financial instability, elevated labor costs, and increasing patient acuity. A commenter recommended that CMS consider using a multi-year rolling average for charge inflation calculations or linking the charge inflation factor to the market basket or another reasonable trend factor to moderate the proposed increase while maintaining the targeted outlier payment level. The commenter noted that CMS recognized anomalies in recent outlier reconciliation data by relying on older FY 2019 reconciliation assumptions instead of FY 2021 data and urged CMS to exercise similar caution when establishing the FY 2027 outlier threshold.

Another commenter stated that that CMS's significantly higher proposed charge inflation factor for FY 2027 suggests that CCRs would decrease more rapidly than CMS's 2.25 percent projection of the change in CCRs, given that CMS is also projecting cost inflation for FY 2027 will remain relatively steady. The commenter recommended that CMS consider this discrepancy and whether the charge inflation factor requires any downward adjustment.

A different commenter expressed concern that the proposed FY 2027 outlier threshold methodology may be distorted by unusual CCR trends during a period of high inflation. The commenter stated that CMS's methodology relies on historical CCR and outlier reconciliation data that may not accurately reflect current cost conditions. The commenter asserted that more recent data suggest CCRs are declining and recommended that CMS reexamine its outlier threshold methodology to better reflect current cost conditions. The commenter also urged CMS to consider temporary modifications to mitigate the impact of large year-over-year increases in the outlier threshold, particularly for hospitals serving high-acuity Medicare populations that rely on outlier payments.

Another commenter expressed concern that the data and assumptions used to calculate the proposed FY 2027 outlier threshold are subject to significant variability because they rely on data that are two years old and one-year trends in charges and CCRs. The commenter stated that this methodology may not adequately reflect longer-term trends and may have contributed to the unusually large increase in the proposed outlier threshold. The commenter urged CMS to reevaluate the charge inflation and CCR adjustment factors and to ensure the outlier payment methodology reflects actual year-over-year changes in CCRs as more recent data become available.

Response: We appreciate the commenters sharing their concerns and recommendations. The charge inflation factor (which is based on the latest available MedPAR files that are publicly available at the time of this final rule), CCR adjustment factor, and CCRs used to establish the FY 2027 outlier threshold are based on the most recent data available at the time of rulemaking. Because the outlier threshold is established prospectively, it necessarily relies on projections using the best available data. Although several commenters suggested alternative methodologies, such as using multi-year averages, limiting the annual increase in the threshold, or using different trend factors, they did not provide evidence demonstrating that these approaches would more accurately predict the outlier threshold needed to achieve the target of outlier payments equal to 5.1 percent of total operating DRG payments. Moreover, adopting such alternatives without evidence that they improve the accuracy of our projections could increase the likelihood that estimated outlier payments would deviate from the 5.1 percent target, resulting in non-budget neutral outlier payments. Accordingly, we continue to believe that using the most recent available data provides the best basis for estimating an outlier threshold for FY 2027 that would ensure that outlier payments are equal to the 5.1 percent target.

Comment: A commenter requested that CMS apply trims when calculating charge inflation as it does under the LTCH PPS to ''remove all claims from providers whose growth in average charges was a statistical outlier''.

Response: We responded to a similar comment in the FY 2024 IPPS/LTCH final rule (88 FR 59351–59352). We refer the reader to the FY 2024 IPPS/LTCH final rule for complete details.

Comment: A commenter requested that CMS consider whether it is appropriate to include extreme cases when calculating the threshold. This commenter explained that high charge cases have a significant impact on the threshold. The commenter stated that it examined the data and stated that it observed that the inclusion of extreme cases in the calculation of the threshold, the rate of which are increasing over time, significantly impacts CMS' determination of the fixed-loss threshold. If this trend continues (that is, if the number (and proportion) of extreme cases continues to increase each year), the commenter stated that the impact of this population of cases on the threshold will likewise increase. Thus, the commenter recommended that CMS study the trend, evaluate whether such cases should be excluded from the threshold calculation or addressed through a separate payment mechanism, and adopt an approach that produces a threshold more representative of typical cases.

Response: We responded to a similar comment in prior rulemaking, most recently in the FY 2026 IPPS/LTCH PPS final rule (90 FR 37226). As we explained in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38526) and other prior rulemaking, the methodology used to calculate the outlier threshold includes all claims to account for all different types of cases, including high charge cases, to ensure that CMS meets the 5.1 percent target. As the commenter pointed out, the volume of these cases continues to rise, making their impact on the threshold significant. We continue to believe excluding these cases would artificially lower the threshold. We continue to believe it is important to include all cases in the calculation of the threshold no matter how high or low the charges. Including these cases with high charges lends more accuracy to the threshold, as these cases have an impact on the threshold and continue to rise in volume. Therefore, we believe the inclusion of the high-cost outlier cases in the calculation of the outlier threshold is appropriate.

Comment: A commenter stated that it believes that CMS should disclose all aspects of its edits to the most current data used for the proposed rule and commit to the same process and methods when it recalculates the threshold for purposes of the final rule. Additionally, the commenter stated CMS should commit to make public the data files it uses for the final rule, including all edits and calculations, when it publishes the final rule.

Response: We refer the reader to the FY 2022 IPPS/LTCH final rule (86 FR 45540) where we responded to a similar comment.

Comment: A commenter noted the final fixed-loss threshold established by CMS has consistently been lower than the threshold set forth in the proposed rule, and the variance between the proposed and final thresholds has generally exceeded 4 percent. The commenter emphasized that this demonstrates that CMS must ordinarily use the most recent data to appropriately calculate the outlier threshold.

Response: We responded to similar comments in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50378 through 50379) and refer readers to that rule for our response. We reiterate that CMS' historical policy is to use the best available data when setting the payment rates and factors in both the proposed and final rules. Sometimes there are variables that change between the proposed and final rule as result of the availability of more recent data, such as the charge inflation factor and the CCR adjustment factors that can cause fluctuations in the threshold amount. Other factors such as changes to the wage indexes and market basket increase can also cause the outlier fixed loss cost threshold to fluctuate between the proposed rule and the final rule each year. We use the latest data that is available at the time of the development of the proposed and final rules, such as the most

recent update of MedPAR claims data and CCRs from the most recent update of the PSF.

Comment: Some commenters requested that, if anomalous data are driving the proposed increase in the FY 2027 outlier threshold, CMS maintain the FY 2026 outlier threshold of $40,397 for FY 2027, consistent with its approach for the LTCH outlier threshold. Other commenters suggested CMS to reconsider the calculation of the FY 2027 threshold and finalize an amount that protects hospitals from such a large year-over-year swing in outlier payments. A commenter urged CMS to provide additional sensitivity analysis regarding the proposed threshold and consider phasing in significant year-over-year increases to preserve the financial protection the outlier policy is designed to provide. Another commenter suggested that CMS cap the annual increase (for example, at 5 percent), which the commenter stated would result in an outlier threshold of approximately $43,500 instead of the proposed $51,704.

Another commenter expressed concern that the proposed FY 2027 outlier threshold increase is not supported by recent outlier payment experience. The commenter stated that its analysis of cost report data found outlier payments were below the statutory target in recent years and noted that CMS estimated FY 2025 outlier payments at 4.86 percent of total operating payments, below the 5.1 percent target. The commenter asserted that the proposed threshold increase could result in outlier payments falling below the target and urged CMS to limit the increase in the FY 2027 outlier threshold to reduce payment risk for hospitals.

Response: As noted previously, section 1886(d)(5)(A)(iv) of the Act states that outlier payments may not be less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on DRG prospective payment rates for discharges in that year. We believe that the commenters suggestions to cap or maintain the threshold the same as the prior year would be inconsistent with the statute as such a threshold would not result in a projection of outlier payments that are not less than 5 percent nor more than 6 percent of projected total payments for FY 2027. Additionally, each year we present our methodology to meet the statutory target. We believe we have thoroughly explained our proposed methodology so that commenters can review and provide meaningful comments. There are many factors that can drive the threshold to increase or decrease from one fiscal year to the next making it challenging to pinpoint which exact factor is causing the threshold to increase from one FY to the next.

After consideration of the public comments we received and for the reasons discussed, we are finalizing to use the same methodology we proposed, without modifications, to calculate the final outlier threshold for FY 2027.

For the FY 2027 final outlier threshold, we used the March 2025 MedPAR file of FY 2024 (October 1, 2023 through September 30, 2024) charge data (released in conjunction with the FY 2026 IPPS/LTCH PPS final rule) and the March 2026 MedPAR file of FY 2025 (October 1, 2024 through September 30, 2025) charge data (released in conjunction with this FY 2027 IPPS/LTCH PPS final rule) to determine the charge inflation factor. To compute the 1-year average annual rate-of-change in charges per case, we compared the average covered charge per case of $ 90,928.19 ($628,141,824,405/6,908,109 cases) from October 1, 2023 through September 31, 2024, to the average covered charge per case of $ 97,536.48 ($681,287,940,919/6,984,955 cases) from October 1, 2024 through September 31, 2025. This rate-of-change was 7.3 percent (1.07268) or 11.3 percent (1.15064) over 2 years. The billed charges are obtained from the claims from the MedPAR file and inflated by the inflation factor specified previously.

As we have done in the past, we are establishing the FY 2027 outlier threshold using hospital CCRs from the March 2026 update to the Provider-Specific File (PSF), the most recent available data at the time of the development of the final rule. We applied the following edits to providers' CCRs in the PSF. We believe these edits are appropriate to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replaced these CCRs with the statewide average CCR for the upcoming fiscal year. We also assigned the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We did not apply the adjustment factors described later in this section to hospitals assigned the statewide average CCR. For FY 2027, we also are continuing to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained later in this section).

For this final rule, as we have done since FY 2014 (with the exception of FYs 2022 and 2023, as discussed in the FY 2022 and FY 2023 IPPS/LTCH PPS proposed and final rules), we are adjusting the CCRs from the March 2026 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2025 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2026 update of the PSF. We note that we used total transfer-adjusted cases from FY 2025 to determine the national average case weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the methodology noted earlier, for this final rule, we calculated a March 2025 operating national average case-weighted CCR of 0.240425 and a March 2026 operating national average case-weighted CCR of 0.233434. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the March 2025 operating national average case weighted CCR from the March 2026 operating national average case-weighted CCR and then dividing the result by the March 2025 national operating average case-weighted CCR. This resulted in a national operating CCR adjustment factor of 0.970922.

We used the same methodology earlier to adjust the capital CCRs. Specifically, for this final rule, we calculated a March 2025 capital national average case-weighted CCR of 0.016402 and a March 2026 capital national average case-weighted CCR of 0.01528. We then calculated the percentage change between the two national capital case weighted CCRs by subtracting the March 2025 capital national average case-weighted CCR from the March 2026 capital national average case-weighted CCR and then dividing the result by the March 2025 capital national average case-weighted CCR. This resulted in a national capital CCR adjustment factor of 0.931594.

As discussed previously, for purposes of estimating the final outlier threshold for FY 2027, we used a wage index that reflects the policies discussed in this final rule. This includes the following:

- Application of the rural and imputed floor adjustment.
- The frontier State floor adjustments in accordance with section 10324(a) of the Affordable Care Act.
- The out migration adjustment as added by section 505 of Public Law 108–173.
- Incorporating our policy (described in section III.6. of the preamble of this final rule) to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline.
- The continuation of the transition for the discontinuation of the low wage index hospital policy (as described in section III.F.6 of the preamble of this final rule).

As stated previously, if we did not take the above into account, our estimate of total FY 2027 payments would be too low, and, as a result, the outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.14 percent of total payments (which reflects the estimate of outlier reconciliation calculated for this final rule).

- We excluded the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.
- We used the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.
- Based on the policy finalized, as previously described, we used the estimated per-discharge supplemental payments to hospitals eligible for the supplemental payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the

Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we are finalizing to incorporate an estimate of FY 2027 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, we are finalizing to hold the data constant and to use the FY 2025 final rule percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 from the FY 2025 IPPS/LTCH PPS final rule which is based on FY 2019 cost reports and PSF data. As discussed in the FY 2025 IPPS/LTCH PPS final rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) was a negative 0.041994 percent, which, when rounded to the second digit, is −0.04 percent. Therefore, for FY 2027, we incorporated a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.14 percent [5.1 percent–(−.04 percent)]. Under this approach, we determined a threshold of $49,346 and calculated total outlier payments of $ 4,660,920,375 and total operating Federal payments of $86,015,121,737. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.14 percent target, which incorporated an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). We note that, if calculated without applying our methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold, the threshold would be $49,728. We are finalizing an outlier fixed-loss cost threshold for FY 2027 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and any add on payments for new technology, plus $49,346.

(3) Other Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a higher percentage of outlier payments for capital-related costs than for operating costs. We project that the threshold for FY 2027 (which reflects our methodology to incorporate an estimate of operating outlier reconciliation) would result in outlier payments that would equal 5.1 percent of operating DRG payments and we estimate that capital outlier payments would equal 3.23 percent of capital payments based on the Federal rate (which reflects our methodology discussed previously to incorporate an estimate of capital outlier reconciliation).

In accordance with section 1886(d)(3)(B) of the Act and as discussed previously, we reduce the FY 2027 standardized amount by 5.1 percent to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that would be applied to the operating standardized amount and capital Federal rate based on the FY 2027 outlier threshold are as follows:

	Operating Standardized Amounts	Capital Federal Rate*
National	0.949	0.967684

*The adjustment factor for the capital Federal rate includes an adjustment to the estimated percentage of FY 2027 capital outlier payments for capital outlier reconciliation, as discussed previously and in section III.A.2 in this Addendum.

We are applying the outlier adjustment factors to the FY 2027 payment rates after removing the effects of the FY 2026 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we currently apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.267 or capital CCRs greater than 0.126 or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the range previously specified. These statewide average ratios would be effective for discharges occurring on or after October 1, 2026, and would replace the statewide average ratios from the prior fiscal year. Table 8B listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the comparable statewide average capital CCRs. As previously stated, the CCRs in Tables 8A and 8B would be used during FY 2027 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted previously. Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that section 20.1.2 of chapter three of the Medicare Claims Processing Manual (on the internet *at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) covers an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in the manual. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR at any time as long as the guidelines of the manual are followed. In addition, the manual outlines the outlier reconciliation process for hospitals and Medicare contractors. We refer hospitals to the manual instructions for complete details on outlier reconciliation.

(4) FY 2025 Outlier Payments

Our current estimate, using available FY 2025 claims data, is that actual outlier payments for FY 2025 were approximately 4.90 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2025, the percentage of actual outlier payments relative to actual total payments is lower than we projected for FY 2025. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2025 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier final rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the statutory language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section states that outlier payments be equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe that an important goal of a PPS

is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that, because the MedPAR claims data for the entire FY 2026 period would not be available until after September 30, 2026, we are unable to provide an estimate of actual outlier payments for FY 2026 based on FY 2026 claims data in this final rule. We will provide an estimate of actual FY 2026 outlier payments in the FY 2028 IPPS/LTCH PPS proposed rule.

5. FY 2027 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the internet on the CMS website) contain the national standardized amounts that we are applying to all hospitals, except hospitals located in Puerto Rico, for FY 2027. The standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). The amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 66.0 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are applying a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we would apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000. In addition, Tables 1A and 1B include the standardized amounts reflecting the applicable percentage increases for FY 2027.

The labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2027 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). Similarly, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2026 national standardized amounts to the FY 2027 national standardized amounts. The second through fifth columns display the changes from the FY 2026 standardized amounts for each applicable FY 2027 standardized amount. The first row of the table shows the updated (through FY 2026) average standardized amount after restoring the FY 2026 offsets for outlier payments, geographic reclassification, rural demonstration, transition for the discontinuation of the low wage index hospital policy and wage index cap policy. The MS–DRG reclassification and recalibration before cap, cap policy for MS–DRG weight and recalibration and wage index budget neutrality factors, are cumulative (that is, we have not restored the offsets). Accordingly, those FY 2026 adjustment factors have not been removed from the base rate in the following table.

BILLING CODE 4169–69–P

CHANGES FROM FY 2026 STANDARDIZED AMOUNTS TO THE FY 2027 STANDARDIZED AMOUNTS

	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
FY 2026 Base Rate after removing: 1. FY 2026 Geographic Reclassification Budget Neutrality (0.956835) 2. FY 2026 Operating Outlier Offset (0.949) 3. FY 2026 Cap Policy Wage Index Budget Neutrality Factor (0.999397) 4. Transition for the Discontinuation of the Low Wage Index Hospital Policy Budget Neutrality Factor (0.999726) 5. FY 2026 Rural Demonstration Budget Neutrality Factor (0.999552)	If Wage Index is Greater Than 1.0000: Labor (66.0%): $4,914.60 Nonlabor (34.0%): $2,531.76	If Wage Index is Greater Than 1.0000: Labor (66.0%): $4,914.60 Nonlabor (34.0%): $2,531.76	If Wage Index is Greater Than 1.0000: Labor (66.0%): $4,914.60 Nonlabor (34.0%): $2,531.76	If Wage Index is Greater Than 1.0000: Labor (66.0%): $4,914.60 Nonlabor (34.0%): $2,531.76
	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $4,616.74 Nonlabor (38%): $2,829.62	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $4,616.74 Nonlabor (38%): $2,829.62	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $4,616.74 Nonlabor (38%): $2,829.62	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $4,616.74 Nonlabor (38%): $2,829.62
FY 2027 Update Factor	1.023	0.999	1.015	0.991
FY 2027 MS-DRG Reclassification and Recalibration Budget Neutrality Factor Before Cap	0.998748	0.998748	0.998748	0.998748
FY 2027 Cap Policy MS-DRG Weight Budget Neutrality Factor	0.999730	0.999730	0.999730	0.999730
FY 2027 Wage Index Budget Neutrality Factor	1.000312	1.000312	1.000312	1.000312
FY 2027 Reclassification Budget Neutrality Factor	0.949363	0.949363	0.949363	0.949363
FY 2027 Cap Policy Wage Index Budget Neutrality Factor	0.999379	0.999379	0.999379	0.999379
FY 2027 Transition for the Discontinuation of the Low Wage Index Hospital Policy Budget Neutrality Factor	0.999777	0.999777	0.999777	0.999777
FY 2027 Operating Outlier Factor	0.949	0.949	0.949	0.949
National Standardized Amount for FY 2027 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (66.0/34.0)	**Labor: $4,520.33 Nonlabor: $2,328.65**	**Labor: $4,414.28 Nonlabor: $2,274.02**	**Labor: $4,484.98 Nonlabor: $2,310.44**	**Labor: $4,378.93 Nonlabor: $2,255.81**
National Standardized Amount for FY 2027 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)	**Labor: $4,246.37 Nonlabor: $2,602.61**	**Labor: $4,146.75 Nonlabor: $2,541.55**	**Labor: $4,213.16 Nonlabor: $2,582.26**	**Labor: $4,113.54 Nonlabor: $2,521.20**

BILLING CODE 4169–69–C

Comment: A few commenters believe Congress required CMS to calculate the standardized amount using the ''average standardized amount computed for the previous fiscal year under paragraph (2)(D) or this subparagraph'' (with the subparagraph referring to section 1886(d)(3)(A) of the Act), as they commented in the FY 2026 rulemaking. The commenters believe that CMS should use the FY 1985 standardized amount before it was adjusted to offset projected outlier payments under section 1886(d)(3)(B) of the Act and the neutrality provisions of sections 1886(d)(3)(C)(i) and (e)(1)(B) of the Act. The commenters believe that the FY 1986 IPPS rates reduced the standardized rate in that year and all subsequent years, including the time-period at issue here. To correct this error, the commenters believe CMS should either adjust the standardized amount or adjust the standardized amount and the MS–DRG weights.

Response: We responded to these comments in the FY 2026 IPPS final rule (90 FR 37226 through 37227) and refer readers to that discussion. As we stated in that rule, we understand that commenters now express disagreement with those decisions made after notice and comment nearly forty years ago. However, we do not believe it is appropriate to address these concerns again now, particularly in light of the fact that we did not solicit comments on the issue of revisiting the FY 1986 adjustment. It would be inappropriate to revise a long-standing decision made following notice and an opportunity for comment without providing notice that we were considering revisions of the issue.

Comment: One commenter urged CMS to correct what they contend is a longstanding error in the calculation of the IPPS standardized amount. The commenter argued that when CMS established the original standardized amount in 1983, it improperly counted hospital transfer cases as discharges, despite adopting a prospective payment policy that treated transfers differently from discharges. They assert that this inflated the discharge count, understated the standardized amount, and has resulted in lower Medicare inpatient payments to hospitals for more than four decades because the standardized amount has only been updated for inflation since its initial calculation. The commenter cited several court decisions which they believe support CMS's authority and obligation to correct this historical calculation. Accordingly, the commenter requested that CMS remove transfer cases from the standardized amount calculation for FY 2027, quantify the fiscal impact of correcting the error, and disclose that impact in the FY 2027 IPPS Final Rule.

Response: We did not solicit comments in this year's IPPS on our treatment of transfers

in the original calculation of the standardized amount calculated more than 40 years ago. The original IPPS standardized amount is policy was established following notice and comment rulemaking has remained consistent since the IPPS was first established. It would be inappropriate to revise a long-standing decision made following notice and an opportunity for comment without providing notice that we were considering revisions of the issue.

B. Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the internet on the CMS website), contain the labor-related and nonlabor-related shares that we are using to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2027. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. For FY 2027, as discussed in section IV.B.3. of the preamble of this final rule, we are applying a labor-related share of 66.0 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000. In section III. of the preamble of this final rule, we discuss the data and methodology for the FY 2027 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor. For FY 2011 and in prior fiscal years, we used the most recent cost-of-living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) website at *https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/nonforeign-areas/#url=COLA-Rates* to update this nonlabor portion.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the OPM every 4 years (coinciding with the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45546 through 45547), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule and Consumer Price Indices (CPIs) data through 2020. Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we utilized these COLA factors for FYs 2022 through 2025 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii.

In general, under our existing methodology, we update the 2009 OPM COLA factors by a comparison of the growth in the CPIs for the areas of Urban Alaska and Urban Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). We use the comparison of the growth in the overall CPI relative to the growth in the CPI for those areas to update the COLA factors for all areas in Alaska and Hawaii, respectively, because BLS publishes CPI data for only Urban Alaska and Urban Hawaii. Using the respective CPI commodities index and CPI services index and using the approximate commodities/services shares obtained from the IPPS market basket, we create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. Lastly we exercised our discretionary authority to adjust payments to hospitals in Alaska and Hawaii by incorporating the statutorily mandated cap of 25 percent that was applied when determining OPM's COLA factors. (For additional information, refer to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45546 through 45547).)

We previously stated our intention to update the COLA factors at the same time as the update to the labor-related share of the IPPS market basket. In the FY 2026 IPPS/LTCH PPS proposed rule, we proposed to update the labor-related share of the IPPS market basket. We also stated that at that time, we believed it would be appropriate to maintain the current COLA factors for FY 2026 to allow us to consider whether it would be appropriate to incorporate additional data sources or other methodology changes in determining the COLA factors we apply to IPPS payments to account for the unique circumstances of hospitals located in Alaska and Hawaii (90 FR 18437 through 18438). Therefore, we proposed to continue to use the FY 2025 COLA factors to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii for FY 2026. We solicited comments on any possible data sources that could be considered in the development of the COLA factors.

As summarized in the FY 2026 IPPS/LTCH PPS final rule (90 FR 37230), a commenter supported CMS' proposal to maintain the current COLA methodology temporarily while we evaluate alternative approaches. The commenter requested that CMS utilize a more sensitive adjustment to reflect cost variation across Alaska. The commenter stated that tying Alaska's COLA to a single urban index does not reflect higher costs in more remote areas. The commenter also requested that CMS reconsider the 25-percent cap on the COLAs and engage with providers during the development of the new methodology. After consideration of the public comment we received, we finalized our proposal to continue to use the FY 2025 COLA factors to adjust the nonlabor related portion of the standardized amount for hospitals located in Alaska and Hawaii for FY 2026.

After further consideration, effective for FY 2027, we proposed to adjust non-labor related costs for hospitals located in Alaska and Hawaii, using the Overseas Cost-of-Living Allowance (OCOLA) data [728] published by the Department of Defense (DOD). These OCOLAs are received by Service members serving outside of the contiguous U.S. (OCONUS) and are designed to offset higher prices of non-housing goods and services in order to equalize purchasing power with members stationed in the contiguous U.S. (CONUS). To calculate the OCOLAs for each OCONUS area, DOD currently uses Living Pattern Survey (LPS) data on purchasing patterns of Service members (*e.g.* how and where they purchase certain goods and services including whether these are purchased from a commissary, retail store, or online) and price data for approximately 150 goods and services.[729] The DOD compares the OCONUS LPS and price data with similar data obtained in CONUS.

We stated in the proposed rule that we believe the DOD OCOLAs are an appropriate data source to capture the cost differences of hospital nonlabor-related inputs purchased in the areas of Hawaii and Alaska compared to the continental U.S. The DOD OCOLAs reflect the relative price differences in a basket of non-housing goods and services that would be consistent with many of the nonlabor-related goods and services that hospitals purchase (such as pharmaceuticals, food, and cleaning supplies). In addition, unlike the prior approach that relied on CPI data for urban areas, these relative price differences would account for the additional shipping costs to remote areas. Specifically, the DOD OCOLAs are reflective of the specific areas of Alaska and Hawaii where hospitals are located.

For the proposed COLA factors for IPPS hospitals located in Alaska and Hawaii for

[728] *https://www.travel.dod.mil/Allowances/Overseas-Cost-of-Living-Allowance/.*

[729] Previously, pricing data was collected by Country Allowance Coordinators in each OCONUS location using the Retail Price Schedule. Effective August 2025, the DOD has outsourced the pricing data collection process for OCONUS to a private contractor.

FY 2027, we proposed to use the OCOLAs published by DOD effective for January 1, 2026. The DOD OCOLAs are available for 26 Alaska locality areas and 6 Hawaii locality areas. Similar to the COLAs used for Alaska and Hawaii for FY 2022 through FY 2026 that are based on the original OPM COLAs, we proposed to continue to use the four Nonforeign COLA Areas designated by OPM for Alaska and the four Nonforeign COLA Areas designated by OPM for Hawaii as shown in Table II.B.2 of the proposed rule.

For each of the designated OPM areas for cities in Alaska (City of Anchorage, City of Fairbanks, and City of Juneau), if there is more than one DOD OCOLA within a 50-mile radius of the city, we proposed to average the DOD OCOLAs within the designated OPM area to calculate the proposed COLA. Specifically, for the COLA factor for the City of Anchorage, we proposed to average the DOD OCOLAs for the Anchorage and Wasilla locality areas. For the COLA factor for the City of Fairbanks, we proposed to average the DOD OCOLAs for the College, Eielson Air Force Base, and Fairbanks locality areas. For the Rest of Alaska COLA, given that there are IPPS hospitals located in two locality areas (Bethel and Kenai), we proposed to average the DOD OCOLAs for these two locality areas to calculate the proposed COLA.

For Hawaii, the OCOLAs published by DOD are generally consistent with the OPM designated areas. To obtain the COLA factor for the OPM designated area of County of Maui and County of Kalawao, we proposed to average the DOD OCOLAs for the Maui and Molokai locality areas.

Starting with the FY 2027 payment year, we proposed to no longer cap the COLA factors at 25 percent. We noted that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent [730] and we had exercised our discretionary authority to adjust payments to hospitals in Alaska and Hawaii by incorporating this 25-percent cap. We stated that since we are no longer proposing to use the OPM COLA factors, as well as in consideration of the public comment we received, we are exercising our discretionary authority to no longer cap the COLA factors at 1.25. Lastly, for fiscal years after FY 2027, in order to facilitate stability in payment rates, we proposed to continue to update the COLA factors at the same time the labor-related share of the IPPS market basket is updated.

In the proposed rule (91 FR 19813 through 19814), we presented a table with the proposed COLA factors for FY 2027, as calculated using this proposed methodology, which indicated that changing the data source and eliminating the 25-percent cap has different impacts by area. We solicited comments on this proposed methodology and the use of the DOD OCOLAs, including any comments on how the use of survey data that are specific to Service members, including their access to discounted commissary prices that might be variable by geographic area, may result in differential impacts across the designated areas. We also requested comment on any potential modifications to this proposed methodology, including a potential phase-in of the use of these data or a transition period for implementation, which we stated we may consider finalizing in the FY 2027 IPPS/LTCH PPS final rule, after consideration of the comments received.

Comment: Several commenters supported the proposal to remove the 25 percent cap on COLA factors for Hawaii and Alaska. A commenter strongly supported the proposed adoption of the DOD OCOLA data. The commenter stated that the prior methodology's reliance on CPI–U for Anchorage, Alaska, as a proxy for cost differences across the entire state of Alaska was fundamentally flawed. The commenter stated that the vast majority of goods arriving in Alaska pass through Anchorage by port or airport before being transported further—often by road, boat, barge, or small aircraft—to their final destinations in communities like Kenai, Bethel, Fairbanks, and Mat-Su. The commenter further claimed that the additional shipping, freight, and logistics costs incurred by hospitals outside of Anchorage are real, significant, and were entirely unaccounted for under the prior CPI-based approach. The commenter also stated that they agreed with the proposed methodology for the ''Rest of Alaska'' COLA of averaging the DOD OCOLAs for the Bethel and Kenai locality areas. The commenter urged CMS to finalize these changes without modification, and specifically without any phase-in or transition period that would delay their implementation.

Other commenters opposed the use of the DOD OCOLA and stated that these data fail to measure cost differences faced by hospitals in Hawaii. A commenter recommended CMS continue to use the CPI–U as the basis for COLA adjustments. The commenter requested that CMS defer the proposed change to the basis for COLA adjustments from CPI–U until a more appropriate basis can be determined that would not undermine either Alaska or Hawaii. The commenter raised concerns about the OCOLA stating it was designed to measure consumer retail purchasing power for military personnel stationed overseas, not the operational cost structure of hospitals in non-contiguous U.S. states. The commenter stated that the OCOLA data fail to capture many other core drivers of hospital expenses, including real estate premiums and high energy and utility costs that are unique to Hawaii. The commenter also referenced concerns from a report by the Government Accounting Office (GAO) regarding the DOD Cost-of-Living Allowances,[731] published April 2026. The commenter claimed the OCOLA data was empirically unstable and undergoing significant methodological transition.

Some commenters requested that CMS consider alternative data sources or work to develop an appropriate data source to measure hospital nonlabor related cost differences. A commenter stated CMS should direct the Office of the Actuary or the Office of Assistant Secretary for Planning Evaluation to conduct a rigorous evaluation of alternative data sources that reflect the actual cost structure of non-DoD hospitals in non-contiguous states.

Commenters also raised equity considerations beyond Alaska and Hawaii, with some urging CMS to explore extending COLA adjustments to U.S. territories, and another commenter recommending that a COLA be implemented under the OPPS as well. Commenters supported our proposal to continue to update the COLA factors at the same time the labor-related share of the IPPS market basket is updated.

Response: The recent GAO report discussing the DOD OCOLA methodology included recommendations for improvements, a few of which DOD has acknowledged they will look to implement, but overall does not suggest the DOD OCOLA is not a valid data source.

We have been unable to identify a data source that directly reflects the prices of specific hospital expenses included in the nonlabor-related share for geographic areas in Alaska and Hawaii to compare with those same expenses in the contiguous U.S. Therefore, as done previously with the use of the OPM COLAs, we proposed to use a data source that reflects the relative price differences in a basket of goods and services that would be consistent with many of the nonlabor-related goods and services that hospitals purchase (such as pharmaceuticals, food, and cleaning supplies). As stated in the FY 2027 IPPS/LTCH PPS proposed rule, we continue to believe the DOD OCOLAs are an appropriate data source to capture the price differences of hospital nonlabor-related inputs purchased in the areas of Hawaii and Alaska compared to the continental U.S.

However, we appreciate and recognize the commenter's concerns that the current DOD OCOLA may not reflect all purchases made by hospitals, with specific concerns related to high real estate premiums and energy and utility costs that are unique to Hawaii. Since the CMS COLA factors apply to both operating and capital IPPS payments, we will continue to explore other data sources and methodologies for the CMS COLA factors to ensure they are adequately capturing the price differences facing hospitals. We also welcome recommendations regarding any additional data sources that could be used to develop the COLA factors (including those that might specifically capture capital and utility prices for Alaska and Hawaii and the contiguous U.S.). Commenters can send an email with feedback or suggestions on possible data sources to be used in developing the COLA factors to the following email: *cmsdnhs@cms.hhs.gov*.

With respect to commenters who asked CMS to explore extending COLA adjustments to U.S. territories and to establish a COLA under the OPPS, we note the COLA adjustment made under section 1886(d)(5)(H) of the Act specifies an appropriate adjustment to take into account the unique circumstances of hospitals located in Alaska and Hawaii. We refer commenters to the CY 2027 OPPS proposed rule (91 FR 41927

[730] Section 5941 of title 5, United States Code, and Executive Order 10000 (as amended) authorize the payment of COLAs in nonforeign areas (*https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/nonforeign-areas/*). Section 5941 states that the allowance may not exceed 25 percent.

[731] *https://files.gao.gov/reports/GAO-26-107490/index.html?_gl=1*n3r0hv*_ga*MTAxNzI0Nzk0Ny4xNzgxMDA0MTEx*_ga_V393SNS3SR*czE3ODEwMDQxMTAkbzEkZzEkdDE3ODEwMDQyNjQkajYwJGwwJGgw.*

through 41928), in which we proposed to implement a COLA using our authority under section 1833(t)(2)(E) of the Act. We note that we did not propose to extend COLA adjustments to U.S. territories and may consider these requests in future rulemaking.

We appreciate the commenters' support for our proposal to continue to update the COLA factors in conjunction with the labor-related share of the IPPS market basket.

As stated in the FY 2027 IPPS/LTCH PPS proposed rule, we requested comments on any potential modifications to our proposed methodology, including a potential phase-in of the use of these data or a transition period for implementation. We appreciate the commenters' support to no longer cap the COLA factors at 25 percent. As we stated in the proposed rule. OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent and we had exercised our discretionary authority to adjust payments to hospitals in Alaska and Hawaii by incorporating this 25-percent cap. Since we are no longer proposing to use the OPM COLA factors, we are exercising our discretionary authority to no longer cap the OCOLA-based COLA factors at 1.25. After consideration of public comments, we are finalizing our proposed methodology to use the DOD OCOLAs to determine the COLA factors, to no longer cap these OCOLA-based COLA factors at 25 percent, and to continue to update the COLA factors in conjunction with the labor-related share of the IPPS market basket. However, given the concerns raised by commenters, in particular that the OCOLA data may not reflect some of the high costs directly affecting Hawaii, for any locality area where the COLA factors would decrease using the DOD OCOLA data, we will maintain the COLA factors that were in place for FY 2022 through FY 2026. This would allow us to avoid adverse financial impacts to these areas while CMS can more fully evaluate the issues raised by commenters.

Therefore, as shown in Table H–01, we are finalizing the use of the DOD OCOLAs to determine the COLAs for each of the designated OPM areas in Alaska and for the designated OPM areas for County of Hawaii and County of Kauai and to no longer cap these OCOLA-based COLA factors at 25 percent. For the areas of City and County of Honolulu and County of Maui and County of Kalawao, given that the DOD OCOLA data would result in a decrease in the COLA factor, we will maintain the current COLA factors of 1.25. The following table lists the COLA factors for FY 2027 for the OPM designated areas of Alaska and Hawaii.

TABLE H-01: COST-OF-LIVING ADJUSTMENT FACTORS: ALASKA AND HAWAII HOSPITALS

Areas	Finalized FY 2027
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.28
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.32
City of Juneau and 80-kilometer (50-mile) radius by road	1.36
Rest of Alaska	1.44
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.32
County of Kauai	1.26
County of Maui and County of Kalawao	1.25

C. Calculation of the Prospective Payment Rates

1. General Formula for Calculation of the Prospective Payment Rates for FY 2027

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs and MDHs, for FY 2027 equals the Federal rate (which includes uncompensated care payments). As previously discussed, section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75) extended the MDH program for FY 2027 discharges occurring before January 1, 2027. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2027.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment:

- The Federal national rate (which, as discussed in section V.E. of the preamble of this final rule, includes uncompensated care payments).
- The updated hospital-specific rate based on FY 1982 costs per discharge.
- The updated hospital-specific rate based on FY 1987 costs per discharge.
- The updated hospital-specific rate based on FY 1996 costs per discharge.
- The updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2027 equals the higher of the applicable Federal rate, or the hospital-specific rate as described later in this section. The prospective payment rate for MDHs for discharges occurring before January 1, 2027, equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described in this section. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

2. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula specified in this section is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described previously) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

Step 1—Determine the MS–DRG and MS–DRG relative weight (from Table 5) for each claim primarily based on the ICD–10–CM diagnosis and ICD–10–PCS procedure codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described previously.

Step 3—Compute the operating and capital Federal payment rate:

—Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost-of-Living Adjustment)] × (1 + IME + (DSH * 0.25))

—Federal Payment for Capital Costs = MS–DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (l + IME + DSH)

Step 4—Determine operating and capital costs:

—Operating Costs = (Billed Charges × Operating CCR)

—Capital Costs = (Billed Charges × Capital CCR).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital

outlier threshold to account for local cost variation):

—Operating CCR to Total CCR = (Operating CCR)/(Operating CCR + Capital CCR)
—Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating CCR to Total CCR + Federal Payment with IME, DSH + Uncompensated Care Payment + supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals + New Technology Add-On Payment Amount
—Capital CCR to Total CCR = (Capital CCR)/(Operating CCR + Capital CCR)
—Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6—Compute operating and capital outlier payments:

—Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)
—Operating Outlier Payment = (Operating Costs − Operating Outlier Threshold) × Marginal Cost Factor
—Capital Outlier Payment = (Capital Costs − Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we add the uncompensated care payment and supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals to the total claim payment amount. As noted in the previous formula, we take uncompensated care payments, supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and new technology add-on payments into consideration when calculating outlier payments.

3. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment. As discussed previously, currently MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the greater of the updated hospital-specific rates based on either FY 1982, FY 1987, or FY 2002 costs per discharge. As noted, under current law, the MDH program is effective for FY 2027 discharges before January 1, 2027.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990, final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2027

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. As discussed in section V.F. of the preamble of this final rule, section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75) extended the MDH program for FY 2027 discharges occurring before January 1, 2027. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2027.

Accordingly, the applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs are the following:

FY 2027	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	3.2	3.2	3.2	3.2
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.8	-0.8
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.4	0	-2.4
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.9	-0.9	-0.9	-0.9
Applicable Percentage Increase Applied to Standardized Amount	**2.3**	**-0.1**	**1.5**	**-0.8**

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section V.F. of the preamble of this final rule. In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital specific-rate for an SCH or MDH is adjusted by the MS–DRG reclassification and recalibration budget neutrality factor, as discussed in section III. of this Addendum and listed in the table in section II. of the Addendum of this final rule. In addition, as discussed in section II.E.2.d. of the preamble this final rule and previously, we are applying a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, as finalized in the FY 2023 IPPS/LTCH PPS final rule. Because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, consistent with the policy adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48897 through 48900 and 49432 through 49433), the hospital specific-rate for an SCH or MDH would be adjusted by the MS–DRG 10-percent cap budget neutrality factor. The resulting rate is used in determining the payment rate that an SCH or MDH would receive for its discharges beginning on or after October 1, 2026.

III. Changes to Payment Rates for Acute Care Hospital Inpatient Capital Related Costs for FY 2027

The PPS for acute care hospital inpatient capital related costs was implemented for cost reporting periods beginning on or after October 1, 1991. The basic methodology for determining Federal capital prospective rates is set forth in- the regulations at 42 CFR 412.308 through 412.352. In this section of this Addendum, we discuss the factors that we used to determine the capital Federal rate for FY 2027, which would be effective for

discharges occurring on or after October 1, 2026.

All hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. We annually update the capital standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital related costs, which currently specifies capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the Federal rate.

A. Determination of the Federal Hospital Inpatient Capital Related- Prospective Payment Rate Update for FY 2027

In the discussion that follows, we explain the factors that we used to determine the capital Federal rate for FY 2027. In particular, we explain why the FY 2027 capital Federal rate will increase approximately 3.03 percent, compared to the FY 2026 capital Federal rate. As discussed in the impact analysis in Appendix A to this final rule, we estimate that capital payments per discharge will increase approximately 3.0 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a 1-percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate of change, as appropriate, each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The update factor for FY 2027 under that framework is 3.4 percent based on a projected 3.1 percent increase in the 2023-based CIPI, a 0.0 percentage point adjustment for intensity, a 0.0 percentage point adjustment for case-mix, a 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a forecast error correction of 0.3 percentage point. As discussed in section III.C. of the Addendum of this final rule, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2027 CIPI projection in that same section of this Addendum. In this final rule, we describe the policy adjustments that we applied in the update framework for FY 2027.

The case mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case- mix- index corresponds to an equal percentage increase in hospital payments.

The case mix- index can change for any of several reasons—

- The average resource use of Medicare patient changes (''real'' case mix- change);
- Changes in hospital documentation and coding of patient records result in higher weighted- DRG assignments (''coding effects''); or
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case mix change as actual changes in the mix (and resource requirements) of Medicare patients, as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004, IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts, as discussed in section II. of appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2027, we are projecting a 0.5 percent total increase in the case mix index. We estimate that the real case-mix increase will equal 0.5 percent for FY 2027. The net adjustment for change in case mix is the difference between the projected real increases in case mix and the projected total increase in case mix. Therefore, the net adjustment for case-mix change in FY 2027 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, for this final rule, we have the FY 2025 MedPAR claims data available to evaluate the effects of the FY 2025 DRG reclassification and recalibration as part of our update for FY 2027. We assume for purposes of this adjustment, that the estimate of FY 2025 DRG reclassification and recalibration would result in no change in the case-mix when compared with the case mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, as proposed, we are making a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2027.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if the difference in the actual increase and projected increase of the capital input price index for any year is greater than 0.25 percentage point in absolute terms. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. The forecast error in any given year can be derived as the actual CIPI increase less the forecasted CIPI increase. A forecast error of 0.3 percentage point was calculated for the FY 2025 update, for which there are historical data. That is, current historical data indicate that actual realized price increases (2.9 percent) were 0.3 percentage point higher than the forecasted FY 2025 CIPI increase (2.6 percent) used in calculating the FY 2025 update factor. Since this exceeds the 0.25 percentage point threshold, we are making an adjustment for forecast error in the update for FY 2027.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculate this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove non cost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the Consumer Price Index for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity changes that are due, respectively, to ineffective practice patterns and the

combination of quality enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual change is due to each of these factors. Thus, the capital update framework provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this final rule, as proposed, we are continuing to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2027 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 0436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2027, we are using an intensity measure that is based on an average of cost per-discharge data from the 5-year period beginning with FY 2020 and extending through FY 2024. Based on these data, we estimated that case-mix constant intensity declined during FYs 2020 through 2024. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimated that intensity declined during that 5-year period, we believe it is appropriate to continue to apply a zero-intensity adjustment for FY 2027. Therefore, as proposed, we are making a 0.0 percentage point adjustment for intensity in the update for FY 2027.

Earlier, we described the basis of the components we used to develop the 3.4 percent capital update factor under the capital update framework for FY 2027, as shown in the following table.

FY 2027 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	3.1
Intensity:	0.0
Case-Mix Adjustment Factors:	
Projected Case-Mix Change	-0.5
Real Across DRG Change	0.5
Subtotal	0.0
Effect of FY 2025 Reclassification and Recalibration	0.0
Forecast Error Correction	0.3
Total Update	3.4

*The capital input price index represents the 2023-based CIPI.

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital related costs. A shared threshold is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier threshold is set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments. For FY 2027, as proposed, we continue to incorporate the impact of estimated operating outlier reconciliation payment amounts into the outlier threshold model. (For more details on our methodology to incorporate an estimate of the impact of operating outlier reconciliation payment amounts into the outlier threshold model, see section II.A.4.i. of the Addendum to this final rule.)

For FY 2026, we estimated that outlier payments for capital-related PPS payments will equal 3.84 percent of inpatient capital related-payments based on the capital Federal rate. Based on the threshold discussed in section II.A. of the Addendum of this final rule, we estimate that prior to taking into account projected capital outlier reconciliation payments, outlier payments for capital-related costs will equal 3.26 percent of inpatient capital-related payments based on the capital Federal rate in FY 2027. Using the methodology outlined in section II.A.4.i. of the Addendum of this final rule, we estimate that taking into account projected capital outlier reconciliation payments will decrease the estimated percentage of FY 2027 capital outlier payments by 0.03 percent. Therefore, accounting for estimated capital outlier reconciliation, the estimated outlier payments for capital-related PPS payments will equal 3.23 percent (3.26 percent—0.03 percent) of inpatient capital-related payments based on the capital Federal rate in FY 2027. Accordingly, we applied an outlier adjustment factor of 0.9677 in determining the capital Federal rate for FY 2027. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2027 will be lower than the percentage we estimated for FY 2026.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The FY 2027 outlier adjustment of 0.9677 is a 0.63 percent change from the FY 2026 outlier adjustment of 0.9616. Therefore, the net change in the outlier adjustment to the capital Federal rate for FY 2027 is 1.0063 (0.9677/0.9616) so that the outlier adjustment will increase the FY 2027 capital Federal rate by approximately 0.63 percent compared to the FY 2026 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate, after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF, are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes.

As discussed in section III.F.6. of the preamble of this final rule, in the FY 2025 interim final action with comment period (IFC) (89 FR 80405 through 80421), we recalculated the FY 2025 IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. The recalculation of the FY 2025 hospital wage index impacted the FY 2025 GAFs. We also removed the budget neutrality adjustment for changes to the GAF for the lowest quartile adjustment from the FY 2025 capital Federal rate. For FY 2026 and subsequent fiscal years, after considering the D.C. Circuit's decision in *Bridgeport Hospital* v. *Becerra,* we discontinued the low wage index hospital policy.

For FY 2026, we established a payment transition with a budget neutrality adjustment for hospitals significantly impacted by the discontinuation of the low wage index hospital policy. The transitional payment exception for FY 2026 was equal to the additional FY 2026 amount the hospital would be paid under the IPPS if its FY 2026 wage index were equal to 90.25 percent of its FY 2024 wage index. Under that transitional policy, we made a budget neutral equivalent exception under the capital IPPS for FY 2026. We refer readers to the FY 2026 IPPS/LTCH PPS final rule (90 FR 37234 through 37235) for a full discussion on the FY 2026 transitional payment exception under the capital IPPS.

As discussed in III.F.6 of this final rule, we recognize that some hospitals that previously benefitted from the low wage index hospital policy would experience decreases of 15 percent or more over the three years from their FY 2024 wage index (with the low wage index hospital policy applied) to their FY 2027 wage index. Therefore, in addition to our 5-percent wage index cap policy at 42

CFR 412.64(h)(7), we are extending the transitional exception to the calculation of payments for FY 2027 for hospitals significantly impacted by the discontinuation of the low wage index hospital policy in a budget neutral manner. The transitional payment exception will end when the impact of discontinuing the low wage index hospital policy is mitigated and the hospital's wage index decrease is less than 95 percent for each year since 2024 (also expressed as 0.95∧n, with n being the number of years since FY 2024). Specifically, for FY 2027, for hospitals that benefitted from the low wage index hospital policy in FY 2024 and whose FY 2027 wage index is decreasing by more than 14.2625 percent from the hospital's FY 2024 wage index, we are continuing a transitional payment exception for FY 2027 for that hospital that would be equal to the additional FY 2027 amount the hospital would be paid under the IPPS if its FY 2027 wage index were equal to 85.7375 percent of its FY 2024 wage index. Under this policy, we are making a budget neutral equivalent exception under the capital IPPS. In this section, we refer to this policy as the transition for the discontinuation of the low wage index hospital policy.

As referenced previously, beginning in FY 2023, we finalized at 42 CFR 412.64(h)(7) a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY regardless of the circumstances causing the decline. That is, under this policy, a hospital's wage index value would not be less than 95 percent of its prior year value (87 FR 49018 through 49021). In this section, we refer to our policy to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year as the 5-percent cap on wage index decreases policy. We note that the transitional payment exception for FY 2027 discussed previously will be applied after the application of the 5-percent cap on wage index decreases policy.

For this final rule, as we proposed, we used a 2-step methodology for computing the budget neutrality factor for changes in the GAFs in light of the effect of those wage index changes on the GAFs. In the first step, we calculate a factor to ensure budget neutrality for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy, consistent with our historical GAF budget neutrality factor methodology. In the second step, we calculate a factor to ensure budget neutrality for changes to the GAFs due to the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy.

The budget neutrality factors applied for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are built permanently into the capital Federal rate; that is, they are applied cumulatively in determining the capital Federal rate. However, the budget neutrality factor for the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy is not permanently built into the capital Federal rate. This is because the GAFs with 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy applied from the previous year are not used in the budget neutrality factor calculations for the current year. Accordingly, and consistent with this approach, prior to calculating the GAF budget neutrality factors for FY 2027, we removed from the capital Federal rate the budget neutrality factor applied in FY 2026 for the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy. Specifically, we divided the capital Federal rate by the FY 2026 budget neutrality factor of 0.9989 (90 FR 37235 through 37236). (We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45552) for additional discussion on our policy of removing from the capital Federal rate the prior year budget neutrality factor(s) that are not used in the budget neutrality factor calculations for the current year.)

We discuss our 2-step calculation of the GAF budget neutrality factors for FY 2027 as follows. To determine the GAF budget neutrality factors for FY 2027, we first compared estimated aggregate capital Federal rate payments based on the FY 2026 MS–DRG classifications and relative weights and the FY 2026 GAFs to estimated aggregate capital Federal rate payments based on the FY 2026 MS–DRG classifications and relative weights and the FY 2027 GAFs without incorporating the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy. To achieve budget neutrality for these changes in the GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9916 for FY 2027.

Next, we compared estimated aggregate capital Federal rate payments based on the FY 2027 GAFs with and without the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy. For this calculation, estimated aggregate capital Federal rate payments were calculated using the FY 2027 MS–DRG classifications and relative weights (after application of the 10-percent cap discussed later in this section) and the FY 2027 GAFs (both with and without the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy). (We note, for this calculation the GAFs included the imputed floor, out-migration, and Frontier State adjustments.) To achieve budget neutrality for the effects of the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy on the FY 2027 GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9990.

The budget neutrality factor for the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy is not permanently built into the capital Federal rate. Consistent with this, we present the budget neutrality factor for the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy calculated under the second step of this 2-step methodology separately from the other budget neutrality factors in the discussion that follows, and this factor is not included in the calculation of the combined GAF/DRG adjustment factor described later in this section.

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. Consistent with our historical methodology for adjusting the capital standard Federal rate to ensure that the effects of the annual DRG reclassification and the recalibration of DRG weights are budget neutral under § 412.308(c)(4)(ii), we finalized to apply an additional budget neutrality factor to the capital standard Federal rate so that the 10-percent cap on decreases in an MS–DRG's relative weight is implemented in a budget neutral manner (87 FR 49436). Specifically, we augmented our historical methodology for computing the budget neutrality factor for the annual DRG reclassification and recalibration by computing a budget neutrality adjustment for the annual DRG reclassification and recalibration in two steps. We first calculate a budget neutrality factor to account for the annual DRG reclassification and recalibration prior to the application of the 10-percent cap on MS–DRG relative weight decreases. Then we calculate an additional budget neutrality factor to account for the application of the 10-percent cap on MS–DRG relative weight decreases.

To determine the DRG budget neutrality factors for FY 2027, we first compared estimated aggregate capital Federal rate payments based on the FY 2026 MS–DRG classifications and relative weights to estimated aggregate capital Federal rate payments based on the FY 2027 MS–DRG classifications and relative weights prior to the application of the 10-percent cap. For these calculations, estimated aggregate capital Federal rate payments were calculated using the FY 2027 GAFs without the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy. The incremental adjustment factor for DRG classifications and changes in relative weights prior to the application of the 10-percent cap is 0.9987. Next, we compared estimated aggregate capital Federal rate payments based on the FY 2027 MS–DRG classifications and relative weights prior to the application of the 10-percent cap to estimated aggregate capital Federal rate payments based on the FY 2027 MS–DRG classifications and relative weights after the application of the 10-percent cap. For these calculations, estimated aggregate capital Federal rate payments were also calculated using the FY 2027 GAFs without the 5 percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy. The incremental adjustment factor for the application of the 10-percent cap on relative weight decreases is 0.9997. Therefore, to achieve budget neutrality for the FY 2027 MS–DRG reclassification and recalibration

(including the 10-percent cap), based on the calculations described previously, we applied an incremental budget neutrality adjustment factor of 0.9984 (0.9987 × 0.9997) for FY 2027 to the capital Federal rate. We note that all the values are calculated with unrounded numbers.

The incremental adjustment factor for the FY 2027 MS–DRG reclassification and recalibration (0.9984) and for changes in the FY 2027 GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy (0.9916) is 0.9901 (0.9984 × 0.9916). This incremental adjustment factor is built permanently into the capital Federal rates.

To achieve budget neutrality for the effects of the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy on the FY 2027 GAFs, as described previously, we calculated a budget neutrality adjustment factor of 0.9990 for FY 2027. We refer to this budget neutrality factor for the remainder of this section as the cap/transition adjustment factor.

We applied the budget neutrality adjustment factors described previously to the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are determined separately. Under the capital IPPS, there is a single budget neutrality adjustment factor for changes in the GAF that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy. In addition, there is no adjustment for the effects that geographic reclassification, the 5-percent cap on wage index decreases policy, or the transition for the discontinuation of the low wage index hospital policy described previously have on the other payment parameters, such as the payments for DSH or IME.

The incremental GAF/DRG adjustment factor of 0.9901 accounts for the MS–DRG reclassifications and recalibration (including application of the 10-percent cap on relative weight decreases) and for changes in the GAFs that result from updates to the wage data, the effects on the GAFs of FY 2027 geographic reclassification decisions made by the MGCRB compared to FY 2026 decisions, and the application of the rural floor policy. The cap/transition adjustment factor of 0.9990 accounts for changes that result from the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy. However, these factors do not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Capital Federal Rate for FY 2027

For FY 2026, we established a capital Federal rate of $524.15 (90 FR 37236). We are establishing an update of 3.4 percent in determining the FY 2027 capital Federal rate for all hospitals. As a result of this final update and the budget neutrality factors discussed earlier, we are establishing a national capital Federal rate of $540.03 for FY 2027. The national capital Federal rate for FY 2027 was calculated as follows:

- The FY 2027 update factor is 1.034; that is, the update is 3.4 percent.
- The FY 2027 GAF/DRG budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS–DRG classifications and relative weights (including application of the 10-percent cap on relative weight decreases) and changes in the GAFs that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy is 0.9901.
- The FY 2027 cap/transition budget neutrality adjustment factor that is applied to the capital Federal rate for changes due to the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy is 0.9990.
- The FY 2027 outlier adjustment factor is 0.9677.

We are providing the following chart that shows how each of the factors and adjustments for FY 2027 affects the computation of the FY 2027 national capital Federal rate in comparison to the FY 2026 national capital Federal rate. The FY 2027 update factor has the effect of increasing the capital Federal rate by 3.4 percent compared to the FY 2026 capital Federal rate. The GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.99 percent. The FY 2027 cap/transition budget neutrality adjustment factor has the effect of increasing the capital Federal rate by 0.01 percent compared to the FY 2026 capital Federal rate. The FY 2027 outlier adjustment factor has the effect of increasing the capital Federal rate by 0.63 percent compared to the FY 2026 capital Federal rate. The combined effect of all the changes will increase the national capital Federal rate by approximately 3.03 percent, compared to the FY 2026 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2026 CAPITAL FEDERAL RATE AND THE FY 2027 CAPITAL FEDERAL RATE

	FY 2026	FY 2027	Change	Percent Change
Update Factor[1]	1.0280	1.034	1.034	3.4
GAF/DRG Adjustment Factor[1]	0.9918	0.9901	0.9901	-0.99
GAF Cap/Transition Adjustment Factor[2]	0.9989	0.9990	1.0001	0.01
Outlier Adjustment Factor[3]	0.9616	0.9677	1.0063	0.63
Capital Federal Rate	$524.15	540.03	1.0303	3.03

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rate. Thus, for example, the incremental change from FY 2026 to FY 2027 resulting from the application of the 0.9901 GAF/DRG budget neutrality adjustment factor for FY 2027 is a net change of 0.9901 (or -0.99 percent).

[2] The GAF Cap/Transition budget neutrality adjustment factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2027 GAF Cap/Transition budget neutrality adjustment factor is 0.9990/0.9989 or 1.0001 (or 0.01 percent).

[3] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2027 outlier adjustment factor is 0.9677/0.9616 or 1.0063 (or 0.63 percent).

[4] Percent change may not sum due to rounding.

B. Calculation of the Inpatient Capital Related-Prospective Payments for FY 2027

For purposes of calculating payments for each discharge during FY 2027, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. Section 412.312(c) provides for a shared threshold to identify outlier cases for both inpatient operating and inpatient capital-related payments. The outlier threshold for FY 2027 is in section II.A. of the Addendum of this final rule. For FY 2027, a case will qualify as a cost outlier if the cost for the case is greater than the prospective payment rates for the MS–DRG plus IME and DSH payments (including the empirically justified Medicare DSH payment and the estimated uncompensated care payment), estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and any add-on payments for new technology, plus the fixed-loss amount of $49,346.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation, unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect, the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted average of past capital purchase prices up to and including the current year.

For this final rule, as we proposed, we are using the IPPS operating and capital market baskets that reflect a 2023 base year. For a complete discussion of the rebasing of the IPPS operating and capital market baskets, we refer readers to section IV. of the preamble of the FY 2026 IPPS/LTCH PPS final rule (90 FR 36859 through 36879).

2. Forecast of the CIPI for FY 2027

Based on IHS Global Inc.'s second quarter 2026 forecast, for this final rule, we are forecasting the 2023-based CIPI to increase 3.1 percent in FY 2027. This reflects a projected 3.7 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), a projected 0.4 percent increase in vintage-weighted interest expense prices and a projected 3.2 percent increase in other capital expense prices in FY 2027. The weighted average of these three factors produces the forecasted 3.1 percent increase for the 2023-based CIPI in FY 2027.

As we proposed, we are using the more recent data available to determine the FY 2027 capital update factor for this final rule.

IV. Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2027

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are paid on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital, based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage specified in § 413.40(c)(3). In addition, as specified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38536), effective for cost reporting periods beginning during FY 2018, the annual update to the target amount for extended neoplastic disease care hospitals (hospitals described in § 412.22(i) of the regulations) also is the rate-of-increase percentage specified in § 413.40(c)(3). (We note that, in accordance with § 403.752(a), religious nonmedical health care institutions (RNHCIs) are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

For the FY 2027 IPPS/LTCH PPS proposed rule, based on IGI's 2025 fourth quarter forecast, we estimated that the proposed 2023-based IPPS operating market basket percentage increase for FY 2027 was 3.2 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the FY 2027 rate-of-increase percentage that would be applied to the FY 2026 target amounts in order to calculate the FY 2027 target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa was 3.2 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we proposed that if more recent data became available for the FY 2027 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2027.

More recent data has become available. Based on IGI's second quarter 2026 forecast, we estimate that the 2023-based IPPS operating market basket percentage increase for FY 2027 is 3.2 percent (that is, the estimate of the market basket rate-of-increase). Accordingly, the FY 2027 rate-of-increase percentage that we will apply to the FY 2026 target amounts in order to calculate the FY 2027 target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 3.2 percent, which is based on IGI's second quarter 2026 forecast.

IRFs and rehabilitation distinct part units, IPFs and psychiatric units, and LTCHs are excluded from the IPPS and paid under their respective PPSs. The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section IX. of the preamble and section V. of the Addendum of this final rule for the changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2027. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

We received no comments on this proposal and therefore are finalizing this provision without modification. Incorporating more recent data available for this final rule, as we proposed, we are adopting a 3.2 percent update for FY 2027.

V. Changes to the Payment Rates for the LTCH PPS for FY 2027

A. LTCH PPS Standard Federal Payment Rate for FY 2027

1. Overview

In section VIII. of the preamble of this final rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2027.

Under § 412.523(c)(3) of the regulations, for FY 2012 and subsequent years, we updated the standard Federal payment rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3) (citing sections 1886(b)(3)(B)(xi)(II) and 1886(m)(4) of the Act as set forth in the regulations at § 412.523(c)(3)(viii) through (xvii)). (For a summary of the payment rate development prior to FY 2012, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38310 through 38312) and references therein.)

Section 1886(m)(3)(A) of the Act specifies that, for rate year 2012 and each subsequent rate year, any annual update to the standard Federal payment rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as discussed in section IX.C.2. of the preamble of this final rule. This section of the Act further provides that the application of section 1886(m)(3)(B) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VIII.C.2. of the preamble of this final rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For LTCHs that fail to submit the required quality reporting data in accordance with the LTCH QRP, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

2. Development of the FY 2027 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice and § 412.523(c)(3)(xvii), for FY 2027, as we proposed, we are applying the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the LTCH PPS standard Federal payment rate for FY 2027, we also are making certain regulatory adjustments, consistent with past practices. Specifically, in determining the FY 2027 LTCH PPS standard Federal payment rate, as we proposed, we are applying a budget neutrality adjustment factor for the changes related to the area wage level adjustment (that is, changes to the wage data and labor-related share) as discussed in section V.B.6. of the Addendum of this final rule.

In this final rule, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 2.3 percent (that is, the most recent estimate of the 2022-based LTCH market basket increase of 3.2 percent less the productivity adjustment of 0.9 percentage point). Therefore, in accordance with § 412.523(c)(3)(xvii), we are applying an update factor of 1.023 to the FY 2026 LTCH PPS standard Federal payment rate of $50,824.51 to determine the FY 2027 LTCH PPS standard Federal payment rate. Also, in accordance with § 412.523(c)(3)(xvii) and (c)(4), we are required to reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points for LTCHs that fail to submit the required quality reporting data for FY 2027 as required under the LTCH QRP. Therefore, for LTCHs that fail to submit quality reporting data under the LTCH QRP, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 0.3 percent (or an update factor of 1.003). This update reflects the annual market basket update of 3.2 percent reduced by the 0.9 percentage point productivity adjustment, as required by section 1886(m)(3)(A)(i) of the Act, minus 2.0 percentage points for LTCHs failing to submit quality data under the LTCH QRP, as required by section 1886(m)(5) of the Act. Consistent with § 412.523(d)(4), we are applying an area wage level budget neutrality factor to the FY 2027 LTCH PPS standard Federal payment rate of 1.002679, based on the best available data at this time, to ensure that any changes to the area wage level adjustment (that is, the annual update of the wage index (including application of the 5-percent cap on wage index decreases, discussed later in this section), and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are establishing an LTCH PPS standard Federal payment rate of $52,132.76 (calculated as $50,824.51 × 1.023 × 1.002679) for FY 2027. For LTCHs that fail to submit quality reporting data for FY 2027, in accordance with the requirements of the LTCH QRP under section 1866(m)(5) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $51,113.55 (calculated as $50,824.51 × 1.003 × 1.002679) for FY 2027.

B. Adjustment for Area Wage Levels Under the LTCH PPS for FY 2027

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

The FY 2027 LTCH PPS standard Federal payment rate wage index values that will be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2026, through September 30, 2027, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of this Addendum and available via the internet on the CMS website.

2. Geographic Classifications (Labor Market Areas) Under the LTCH PPS

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by OMB, and a ''rural area'' is defined as any area outside of an urban area.

The geographic classifications (labor market area definitions) currently used under the LTCH PPS are based on the Core Based Statistical Areas (CBSAs) established by OMB. In the July 16, 2021, **Federal Register** (86 FR 37777), OMB finalized a schedule for future updates based on results of the decennial Census updates to commuting patterns from the American Community Survey. In accordance with that schedule, on July 21, 2023, OMB released Bulletin No. 23–01. According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (''the 2020 Standards''), which appeared in the **Federal Register** on July 16, 2021 (86 FR 37770 through 37778), and the application of those standards to Census Bureau population and journey-to-work data (that is, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data). A copy of OMB Bulletin No. 23–01 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.*

In the FY 2025 IPPS/LTCH PPS final rule, we stated that we believe that adopting the CBSA-based labor market area delineations established in OMB Bulletin No. 23–01 will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (89 FR 69974). We also noted that our adoption of the revised delineations announced in OMB Bulletin No. 23–01 is consistent with the changes under the IPPS for FY 2025. Therefore, in that same final rule, we adopted the updates set forth in OMB Bulletin No. 23–01, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, for the LTCH PPS effective for FY 2025. We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69973 through 69975), for a full discussion of our use of the OMB delineations based on OMB Bulletin No. 23–01 for the LTCH PPS. For additional information on the CBSA-based labor market area (geographic classification) delineations used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).

We continue to believe that the CBSA-based labor market area delineations, as established in OMB Bulletin No. 23–01, ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (89 FR 69974). Therefore, for FY 2027, we are continuing to use the CBSA-based labor market area delineations as established in OMB Bulletin No. 23–01 and adopted in the FY 2025 IPPS/LTCH final rule.

CBSAs are made up of one or more constituent counties. For FY 2027, we are continuing to use the Federal Information Processing Standard (FIPS) county codes, maintained by the U.S. Census Bureau, for purposes of crosswalking counties to CBSAs. The current county-to-CBSA crosswalk was adopted under the LTCH PPS in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69973 through 69975) and is located on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/long-term-care-hospital/other-files-download.*

3. Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs and a labor-related portion of capital costs using the applicable LTCH market basket. Additional background information on the historical development of the labor-related share under

the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

Effective FY 2025, we rebased and revised the 2017-based LTCH market basket to reflect a 2022 base year and determined the labor-related share annually as the sum of the relative importance of each labor-related cost category in the 2022-based LTCH market basket using the most recent available data. (For more details, we refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69435 through 69455).)

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19824), consistent with our historical practice, we proposed that the LTCH PPS labor-related share for FY 2027 would be the sum of the FY 2027 relative importance of each labor-related cost category in the LTCH market basket using the most recent available data. Specially, we proposed that the labor-related share for FY 2027 is the sum of the labor-related portion of operating costs from the 2022-based LTCH market basket (that is, the sum of the FY 2027 relative importance shares of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services) and a portion of the relative importance of Capital-Related cost weight from the 2022-based LTCH market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2022) and FY 2027. Based on IHS Global Inc.'s fourth quarter 2025 forecast of the 2022-based LTCH market basket, the sum of the FY 2027 relative importance for Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; and All Other: Labor-Related Services was 69.1 percent. The portion of capital-related costs that is influenced by the local labor market was estimated to be 46 percent (that was, the same percentage applied to the 2009-based, 2013-based, and 2017-based LTCH market basket capital-related costs relative importance). Since the FY 2027 relative importance for capital-related costs was 8.4 percent based on IHS Global Inc.'s fourth quarter 2025 forecast of the 2022-based LTCH market basket, we took 46 percent of 8.4 percent to determine the labor-related share of capital-related costs for FY 2027 of 3.9 percent. Therefore, we proposed a total labor-related share for FY 2027 of 73.0 percent (the sum of 69.1 percent for the labor-related share of operating costs and 3.9 percent for the labor-related share of capital-related costs). Consistent with our historical practice, we also proposed that if more recent data become available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the relative importance of each labor-related cost category of the 2022-based LTCH market basket), we would use such data, if appropriate, to determine the FY 2027 LTCH PPS labor-related share.

Comment: A commenter stated that they did not object to maintaining the current labor-related share, but CMS should continue evaluating whether current labor market measures adequately capture the persistent and structurally embedded cost pressures hospitals face (specifically, in regard to contract labor costs).

Response: We acknowledge the commenter's concern. The proposed labor-related share for FY 2027 was 73.0 percent (0.1 percentage point higher than the FY 2026 labor-related share), which reflects the sum of the FY 2027 relative importance shares of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a portion of the relative importance of Capital-Related cost weight from the 2022-based LTCH market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2022) and FY 2027.

After consideration of public comments, we are finalizing the FY 2027 labor-related share using the most recently available data—specifically, IHS Global Inc.'s second quarter 2026 forecast with historical data through the first quarter of 2026. Based on this forecast, the FY 2027 labor-related share for the final rule is still estimated at 73.0 percent. Therefore, we are finalizing a labor-related share for FY 2027 of 73.0 percent.

4. Wage Index for FY 2027 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider. As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also employ a policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2027 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, as we proposed, we are continuing to employ our historical practice of using the same data we used to compute the FY 2027 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this final rule (that is, wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2023) because these data are the most recent complete data available.

Comment: A commenter opposed CMS's use of unadjusted FY 2023 cost report data for determining the applicable area wage index values for the FY 2027 LTCH PPS standard Federal payment rate. The commenter noted that pandemic-driven labor costs, especially contract labor, were unusually high and not representative of expected labor costs in FY 2027. The commenter argued that using data from this period without appropriate adjustments will distort wage index values.

Response: As we stated in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69266 through 69268) and the FY 2026 IPPS/LTCH PPS final rule (90 FR 37239), it is not readily apparent how any changes due to the COVID–19 PHE differentially impacted the wages paid by individual hospitals. The commenter did not provide specific examples or data to show that certain providers or CBSAs were disproportionately affected by the PHE or contract labor costs. The commenter also did not suggest any specific adjustments CMS should make to the wage data. The concerns raised appear to be generalized without evidence of specific distortions in the FY 2023 wage data. As we stated in previous rules, even if CMS applied a uniform adjustment to contract labor salaries and hours, it would proportionally affect both area and national average hourly wages (AHW), leaving the wage index—which is a relative measure—essentially unchanged.

Taking all of these factors into account, we believe the FY 2023 wage data is the best available wage data to use for FY 2027. Therefore, as we proposed, consistent with our historical practice, we are using the most recent data available to determine the final applicable area wage index values for the FY 2027 LTCH PPS standard Federal payment rate in this final rule.

In addition, as we proposed, we computed the FY 2027 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, the labor market areas based on the OMB area delineations from Bulletin No. 23–01 as previously discussed in section V.B. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. As we proposed, we also continued to apportion the wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2027, as we proposed, we continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2023 IPPS wage data that we used to determine the FY 2027 LTCH PPS area wage index values in this final rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980).

Consistent with our existing methodology, we calculated the FY 2027 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12054, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 31924, 40660, 42340, 46660, and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum of this final rule.

Based on the FY 2023 IPPS wage data that we used to determine the FY 2027 LTCH PPS area wage index values in this final rule, there are no IPPS wage data for rural North Dakota (CBSA 35). Consistent with our existing methodology, we calculated the FY 2027 wage index value for CBSA 35 as the average of the wage index values for all CBSAs that are contiguous to the rural counties of the State (that is, CBSAs 13900, 22020, 24220, and 33500), as shown in Table 12B, which is listed in section VI. of this Addendum. We note that, as IPPS wage data are dynamic, it is possible that the number of urban and rural areas without IPPS wage data will vary in the future.

5. Cap on Wage Index Decreases

a. Cap on LTCH PPS Wage Index Decreases

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49440 through 49442), we finalized a policy that applies a permanent 5-percent cap on any decrease to an LTCH's wage index from its wage index in the prior year. Consistent with the requirement at § 412.525(c)(2) that changes to area wage level adjustments are made in a budget neutral manner, we include the application of this policy in the determination of the area wage level budget neutrality factor that is applied to the standard Federal payment rate, as is discussed later in section V.B.6. of this Addendum.

Under this policy, an LTCH's wage index will not be less than 95 percent of its wage index for the prior fiscal year. An LTCH's wage index cap adjustment is determined based on the wage index value applicable to the LTCH on the last day of the prior Federal fiscal year. However, for newly opened LTCHs that become operational on or after the first day of the fiscal year, these LTCHs will not be subject to the LTCH PPS wage index cap since they were not paid under the LTCH PPS in the prior year. For example, newly opened LTCHs that become operational during FY 2027 would not be eligible for the LTCH PPS wage index cap in FY 2027. These LTCHs would receive the calculated wage index for the area in which they are geographically located, even if other LTCHs in the same geographic area are receiving a wage index cap. The cap on wage index decreases policy is reflected at § 412.525(c)(1).

For each LTCH we identify in our rulemaking data, we are including in a supplemental data file the wage index values from both fiscal years used in determining its capped wage index. This includes the LTCH's final prior year wage index value, the LTCH's uncapped current year wage index value, and the LTCH's capped current year wage index value. Due to the lag in rulemaking data, a new LTCH may not be listed in this supplemental file for a few years. For this reason, a newly opened LTCH could contact their MAC to ensure that its wage index value is not less than 95 percent of the value paid to it for the prior Federal fiscal year. This supplemental data file for public use will be posted on the CMS website for this final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Comment: A commenter stated that while they support the permanent cap on LTCH PPS wage index decreases policy, they urge CMS to implement this policy in a non-budget-neutral manner to address financial strain that LTCHs continue to face.

Response: Implementation of this policy in a budget neutral manner is consistent with the requirement at § 412.525(c)(2) that changes to area wage level adjustments are made in a budget neutral manner. Consistent with this requirement, we continue to believe that changes to area wage level adjustments, including the 5-percent cap on the decrease on an LTCH's wage index, should not result in any change in estimated aggregate LTCH PPS payments. Furthermore, we also continue to anticipate that, in the absence of wage index policy changes beyond an annual update of the wage data, most LTCHs will experience year-to-year wage index declines less than 5 percent in any given year, and that the overall budget neutrality adjustments associated with the cap on wage index decreases will therefore be relatively small and will not create volatility in LTCH PPS payments. We note that approximately 32 LTCHs are expected to receive the 5-percent cap on wage index decreases in FY 2027.

b. Cap on IPPS Comparable Wage Index Decreases

Determining LTCH PPS payments for short-stay-outlier cases (reflected in § 412.529) and site neutral payment rate cases (reflected in § 412.522(c)) requires calculating an ''IPPS comparable amount.'' For information on this ''IPPS comparable amount'' calculation, we refer the reader to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49608 through 49610). Determining LTCH PPS payments for LTCHs that do not meet the applicable discharge payment percentage (reflected in § 412.522(d)) requires calculating an ''IPPS equivalent amount.'' For information on this ''IPPS equivalent amount'' calculation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439 through 42445).

Calculating both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' requires adjusting the IPPS operating and capital standardized amounts by the applicable IPPS wage index for nonreclassified IPPS hospitals. That is, the standardized amounts are adjusted by the IPPS wage index for nonreclassified IPPS hospitals located in the same geographic area as the LTCH. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49442 through 49443), we finalized a policy that applies a permanent 5-percent cap on decreases in an LTCH's applicable IPPS comparable wage index from its applicable IPPS comparable wage index in the prior year. Historically, we have not budget neutralized changes to LTCH PPS payments that result from the annual update of the IPPS wage index for nonreclassified IPPS hospitals. Consistent with this approach, the cap on decreases in an LTCH's applicable IPPS comparable wage index is not applied in a budget neutral manner.

Under this policy, an LTCH's applicable IPPS comparable wage index will not be less than 95 percent of its applicable IPPS comparable wage index for the prior fiscal year. An LTCH's applicable IPPS comparable wage index cap adjustment is determined based on the wage index value applicable to the LTCH on the last day of the prior Federal fiscal year. However, for newly opened LTCHs that become operational on or after the first day of the fiscal year, these LTCHs will not be subject to the applicable IPPS comparable wage index cap since they were not paid under the LTCH PPS in the prior year. For example, newly opened LTCHs that become operational during FY 2027 would not be eligible for the applicable IPPS comparable wage index cap in FY 2027. This means that these LTCHs would receive the calculated applicable IPPS comparable wage index for the area in which they are geographically located, even if other LTCHs in the same geographic area are receiving a wage cap. The cap on IPPS comparable wage index decreases policy is reflected at § 412.529(d)(4)(ii)(B) and (d)(4)(iii)(B).

Similar to the information we are making available for the cap on the LTCH PPS wage index values (described previously), for each LTCH we identify in our rulemaking data, we are including in a supplemental data file the wage index values from both fiscal years used in determining its capped applicable IPPS comparable wage index. Due to the lag in rulemaking data, a new LTCH may not be listed in this supplemental file for a few years. For this reason, a newly opened LTCH could contact its MAC to ensure that its applicable IPPS comparable wage index value is not less than 95 percent of the value paid to them for the prior Federal fiscal year. This supplemental data file for public use will be posted on the CMS website for this final rule at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

6. Budget Neutrality Adjustments for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that is applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we have applied an area wage level adjustment budget neutrality factor in determining the standard

Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

For FY 2027, in accordance with § 412.523(d)(4), we are applying an area wage level budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments, consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). As discussed in section V.B.5. of this Addendum, consistent with, § 412.525(c)(2), we include the application of the 5-percent cap on wage index decreases in the determination of the area wage level budget neutrality factor. Specifically, as we proposed, we determined an area wage level adjustment budget neutrality factor that is applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2027 using the following methodology:

Step 1—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2026 wage index values and the FY 2026 labor-related share of 72.9 percent.

Step 2—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2027 wage index values (including the application of the 5-percent cap on wage index decreases) and the FY 2027 labor-related share of 73.0 percent. (As noted previously, the changes to the wage index values based on updated hospital wage data are discussed in section V.B.4. of this Addendum and the labor-related share is discussed in section V.B.3. of this Addendum.)

Step 3—Calculate the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2026 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the FY 2027 updates to the area wage level adjustment (calculated in Step 2) to determine the budget neutrality factor for updates to the area wage level adjustment for FY 2027 LTCH PPS standard Federal payment rate payments.

Step 4—Apply the FY 2027 updates to the area wage level adjustment budget neutrality factor from Step 3 to determine the FY 2027 LTCH PPS standard Federal payment rate after the application of the FY 2027 annual update.

As we proposed, we used the most recent data available, including claims from the FY 2025 MedPAR file, in calculating the FY 2027 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor. We note that, because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, consistent with historical practice, we only used data from claims that qualified for payment at the LTCH PPS standard Federal payment rate under the dual rate LTCH PPS to calculate the FY 2027 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor.

For this final rule, using the steps in the methodology previously described, we determined a FY 2027 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.002679. Accordingly, in section V.A. of this Addendum, we applied the area wage level adjustment budget neutrality factor of 1.002679 to determine the FY 2027 LTCH PPS standard Federal payment rate, in accordance with § 412.523(d)(4).

C. Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels.

For FY 2011 and in prior fiscal years, we used the most recent cost-of-living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) website at *https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/nonforeign-areas/#url=COLA-Rates* to update this nonlabor portion.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by OPM every 4 years (coinciding with the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28019 through 28020 and 77 FR 53481 through 53482, respectively). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45559 through 45560), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule and Consumer Price Indices (CPIs) data through 2020. Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we utilized these COLA factors for FYs 2022 through 2025 to adjust the nonlabor-related portion of the standard Federal payment rate for LTCHs located in Alaska and Hawaii.

In general, under our existing methodology, we update the 2009 OPM COLA factors by a comparison of the growth in the CPIs for the areas of Urban Alaska and Urban Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). We use the comparison of the growth in the overall CPI relative to the growth in the CPI for those areas to update the COLA factors for all areas in Alaska and Hawaii, respectively, because BLS publishes CPI data for only Urban Alaska and Urban Hawaii. Using the respective CPI commodities index and CPI services index and using the approximate commodities/services shares obtained from the IPPS market basket, we create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. Lastly, we exercised our discretionary authority to adjust payments to LTCHs in Alaska and Hawaii by incorporating the statutorily mandated cap of 25 percent that was applied when determining OPM's COLA factors. (For additional information, refer to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45559 through 45560).)

We previously stated our intention to update the COLA factors at the same time as the update to the labor-related share of the IPPS market basket. In the FY 2026 IPPS/LTCH PPS proposed rule, we proposed to update the labor-related share of the IPPS market basket. We also stated that at that time, we believed it would be appropriate to maintain the current COLA factors for FY 2026 to allow us to consider whether it would be appropriate to incorporate additional data sources or other methodology changes in determining the COLA factors we apply to LTCH PPS payments to account for the unique circumstances of LTCHs located in Alaska and Hawaii (90 FR 18448 through 18449). Therefore, we proposed to continue to use the FY 2025 COLA factors to adjust the nonlabor-related portion of the standard Federal payment rate for LTCHs located in Alaska and Hawaii for FY 2026. We solicited comments on any possible data sources that could be considered in the development of the COLA factors.

Although we received no comments on our FY 2026 LTCH PPS proposal, a commenter, as summarized in the FY 2026 IPPS/LTCH PPS final rule (90 FR 37230), supported CMS' proposal to maintain the current COLA methodology under the IPPS temporarily while we evaluate alternative approaches. The commenter requested that CMS utilize a more sensitive adjustment to reflect cost variation across Alaska. The commenter stated that tying Alaska's COLA to a single urban index does not reflect higher costs in more remote areas. The commenter also requested that CMS reconsider the 25-percent cap on the COLAs and engage with providers during the development of the new methodology. After consideration of the public comment we received, we finalized our proposal to continue to use the FY 2025 COLA factors to adjust the nonlabor-related portion of the standard Federal payment rate for LTCHs located in Alaska and Hawaii for FY 2026.

After further consideration and consistent with the approach proposed under the IPPS, effective for FY 2027, we proposed to adjust nonlabor-related costs for LTCHs located in Alaska and Hawaii, using the Overseas Cost-

of-Living Allowance (OCOLA) data[732] published by the Department of Defense (DOD). These OCOLAs are received by Service members serving outside of the contiguous U.S. (OCONUS) and are designed to offset higher prices of non-housing goods and services in order to equalize purchasing power with members stationed in the contiguous U.S. (CONUS). To calculate the OCOLAs for each OCONUS area, DOD currently uses Living Pattern Survey (LPS) data on purchasing patterns of Service members (*e.g.* how and where they purchase certain goods and services including whether these are purchased from a commissary, retail store, or online) and price data for approximately 150 goods and services.[733] The DOD compares the OCONUS LPS and price data with similar data obtained in CONUS.

We stated in the proposed rule that we believe the DOD OCOLAs are an appropriate data source to capture the cost differences of LTCH nonlabor-related inputs purchased in the areas of Hawaii and Alaska compared to the continental U.S. The DOD OCOLAs reflect the relative price differences in a basket of non-housing goods and services that would be consistent with many of the nonlabor-related goods and services that LTCHs purchase (such as pharmaceuticals, food, and cleaning supplies). In addition, unlike the prior approach that relied on CPI data for urban areas, these relative price differences would account for the additional shipping costs to remote areas. Specifically, the DOD OCOLAs are reflective of the specific areas of Alaska and Hawaii where LTCHs are located.

For the proposed COLA factors for LTCHs located in Alaska and Hawaii for FY 2027, we proposed to use the OCOLAs published by DOD effective for January 1, 2026. The DOD OCOLAs are available for 26 Alaska locality areas and 6 Hawaii locality areas. Similar to the COLAs used for Alaska and Hawaii for FY 2022 through FY 2026 that are based on the original OPM COLAs, we proposed to continue to use the four Nonforeign COLA Areas designated by OPM for Alaska and the four Nonforeign COLA Areas designated by OPM for Hawaii as shown in Table V.C.1 of the proposed rule.

For each of the designated OPM areas for cities in Alaska (City of Anchorage, City of Fairbanks, and City of Juneau), if there is more than one DOD OCOLA within a 50-mile radius of the city, we proposed to average the DOD OCOLAs within the designated OPM area to calculate the proposed COLA. Specifically, for the COLA factor for the City of Anchorage, we proposed to average the DOD OCOLAs for the Anchorage and Wasilla locality areas. For the COLA factor for the City of Fairbanks, we proposed to average the DOD OCOLAs for the College, Eielson Air Force Base, and Fairbanks locality areas. For the Rest of Alaska COLA, given that there are IPPS hospitals located in two locality areas (Bethel and Kenai), we proposed to average the DOD OCOLAs for these two locality areas to calculate the proposed COLA. We note there is currently only one LTCH in Alaska, located in Anchorage.

For Hawaii, the OCOLAs published by DOD are generally consistent with the OPM designated areas. To obtain the COLA factor for the OPM designated area of County of Maui and County of Kalawao, we proposed to average the DOD OCOLAs for the Maui and Molokai locality areas. We note there are currently no LTCHs located in Hawaii.

Starting with the FY 2027 payment year, we proposed to no longer cap the COLA factors at 25 percent. We noted that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent[734] and we had exercised our discretionary authority to adjust payments to LTCHS in Alaska and Hawaii by incorporating this 25-percent cap. We stated that since we proposed to no longer use the OPM COLA factors, we also proposed to exercise our discretionary authority to no longer cap the COLA factors at 1.25. Lastly, for fiscal years after FY 2027, in order to facilitate stability in payment rates, we proposed to continue to update the COLA factors at the same time the labor-related share of the IPPS market basket is updated. In addition, in the proposed rule we solicited comments on this proposed methodology and the use of the DOD OCOLAs, including any comments on how the use of survey data that are specific to Service members, including their access to discounted commissary prices that might be variable by geographic area, may result in differential impacts across the designated areas. We also requested comment on any potential modifications to this proposed methodology, including a potential phase-in of the use of these data or a transition period for implementation.

We received no comments on these proposals and therefore are finalizing this provision without modification. Therefore, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, effective for FY 2027, as we proposed, we used the DOD OCOLAs to determine the COLAs for each of the designated OPM areas in Alaska and Hawaii and no longer capped these COLA factors at 25 percent. Below is a table with the finalized COLA factors for FY 2027, as calculated using this finalized methodology.

TABLE V.C.1: COST-OF LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII UNDER THE LTCH PPS FOR FY 2027

Areas	FY 2022 to FY 2026	FY 2027
Alaska:		
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22	1.28
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22	1.32
City of Juneau and 80-kilometer (50-mile) radius by road	1.22	1.36
Rest of Alaska	1.24	1.44
Hawaii:		
City and County of Honolulu	1.25	1.20
County of Hawaii	1.22	1.32
County of Kauai	1.25	1.26
County of Maui and County of Kalawao	1.25	1.24

[732] *https://www.travel.dod.mil/Allowances/Overseas-Cost-of-Living-Allowance/.*

[733] Previously, pricing data was collected by Country Allowance Coordinators in each OCONUS location using the Retail Price Schedule. Effective August 2025, the DOD has outsourced the pricing data collection process for OCONUS to a private contractor.

[734] Section 5941 of title 5, United States Code, and Executive Order 10000 (as amended) authorize the payment of COLAs in nonforeign areas (*https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/nonforeign-areas/*) and states that the allowance may not exceed 25 percent.

D. Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the FY 2016 IPPS/LTCH PPS final rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8-percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases that would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

To maintain budget neutrality, consistent with the budget neutrality requirement at § 412.523(d)(1) for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulations for further details.) For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

As noted previously, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS and are also used to determine payments for site neutral payment rate cases. As noted earlier, in determining HCO and the site neutral payment rate payments (regardless of whether the case is also an HCO), we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding CCRs and HCO adjustments for either LTCH PPS payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs in excess of the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. LTCH Total CCR Ceiling

Consistent with our historical practice, as we proposed, we used the best available data to determine the LTCH total CCR ceiling for FY 2027 in this final rule. Specifically, in this final rule, we used our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the March 2026 update of the Provider Specific File (PSF), which is the most recent data available. Accordingly, we are establishing an LTCH total CCR ceiling of 1.342 under the LTCH PPS for FY 2027 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCO cases under either payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48117 through 48119).)

We did not receive any public comments on our proposals and are finalizing our proposals as described previously.

c. LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on ''total'' IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C), the SSO policy at § 412.529(f)(4)(iii), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this final rule, as we proposed, we are using our established methodology for determining the LTCH PPS statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the March 2026 update of the PSF. As we proposed, we are establishing LTCH PPS statewide average total CCRs for urban and rural hospitals that will be effective for discharges occurring on or after October 1, 2026, through September 30, 2027, in Table 8C listed in section VI. of the Addendum of this final rule (and available via the internet on the CMS website).

Under the current LTCH PPS labor market areas, all areas in the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, as we proposed, we are continuing to use, as a proxy, the national average total

CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are using this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

Furthermore, although Connecticut, Massachusetts, and North Dakota have areas that are designated as rural under the current LTCH PPS labor market areas, in our calculation of the LTCH statewide average CCRs, there were no trimmed CCR data available from IPPS hospitals located in these rural areas as of March 2026. We refer the reader to section II.A.4.i.(2). of this Addendum for details on the trims applied to the IPPS CCR data from the March 2026 update of the PSF, which are the same data used to calculate the LTCH statewide average total CCRs. Therefore, consistent with our existing methodology, we used the national average total CCR for rural IPPS hospitals for rural Connecticut, Massachusetts, and North Dakota in Table 8C. We note that there were no LTCHs located in these rural areas as of March 2026.

We did not receive any public comments on our proposals. We are finalizing our proposals as described previously.

d. Reconciliation of HCO Payments

Under the HCO policy at § 412.525(a)(4)(iv)(D), the payments for HCO cases are subject to reconciliation (regardless of whether payment is based on the LTCH standard Federal payment rate or the site neutral payment rate). Specifically, any such payments are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge. For additional information on the reconciliation policy, we refer readers to sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4), as added by Change Request 7192 (Transmittal 2111; December 3, 2010) and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821), and most recently modified by Change Request 14233 (Transmittal 13428; September 22, 2025) with an update to the outlier reconciliation criteria.

3. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

Under the regulations at § 412.525(a)(2)(ii) and as required by section 1886(m)(7) of the Act, the fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases. (For more details on the requirements for high-cost outlier payments in FY 2018 and subsequent years under section 1886(m)(7) of the Act and additional information regarding high-cost outlier payments prior to FY 2018, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38544).)

b. Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2027

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments (that is, the target percentage) under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, the historical LTCH PPS HCO policy would continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount for LTCH PPS standard Federal payment rate cases would be determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19829 through 19830), for the reasons discussed below, we proposed to depart from our historical methodology for determining the fixed-loss amount, which we used to determine the FY 2026 fixed-loss amount in the FY 2026 IPPS/LTCH PPS final rule (90 FR 37243 through 37247). Under our historical methodology, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been an LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. Due to the lag time in the availability of claims data, under our historical methodology, we inflate charges from the claims data by a uniform factor based on the historical growth in charges for LTCH PPS standard Federal payment rate cases. We then multiply the inflated charges by each provider's best available CCR, which has been adjusted by a factor calculated from historical changes in the average case-weighted CCR for LTCHs. In accordance with § 412.525(a)(2)(ii), the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

On September 22, 2025, we issued Change Request (CR) 14233, which is available at *https://www.cms.gov/medicare/regulations-guidance/transmittals/2025-transmittals/r13428cp*. CR 14233 provides additional instructions to MACs that expand the criteria for identifying cost reports MACs are to refer to CMS for approval of outlier reconciliation. The original criteria issued in July 2003 instructed MACS to identify for CMS any instances where: (1) the actual CCR is found to be plus or minus 10 percentage points from the CCR used during that cost reporting period to make outlier payments, and (2) the total outlier payments exceeded $500,000 for that cost reporting period. CR14233 expanded this criteria for cost reports beginning on or after October 1, 2025, by instructing MACs to also identify for CMS any instances where: (1) the actual CCR is found to be plus or minus 20 percent or more from the CCR used during that time period to make outlier payments, and (2) the total outlier payments exceeded $500,000 for that cost reporting period.

For the proposed rule, we analyzed the FY 2023 cost reports to better understand the potential impact the expanded criteria would have on LTCH payments. We found that approximately 2 percent of LTCH cost reports met the original reconciliation criteria, while approximately 24 percent of LTCH cost reports would have met the expanded reconciliation criteria. For the vast majority of the cost reports that would have met the expanded criteria, the LTCHs increased their charges during their cost reporting period at rates that far exceed their costs. This practice of significant year-over-year charge increases has been documented in the charge inflation factors we have calculated in recent rules. (As an example, in the FY 2026 IPPS/LTCH PPS final rule (90 FR 37246), we determined that LTCHs, on average, increased their charges approximately 13 percent from FY 2023 to FY 2024.) Based on the most recent data available for the proposed rule, we determined that LTCHs, on average, increased their charges approximately 17 percent from FY 2024 to FY 2025.

As discussed in greater detail below, in the proposed rule we stated our belief that our historical methodology, which relies on the most recently available data, would not accurately estimate outlier payments for LTCHs in FY 2027. Ordinarily, the best available data to use for ratesetting is the most recently available data. However, in light of the issuance of CR 14233, we do not believe the most recently available data for estimating outlier payments is reflective of the expected LTCH experience in FY 2027. With an incentive to avoid outlier reconciliation, we believe LTCHs will not continue to increase their charges relative to costs at the rates reflected in the most recently available data. Specifically, we do not believe the recent annual increase in average charges of approximately 17 percent is a reliable indicator for forecasting future annual increases in charges that will occur for purposes of estimating outlier payments in FY 2027. Similarly, we do not believe the historical changes in LTCHs' CCRs observed from cost reporting periods subject to only the original criteria can be used to reliably predict future CCR levels for purposes of estimating outlier payments in FY 2027.

In the proposed rule, we discussed that we currently lack sufficient information to reasonably quantify the magnitude a behavioral change would have on charging practices and outlier payment trends in FY 2027. Using a variety of assumptions for charge inflation and degree of outlier reconciliation, in the proposed rule we estimated that a fixed-loss amount that would meet the statutory budget neutral target of estimated LTCH PPS outlier payments in FY 2027 would fall in the range of approximately $67,000 (a decrease of approximately $12,000 compared to the current fixed-loss amount) to $109,000 (an increase of approximately $30,000 compared to the current fixed-loss amount). Given this

wide range of uncertainty in attempting to adopt assumptions about charge inflation and degree of outlier reconciliation for purposes of estimating the fixed-loss amount for FY 2027 and the aforementioned issues with using the historic methodology for purposes of estimating the fixed-loss amount for FY 2027, in the proposed rule we stated our belief that maintaining the fixed-loss amount at its FY 2026 level of $78,936 is a reasonable estimate of a fixed-loss amount that will result in estimated LTCH PPS outlier payments being equal to 7.975 percent of total LTCH PPS payments for FY 2027. Therefore, we proposed a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2027 of $78,936 and stated our belief that setting the FY 2027 fixed-loss amount at the FY 2026 level would provide stability and predictability while allowing CMS time to gain insight into LTCHs' response to the additional reconciliation criteria.

Comment: Several commenters, while supportive of CMS's proposal to maintain the FY 2027 fixed-loss amount at the FY 2026 level, recommended that CMS instead calculate the FY 2027 fixed-loss amount using alternative methodological approaches that commenters believe would produce a lower amount. Like previous years, several commenters requested that CMS return to the methodology employed prior to FY 2022 in which the charge inflation factor was set equal to the market basket update. Some commenters stated this change has been a primary driver of the increases in the fixed-loss amount in recent years. Commenters argued that the prior methodology better aligned the threshold with overall payment growth and provided greater predictability from year to year. Some commenters requested that CMS recalculate the FY 2026 fixed-loss amount using this methodology and cap the FY 2027 fixed-loss amount at the resulting value. Commenters independently calculated that the FY 2026 fixed-loss amount would have been approximately $51,000 under the prior methodology.

Other commenters recommended that CMS calculate the FY 2027 fixed-loss amount using a charge inflation assumption based on IPPS hospital data. These commenters stated that CMS should establish the FY 2027 fixed-loss amount as the lower of the FY 2026 amount or the amount derived using the IPPS charge inflation assumption. These commenters noted that prior to the COVID–19 public health emergency (PHE), the LTCH PPS and IPPS fixed-loss amounts and year-to-year changes were closely aligned, and expressed an expectation that charge growth for LTCHs will return to levels similar to IPPS hospitals as COVID–19 cost effects subside and site-neutral payment policies are fully implemented.

Some commenters encouraged CMS to calculate the fixed-loss amount for the final rule using the most recently available MedPAR claims and cost report data, specifically the June 2026 updates of these data rather than the March 2026 updates, and recommended that if the resulting calculated amount is lower than the FY 2026 amount, CMS should adopt the lower amount rather than maintaining the FY 2026 amount.

Like previous years, a commenter urged CMS to exclude dialysis patients from the FY 2025 claims data when determining the fixed-loss amount, presenting evidence that the cost of treating dialysis patients in LTCHs has significantly increased and is expected to continue to rise. The commenter argued that CMS's ratesetting methodology is unable to capture these rising costs due to the lag in claims and cost report data, and that including these cases skews the calculation of the fixed-loss amount.

Response: We appreciate the feedback and suggestions that commenters provided regarding specific changes to our methodology for determining the fixed-loss amount. As we did in prior rules, we acknowledge that in recent years the calculated fixed-loss amount would have been lower if we had estimated charge inflation based on the market basket update. However, while the market basket methodology would have yielded lower fixed-loss amounts, we reiterate that the methodology would have resulted in high cost outlier payments that significantly exceeded the statutory target compared to the current methodology. For these reasons, we are not adopting commenters' recommendation to revert to the market basket-based charge inflation methodology for FY 2027 nor are we adopting commenters' recommendation to set the FY 2027 amount equal to the amount that would have been determined in FY 2026 using this methodology.

We understand commenters' expectation that LTCH charge growth will return to levels more consistent with IPPS hospitals as the effects of the COVID–19 PHE continue to subside. However, the most recent data available does not yet support that conclusion. Based on the data used in this final rule, we estimate that LTCHs increased their charges on average by 17 percent from FY 2024 to FY 2025, while IPPS hospitals increased their charges on average by 7 percent over the same period. Considering this significant divergence in the most recently available data, we do not believe it would be appropriate to base our LTCH charge inflation assumption on IPPS hospital data. Therefore, we are not adopting commenters' recommendation to calculate the FY 2027 fixed-loss amount using a charge inflation assumption based on IPPS hospital data.

We appreciate the commenters' suggestion to use the most recently available MedPAR claims and cost report data when calculating the fixed-loss amount for this final rule. We are unable to adopt commenters' recommendation to use the June 2026 updates of the MedPAR claims and cost report data, as these data are not available at the time we calculate the rates for this final rule.

With regard to the suggestion to exclude dialysis claims when calculating the fixed-loss amount, as we noted in the FY 2026 final rule, the commenter has again provided evidence supporting their belief that the costs of treating dialysis patients have increased in recent years and are likely to continue to increase. However, we note that if the commenter's assertion that dialysis costs are increasing at a rate faster than other LTCH cases is correct, a potential appropriate technical adjustment under our payment model would not be to exclude these cases. Excluding these cases from the dataset would reduce the accuracy of our payment model by removing standard Federal payment rate cases for which the outlier policy is designed to provide payment support. For these reasons, we are not adopting the recommendation to calculate the FY 2027 fixed-loss amount excluding dialysis patients from the MedPAR claims data.

Comment: Several commenters urged CMS to account for anticipated outlier reconciliation recoupments under the expanded reconciliation criteria when calculating the fixed-loss amount, consistent with CMS's existing approach for the IPPS. Commenters argued that the new reconciliation criteria will ''lower the bar'' for reconciliation and result in a greater number of LTCHs having outlier payments recouped at cost report settlement. Commenters stated that CMS's failure to make this adjustment for LTCHs, while doing so for IPPS hospitals, will result in artificially high fixed-loss thresholds that do not reflect the actual outlier payments LTCHs will remain after cost report settlement.

Response: As we stated in the FY 2026 IPPS/LTCH PPS final rule, we agree with commenters that incorporating an estimate of reconciled outlier dollars for the fiscal year into our methodology for determining the fixed-loss amount would improve its accuracy. We continue to believe that it would be difficult to predict the specific LTCHs that will have CCRs and outlier payments reconciled in any given year, as there are many different factors that determine whether a specific case will be eligible for an outlier payment, including the CCR, the estimated costs of the case, the payment amounts, and the fixed-loss amount itself. We also note, commenters did not provide any suggestions for how to make such predictions or develop a proxy for the specific LTCHs that will have CCRs and outlier payments reconciled in any given year. Historically, under the IPPS, an outlier reconciliation adjustment to the fixed-loss threshold has generally been computed using the percentage of total outlier reconciliation dollars to total Federal payments for a historical cost report data year. Rather than trying to predict which claims and/or hospitals may be subject to outlier reconciliation, we adopted a methodology that incorporates an estimate of outlier reconciliation dollars based on actual outlier reconciliation amounts reported in historical cost reports, as we believe such an approach would be more feasible and would provide a better estimate and predictor of outlier reconciliation for the upcoming fiscal year (84 FR 42623). We continue to believe that any such adjustment to the determination of the fixed-loss amount for LTCH PPS standard Federal payment rate cases would involve similar considerations and could therefore be computed in a similar manner.

In direct response to comments received in the FY 2026 rulemaking cycle, CMS requested supplemental LTCH PPS outlier reconciliation payment data from the MACs

for FY 2023 to potentially be used in FY 2027 rulemaking. The data CMS received is comparable to the supplemental outlier reconciliation data requested and received for IPPS hospitals, as discussed in detail in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69948 through 69955). CMS considered how these data could be incorporated into the methodology for determining the FY 2027 LTCH PPS fixed-loss amount. As discussed in the proposed rule, we found that 24 percent of FY 2023 LTCH cost reports would have met the expanded reconciliation criteria. We also stated in the proposed rule our belief that LTCHs will be incentivized to take steps to avoid outlier reconciliation. Therefore, we determined that these supplemental data could not be used directly to accurately estimate outlier reconciliation payments for LTCHs in FY 2027, as the data reflect a degree of outlier reconciliation that we do not expect to be representative of future years, once LTCHs have had the opportunity to adjust their behavior in response to the expanded reconciliation criteria.

As discussed in the proposed rule, we ran payment simulations that determined fixed-loss amounts assuming a varying degree of reconciliation, and these data helped inform the parameters used in those simulations, which led to our proposal to maintain the fixed-loss amount at its FY 2026 level. For these reasons, we are not adopting commenters' suggestion for FY 2027 to directly incorporate an estimate of outlier reconciliation into our methodology for determining the fixed-loss amount. However, we continue to welcome recommendations or suggestions on how to account for the potential impact of reconciliation in the determination of the fixed-loss amount for LTCH PPS standard Federal payment rate cases for future rulemaking.

Comment: A commenter recommended that CMS set the threshold at the lowest value within the estimated range of $67,000 to $109,000 presented by CMS in the proposed rule—a range derived by applying varying assumptions for charge inflation and the degree of outlier reconciliation—that would meet the statutory requirement that outlier payments equal approximately 8 percent of total LTCH PPS payments. The commenter stated that this approach would better support LTCHs that care for highly complex patients while remaining consistent with statutory obligations.

Response: We do not believe it would be appropriate to anchor the fixed-loss amount to either extreme end of this range. The lower bound of $67,000 and the upper bound of $109,000 each reflect our most extreme assumptions regarding charge inflation and the degree of outlier reconciliation, and we do not believe either set of assumptions is the most likely to reflect actual LTCH experience in FY 2027. We believe it is most reasonable to assume that the actual values for both charge inflation and the degree of outlier reconciliation will fall somewhere between these extremes, and that a fixed-loss amount at either end of the range would therefore be much less likely to result in actual outlier payments meeting the statutory target.

Comment: A commenter requested that CMS account for the effects of the COVID–19 PHE on the FY 2024 cost report data being used for FY 2027 LTCH PPS ratesetting. The commenter stated that the FY 2024 cost report data used for FY 2027 ratesetting overlaps with the PHE period and that the COVID–19 utilization and acuity patterns that occurred in FY 2024 will not resemble those expected in FY 2027. The commenter cited CDC data demonstrating decreases in COVID–19 hospitalizations and deaths since FY 2024 and provided facility-level data on the total number of COVID–19 patients treated at their LTCHs from 2020 to 2024. The commenter also argued that the FY 2024 cost report data reflects abnormally elevated pandemic-era labor costs that CMS is not accounting for when setting FY 2027 rates. The commenter additionally argued that CMS's proposal to maintain the FY 2026 fixed-loss amount for FY 2027 does not resolve the commenter's concern that the FY 2026 fixed-loss amount was itself calculated using data the commenter asserts were materially affected by the COVID–19 PHE—specifically FY 2023 cost report data and FY 2024 claims data. The commenter argued that carrying this amount forward without modification compounds what the commenter characterized as an error in the FY 2026 ratesetting and requested that CMS apply appropriate modifications to the data underlying the FY 2026 fixed-loss amount to account for the PHE's impact before carrying that amount forward into FY 2027.

Response: We disagree with the commenter's statement that the FY 2024 cost report data overlaps with the COVID–19 PHE period. The COVID–19 PHE expired on May 11, 2023, and the earliest FY 2024 cost reports began on October 1, 2023—nearly five months after the PHE expired. Furthermore, approximately 57 percent of LTCHs' FY 2024 cost reports began on or after June 1, 2024—more than a year after the PHE expired. Therefore, the FY 2024 cost report data used in this final rule does not overlap with the PHE period. We also disagree with the commenter's assertion that utilization at LTCHs in FY 2024 was significantly influenced by COVID–19. Our review of the FY 2024 MedPAR file found that approximately 3 percent of LTCH standard Federal payment rate cases included a COVID–19 diagnosis, which is not significantly different from the approximately 2 percent observed in the FY 2025 MedPAR file. We do not believe the level of COVID–19 prevalence in the FY 2024 claims data is sufficient to conclude that FY 2024 LTCH utilization and acuity patterns were significantly distorted by COVID–19 in a manner that would meaningfully affect FY 2027 ratesetting calculations. We also disagree with the commenter's assertion that CMS needs to account for elevated pandemic labor costs in the FY 2024 cost report data when determining FY 2027 rates. While the commenter provided evidence that labor costs increased significantly during the PHE, they did not provide evidence that these costs are no longer elevated and wouldn't be representative of expected costs in FY 2027. Rather the commenter stated in their letter that labor costs at their facilities remain abnormally high. For these reasons, we are not adopting the commenter's recommendation to apply modifications to the FY 2024 cost report data used in FY 2027 ratesetting to account for the effects of the COVID–19 PHE.

We also disagree with the commenter's assertion that CMS did not properly account for the impact of the COVID–19 PHE on the FY 2023 cost report data and FY 2024 claims data used to determine the FY 2026 fixed-loss amount. We discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 37243 through 37244) why we did not believe such adjustments were appropriate. For the same reasons discussed in that final rule, we do not believe it would be appropriate to apply modifications to the data underlying the FY 2026 fixed-loss amount for purposes of determining the FY 2027 fixed-loss amount.

Comment: Several commenters asserted that the implementation of the dual payment rate structure has contributed significantly to the increases in the fixed-loss amount in recent years. Commenters noted that because CMS only uses cases that would have been paid the standard Federal rate, the claims dataset used in the calculation is smaller and thus more susceptible to year-to-year fluctuations. Commenters also stated that the dual payment rate structure has incentivized LTCHs to prioritize higher-acuity admissions through the ICU and Ventilator Criterion exceptions to site-neutral payment, making these patients more likely to qualify for outlier payments. Commenters further stated that CMS has not updated its outlier policies to reflect the changes caused by the implementation of the dual payment rate system. Several commenters requested that CMS implement a non-budget neutral cap on future increases to the fixed-loss amount. Some commenters stated a cap is necessary until CMS has had time to adopt permanent reforms to its outlier policies. Some commenters stated that this cap would be similar to the cap policies CMS already applies to the LTCH PPS wage index and MS–LTC–DRG relative weights. Some commenters stated that the cap should be set equal to the annual market basket percent increase. Others requested that CMS establish a minimum two-year transition period before any future fixed-loss amount increases take effect.

Response: We agree with commenters that the implementation of the dual payment rate structure has led to fewer standard Federal rate cases, thereby resulting in lower aggregate LTCH PPS standard Federal rate payments. We also understand commenters' concerns regarding the concentration of standard Federal payment rate cases among a smaller and higher-acuity claims dataset under the dual rate payment structure, and the potential impact this may have on the fixed-loss amount calculation. Section 1886(m)(7) of the Act directs the Secretary to establish a fixed-loss amount for LTCH PPS standard Federal payment rate cases that would result in total estimated outlier payments being equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Implementing a cap or transition policy of the types requested by commenters would result in fixed-loss amounts that do not achieve the statutory target of 7.975 percent,

and we therefore do not believe it would be appropriate to adopt such an approach at this time. We note that the LTCH PPS wage index and MS–LTC–DRG relative weights cap policies referenced by some commenters are applied in a budget neutral manner.

Comment: A commenter disputed CMS's assertion in the proposed rule that most of the LTCHs whose FY 2023 cost reports would have met the expanded criteria increased their charges during their cost reporting period at rates that far exceed their costs. The commenter argued that that pandemic-era charge increases were driven by genuine cost pressures rather than profit-maximization.

Response: We disagree with the commenter. We believe the historical FY 2023 cost report data referenced in the proposed rule clearly demonstrate that these LTCHs increased their charges at rates that greatly exceeded their growth in costs during that period. Our analysis of FY 2023 cost report data found that the actual CCRs for approximately 23 percent of LTCHs were at least 20 percent lower than their ''paid CCRs'' (historical CCRs that were used to make claim payments). This means that for nearly one in four LTCHs, the actual relationship between costs and charges in FY 2023 had declined substantially relative to the historical cost reporting period from which their paid CCR was calculated.

Tentative settlement of a cost report typically occurs within 8 months after the close of the cost reporting period, therefore, the paid CCRs in effect during FY 2023 were generally derived from cost reports covering FY 2021 or FY 2022. (For example, the CCR from a LTCH's cost report period that ended on 3/31/2022 would typically be the paid CCR used for claim payments beginning 11/1/2022.) For simplicity, if we assume the paid CCRs were calculated from FY 2021 cost reports, an LTCH's charges would need to have grown at a rate of approximately 12 percentage points per year faster than costs between FY 2021 and FY 2023 for its CCR to decline 20 percent.

To illustrate, assume an LTCH's CCR for FY 2021 is 1.00. For the LTCH's CCR to decline 20 percent by FY 2023, the FY 2021 CCR must fall from 1.00 to 0.80. If costs grow at 3.0 percent per year (a factor of 1.030), the numerator of the CCR (costs) would increase by 6.09 percent (or 1.030×1.030) in 2 years. For the CCR to be equal to 0.80, the denominator of the CCR (charges) would have to increase by 32.61 percent (a factor 1.3261) in 2 years (that is, CCR = costs/charges = 1.0609/1.3261 = 0.80). This is an annual growth in charges of approximately 15.2 percent per year ($\sqrt{1.3261} = 1.1515$ or 15.2 percent per year). Therefore, the annual charge growth was approximately 12 percentage points per year faster than the annual cost growth from FY 2021 to FY 2023 (15.2 percent annual charge growth − 3.0 percent annual cost growth = 12.2 percentage points). Thus, for a hospital's CCR to be 20 percent lower by FY 2023, its billed charges would have had to rise dramatically faster than its actual costs (that is, about 12 percentage points more each year.)

Comment: A commenter requested that CMS disclose its projected FY 2026 LTCH high-cost outlier expenditures and assess proximity to the approximately 8 percent outlier target, as provided in prior proposed rules.

Response: We understand the commenter's interest in these projections. In prior proposed rules, we were able to provide projected LTCH high-cost outlier expenditures for the year preceding the ratesetting year—for example, projected FY 2025 outlier expenditures in the FY 2026 rule—and assess proximity to the 8 percent outlier target, because the historical data underlying our payment model provided a reliable basis for producing such projections. As discussed in detail in this proposed rule and described previously, the historical data currently available for projecting LTCH high-cost outlier payments are subject to significant uncertainty. Specifically, the same concerns regarding the reliability of the historical data that preclude us from determining a fixed-loss amount for FY 2027 using our historical methodology also hinder our ability to produce a reliable projection of FY 2026 outlier expenditures.

Comment: Several commenters expressed support for CMS's proposal to maintain the FY 2027 fixed-loss amount at the FY 2026 level of $78,936. Commenters acknowledged the uncertainty surrounding charge inflation and the implementation of the new outlier reconciliation policy and agreed that maintaining the threshold at the current amount represents a reasonable and measured approach that promotes stability and predictability for LTCHs while CMS continues to evaluate evolving data and provider behavior. Other commenters argued that requiring a hospital to absorb $78,936 in losses before qualifying for outlier payment undermines the intended purpose of the outlier policy and imposes financial and operational harm on LTCHs and the Medicare beneficiaries they serve. The commenters noted that the current fixed-loss amount is causing a negative effect on LTCH admissions of high-acuity patients, as LTCHs are increasingly unwilling to absorb the fixed-loss amount. The commenter argued that these declines in admissions are creating downstream consequences, including increased backlogs in IPPS hospital ICUs, fewer discharge options for complex patients, and additional LTCH closures.

Response: We thank the commenters for their support of our proposal to maintain the FY 2027 LTCH PPS high-cost outlier fixed-loss amount at the FY 2026 level of $78,936. We agree with commenters that keeping the threshold unchanged is a reasonable and measured approach that promotes stability and predictability for LTCHs while we continue to assess the data and provider behavior. We understand the comments on the impact the fixed-loss amount has on LTCH finances and access to care under the LTCH PPS and will continue to consider those issues for future rulemaking. As discussed in detail earlier in this section, we have considered and are not adopting the various alternative recommendations made by commenters that they believe would result in a lower fixed-loss amount for FY 2027.

After consideration of all comments received, we are finalizing our proposal to maintain the FY 2027 LTCH PPS high-cost outlier fixed-loss amount at its FY 2026 level of $78,936. We continue to believe that maintaining the fixed-loss amount at its FY 2026 level of $78,936 is a reasonable estimate of a fixed-loss amount that will result in estimated LTCH PPS outlier payments being equal to 7.975 percent of total LTCH PPS payments for FY 2027. We intend to reassess the appropriateness of returning to our historical calculation methodology for future years as more representative data becomes available.

Therefore, under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, as we proposed, we are establishing a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2027 of $78,936 that would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2027 payments for such cases. As such, we will make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed adjusted LTCH PPS standard Federal payment rate payment and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of $78,936).

4. High-Cost Outlier Payments for Site Neutral Payment Rate Cases

When we implemented the application of the site neutral payment rate in FY 2016, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. We again relied on these considerations and actuarial projections in FY 2017 and FY 2018 because the historical claims data available in each of these years were not all subject to the LTCH PPS dual rate payment system. Similarly, for FYs 2019 through 2025, we continued to rely on these considerations and actuarial projections because, due to the transitional blended payment policy for site neutral payment rate cases and the provisions of section 3711(b)(2) of the CARES Act, the historical claims data available in each of these years were not subject to the full effect of the site neutral payment rate.

For FYs 2016 through 2025, our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for

cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49617 through 49619 and 81 FR 57305 through 57307). For those reasons, we stated that we believed that the most appropriate fixed-loss amount for site neutral payment rate cases for FYs 2016 through 2025 would be equal to the IPPS fixed-loss amount for that particular fiscal year. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the corresponding IPPS fixed-loss amounts for FYs 2016 through 2025.

In the FY 2026 IPPS/LTCH PPS final rule (90 FR 37247) we discussed that section 3711(b)(2) of the CARES Act provided a waiver of the application of the site neutral payment rate for LTCH cases. This waiver applied to patients admitted during the COVID–19 PHE period and expired on May 11, 2023. Although the vast majority of LTCH discharges in FY 2024 were not subject to the waiver of the application of the site neutral payment rate, we believed LTCHs' admission patterns may still have been adapting to the expiration of the waiver of the application of the site neutral payment rate. Therefore, we did not believe it was appropriate to use FY 2024 data to develop a fixed-loss amount for site neutral payment rate cases for FY 2026. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the FY 2026 IPPS fixed-loss amount of $40,397 (90 FR 37247).

As discussed above, the waiver of the application of the site neutral payment rate under section 3711(b)(2) of the CARES Act expired on May 11, 2023. While FY 2024 and FY 2025 claims data reflect discharges that were not subject to this waiver, we believe that only two years of data subject to the full application of the site neutral payment rate is not sufficient for establishing a separate methodology for determining the fixed-loss amount for site neutral payment rate cases. We remain concerned that LTCH admission patterns may still be evolving following the expiration of the PHE waiver, and that adjusting our current policy based on this limited period of data would not be appropriate. We will continue to monitor claims data in future years to assess whether adjustments to this policy may be warranted as we accumulate a more robust dataset reflecting the post-PHE environment. For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for LTCHs for FY 2027 is the IPPS fixed-loss amount for FY 2027.

Accordingly, for FY 2027, as we proposed, we are establishing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. That is, we are establishing a fixed-loss amount for site neutral payment rate cases of $49,346, which is the same FY 2027 IPPS fixed-loss amount discussed in section II.A.4.i.(2). of the Addendum of this final rule. Accordingly, under this policy, for FY 2027, we will calculate an HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the site neutral payment rate payment and the fixed-loss amount for site neutral payment rate cases of $49,346).

In establishing an HCO policy for site neutral payment rate cases, we established a budget neutrality adjustment under § 412.522(c)(2)(i). We established this requirement because we believed, and continue to believe, that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases is budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments.

To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2027 would not result in any increase in estimated aggregate FY 2027 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2027. Consistent with our historical practice, as we proposed, we are continuing this policy.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate the fixed-loss threshold would result in FY 2027 HCO payments for site neutral payment rate cases to equal 5.1 percent of the site neutral payment rate payments that are based on the IPPS comparable per diem amount. As such, to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2027 would not result in any increase in estimated aggregate FY 2027 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate amount paid under § 412.522(c)(1)(i) by 5.1 percent to account for the estimated additional HCO payments payable for site neutral payment rate cases in FY 2027. To achieve this, for FY 2027, as we proposed, we are applying a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as 1.0 − 5.1/100 = 0.949) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We note that, consistent with our current policy, this HCO budget neutrality adjustment will not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

Comment: A commenter expressed concern with the proposed increase to the fixed-loss amount for site-neutral rate cases, stating it would result in fewer cases qualifying for an outlier payments and result in hospitals absorbing more financial risk for expensive and highly complex patients.

Response: We acknowledge the commenters' concern. We note that the commenter did not suggest any modifications for CMS to make in establishing the fixed-loss amount for site-neutral rate cases in this final rule. We believe it is reasonable for LTCH PPS site neutral payment rate cases to receive similar HCO payments to those cases that would be paid under the IPPS while we assess whether establishing a separate methodology for determining the fixed-loss amount for site neutral payment rate cases is warranted. Therefore, after consideration of comments received, we are finalizing our proposals as described previously, without modification.

E. Update to the IPPS Comparable Amount To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy to reflect the changes to the Medicare IPPS DSH payment adjustment methodology made by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the site neutral payment rate at § 412.522. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under the age of 65 who are uninsured, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments.

To reflect the Medicare DSH payment adjustment methodology statutory changes in section 3133 of the Affordable Care Act in the

calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766) that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating Medicare DSH payment amount that has historically been reflected in the LTCH PPS payments that are based on IPPS rates). We also stated, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19832), for FY 2027, based on the most recent data available at that time, we proposed to establish that the calculation of the ''IPPS comparable amount'' under § 412.529 would include an applicable operating Medicare DSH payment amount that is equal to 73.75 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we proposed that, if more recent data became available, we would use that data to determine the applicable operating Medicare DSH payment amount used to calculate the ''IPPS comparable amount'' in the final rule.

We did not receive any public comments in response to our proposal, and as such are finalizing this proposal. However, as we proposed, we are determining the applicable operating Medicare DSH payment amount used to calculate the ''IPPS comparable amount'' in this final rule using more recent data.

For FY 2027, as discussed in greater detail in section IV.E.2.b. of the preamble of this final rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 67.14 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2027. In other words, the amount of the Medicare DSH payments that would have been made prior to the amendments made by the Affordable Care Act is adjusted to 50.36 percent (the product of 75 percent and 67.14 percent) and the resulting amount is used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2027, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 75.36 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of the amendments made by the Affordable Care Act (that is, 25 percent + 50.36 percent = 75.36 percent). Therefore, for FY 2027, consistent with our proposal, we are establishing that the calculation of the ''IPPS comparable amount'' under § 412.529 will include an applicable operating Medicare DSH payment amount that is equal to 75.36 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act.

F. Computing the Adjusted LTCH PPS Federal Prospective Payments for FY 2027

Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages; we make this adjustment by multiplying the labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the FY 2027 values are shown in Tables 12A through 12B listed in section VI. of the Addendum of this final rule and are available via the internet on the CMS website). The LTCH PPS standard Federal payment rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the FY 2027 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this final rule, we are establishing an LTCH PPS standard Federal payment rate for FY 2027 of $52,132.76, as discussed in section V.A. of this Addendum. We illustrate the methodology to adjust the LTCH PPS standard Federal payment rate for FY 2027, applying our LTCH PPS amounts for the standard Federal payment rate, MS–LTC–DRG relative weights, and wage index in the following example:

Example: During FY 2027, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is, an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in CBSA 16984, which has a FY 2027 LTCH PPS wage index value of 1.0102 (as shown in Table 12A listed in section VI. of the Addendum of this final rule). The Medicare patient case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a relative weight for FY 2027 of 0.9678 (as shown in Table 11 listed in section VI. of the Addendum of this final rule). The LTCH submitted quality reporting data for FY 2027 in accordance with the LTCH QRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient case in FY 2027, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted FY 2027 LTCH PPS standard Federal payment rate ($52,132.76) by the labor-related share (73.0 percent) and the wage index value (1.0102). This wage-adjusted amount was then added to the nonlabor-related portion of the unadjusted LTCH PPS standard Federal payment rate (27.0 percent; adjusted for cost of living, if applicable) to determine the adjusted LTCH PPS standard Federal payment rate, which is then multiplied by the MS–LTC–DRG relative weight (0.9678) to calculate the total adjusted LTCH PPS standard Federal payment for FY 2027 ($50,829.77). The table illustrates the components of the calculations in this example.

EXAMPLE: LTCH'S TOTAL ADJUSTED FEDERAL PROSPECTIVE PAYMENT

Unadjusted LTCH PPS Standard Federal Prospective Payment Rate	$52,132.76
Labor-Related Share	x 0.730
Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $38,056.91
Wage Index (CBSA 16984)	x 1.0102
Wage-Adjusted Labor Share of the LTCH PPS Standard Federal Payment Rate	= $38,445.09
Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($52,132.76 x 0.270)	+ $14,075.85
Adjusted LTCH PPS Standard Federal Payment Amount	= $52,520.94
MS-LTC-DRG 189 Relative Weight	x 0.9678
Total Adjusted LTCH PPS Standard Federal Prospective Payment	= $50,829.77

VI. Tables Referenced in This Final Rule Generally Available Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this final rule and in the Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2026, for the FY 2027 rulemaking cycle, the IPPS and LTCH PPS tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be on the CMS website. Specifically, all IPPS tables listed in the final rule, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, will generally be available on the CMS website. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules.

Tables 7A and 7B historically contained the Medicare prospective payment system selected percentile lengths of stay for the MS–DRGs for the prior year and upcoming fiscal year. We note, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49452), we finalized beginning with FY 2023, to provide the percentile length of stay information previously included in Tables 7A and 7B in the supplemental AOR/BOR data file. The AOR/BOR files can be found on the FY 2027 IPPS final rule home page on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

As discussed in section II.E.6. of the preamble to this final rule, for certain FY 2027 new technology add-on payment applications, we are making available separate tables listing the ICD–10–PCS codes or ICD–10–CM codes that would be used to identify the relevant indication, or exclude cases related to a different technology, for purposes of the new technology add-on payment, in Table 10 associated with this final rule.

After hospitals have been given an opportunity to review and correct their calculations for FY 2027, we will post Table 15 (which will be available via the CMS website) to display the final FY 2027 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October 1, 2026. We expect Table 15 will be posted on the CMS website in the Fall 2026.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified in this final rule should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this final rule are generally available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled ''FY 2027 IPPS Final Rule Home Page'' or ''Acute Inpatient -Files- for Download.''

Table 2.—Case-Mix Index and Wage Index Table by CCN—FY 2027 Final Rule
Table 3.—Wage Index Table by CBSA—FY 2027 Final Rule
Table 4A.—List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2027 Final Rule
Table 4B.—Counties Redesignated under Section 1886(d)(8)(B) of the Act (LUGAR Counties)—FY 2027 Final Rule
Table 5.—List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2027 Final Rule
Table 6A.—New Diagnosis Codes—FY 2027
Table 6B.—New Procedure Codes—FY 2027
Table 6C.—Invalid Diagnosis Codes—FY 2027
Table 6D.—Invalid Procedure Codes—FY 2027
Table 6E.—Revised Diagnosis Code Titles—FY 2027
Table 6F.—Revised Procedure Code Titles—FY 2027
Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2027
Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2027
Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2027
Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2027
Table 6I.—Complete MCC List
Table 6I.1.—Additions to the MCC List—FY 2027
Table 6J.—Complete CC List
Table 6J.1.—Additions to the CC List—FY 2027
Table 6J.2.—Deletions to the CC List—FY 2027
Table 6K.—Complete CC Exclusions List—FY 2027.
Table 8A.—FY 2027 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)—FY 2027 Final Rule
Table 8B.—FY 2027 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals—FY 2027 Final Rule
Table 10.—Relevant ICD–10 Codes for Certain FY 2027 New Technology Add-On Payments
Table 16A.—Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2027
Table 18.—FY 2027 Medicare DSH Uncompensated Care Payment Factor 3 Amounts

The following LTCH PPS tables for this FY 2027 final rule are available through the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1849–F:

Table 8C.—FY 2027 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)—FY 2027 Final Rule
Table 11.—MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2026, through September 30, 2027—FY 2027 Final Rule
Table 12A.—LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2026, through September 30, 2027—FY 2027 Final Rule
Table 12B.—LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2026, through September 30, 2027—FY 2027 Final Rule

TABLE 1A.— NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (66.0 PERCENT LABOR SHARE/34.0 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)--FY 2027 FINAL RULE

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.3 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = -0.1 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.5 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.9 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,520.33	$2,328.65	$4,414.28	$2,274.02	$4,484.98	$2,310.44	$4,378.93	$2,255.81

TABLE 1B.— NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2027 FINAL RULE

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.3 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = -0.1 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.5 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.9 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,246.37	$2,602.61	$4,146.75	$2,541.55	$4,213.16	$2,582.26	$4,113.54	$2,521.20

TABLE 1C.— ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1);—FY 2027 FINAL RULE

	Rates if Wage Index Greater Than 1		Hospital is a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 2.3 Percent)		Hospital is NOT a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = -0.1 Percent)	
	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
National[1]	Not Applicable	Not Applicable	$4,246.37	$2,602.61	$4,146.75	$2,541.55

[1] For FY 2027, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D.— CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2027 FINAL RULE

	Rate
National	$540.03

TABLE 1E.— LTCH PPS STANDARD FEDERAL PAYMENT RATE--FY 2027 FINAL RULE

	Full Update (2.3 Percent)	Reduced Update* (0.3 Percent)
Standard Federal Rate	$52,132.76	$51,113.55

* For LTCHs that fail to submit quality reporting data for FY 2027 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary to make payment and policy changes under the IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This final rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS. Also, as we note later in this Appendix, the primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In

addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this final rule, such as the updates to the IPPS and LTCH PPS rates, and the policies and discussions relating to applications for new technology add-on payments, are needed to further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries.

We expect that these changes will ensure that the outcomes of the prospective payment systems are reasonable and provide equitable payments, while avoiding or minimizing unintended adverse consequences.

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

a. Update to the IPPS Payment Rates

In accordance with section 1886(b)(3)(B) of the Act and as described in section VI.B. of the preamble of this final rule, we are updating the national standardized amount for inpatient hospital operating costs by the applicable percentage increase of 2.3 percent (that is, a 3.2 percent market basket percentage increase with a reduction of 0.9 percentage point for the productivity adjustment). We are also updating the hospital-specific rates by the applicable percentage increase (including the market basket percentage increase and the productivity adjustment).

Subsection (d) hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act will receive an applicable percentage increase of 1.5 percent, which reflects a one-quarter percent reduction of the market basket update for failure to submit quality data. Hospitals that are not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act will receive an applicable percentage increase of −0.1 percent, which reflects a three-quarter percent reduction of the market basket update for not meeting the requirements to be a meaningful EHR user.

Hospitals that are not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act will receive an applicable percentage increase of −0.9 percent, which reflects a one-quarter percent reduction of the market basket update for failure to submit quality data and a three-quarter percent reduction of the market basket update for not meeting the requirements to be a meaningful EHR user.

b. Changes for the Add-On Payments for New Services and Technologies

Consistent with sections 1886(d)(5)(K) and (L) of the Act, we review applications for new technology add-on payments based on the eligibility criteria at 42 CFR 412.87. As set forth in 42 CFR 412.87(f)(1), we consider whether a technology meets the criteria for the new technology add-on payment and announce the results as part of the annual updates and changes to the IPPS. New technology add-on payments are not budget neutral.

As discussed in section II.E.7. of the preamble of this final rule, we are finalizing our proposal that for all applications received for new technology add-on payments for FY 2028 and subsequent fiscal years, including applications for FDA-designated Breakthrough Devices and QIDPs, or drugs approved under FDA's LPAD pathway, we would evaluate whether the technology is new and not substantially similar to an existing technology, and the technology must demonstrate that it meets the requirements under § 412.87(b) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries, unless the technology is specifically grandfathered under the alternative pathway eligibility criteria. We note that this policy will be effective beginning with applications received for new technology add-on payments for FY 2028 and subsequent fiscal years, and there will be no impact of this policy in FY 2027. In addition, we are finalizing our proposal that all applications received for OPPS device pass-through payment status on or after October 1, 2026, including all applications received through the remainder of the CY 2028 OPPS application cycle ending on March 1, 2027, and subsequent calendar years would have to demonstrate that the technology meets the requirements currently reflected at § 419.66(c)(2)(i), unless specifically grandfathered under the alternative pathway eligibility criteria.

If all of the future Breakthrough Devices, QIDPs, and LPADs that would have applied for new technology add-on payments would have been approved under the criteria at § 412.87(b), this change has no impact relative to current policy. To the extent that there are future Breakthrough Devices, QIDPs, and LPADs that are the subject of applications for new technology add-on payments under the traditional pathway, and those applications would have been approved under the current new technology add-on payment alternative pathway criteria, but would not meet the requirement to be new and not substantially similar to existing technologies and the requirements under § 412.87(b), this change would result in additional savings, but the savings are not estimable. Additional savings would be reduced to the extent that future Breakthrough Devices, QIDPs, and LPADs are grandfathered under the alternative pathway eligibility criteria.

For future Breakthrough Devices that would have applied for OPPS device pass-through payment and would have met the criteria currently at § 419.66(c)(2)(i), this change has no impact relative to current policy. To the extent that there are future Breakthrough Devices that are the subject of applications for OPPS device pass-through payment under the traditional pathway, and those applications would have been approved under the current OPPS device pass-through payment alternative pathway criteria, but would not meet the requirements currently under § 419.66(c)(2)(i), this change would result in additional savings, but the savings are not estimable. Additional savings would be reduced to the extent that future Breakthrough Devices, QIDPs, and LPADs are grandfathered under the alternative pathway eligibility criteria.

c. Continued Transition for the Discontinuation of the Low Wage Index Hospital Policy

In the FY 2025 interim final action with comment period (IFC) (89 FR 80405 through 80421), we recalculated the FY 2025 IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. We also removed the low wage index budget neutrality factor from the FY 2025 standardized amounts. For FY 2026 and subsequent fiscal years, consistent with the FY 2025 IFC, after considering the D.C. Circuit's decision in *Bridgeport Hospital* v. *Becerra,* we discontinued the low wage index hospital policy and the application of the low wage index budget neutrality factor to the standardized amounts (90 FR 36854).

For FY 2025 and FY 2026, consistent with our past practice to establish temporary transition policies to mitigate short-term instability and payment fluctuations, we established transition policies for hospitals significantly impacted by the discontinuation of the low wage index hospital policy using our authority under section 1886(d)(5)(I) of the Act. The transitional payment exception for FY 2025 for those hospitals was equal to the additional FY 2025 amount a hospital would have been paid under the IPPS if its FY 2025 wage index were equal to 95 percent of its FY 2024 wage index. The transitional payment exception for FY 2026 was equal to the additional FY 2026 amount the hospital would be paid under the IPPS if its FY 2026 wage index were equal to 90.25 percent of its FY 2024 wage index.[735] For FY 2025, we opted not to budget neutralize the interim transition policy given the timing of the *Bridgeport Hospital* v. *Becerra* decision. However, for FY 2026, we finalized a payment transition with a budget neutrality adjustment through notice-and-comment rulemaking for hospitals facing significant reductions over two years that would not be sufficiently mitigated by the wage index cap policy at 42 CFR 412.64(h)(7). We refer readers to the FY 2025 IFC (89 FR 80405 through 80421) and to the FY 2026 IPPS/LTCH PPS Final Rule (90 FR 36855 through 36857) for a full discussion of these transitional payment policies.

Some hospitals that previously benefitted from the low wage index hospital policy would continue to experience decreases of approximately 5 percent or more per year from their FY 2024 wage index (with the low wage index hospital policy applied). Therefore, we proposed to extend the transitional exception to the calculation of payments for FY 2027 for these hospitals in the same manner as we did for the FY 2026 wage index. In section III.F.6. of the preamble to this final rule, for FY 2027 we are finalizing as proposed to use our authority under section 1886(d)(5)(I)(i) of the Act twice. First, we are finalizing to adopt a narrow transitional exception to the calculation of FY 2027 IPPS payments for

[735] 90.25 percent = 95 percent for FY 2025 * 95 percent for FY 2026. This can also be expressed as .95^2.

low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy. Second, we are finalizing to exercise our authority again to do so in a budget neutral manner. We refer readers to section III.F.6. of the preamble to this final rule for a detailed discussion of the continued transition for the discontinuation of the low wage index hospital policy, which is being implemented in a budget-neutral manner.

d. Additional Payment for Uncompensated Care to Medicare Disproportionate Share Hospitals (DSHs) and Supplemental Payment

In this final rule, as required by section 1886(r)(2) of the Act, we are updating our estimates of the 3 factors used to determine uncompensated care payments for FY 2027. Beginning with FY 2023 (87 FR 49036 through 49038), we adopted a multiyear averaging methodology to determine Factor 3 of the uncompensated care payment methodology, which helps mitigate any large fluctuations in uncompensated care payments from year to year. Under this methodology, for FY 2025 and subsequent fiscal years, we determine Factor 3 for all eligible hospitals using a 3-year average of the data on uncompensated care costs from Worksheet S–10 for the 3 most recent fiscal years for which audited data are available. We are using a 3-year average of audited data on uncompensated care costs from Worksheet S–10, from the FY 2021, FY 2022, and FY 2023 cost reports, to calculate Factor 3 for FY 2027 for all eligible hospitals.

Beginning with FY 2023 (87 FR 49047 through 49051), we also established a supplemental payment for IHS and Tribal hospitals and hospitals located in Puerto Rico. In section IV.D. of the preamble of this final rule, we summarize the ongoing methodology for supplemental payments.

e. Rural Community Hospital Demonstration Program

We note, in section V.N. of the preamble of this final rule, we discuss the Rural Community Hospital (RCH) demonstration program. In past years, we made an adjustment to ensure the effects of the RCH demonstration program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. As discussed in that section, as we are not yet able to finalize the FY 2027 estimated costs of the demonstration at this time, we did not propose to apply a budget neutrality offset in this FY 2027 IPPS/LTCH PPS proposed rule. Rather, we proposed to apply budget neutrality offsets for both FY 2027 and FY 2028 to the national IPPS rates in the FY 2028 IPPS/LTCH PPS rulemaking. We would also incorporate any statutory change that might affect the methodology for determining hospital costs either with or without the demonstration. We refer the reader to section VI.N. of the preamble of this final rule for complete details on this proposal.

2. Frontier Community Health Integration Project (FCHIP) Demonstration

The Frontier Community Health Integration Project (FCHIP) demonstration was authorized under section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act of 2010 (Pub. L. 114–158), and most recently re-authorized and extended by the Consolidated Appropriations Act of 2021 (Pub. L. 116–260). The legislation authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries in certain rural areas. The FCHIP demonstration initial period was conducted in 10 critical access hospitals (CAHs) from August 1, 2016, to July 31, 2019, and the demonstration ''extension period'' began on January 1, 2022, to run through June 30, 2027.

The authorizing legislation requires the FCHIP demonstration to be budget neutral. In this final rule, we proposed to continue with the budget neutrality approach used in the demonstration initial period for the demonstration extension period—to offset payments across CAHs nationally—should the demonstration incur costs to Medicare.

3. Update to the LTCH PPS Payment Rates

The update to the LTCH PPS standard Federal payment rate for FY 2027 is discussed in section VIII.C. of the preamble of this final rule. For FY 2027, we are establishing an annual market basket update to the LTCH PPS standard Federal payment rate of 2.3 percent (that is, the 3.2 percent market basket increase with a reduction of 0.9 percentage point for the productivity adjustment, as required by section 1886(m)(3)(A)(i) of the Act). LTCHs that failed to submit quality data, as required by 1886(m)(5)(A)(i) of the Act will receive an update of 0.3 percent for FY 2027, which reflects a 2.0 percentage point reduction for failure to submit quality data.

4. Hospital Quality Programs

Section 1886(b)(3)(B)(viii) of the Act requires subsection (d) hospitals to report data in accordance with the requirements of the Hospital Inpatient Quality Reporting Program for purposes of measuring and making publicly available information on health care quality and links the quality data submission to the annual applicable percentage increase. Sections 1886(b)(3)(B)(ix), 1886(n), and 1814(l) of the Act require eligible hospitals and CAHs to demonstrate they are meaningful users of certified EHR technology for purposes of electronic exchange of health information to improve the quality of health care and link the submission of information demonstrating meaningful use to the annual applicable percentage increase for eligible hospitals and the applicable percent for CAHs. Section 1886(m)(5) of the Act requires each LTCH to submit quality measure data in accordance with the requirements of the Long Term Care Hospital Quality Reporting Program for purposes of measuring and making publicly available information on health care quality, and to avoid a 2-percentage point reduction. Section 1886(o) of the Act requires the Secretary to establish a value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet the performance standards established on an announced set of quality and efficiency measures for the fiscal year. The purposes of the Hospital Value-based Purchasing Program include measuring the quality of hospital inpatient care, linking hospital measure performance to payment, and making publicly available information on hospital quality of care. Section 1886(p) of the Act requires a reduction in payment for subsection (d) hospitals that rank in the worst-performing 25 percent with respect to measures of hospital-acquired conditions under the Hospital Acquired Condition Reduction Program for the purpose of measuring HACs, linking measure performance to payment, and making publicly available information on health care quality. Section 1886(q) of the Act requires a reduction in payment for subsection (d) hospitals for excess readmissions based on measures for applicable conditions under the Hospital Readmissions Reduction Program for the purpose of measuring readmissions, linking measure performance to payment, and making publicly available information on health care quality. Section 1866(k) of the Act applies to hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-exempt cancer hospitals'' or ''PCHs'') and requires PCHs to report data in accordance with the requirements of the PCH Quality Reporting Program for purposes of measuring and making publicly available information on the quality of care furnished by PCHs. However, there is no reduction in payment to a PCH that does not report data.

5. Other Provisions

a. Transforming Episode Accountability Model (TEAM)

In section X.A. of the preamble of this final rule, we discuss the alternative payment model called the Transforming Episode Accountability Model (TEAM), is tested under the authority at section 1115A of the Act. Section 1115A of the Act authorizes the testing of innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and CHIP beneficiaries while reducing program expenditures. The underlying issue addressed by TEAM is that under the traditional fee-for-service (FFS) payment system, Medicare makes separate payments to providers and suppliers for items and services furnished to a beneficiary over the course of an episode of care. Because providers and suppliers are paid for each individual item or service delivered, this may lead to care that is fragmented, unnecessary or duplicative, while making it challenging to invest in quality improvement or care coordination that would maximize patient benefit. We anticipate TEAM may reduce costs while maintaining or improving quality of care by bundling payment for items and services for a given episode and holding TEAM participants accountable for spending and quality performance, as well as by providing incentives to promote high quality and efficient care. Further, testing TEAM will allow us to learn more about the patterns of potentially inefficient utilization of health care services, as well as how to improve the

beneficiary care experience during care transitions and incentivize quality improvements for common surgical episodes. This information could inform future Medicare payment policy and potentially establish the framework for managing clinical episodes as a standard practice in Original Medicare.

TEAM was finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) and subsequent updates were made in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36536)). The final policies within this final rule increase hospital and beneficiary participation, address policy gaps, and make technical or conforming updates to ensure TEAM has sound and well developed technical, administrative, and operational policies.

We received no comments on the statement of need and therefore are finalizing this provision without modification.

b. Comprehensive Care for Joint Replacement Expanded (CJR–X) Model

In section X.C of the preamble of this final rule, we finalize the expansion of the Comprehensive Care for Joint Replacement (CJR) model, with the expanded model referred to as CJR–X. Section 1115A of the Act authorizes the testing of innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and CHIP beneficiaries while reducing program expenditures. CJR–X participants will be accountable for the cost and quality of care for beneficiaries who receive a LEJR episode of care at their hospital. We anticipate the model will reduce costs while maintaining or improving quality of care, as well as by providing incentives to promote high quality and efficient care.

Based on our analysis, the CJR–X model will build upon the successful test of the CJR model. Given the strength of evidence from the CJR Model test, we believe its expansion across all eligible acute care hospitals is the logical follow on to continue driving value-based care for Medicare beneficiaries. Further, we believe CJR–X establishes a solid framework for managing clinical episodes as a standard practice in Original Medicare and could be used to inform episodes of care for Medicare Advantage or other payers.

Under the CJR–X model, acute care hospitals paid under the IPPS and OPPS, with limited exclusions, will be accountable for LEJR episodes of care. We believe the model will benefit Medicare beneficiaries through improving the coordination of items and services paid for through Medicare FFS payments, encouraging provider investment in health care infrastructure and redesigned care processes, and incentivizing higher value care across the inpatient and post-acute care settings for the episode. The model will also provide financial incentives for providers to coordinate their efforts to meet patient needs and prevent future costs. CJR–X may benefit beneficiaries by holding hospitals accountable for the quality and cost of care for during the anchor hospitalization or anchor procedure and for 90 days after a beneficiary is discharged from the anchor hospitalization or anchor procedure, which could promote high quality and efficient service delivery that focuses on patient-centered care.

We received no comments on the statement of need and therefore are finalizing this provision without modification.

c. Provisions Regarding Acquisition Costs, Reasonable Costs, and Other Cost-Related Policies

In section X.D. of the preamble of this final rule, we are making payment and policy changes to ensure that Medicare reimburses non-renal organ acquisition costs to IOPOs and HCLs on a reasonable cost basis, in accordance with sections 1881(b)(2)(A) and 1861(v) of the Act. This final rule is also clarifying, revising, and/or codifying, for all providers, Medicare's reasonable cost payment policies related to allowable costs, and clarifying and codifying, for all providers, Medicare's policies related to overhead allocation. This final rule is necessary to increase compliance with reasonable cost principles, increase payment accuracy, and increase provider understanding of reasonable cost principles. This final rule is also necessary to make a technical change to IOPO and HCL appeals policy, by codifying requirements that provide more consistency in the appeals process. Finally, this final rule is necessary to make technical corrections to clarify or correct regulation text.

The finalized policies in this final rule reflect our commitment to increasing payment accuracy for providers paid under reasonable cost principles, assisting providers in understanding reasonable cost principles, assisting IOPOs and HCLs in understanding their appeal rights, and responsibly stewarding the Medicare Trust Fund.

After consideration of public comments received on section X.D.1. (91 FR 19729 through 19736), we are finalizing, with modifications, our proposal to reconcile non-renal organ acquisition costs for IOPOs and HCLs. Specifically, we are finalizing a 2-year implementation delay, effective for cost reporting periods beginning on or after October 1, 2028, rather than the 1-year delay originally proposed. We are also finalizing, with modifications, our proposal regarding the establishment of IOPO non-renal SACs and HCL non-renal testing rates. Rather than requiring the Medicare contractor to establish these rates, we are finalizing a revised approach. IOPOs will submit to the Medicare contractor a reasonable estimate of their non-renal SACs by organ, based on prior year costs and a reasonable, documented estimate of projected costs and organ volumes for the subsequent year. The Medicare contractor will review the estimate for reasonableness and provide approval. Independent HCLs will submit to the Medicare contractor a reasonable estimate of their non-renal testing rates, based on prior year costs and a reasonable, documented estimate of projected testing costs and volumes for the subsequent year. The Medicare contractor will review the estimate for reasonableness and provide approval.

We are also finalizing, with modifications, our proposal regarding rate adjustments. IOPOs must provide the Medicare contractor with an estimated adjusted non-renal SAC by organ, based on actual cost data and a reasonable, documented estimate of costs through the end of its accounting period. The Medicare contractor will review the proposed adjustment for reasonableness and provide approval. Additionally, Independent HCLs must provide the Medicare contractor with adjusted non-renal organ testing rates, based on actual cost data and a reasonable, documented estimate of costs through the end of its accounting period. The Medicare contractor will review the interim rate adjustment for reasonableness and provide approval.

Finally, we are finalizing, as proposed, the policy requiring the Medicare contractor to publish IOPO non-renal SACs and HCL non-renal testing rates. Comments related to IOPO or HCL impacts are included in Appendix A, section I.G.14.a.

After consideration of public comments received on section X.D.2. (91 FR 19736 to 19744), we are finalizing our proposals, with certain modifications, pertaining to longstanding Medicare reasonable cost reimbursement policies applicable to all providers. We are also finalizing our provision pertaining to OPO public education to be effective with the effective date of this final rule; however, we are allowing a 1-year delay in enforcement to address concerns raised by some providers.

After consideration of public comments received on section X.D.3. (91 FR 19744 to 19747), we are finalizing, as proposed, our clarification and codification of cost allocation principles. No modifications were made to this provision. Additionally, after consideration of public comments received on section X.D.4. (91 FR 19747 to 19751), we are finalizing, as proposed, the codification of the discretionary Administrator review of CMS reviewing official determinations with respect to appeals under § 413.420(g) for IOPOs and HCLs. No modifications were made to this provision. Finally, we are also finalizing, as proposed, the technical corrections and clarifications in section X.D.5. (91 FR 19751).

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, '' Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect

on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1). We have prepared a regulatory impact analysis that to the best of our ability presents the costs and benefits of the rulemaking. OMB has reviewed these regulations, and the Departments have provided the following assessment of their impact.

We estimate that the changes for FY 2027 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in this final rule, would result in an estimated $2.9 billion increase in payments in FY 2027, primarily driven by the net effect of changes in FY 2027 operating payments, including uncompensated care payments, FY 2027 capital payments, the expiration of the temporary changes in the low-volume hospital program, the expiration of the MDH program, and new technology add-on payment changes. These changes are relative to payments made in FY 2026. The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience an increase in payments of approximately $54 million in FY 2027 relative to FY 2026.

Our operating payment impact estimate includes the 2.3 percent applicable percentage increase to the standardized amount (reflecting the 3.2 percent market basket rate-of-increase reduced by the 0.9 percentage point productivity adjustment). The estimates of IPPS operating payments to acute care hospitals generally do not reflect any changes in hospital admissions or real case-mix intensity, which would also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this final rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This final rule will affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant.

C. Objectives of the IPPS and the LTCH PPS

The primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this final rule will further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this final rule contains a range of policies, we refer readers to the section of the final rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the final policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy changes, as well as statutory changes effective for FY 2027, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case, while holding all other payment policies constant. We use the best data available, but, generally, unless specifically indicated, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, case mix, changes to the Medicare population, or incentives. In addition, we discuss limitations of our analysis for specific policies in the discussion of those policies as needed.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital related- costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 26 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short term, acute care hospitals, hospitals in Maryland are paid in accordance with the AHEAD Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 6 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of March 2026, there were 3,005 IPPS acute care hospitals included in our analysis. This represents approximately 51 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,388 CAHs. These small, limited-service hospitals are paid on the basis of reasonable costs, rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, cancer hospitals, extended neoplastic disease care hospital, and short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this final rule. The impact of the update and policy changes to the LTCH PPS for FY 2027 is discussed in section I.J. of this Appendix.

F. Quantitative Estimates of Effects of the Policy Changes Under the IPPS for Operating Costs and Medicare DSH Uncompensated Care Payments

1. Basis and Methodology of Estimates

In this final rule, we are announcing policy changes and payment rate updates for the IPPS for FY 2027 for operating costs of acute care hospitals and for uncompensated care payments. The FY 2027 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix. A more detailed analysis of the update to uncompensated care payments is discussed in section I.G.2 of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2027 operating payments, including uncompensated care payments, will increase by 1.7 percent compared to FY 2026. The operating payment impacts generally do not reflect changes in the number of hospital admissions or real case-mix intensity, which will also affect overall payment changes.

We have prepared separate impact analyses of the changes on the operating and capital prospective payment systems. This section primarily deals with the changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the best available claims data to enable us to estimate the impacts on payments per case of certain changes in this final rule. However, there are other changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of changes in operating payments per case presented in this section are taken from the FY 2025 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the changes to the operating PPS do not incorporate cost data, data from the best available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not generally adjust for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix.

Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2025 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of payments under the capital IPPS, and the impact of payments other than inpatient operating payments including uncompensated care payments are not analyzed in this section. Estimated payment impacts for the capital IPPS for FY 2027 are discussed in section I.I. of this Appendix.

We discuss the following changes:

- The estimated effects of outlier payments returning to their targeted levels in FY 2027 as compared to the estimated outlier payments for FY 2026 produced from our payment simulation model.
- The effects of the application of the applicable percentage increase of 2.3 percent (that is, a 3.2 percent market basket rate-of-increase with a reduction of 0.9 percentage point for the productivity adjustment), and the applicable percentage increase (including the market basket rate-of-increase and the productivity adjustment) to the hospital-specific rates.
- The effects of the changes to estimated uncompensated care payments in FY 2027 as compared to FY 2026.
- The effects of the expiration of the special payment status for MDHs beginning January 1, 2027 under current law.
- The effects of the changes to the relative weights and MS–DRG GROUPER.
- The effects of the changes in hospitals' wage index values due to the effects of the incorporation of updated wage data from hospitals' cost reporting periods and the changes in wage index reclassifications.
- The total estimated change in payments based on the FY 2027 policies relative to payments based on FY 2026 policies.

To illustrate the impact of the FY 2027 changes, our analysis begins with a FY 2026 baseline simulation model using: the FY 2026 national adjusted operating standardized amount; the FY 2026 MS–DRG GROUPER (Version 43); the FY 2026 CBSA designations for hospitals based on the OMB definitions from the 2020 Census; the FY 2026 wage index, including the FY 2026 labor and nonlabor share percentages; FY 2026 uncompensated care payments; and FY 2026 outlier payments which reflects our estimate of 5.9 percent of total operating MS–DRG and outlier payments as produced by our payment simulation model based on FY 2025 MedPAR data.

Our comparison illustrates the percent change in payments per case from FY 2026 to FY 2027. The update to the standardized amount is a significant factor in the percent change in payments per case. In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2027, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section VI.B. of the preamble of this final rule for a complete discussion of the FY 2027 inpatient hospital update, including the four possible applicable percentage increases. For purposes of the simulations shown later in this section, we modeled the payment changes for FY 2027 using a reduced update for hospitals that (1) failed to submit quality data but are meaningful EHR users; (2) are identified as not meaningful EHR users that do submit quality data; and (3) are identified as not meaningful EHR users that do not submit quality data. The reduced updates used for these hospitals are discussed previously and in section VI.B. of the preamble of this final rule and these hospitals are identified in the impact file posted in conjunction with this final rule.

We note, section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act for hospitals that fail to submit quality data or are not a meaningful EHR users. Accordingly, the applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs for FY 2027 are the same as the four applicable percentage increases discussed in section VI.B. of the preamble of this final rule.

2. Impact Analysis of Changes on Payments for IPPS Operating Costs and Uncompensated Care Payments

Table I displays the results of our analysis of the changes for FY 2027 on payments for IPPS operating costs and uncompensated care payments. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the acute care hospitals included in the analysis.

The next two rows of Table I contain hospitals categorized according to their geographic location: urban and rural. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The last groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2027 payment classifications, including any reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act. For example, the rows labeled urban and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under section 1886(d)(8)(B) of the Act, also known as Lugar hospitals, and section 1886(d)(8)(E) of the Act as implemented at 42 CFR 412.103).

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments.

In the DSH categories, hospitals are grouped according to their DSH status, and whether they are considered urban or rural for DSH payment purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next six rows examine the impacts of the changes on rural hospitals by special payment groups (SCHs and MDHs) and reclassification status from urban to rural in accordance with section 1886(d)(8)(E) of the Act.

The next series of groupings are based on the type of ownership and the hospital's Medicare and Medicaid utilization expressed as a percent of total inpatient days. These data were taken from the most recent available Medicare cost reports.

The next grouping concerns the geographic reclassification status of hospitals. The first subgrouping is based on whether a hospital is reclassified or not. The second and third subgroupings are based on whether urban and rural hospitals were reclassified by the MGCRB for FY 2027 or not, respectively. The fourth subgrouping displays hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) of the Act as implemented at 42 CFR 412.103. The fifth subgrouping displays hospitals deemed urban in accordance with section 1886(d)(8)(B) of the Act, also known as Lugar hospitals.

TABLE I.—IMPACT ANALYSIS OF CHANGES ON PAYMENTS FOR IPPS OPERATING COSTS AND UNCOMPENSATED CARE PAYMENTS FOR FY 2027

	Number of Hospitals[1]	FY 2027 Outlier Payments (1)[2]	FY 2027 Hospital Rate Update (2)[3]	MDH Expiration (3)[4]	FY 2027 Uncompensated Care Payments (4)[5]	FY 2027 Weights and DRG Changes with Application of Recalibration Budget Neutrality (5)[6]	FY 2027 Wage Index (6)[7]	All FY 2027 Changes (7))[8]
All Hospitals	3,005	-0.6	2.2	-0.1	0.2	0.0	0.0	1.7
By Geographic Location:								
Urban hospitals	2,357	-0.7	2.2	-0.1	0.3	0.0	0.0	1.8
Rural hospitals	648	-0.2	2.2	-0.5	-0.1	-0.4	0.0	1.1
Bed Size (Urban):								
0-99 beds	640	-0.5	2.2	-1.4	0.1	0.0	-0.2	0.2
100-199 beds	673	-0.6	2.2	-0.1	0.1	-0.2	0.0	1.5
200-299 beds	400	-0.5	2.2	0.0	0.2	-0.1	-0.1	1.6
300-499 beds	393	-0.6	2.2	0.0	0.2	0.0	-0.1	1.6
500 or more beds	249	-0.8	2.1	0.0	0.4	0.2	0.2	2.1
Bed Size (Rural):								
0-49 beds	309	-0.2	2.1	-0.9	0.0	-0.5	-0.1	0.3
50-99 beds	174	-0.2	2.2	-1.2	0.0	-0.5	0.1	0.5
100-149 beds	95	-0.2	2.2	0.0	-0.1	-0.4	-0.1	1.4
150-199 beds	41	-0.2	2.2	0.0	-0.3	-0.3	0.1	1.4
200 or more beds	29	-0.4	2.2	0.0	0.0	-0.2	0.2	1.9
Urban by Region:								
New England	102	-0.6	2.2	-0.1	0.1	-0.1	0.3	1.9
Middle Atlantic	272	-0.7	2.2	-0.1	0.3	-0.1	1.0	2.7
East North Central	364	-0.5	2.2	-0.2	0.0	0.0	0.6	2.2
West North Central	155	-0.5	2.2	0.0	-0.1	0.1	-0.9	0.7
South Atlantic	393	-0.6	2.1	-0.1	0.3	0.0	0.5	2.3
East South Central	139	-0.6	2.1	0.0	0.3	0.1	-1.0	0.9
West South Central	356	-0.5	2.0	0.0	0.8	0.1	-0.3	2.1
Mountain	177	-0.6	2.2	0.0	0.5	0.1	-0.8	1.4
Pacific	347	-1.0	2.2	0.0	0.1	0.0	-1.0	0.3
Rural by Region:								
New England	19	-0.5	2.3	-1.1	0.1	-0.3	1.0	1.6
Middle Atlantic	46	-0.3	2.2	-0.1	0.1	-0.4	-0.1	1.4
East North Central	104	-0.3	2.2	-1.2	-0.1	-0.3	0.8	1.2
West North Central	71	-0.2	2.2	-0.3	-0.2	-0.3	-0.5	0.7
South Atlantic	110	-0.2	2.1	-0.5	-0.3	-0.4	0.5	1.1
East South Central	119	-0.2	2.1	-0.3	0.1	-0.3	-0.9	0.6
West South Central	114	-0.2	2.1	-0.1	-0.2	-0.3	-0.4	0.9
Mountain	41	-0.1	2.3	0.0	0.2	-0.1	0.1	2.3
Pacific	24	-0.2	2.3	0.0	0.0	-0.6	-0.4	1.2
Puerto Rico								
Puerto Rico Hospitals	52	-0.3	1.4	0.0	0.2	-0.1	-1.8	-0.5
By Payment Classification:								
Urban hospitals	1,524	-0.7	2.2	0.0	0.3	-0.1	-0.3	1.5
Rural areas	1,481	-0.6	2.2	-0.1	0.2	0.0	0.2	1.8
Teaching Status:								
Nonteaching	1,696	-0.6	2.2	-0.3	0.1	-0.1	-0.1	1.2
Fewer than 100 residents	1,003	-0.6	2.2	-0.1	0.2	-0.1	-0.1	1.6
100 or more residents	306	-0.7	2.1	0.0	0.4	0.2	0.2	2.1
Urban DSH:								
Non-DSH	370	-0.6	2.3	-0.1	0.0	0.0	0.2	1.9

	Number of Hospitals[1]	FY 2027 Outlier Payments (1)[2]	FY 2027 Hospital Rate Update (2)[3]	MDH Expiration (3)[4]	FY 2027 Uncompensated Care Payments (4)[5]	FY 2027 Weights and DRG Changes with Application of Recalibration Budget Neutrality (5)[6]	FY 2027 Wage Index (6)[7]	All FY 2027 Changes (7))[8]
100 or more beds	827	-0.7	2.1	0.0	0.4	-0.1	-0.3	1.4
Less than 100 beds	327	-0.5	2.1	0.0	0.2	-0.3	-0.2	1.2
Rural DSH:								
Non-DSH	130	-0.5	2.3	-1.3	0.0	0.0	0.2	0.7
SCH	212	-0.1	2.2	0.0	0.0	-0.4	0.2	2.0
RRC	923	-0.6	2.1	0.0	0.2	0.1	0.2	1.9
100 or more beds	31	-0.6	2.1	-0.1	0.3	0.1	0.9	2.7
Less than 100 beds	185	-0.2	2.1	-2.4	0.0	-0.5	0.1	-1.1
Urban teaching and DSH:								
Both teaching and DSH	480	-0.6	2.1	0.0	0.5	-0.1	-0.2	1.7
Teaching and no DSH	68	-0.6	2.3	-0.3	0.0	-0.1	0.2	1.6
No teaching and DSH	674	-0.7	2.2	0.0	0.2	-0.2	-0.6	0.9
No teaching and no DSH	302	-0.6	2.3	0.0	0.0	0.2	0.2	2.1
Special Hospital Types:								
SCH	419	-0.2	2.3	0.0	0.0	-0.3	0.1	1.9
MDH	166	-0.2	2.2	-8.3	0.0	-0.4	0.1	-6.8
Type of Ownership:								
Voluntary	1,905	-0.6	2.2	-0.1	0.2	0.0	0.1	1.7
Proprietary	693	-0.4	2.2	0.0	0.1	0.0	-0.4	1.4
Government	405	-0.7	2.0	0.0	0.7	0.1	-0.1	2.0
Medicare Utilization as a Percent of Inpatient Days:								
0-25	1,664	-0.6	2.1	0.0	0.4	0.0	0.0	1.9
25-50	1,265	-0.7	2.2	-0.2	0.0	-0.1	0.1	1.5
50-65	41	-0.4	2.3	-0.1	0.0	0.0	0.6	2.3
Over 65	9	-0.2	2.3	-4.6	0.0	0.7	-0.2	-2.2
Medicaid Utilization as a Percent of Inpatient Days:								
0-25	2,037	-0.6	2.2	-0.1	0.1	0.0	0.1	1.7
25-50	860	-0.7	2.1	0.0	0.3	0.1	-0.1	1.8
50-65	84	-0.7	1.8	0.0	1.3	-0.2	-0.7	1.6
Over 65	24	-0.9	2.1	0.0	0.3	-0.2	-1.6	-0.4
FY 2027 Reclassifications:								
All Reclassified Hospitals	1,103	-0.6	2.2	-0.1	0.2	0.0	0.2	1.9
Non-Reclassified Hospitals	1,902	-0.6	2.1	-0.1	0.3	-0.1	-0.2	1.5
Urban Hospitals Reclassified	977	-0.7	2.2	-0.1	0.2	0.1	0.2	1.9
Urban Non-reclassified Hospitals	1,398	-0.7	2.2	0.0	0.3	-0.1	-0.3	1.4
Rural Hospitals Reclassified Full Year	272	-0.2	2.2	-0.2	-0.1	-0.4	-0.1	1.2
Rural Non-reclassified Hospitals Full Year	358	-0.3	2.2	-0.6	0.1	-0.4	0.3	1.2
All hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	885	-0.7	2.2	-0.1	0.2	0.1	0.2	1.9
Other Reclassified Hospitals (Section 1886(d)(8)(B), also known as Lugar hospitals)	52	-0.3	2.2	-1.6	0.1	-0.5	0.0	-0.1

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2025, and hospital cost report data are from the latest available reporting periods.
[2] This column displays the effects of estimated outlier payments returning to their targeted levels in FY 2027 as compared to the estimated outlier payments for FY 2026.
[3] This column displays the payment impact of the hospital rate update, including the 2.3 percent update to the national standardized amount and the hospital-specific rate (the 3.2 percent IPPS market basket rate-of-increase reduced by the 0.9 percentage point for the productivity adjustment).
[4] This column displays the impact of the expiration of the MDH status on January 1, 2027, a non-budget neutral payment provision.
[5] This column displays the effects of the changes to estimated uncompensated care payments in FY 2027 as compared to FY 2026 as a percent change in estimated total payments. See also the table in section I.G.2 of this Appendix.
[6] This column displays the payment impact of Version 44 GROUPER, the changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2025 MedPAR data, and the 10-percent cap where the relative weight for a MS-DRG will decrease by more than ten percent in a given fiscal year. This column displays the application of the recalibration budget neutrality factor and the 10-percent cap budget neutrality factor (which can be found in section II.A.4 of the Addendum of this final rule).
[7] This column displays the effects of the changes to the FY 2027 wage index. This includes: (1) the update to wage index data using FY 2023 cost report data, the application of the wage index budget neutrality factor and the update to the labor and nonlabor shares; (2) the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB), showing the payment impact of going from FY 2026 reclassifications to the reclassifications scheduled to be in effect for FY 2027; (3) the effects of the application of the rural floor; (4) the effects of urban to rural reclassifications under section 1886(d)(8) of the Act on the wage index; (5) the effects of the application of "LUGAR" status under section 1886(d)(10) of the Act on the wage index; and (6) the adjustments to the wage index driven by non-budget neutral policies. These non-budget neutral policies include: (a) the imputed floor for all-urban states; (b) the policy that requires hospitals located in frontier States have a wage index no less than 1.0; and (c) the policy which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. The budget neutrality factors for the effects that are budget neutral can be found in section II.A.4 of the Addendum of this final rule. This column also displays the redistributive effects of the budget neutral transition for the discontinuation of the low wage index hospital policy from hospitals that do not benefit from the transition to hospitals that do benefit (primarily all the hospitals located in Puerto Rico) due to the associated budget neutrality factor. The budget neutrality factor for the transition can be found in section II.A.4 of the Addendum of this final rule.
[8] This column shows the estimated change in payments from FY 2026 to FY 2027.

a. Effects of the Outlier Adjustment (Column 1)

This column reflects the effect of estimated outlier payments returning to their targeted levels in FY 2027 as compared to the estimated outlier payments for FY 2026 produced from our payment simulation model. As discussed in section II.A.4.i. of the Addendum to this final rule, the statute requires that outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments, and also requires that the average standardized amount be reduced by a factor to account for the estimated proportion of total DRG payments made to outlier cases. We continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount, just as we did for FY 2026. Therefore, our estimate of payments per discharge for FY 2027 from our payment simulation model reflects this 5.1 percent outlier payment target. Our payment simulation model shows that estimated outlier payments for FY 2026 were greater than that target by approximately 0.8 percentage points.

Overall, hospitals will experience a 0.6 percent decrease in payments primarily due to the estimated −0.8 percent change in outlier payments produced by our payment simulation model when returning to the 5.1 percent outlier target for FY 2027 in combination with interactive effects among the various add-on payment factors.

b. Effects of the Hospital Update (Column 2)

As discussed in section VI.B. of the preamble of this final rule, this column includes the hospital update, including the 3.2 percent IPPS market basket rate-of-increase reduced by 0.9 percentage point for the productivity adjustment. As a result, we are making a 2.3 percent update to the national standardized amount. This column also includes the update to the hospital-specific rates which includes the 3.2 percent market basket rate-of-increase reduced by 0.9

percentage point for the productivity adjustment. As a result, we are making a 2.3 percent update to the hospital-specific rates. This column also includes any applicable adjustments for hospitals that fail to comply with the quality data submission requirements and/or are not meaningful EHR users.

Overall, hospitals are expected to experience a 2.2 percent increase in payments primarily due to the combined effects of the hospital update to the national standardized amount and the hospital update to the hospital-specific rates.

c. Effects of the Expiration of MDH Special Payment Status (Column 3)

Column 3 shows our estimate of the changes in payments due to the expiration of MDH status, a nonbudget neutral payment provision. Section 6202 of the Consolidated Appropriations Act, 2026 further extended the MDH program through December 31, 2026. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2027. Hospitals that qualify to be MDHs receive the higher of payments made based on the Federal rate or the payments made based on the Federal rate amount plus 75 percent of the difference between payments based on the Federal rate and payments based on the hospital-specific rate (a hospital-specific cost-based rate). Because this provision is not budget neutral, the expiration of this payment provision is estimated to result in a 0.1 percent decrease in IPPS payments overall. There are currently 166 MDHs, of which we estimate 81 would be paid under the blended payment of the Federal rate and hospital-specific rate if the MDH program were not set to expire. Because those 81 MDHs will no longer receive the blended payment and will be paid only under the Federal rate beginning January 1, 2027, it is estimated that those hospitals would experience an overall decrease in payments of approximately $94 million (relative to the MDH program payments they received for FY 2026 discharges).

d. Effects of the Changes in Uncompensated Care Payments (UCP) (Column 4)

Column 4 shows the effects of the changes in uncompensated care payments for eligible hospitals in FY 2027. As discussed in section IV.E. of the preamble of this final rule, the total uncompensated care payments and supplemental payments equal approximately $8.0 billion. Overall, hospitals will experience a 0.2 percent increase in total operating IPPS payments and uncompensated care payments relative to FY 2026 total payments due to the change in uncompensated care payments. For a more detailed impact analysis of the changes to uncompensated care payments, we refer readers to section I.G.2 of appendix A to this final rule.

e. Effects of the Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 5)

Column 5 shows the effects of the changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we calculated a recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral. We also applied the permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given year and an associated recalibration cap budget neutrality factor to account for the 10-percent cap on relative weight reductions to ensure that the overall payment impact is budget neutral.

As discussed in section II.D. of the preamble of this final rule, for FY 2027, we calculated the MS–DRG relative weights using the FY 2025 MedPAR data grouped to the Version 44 (FY 2027) MS–DRGs. The reclassification changes to the GROUPER are described in more detail in section II.C. of the preamble of this final rule.

The ''All Hospitals'' line in Column 5 indicates that changes due to the MS–DRGs and relative weights are expected to result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor (discussed in section II.A.4.a. of the Addendum to this final rule) and the recalibration cap budget neutrality factor to the standardized amount (discussed in section II.A.4.b. of the Addendum to this final rule).

f. Effects of the Wage Index Changes (Column 6)

Column 6 shows the impact of the changes to hospitals' FY 2027 wage index as compared to hospitals' FY 2026 wage index. Overall, the FY 2027 wage index changes are expected to lead to a 0.0 percent change for all hospitals, as shown in Column 6. This column reflects updates to the wage data reported by hospitals, changes in the geographic reclassifications of hospitals, and the interactions of those changes with statutory wage index floors and exceptions. We combine these changes because the complex and interactive ways in which hospitals increasingly seek to maximize their wage index values in a given year render isolation of these effects in a year-over-year context less informative. For example, the impact of the updates to the wage data reported by hospitals in the absence of the changes in geographic reclassification and especially the interaction of both of those with statutory wage index floors and exceptions is less meaningful than showing the combined effect of those factors.

Specifically, this column in Table I shows the combined effects of the application of the following FY 2027 wage index changes relative to FY 2026:

(1) Effects of the Changes to the Wage Data

Column 6 reflects the effects of the updated wage data and the labor and non-labor shares, with the application of the wage index budget neutrality factor for FY 2027 relative to FY 2026.

Section 1886(d)(3)(E) of the Act requires that we annually update the wage data used to calculate the wage index. In accordance with this requirement, the wage index for acute care hospitals for FY 2027 is based on data submitted for hospital cost reporting periods, beginning on or after October 1, 2022, and before October 1, 2023. Column 6 reflects the percentage change in payments when going from a model using the FY 2026 wage index based on FY 2026 reclassifications and the FY 2026 labor-related share of 66.0 percent, to a model using the FY 2027 wage index based on FY 2027 reclassifications (as described in further detail in the next section) and the labor-related share of 66.0 percent, while holding other payment parameters, such as use of the Version 44 MS–DRG GROUPER, constant.

In addition, the column incorporates the application of the wage index budget neutrality to the national standardized amount. As discussed in section II.A.4.c. of the Addendum to this final rule, for FY 2027 we calculated the wage index budget neutrality factor to ensure that payments under the wage index calculated from the updated wage data and the labor-related share of 66.0 percent are budget neutral, without regard to the lower share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. This budget neutrality factor can be found in the summary table of the FY 2027 budget neutrality factors in section II.A.4. of the Addendum to this final rule.

(2) Effects of MGCRB, Urban to Rural, and ''Lugar'' Reclassifications

Column 6 reflects the impact of MGCRB reclassification decisions under section 1886(d)(10) of the Act, urban to rural reclassifications under section 1886(d)(8)(E) of the Act, and Lugar status redesignations under section 1886(d)(8)(B) of the Act on the wage index for FY 2027 relative to FY 2026. The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, as discussed in section II.A.4.d. of the Addendum to this final rule, we apply a reclassification budget neutrality adjustment to ensure that the effects of the reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are budget neutral. This budget neutrality factor can be found in the summary table of the FY 2027 budget neutrality factors in section II.A.4. of the Addendum to this final rule.

Table 2 listed in section VI. of the Addendum to this final rule and available on the CMS website reflects the reclassifications for FY 2027 at the time of development of this final rule. For further information on MGCRB reclassifications, urban to rural reclassifications and Lugar status redesignations, we refer readers to section III.E of the preamble of this final rule.

(3) The Effects of the Rural Floor, Including Budget Neutrality Adjustment

Column 6 reflects the effects of the application of the rural floor and the application of the rural floor budget neutrality on the wage index for FY 2027 relative to FY 2026. As discussed in section III.F.1. of the preamble of this final rule, section 4410 of Public Law 105–33 established the rural floor by requiring that

the wage index for a hospital in any urban area cannot be less than the wage index applicable to hospitals located in rural areas in the same state. We apply a uniform budget neutrality adjustment to the wage index as discussed in section II.A.4.e. of the Addendum to this final rule. All IPPS hospitals in our model have their wage indexes reduced by the rural floor budget neutrality adjustment. This budget neutrality factor can be found in the summary table of the FY 2027 budget neutrality factors in section II.A.4. of the Addendum to this final rule.

(4) Effects the Application of the Imputed Floor, Frontier State Wage Index, and Out-Migration Adjustment

Lastly, this column also reflects the combined effects of the application of the following non-budget neutral provisions for FY 2027 relative to FY 2026: (a) the imputed floor under section 1886(d)(3)(E)(iv)(I) and (II) of the Act for certain all-urban States (as discussed in section III.F.2. of the preamble of this final rule); (b) the minimum post-reclassified wage index of 1.00 for all hospitals located in ''frontier States'' as required by section 1886(d)(3)(E)(iii) Act (as discussed in section III.F.3. of the preamble of this final rule); and (c) the effects of the out-migration adjustment under section 1886(d)(13) of the Act (as discussed in section III.F.4. of the preamble of this final rule).

g. Effects of All FY 2027 Changes (Column 7)

Column 7 shows our estimate of the changes in payments per discharge from FY 2026 and FY 2027, resulting from all changes for FY 2027 included in Table I. It includes the combined effects of the year-over-year change of the factors described in the previous columns in the table.

The average increase in payments under the IPPS for all hospitals is approximately 1.7 percent for FY 2027 relative to FY 2026, which is primarily driven by the changes reflected in Column 1 (outlier payments), Column 2 (hospital update) and Column 4 (uncompensated care payments). As described in Column 2, the annual hospital update for hospitals paid under the national standardized amount, combined with the annual hospital update for hospitals paid under the hospital-specific rates are expected to result in a 2.2 percent increase in payments in FY 2027 relative to FY 2026 for all hospitals. As described in Column 4, uncompensated care payments will result in a 0.2 percent increase in payments in FY 2027 relative to FY 2026 for all hospitals.

Overall payments to hospitals paid under the IPPS are estimated to increase by 1.7 percent for FY 2027 (as compared to FY 2026) due to the outlier adjustment, the applicable percentage increase, the MDH program expiration, and uncompensated care payments. Hospitals in urban areas would experience a 1.8 percent increase in payments per discharge in FY 2027 compared to FY 2026. Hospital payments per discharge in rural areas are estimated to increase by 1.1 percent in FY 2027. The relatively lower projected increase for rural hospitals is due in part to the MDH program expiration (Column 3) and the MS–DRG and relative weight changes with the application of budget neutrality (Column 5). Hospital categories that generally treat relatively less complex cases, such as rural hospitals and smaller urban hospitals, are expected to experience a decrease in their payments, while hospitals that generally treat relatively more complex cases, such as larger urban hospitals, are expected to experience no change in their payments as a result of the changes to the relative weights.

3. Estimated Average Payments per Discharge

Table II displays the results of our analysis of the changes for FY 2027 on estimated average payments per discharge for IPPS operating costs and uncompensated care payments. It presents the impact for the categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2026 with the estimated average payments per discharge for FY 2027, as calculated under our models. It reflects the combined effects of the changes presented in Table I, and therefore the estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 7 of Table I.

TABLE II.--IMPACT ANALYSIS OF CHANGES ON AVERAGE PAYMENTS PER DISCHARGE FOR OPERATING COSTS AND UNCOMPENSATED CARE

	Number of Hospitals (1)	Estimated Average FY 2026 Payment Per Discharge (2)	Estimated Average FY 2027 Payment Per Discharge (3)	FY 2027 Changes (4)
All Hospitals	3,005	18,998	19,324	1.7
By Geographic Location:				
Urban hospitals	2,357	19,476	19,817	1.8
Rural hospitals	648	13,490	13,638	1.1
Bed Size (Urban):				
0-99 beds	640	13,825	13,851	0.2
100-199 beds	673	15,182	15,412	1.5
200-299 beds	400	17,002	17,280	1.6
300-499 beds	393	18,951	19,262	1.6
500 or more beds	249	24,833	25,356	2.1
Bed Size (Rural):				
0-49 beds	309	11,569	11,608	0.3
50-99 beds	174	12,829	12,889	0.5
100-149 beds	95	12,787	12,960	1.4
150-199 beds	41	14,516	14,724	1.4
200 or more beds	29	16,529	16,842	1.9
Urban by Region:				
New England	102	20,665	21,049	1.9
Middle Atlantic	272	22,780	23,403	2.7
East North Central	364	18,363	18,760	2.2
West North Central	155	17,986	18,119	0.7
South Atlantic	393	17,334	17,732	2.3
East South Central	139	15,918	16,065	0.9
West South Central	356	18,616	19,002	2.1
Mountain	177	18,567	18,824	1.4
Pacific	347	23,120	23,200	0.3
Rural by Region:				
New England	19	18,019	18,301	1.6
Middle Atlantic	46	15,327	15,548	1.4
East North Central	104	12,966	13,120	1.2
West North Central	71	13,543	13,639	0.7
South Atlantic	110	12,712	12,853	1.1
East South Central	119	11,920	11,986	0.6
West South Central	114	11,759	11,863	0.9
Mountain	41	15,069	15,410	2.3
Pacific	24	17,509	17,710	1.2
Puerto Rico				
Puerto Rico Hospitals	52	15,440	15,359	-0.5
By Payment Classification:				
Urban hospitals	1,524	16,845	17,094	1.5
Rural areas	1,481	20,376	20,752	1.8
Teaching Status:				
Nonteaching	1,696	13,967	14,136	1.2
Fewer than 100 residents	1,003	16,807	17,071	1.6

	Number of Hospitals (1)	Estimated Average FY 2026 Payment Per Discharge (2)	Estimated Average FY 2027 Payment Per Discharge (3)	FY 2027 Changes (4)
100 or more residents	306	28,424	29,034	2.1
Urban DSH:				
Non-DSH	370	13,641	13,899	1.9
100 or more beds	827	17,836	18,091	1.4
Less than 100 beds	327	13,244	13,402	1.2
Rural DSH:				
Non-DSH	130	16,157	16,272	0.7
SCH	212	14,356	14,640	2.0
RRC	923	21,173	21,579	1.9
100 or more beds	31	19,357	19,885	2.7
Less than 100 beds	185	11,102	10,979	-1.1
Urban teaching and DSH:				
Both teaching and DSH	480	19,466	19,794	1.7
Teaching and no DSH	68	15,058	15,306	1.6
No teaching and DSH	674	14,726	14,862	0.9
No teaching and no DSH	302	12,628	12,894	2.1
Special Hospital Types:				
SCH	419	15,951	16,261	1.9
MDH	166	12,812	11,946	-6.8
Type of Ownership:				
Voluntary	1,905	18,663	18,983	1.7
Proprietary	693	16,911	17,153	1.4
Government	405	23,656	24,123	2.0
Medicare Utilization as a Percent of Inpatient Days:				
0-25	1,664	20,940	21,329	1.9
25-50	1,265	16,769	17,021	1.5
50-65	41	15,903	16,269	2.3
Over 65	9	12,061	11,800	-2.2
Medicaid Utilization as a Percent of Inpatient Days:				
0-25	2,037	16,837	17,121	1.7
25-50	860	22,874	23,281	1.8
50-65	84	29,386	29,859	1.6
Over 65	24	20,125	20,039	-0.4
FY 2027 Reclassifications:				
All Reclassified Hospitals	1,103	19,983	20,358	1.9
Non-Reclassified Hospitals	1,902	17,729	17,993	1.5
Urban Hospitals Reclassified	977	21,055	21,460	1.9
Urban Non-reclassified Hospitals	1,398	16,821	17,054	1.4
Rural Hospitals Reclassified Full Year	272	13,626	13,785	1.2
Rural Non-reclassified Hospitals Full Year	358	13,296	13,461	1.2
All hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	885	21,316	21,721	1.9
Other Reclassified Hospitals (Section 1886(d)(8)(B), also known as Lugar hospitals)	52	12,668	12,652	-0.1

G. Effects of Other Policy Changes

In addition to those policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are making various other changes in this final rule. As noted in section I.D. of this Appendix, our payment simulation model uses the most recent available claims data to estimate the impacts on payments per case of certain changes in this final rule. Generally, we have limited or no specific data available with which to estimate the impacts of these changes using that payment simulation model. For these changes, we have attempted to predict the payment impacts based upon our experience and other more limited data. Our estimates of the likely impacts associated with these other changes are discussed in this section.

1. Effects of the Changes Relating to New Medical Service and Technology Add-On Payments

a. FY 2027 Status of Technologies Approved for FY 2026 New Technology Add-On Payments

In section II.E.4. of the preamble of this final rule, we are continuing to make new technology add-on payments for the technologies listed in the following table in FY 2027 because these technologies would still be considered new for purposes of new technology add-on payments. Under § 412.88(a)(2), the new technology add-on payment for each case would be limited to the lesser of: (1) 65 percent of the costs of the new technology (or 75 percent of the costs for technologies designated as Qualified Infectious Disease Products (QIDPs) or approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway, or for the gene therapies, Casgevy™ (exagamglogene autotemcel) and Lyfgenia™ (lovotibeglogene autotemcel), when indicated and used specifically for the treatment of SCD, which were approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69128 through 69135, and 89 FR 69188 through 69196)); or (2) 65 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case (or 75 percent of the amount for technologies designated as QIDPs; for technologies approved under the LPAD pathway; or for the gene therapies, Casgevy™ and Lyfgenia™, when indicated and used specifically for the treatment of SCD, which were approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69128 through 69135, and 89 FR 69188 through 69196)). Because it is difficult to predict the actual new technology add-on payment for each case, our estimates in this final rule are based on the applicant's estimate at the time they submitted their original application and the increase in new technology add-on payments for FY 2027 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment.

In the following table are estimates for the 41 new technology add-on payments which we are continuing in FY 2027:

FY 2027 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS TO CONTINUE FOR FY 2027				
	Technology Name	Estimated Cases	FY 2027 NTAP Amount (65% or 75%)	Estimated Total FY 2027 Impact
1	Annalise Enterprise CTB Triage - OH	271,200	$241.39	$65,464,968.00
2	ASTar® System	69,000	$97.50	$6,727,500.00
3	Edwards EVOQUE™ Tricuspid Valve Replacement System (“EVOQUE™ System”)	800	$31,850.00	$25,480,000.00
4	GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device)	518	$47,238.75	$24,469,672.50
5	LimFlow™ System	561	$16,250.00	$9,116,250.00
6	Paradise™ Ultrasound Renal Denervation System	200	$14,950.00	$2,990,000.00
7	PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter	3,402	$6,337.50	$21,560,175.00
8	Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter	55	$10,400.00	$572,000.00
9	TriClip™ G4	150	$26,000.00	$3,900,000.00
10	VADER® Pedicle System	200	$28,242.50	$5,648,500.00
11	ZEVTERA™ (ceftobiprole medocaril); ABSSSI and CABP indications	245	$5,287.50	$1,295,437.50
12	ZEVTERA™ (ceftobiprole medocaril); SAB indication	571	$16,215.00	$9,258,765.00
13	CASGEVY™ (exagamglogene autotemcel); Sickle Cell Disease indication	117	$1,650,000.00	$193,050,000.00
14	HEPZATO™ KIT (melphalan for injection/hepatic delivery system)	149	$118,625.00	$17,675,125.00
15	LYFGENIA™ (lovotibeglogene autotemcel)	40	$2,325,000.00	$93,000,000.00
16	4WEB Medical Ankle Truss System	124	$15,275.00	$1,894,100.00
17	AeroPace® System	550	$23,650.90	$13,007,995.00
18	AGENT™ Paclitaxel-Coated Balloon Catheter	9,010	$4,776.36	$43,035,026.13
19	alfapump® system	200	$21,450.00	$4,290,000.00
20	aprevo®-C cervical interbody fusion device	400	$21,125.00	$8,450,000.00
21	CERAMENT® G	466	$5,687.50	$2,650,375.00
22	Emily's Care Nourish Test System (Model 1)	11	$3,347.50	$36,822.50
23	Esprit™ BTK Everolimus Eluting Resorbable Scaffold System	5,300	$6,922.50	$36,689,250.00
24	EUROPA™ Posterior Cervical Fusion System	849	$80,548.00	$68,385,252.00
25	iFuse TORQ TNT™ Implant System	1,392	$4,135.95	$5,757,242.40
26	Merit Wrapsody® Cell Impermeable Endoprosthesis (CIE)	936	$3,770.00	$3,528,720.00
27	Minima Stent System	10	$22,685.00	$226,850.00
28	MY01 Continuous Compartmental Pressure Monitor	2,000	$2,112.50	$4,225,000.00
29	PBC Separator with Selux AST System	68,149	$87.78	$5,982,119.22
30	restor3d TIDAL™ Fusion Cage	96	$18,196.75	$1,746,888.00
31	ShortCut™	550	$9,750.00	$5,362,500.00
32	The WiSE CRT System	209	$41,145.00	$8,599,305.00
33	TriVerity Test	5,755	$243.75	$1,402,781.25
34	VITEK® REVEAL™ AST System	19,000	$81.25	$1,543,750.00
35	EMBLAVEO™ (aztreonam-avibactam)	207	$9,000.68	$1,863,140.76
36	CONTEPO™ (fosfomycin)	573	$4,111.65	$2,355,975.45
37	AURLUMYN™ (iloprost injection)	300	$28,600.00	$8,580,000.00
38	BREYANZI® (lisocabtagene maraleucel)	290	$316,860.05	$91,889,414.50
39	GRAFAPEX™ (treosulfan)	368	$21,411.00	$7,879,248.00
40	IMDELLTRA® (tarlatamab-dlle)	692	$7,117.50	$4,925,310.00
41	TECELRA® (afamitresgene autoleucel)	55	$472,550.00	$25,990,250.00
Aggregate Estimated Total FY 2027 Impact				**$840,505,708.21**

b. FY 2027 Applications for New Technology Add-On Payments

As discussed in sections II.E.5. and 6. of the preamble to this final rule, we are approving 19 technologies (3 traditional and 16 alternative) for new technology add-on payments for FY 2027. As explained in the preamble to this final rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral.

As discussed in section II.E.6. of the preamble of this final rule, under the alternative pathway for new technology add-on payments, new technologies that are medical products with a QIDP designation, approved through the FDA LPAD pathway, or are designated under the Breakthrough Device program will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to demonstrate that the technology represents a substantial clinical improvement. These technologies must still be within the 2- to 3-year newness period, as discussed in section II.E.1.a.(1). of the preamble this final rule, and must also still meet the cost criterion.

As fully discussed in section II.E.6. of the preamble of this final rule, we are approving 16 new technology add-on payments for the alternative pathway applications for FDA market authorized Breakthrough Devices submitted for FY 2027 new technology add-on payments. We did not receive any QIDP or LPAD applications for add-on payments for new technologies for FY 2027.

Based on preliminary information from the applicants at the time of this final rule, we estimate that total payments for the technologies approved under the alternative pathway will be approximately $418 million for FY 2027.

In the following table, we present detailed estimates for the 16 technologies for which we are approving new technology add-on payments under the alternative pathway in FY 2027:

FY 2027 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS FOR TECHNOLOGIES UNDER THE ALTERNATIVE PATHWAY

	Technology Name	Pathway (QIDP, LPAD, or Breakthrough Device)	Estimated Cases	FY 2027 NTAP Amount (65% or 75%)	Estimated Total FY 2027 Impact
1	Bayesian Health Sepsis Flagging Device	Breakthrough Device	89,594	$61.84	$5,540,492.96
2	BriefCase-Triage: CARE (Clinical AI Reasoning Engine) Multi-Triage CT Body	Breakthrough Device	234,300	$137.53	$32,223,279.00
3	Ceribell Delirium Monitor System	Breakthrough Device	84,000	$2,171.00	$182,364,000.00
4	CMORE® CT System (posterior cervico-thoracic system)	Breakthrough Device	100	$60,905.00	$6,090,500.00
5	GORE® VIABAHN® FORTEGRA Venous Stent	Breakthrough Device	567	$7,186.40	$4,074,688.80
6	Infuse™ Bone Graft	Breakthrough Device	2,120	$4,396.60	$9,320,792.00
7	InVision Precision Cardiac Amyloid	Breakthrough Device	6,000	$2,275.00	$13,650,000.00
8	Nelli™ Seizure Monitoring System	Breakthrough Device	1,485	$975.00	$1,447,875.00
9	NEXUS® Aortic Arch Stent Graft System	Breakthrough Device	300	$35,880.00	$10,764,000.00
10	OmniaSecure™ MRI SureScan™ Lead Model 3930M	Breakthrough Device	2,067	$7,796.75	$16,115,882.25
11	PearlMatrix™ P-15 Peptide Enhanced Bone Graft	Breakthrough Device	963	$3,380.00	$3,254,940.00
12	SAPIEN M3 Transcatheter Mitral Valve Replacement System	Breakthrough Device	700	$35,100.00	$24,570,000.00
13	SetPoint System®	Breakthrough Device	82	$38,675.00	$3,171,350.00
14	Spur® Peripheral Retrievable Stent System	Breakthrough Device	15,300	$2,596.75	$39,730,275.00
15	Trilogy™ Transcatheter Aortic Valve Regurgitation System	Breakthrough Device	2,500	$25,675.00	$64,187,500.00
16	ViaOne™ Epicardial Access System	Breakthrough Device	945	$1,300.00	$1,228,500.00
Estimated Total FY 2027 Impact					**$417,734,075.01**

As fully discussed in section II.E.5. of the preamble of this final rule, we are approving new technology add-on payments for 3 technologies that applied under the traditional pathway for new technology add-on payments for FY 2027. Based on information from the applicants at the time of rulemaking, we estimate that total payments for the technologies for which we are making new technology add-on payment is approximately $481 million for FY 2027.

In the following table, we present detailed estimates for the 3 technologies for which we are approving new technology add-on payments under the traditional pathway in FY 2027:

FY 2027 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS FOR TECHNOLOGIES UNDER THE TRADITIONAL PATHWAY				
	Technology Name	Estimated Cases	FY 2027 NTAP Amount (65%)	Estimated Total FY 2027 Impact
1	GAMIFANT® (emapalumab-lzsg)	15	$672,756.50	$10,091,347.50
2	YARTEMLEA® (narsoplimab-wuug)	1,585	$287,079.00	$455,020,215.00
3	ZEVASKYN™ (prademagene zamikeracel)	8	$2,045,550.00	$16,364,400.00
Estimated Total FY 2027 Impact				**$481,475,962.50**

c. Total Estimated Costs for NTAP in FY 2027

In the following table, we present summary estimates for all new technology add-on payments for FY 2027:

FY 2027 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS	
Category	Estimated Total FY 2027 Impact
Technologies Continuing New Technology Add-on Payments in FY 2027	$840,505,708.21
Alternative Pathway Applications	$417,734,075.01
Traditional Pathway Applications	$481,475,962.50
Aggregate Estimated Total FY 2027 Impact	**$1,739,715,745.72**

2. Medicare DSH Uncompensated Care Payments and Supplemental Payment for Indian Health Service Hospitals and Tribal Hospitals and Hospitals Located in Puerto Rico

As discussed in section V.E. of the preamble of this final rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments under section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of uninsured individuals (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has reported uncompensated care. Each hospital that is eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's amount of uncompensated care relative to the aggregate amount of uncompensated care of all hospitals eligible for Medicare DSH payments (Factor 3). The change to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this final rule, we are establishing the amount to be distributed as uncompensated care payments (UCP) to DSH-eligible hospitals for FY 2027, which is $7,939,472,850. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 67.14 percent. For FY 2026, the amount available to be distributed for uncompensated care was $7,713,127,500, or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 62.14 percent. In addition, eligible IHS/Tribal hospitals and hospitals located in Puerto Rico are estimated to receive approximately $109,391,454.46 in supplemental payments in FY 2027, based on the difference between each hospital's base year amount (that is, each hospital's FY 2022 UCP adjusted by 1 plus the percent change in the aggregate amount of uncompensated care payments between FYs 2022 and 2027) and its FY 2027 UCP. *See* 42 CFR 412.106(h)(3). If this difference is less than or equal to zero, the hospital will not receive a supplemental payment. For this final rule, the total UCP and supplemental payments equals approximately $8.049 billion. For FY 2027, we are using 3 years of data on uncompensated care costs from Worksheet S–10 of the FYs 2021, 2022, and 2023 cost reports to calculate Factor 3 for all DSH-eligible hospitals, including IHS/Tribal hospitals and Puerto Rico hospitals. For a complete discussion regarding the methodology for calculating Factor 3 for FY 2027, we refer readers to section V.E. of the preamble of this final rule. For a discussion regarding the methodology for calculating the supplemental payments, we refer readers to section V.D. of the preamble of this final rule.

To estimate the impact of the combined effect of the changes in Factors 1 and 2, as well as the changes to the data used in determining Factor 3, on the calculation of Medicare UCP along with changes to supplemental payments for IHS/Tribal hospitals and hospitals located in Puerto Rico, we compared total UCP and supplemental payments estimated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36536) to the combined total of the UCP and the supplemental payments estimated in this FY 2027 IPPS/LTCH PPS final rule. For FY 2026, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 62.14 percent and multiplied by a Factor 3 calculated using the methodology described in the FY 2026 IPPS/LTCH PPS final rule. For FY 2027, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments during FY 2027 absent section 3133 of the Affordable Care Act, adjusted by a final Factor 2 of 67.14 percent and multiplied by a Factor 3 calculated using the methodology described previously. For this final rule, the supplemental payments for IHS/Tribal hospitals and Puerto Rico hospitals are calculated as the difference between the hospital's base year amount and the hospital's FY 2027 UCP.

Our analysis included 2,277 hospitals that are projected to be DSH-eligible in FY 2027. Our analysis did not include hospitals that had terminated their participation in the Medicare program as of June 10, 2026, Maryland hospitals, new hospitals, and SCHs that are expected to be paid based on their hospital-specific rates. The 22 hospitals that are anticipated to be participating in the Rural Community Hospital Demonstration Program were also excluded from this analysis, as participating hospitals are not eligible to receive empirically justified Medicare DSH payments and UCP. In addition, the data from merged or acquired hospitals were combined under the surviving hospital's CMS certification number (CCN), and the non-surviving CCN was excluded from the analysis. The estimated impact of the changes in Factors 1, 2, and 3 on UCP and supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals across all hospitals projected to be DSH-eligible in FY 2027, by hospital characteristic, is presented in the following table:

MODELED UNCOMPENSATED CARE PAYMENTS* AND SUPPLEMENTAL PAYMENTS FOR ESTIMATED FY 2027 DSHS BY HOSPITAL TYPE					
	Number of Estimated DSHs (1)	FY 2026 Estimated Uncompensated Care Payments and Supplemental Payments ($ in millions) (2)	FY 2027 Estimated Uncompensated Care Payments and Supplemental Payments** ($ in millions) (3)	Dollar Difference: FY 2026 - FY 2027 ($ in millions) (4)	Percent Change*** (5)
Total	**2,277**	**$7,821**	**$8,049**	**$228**	**2.9%**
By Geographic Location					
Urban Hospitals	1,843	7,384	7,632	248	3.4
Other Urban Areas	950	3,240	3,285	45	1.4
Large Urban Areas	893	4,144	4,347	203	4.9
Rural Hospitals	434	437	417	-20	-4.6
Bed Size (Urban)					
0 to 99 Beds	346	316	309	-7	-2.2
100 to 249 Beds	746	1,578	1,608	30	1.9
250+ Beds	751	5,490	5,715	225	4.1
Bed Size (Rural)					0.0
0 to 99 Beds	322	232	223	-9	-3.7
100 to 249 Beds	102	165	153	-12	-7.2
250+ Beds	10	40	40	0	1.0
Urban by Region					
New England	82	203	211	7	3.6
Middle Atlantic	213	867	937	70	8.1
South Atlantic	290	738	724	-14	-1.9
East North Central	99	363	349	-14	-3.9
East South Central	302	1,896	1,932	36	1.9
West North Central	119	471	476	5	1.1
West South Central	244	1,729	1,841	112	6.5
Mountain	142	348	377	29	8.4
Pacific	308	670	686	16	2.3
Puerto Rico	44	98	98	0	0.5
Rural by Region					
New England	7	11	9	-2	-20.8
Middle Atlantic	34	25	26	2	6.3
South Atlantic	65	55	52	-3	-5.7
East North Central	26	27	23	-4	-15.2
East South Central	82	124	120	-3	-2.8
West North Central	94	82	76	-6	-7.5
West South Central	99	92	90	-2	-2.7
Mountain	19	13	13	-1	-4.4
Pacific	8	7	8	1	7.4
By Payment Classification					
Urban Hospitals	1,132	3,177	3,293	117	3.7
Large Urban Areas	608	1,926	2,020	94	4.9
Other Urban Areas	524	1,251	1,274	23	1.8
Rural Hospitals	1,145	4,644	4,756	111	2.4
Teaching Status					
Nonteaching	1,152	1,766	1,775	9	0.5
Fewer than 100 residents	826	2,811	2,862	51	1.8

MODELED UNCOMPENSATED CARE PAYMENTS* AND SUPPLEMENTAL PAYMENTS FOR ESTIMATED FY 2027 DSHS BY HOSPITAL TYPE					
	Number of Estimated DSHs (1)	FY 2026 Estimated Uncompensated Care Payments and Supplemental Payments ($ in millions) (2)	FY 2027 Estimated Uncompensated Care Payments and Supplemental Payments** ($ in millions) (3)	Dollar Difference: FY 2026 - FY 2027 ($ in millions) (4)	Percent Change*** (5)
100 or more residents	299	3,244	3,412	168	5.2
Type of Ownership					
Voluntary	1,470	4,474	4,602	128	2.9
Proprietary	454	1,070	1,056	-14	-1.3
Government	353	2,276	2,390	114	5.0
Medicare Utilization Percent****					
0 to 25	1,469	6,339	6,609	271	4.3
25 to 50	794	1,477	1,435	-42	-2.9
50 to 65	13	5	4	-1	-13.2
Greater than 65	1	0	0	0	
Medicaid Utilization Percent****					
0 to 25	1,360	3,646	3,676	30	0.8
25 to 50	806	3,464	3,620	156	4.5
50 to 65	86	686	727	41	6.0
Greater than 65	25	25	25	0	1.9

Source: Dobson | DaVanzo analysis of 2021, 2022 and 2023 Hospital Cost Reports.
*Dollar UCP calculated by [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, UCP and supplemental payments are estimated to be $7.821 billion in FY 2026, and UCP and supplemental payments are estimated to be $8.049 billion in FY 2027.
** For IHS/Tribal hospitals and Puerto Rico hospitals, this impact table reflects the supplemental payments.
*** Percentage change is determined as the difference between Medicare UCP and supplemental payments modeled for this FY 2027 IPPS/LTCH PPS final rule (column 3) and Medicare UCP and supplemental payments modeled for the FY 2026 IPPS/LTCH PPS final rule (column 2) divided by Medicare UCP and supplemental payments modeled for the FY 2026 IPPS/LTCH PPS final rule (column 2) times 100 percent.
****Hospitals with missing or unknown Medicare utilization or Medicaid utilization are not shown in the table.

The changes in projected FY 2027 UCP and supplemental payments compared to the total of UCP and supplemental payments in FY 2026 are driven by a decrease in Factor 1 and an increase in Factor 2. Factor 1 has decreased from the FY 2026 final rule's Factor 1 of $12.412 billion to this final rule's Factor 1 of $11.825 billion. Factor 2 has increased from the FY 2026 final rule's Factor 2 of 62.14 percent to this final rule's Factor 2 of 67.14 percent. In addition, we note that there is a slight decrease in the number of projected DSH-eligible hospitals to 2,277 at the time of the development of this final rule compared to the 2,364 DSHs at the time of development of the FY 2026 IPPS/LTCH PPS final rule (90 FR 36536). Based on the changes, the impact analysis found that, across all projected DSH-eligible hospitals, FY 2027 UCP and supplemental payments are estimated at approximately $8.049 billion, or an increase of approximately 2.9 percent from FY 2026 UCP and supplemental payments (approximately $7.821 billion). While the changes will result in a net increase in the final rule's total amount available to be distributed in UCP and supplemental payments, the projected payment changes vary by hospital type. This redistribution of payments is caused by changes in Factor 3 and the amount of the supplemental payment for DSH-eligible IHS/Tribal hospitals and Puerto Rico hospitals. As seen in the previous table, a percent change greater than 2.9 percent indicates that hospitals within the specified category are projected to experience a larger increase in payments, on average, compared to the universe of projected FY 2026 DSH-eligible hospitals. Conversely, a percentage change less than 2.9 percent indicates that a hospital type is projected to have a smaller increase compared to the overall average, or a decrease in payments. The variation in the distribution of overall payments by hospital characteristic is largely dependent on a given hospital's uncompensated care costs as reported on the Worksheet S–10 and used in the Factor 3 computation and whether the hospital is eligible to receive the supplemental payment.

Rural hospitals, in general, are projected to experience a decrease in UCP compared to the increase their urban counterparts are projected to experience. Overall, rural hospitals are projected to receive a 4.6 percent decrease in payments, while urban hospitals are projected to receive a 3.4 percent increase in payments, which is slightly above the overall hospital average.

By bed size, rural hospitals with 0 to 99 beds, 100 to 249 beds, and 250+ beds are projected to receive lower than average percent change of approximately −3.7 percent, −7.2 percent, and 1.0 percent, respectively. Among urban hospitals, the largest urban hospitals, those with 250+ beds and 100–249 beds, are projected to receive an above average increase in payments of 4.1 percent. In contrast, smaller urban hospitals with 100–249 beds and with 0–99 beds are projected to receive lower than average percent change in payments of 1.9 percent and −2.2 percent respectively.

By region, rural hospitals are projected to receive a varied range of payment changes. Rural hospitals in the Middle Atlantic and Pacific regions are projected to receive larger than average increase in payments. However, rural hospitals in all other regions including New England, South Atlantic, East North Central, East South Central, West North Central, West South Central, and Mountain regions are projected to receive a decrease in payments. Similarly, urban hospitals are projected to receive a varied range of payment changes. Urban hospitals in New

England, Middle Atlantic, West South Central, and Mountain regions are projected to receive larger than average increase in payments, and those in the East South Central, West North Central, Pacific regions, and Puerto Rico are projected to receive smaller than average increases in payments. However, urban hospitals in South Atlantic and East North Central are projected to receive decreases in payments.

By payment classification, hospitals in urban payment areas overall are expected to receive a larger than average change in UCP and supplemental payments of 3.7 percent. Hospitals in large urban payment areas are also projected to receive a larger than average increase in payments (4.9 percent), while hospitals in other urban payment areas are projected to receive a smaller-than-average increase in payments of 1.8 percent. Hospitals in rural payment areas are projected to receive a smaller than average increase in payments of 2.4 percent.

Nonteaching hospitals and teaching hospitals with fewer than 100 residents are projected to receive smaller than average increase in payments of 0.5 percent and 1.8 percent, respectively. Teaching hospitals with 100+ residents are projected to receive a larger than average increase in payments of 5.2 percent. Voluntary hospitals and proprietary hospitals are projected to receive average payment change of 2.9 percent and −1.3 percent, respectively, while government-owned hospitals are expected to receive a larger than average increase in payments of 5.0 percent.

Hospitals with less than 25 percent Medicare utilization are projected to receive a larger than average increase in payments of 4.3 percent, while hospitals with Medicare utilization between 25–50 percent and 50–65 percent are projected to receive a decrease of 2.9 percent and decrease of 13.2 percent, respectively. (Medicare utilization refers to a hospital's Medicare days divided by a hospital's total inpatient days.) We note that there is one hospital with greater than 65 percent Medicare utilization that did not receive UCP in FY 2026 and is projected to have no UCP in FY 2027. Thus, there is a zero percent change in payments for this hospital. Hospitals with 25–50 percent Medicaid utilization and those with 50–65 percent Medicaid utilization are projected to receive larger than average increase in payments of 4.5 percent and 6.0 percent, respectively. Hospitals with less than 25 percent Medicaid utilization and those with greater than 65 percent Medicaid utilization are projected to receive a smaller than average increase in payments of 0.8 percent and 1.9 percent. (Medicaid utilization refers to a hospital's Medicaid days divided by a hospital's total inpatient days.)

The impact table reflects the final FY 2027 UCP and final supplemental payments for IHS/Tribal and Puerto Rico hospitals. We note that the final supplemental payments to IHS/Tribal hospitals and Puerto Rico hospitals are estimated to be approximately $109.4 million in FY 2027.

3. Effects of Expiration of Temporary Changes to the Low-Volume Hospital Payment Policy

In section V.D. of the preamble of this final rule, we discuss the extension of the temporary changes to the low-volume hospital payment policy originally provided by the Affordable Care Act and extended by subsequent legislation. Specifically, section 6201 of the Consolidated Appropriations Act, 2026 further extended the modified definition of low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals under section 1886(d)(12) through December 31, 2026.

Beginning January 1, 2027, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011, and the preexisting low-volume hospital payment adjustment methodology and qualifying criteria, as implemented in FY 2005, will resume. Therefore, absent further Congressional action, effective for the portion of FY 2027 occurring on or after January 1, 2027, FY 2028 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year.

Using the same methodology used in developing the quantitative analyses of changes in payments per case discussed previously in section I.G. of Appendix A of this final rule, based upon the best available data at this time, we estimate the expiration of the temporary changes to the low-volume hospital payment policy effective for discharges occurring on or after January 1, 2027, and subsequent years would decrease aggregate low-volume hospital payments by $258 million in FY 2027 as compared to FY 2026. This payment estimate was determined based on the estimated payments for the approximately 589 providers that are expected to no longer qualify under the criteria that are effective beginning on January 1, 2027.

Of those 589 hospitals, currently approximately 90 hospitals have a low-volume hospital payment adjustment based on 500 or fewer total discharges, while the remaining approximately 499 hospitals have an adjustment based on having between 500 and 3,800 total discharges. Approximately 55 of the 589 hospitals that currently qualify for a low-volume hospital payment adjustment in FY 2026 have 200 or fewer total discharges and could be eligible to continue to receive the adjustment upon the expiration of the temporary extension of the amended low-volume hospital criteria if they also meet the mileage criterion. However, the distance information needed to project whether those hospitals are more than 25 road miles from another subsection (d) hospital (instead of 15 road miles), and therefore would continue to qualify for a low-volume hospital payment adjustment for FY 2027, is evaluated by each hospitals' MAC. Therefore, we are unable to estimate how many of these 55 hospitals would continue to qualify for the low-volume hospital payment adjustment for FY 2027.

4. Effects of Requirements to Prohibit Unlawful Discrimination by GME and NAH Education Programs.

As discussed in section V.F.2. of the preamble of this final rule, we are finalizing our proposal to require that, in addition to meeting other applicable requirements, an approved medical residency training program must not discriminate, or promote or encourage discrimination, on the basis of race, color, national origin, sex, age, disability, or religion, including the use of those characteristics or intentional proxies for those characteristics as a selection criterion for employment, program participation, resource allocation, or similar activities, opportunities, or benefits. In section V.G.3. of the preamble of this final rule, we discuss the finalization of similar proposals with respect to approved nursing and allied health education programs and accreditors. The effective date of these policies is October 1, 2026. We believe that, as of October 1, 2026, no approved programs or accrediting bodies will continue to, or newly engage in unlawful discrimination on the basis of race or other protected characteristics.

5. Effects of Changes for Determining Net Costs of Approved NAH Education Programs

As discussed in section V.G.4. of this final rule, we are finalizing, with modification, our proposal to revise the regulations at 42 CFR 413.85(d)(2) to state that tuition and other revenue must be subtracted from the allowable direct costs of a hospital's NAH education programs prior to the allocation of indirect costs. This policy was proposed in response to an adverse ruling by the U.S. District Court for the District of Columbia in *Mercy Health—St. Vincent Medical Center LLC d/b/a Mercy St. Vincent Medical Center* v. *Becerra,* 717 F. Supp. 3d 33 (D.D.C. 2024). In addition, we are finalizing our clarification of existing policies regarding the nature of allowable costs for purposes of NAH pass-through payment. We are not finalizing our proposal to require hospitals with approved, provider-operated NAH education programs to follow specific procedures for allocating indirect costs to the NAH cost centers. We are unable to estimate the financial impact of the finalized changes to the regulations text since it is unclear what cost reporting procedures hospitals would employ in the absence of this rulemaking, except for the plaintiffs in the *Mercy St. Vincent* litigation.

6. Effects Under the Hospital Readmissions Reduction Program for FY 2027

In section V.I. of the preamble of this final rule, we are adopting with modification a policy to add sepsis as an applicable condition beginning with the FY 2030 program year; the remaining policies finalized in FY 2026 IPPS/LTCH PPS final rule (90 FR 36923) continue to apply. Specifically, we will adopt the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure beginning with an early look for the FY 2028 (applicable period of July 1, 2024 to June 30, 2026) and FY 2029 (applicable period of July 1, 2025 to June 30, 2027) program years. The measure will then be used in the Hospital Readmissions

Reduction Program for payment adjustment beginning with the FY 2030 program year (applicable period of July 1, 2026 to June 30, 2028) and subsequent years. As finalized in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36923 through 36929), we will integrate Medicare Advantage beneficiaries into the cohorts of the Hospital Readmissions Reduction Program measure set and reduce the applicable period from 3 years to 2 years beginning with the FY 2027 program year.

In section V.I.2.b. of the preamble of this final rule, we are adopting the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Sepsis Hospitalization measure beginning with the FY 2030 program year. While we state in section XII.B.1. of the preamble of this final rule that adopting this measure will not result in any change in information collection burden, we acknowledge that hospitals not currently providing the types of discharge planning and care coordination services that will be expected to minimize readmissions may incur other financial impacts such as updating policies and procedures, increased governance and oversight, and staff training in order to do so. We also recognize that most hospitals have already established standard evidence-based sepsis protocols as part of their existing quality improvement and patient safety frameworks. As such, hospitals are generally well-positioned with respect to the acute clinical management of sepsis, and the additional burden associated with this policy is more likely to center on post-discharge care coordination and transition planning rather than inpatient sepsis treatment protocols. However, because each hospital is unique and we lack insight into what services each may already offer or will elect to offer, we emphasize uncertainty in estimating the costs associated with these impacts. We requested public comment on financial impacts related to post-discharge coordination, transition planning, or other areas associated with the acute clinical management of sepsis that hospitals may incur. We received no comments in response to this request. We refer readers to Table V.I.–05 for the estimated total Medicare savings with and without the Sepsis Readmission measure included in the program measure set. Hospitals can choose either to incur resource costs to improve their sepsis-related practices or they can pay the penalty, predicted to be $170 million as reported in Table V.I.–05. Assuming they typically choose to minimize expenses, $170 million is an upper bound on the resource costs; if there is no non-arbitrary lower bound other than $0, then the midpoint cost estimate is $85 million.

The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating diagnosis-related group (DRG) payments to account for excess readmissions of selected applicable conditions and procedures. The table and analysis in this section illustrate the estimated financial impact of the Hospital Readmissions Reduction Program payment adjustment methodology by hospital characteristic. Hospitals are sorted into quintiles based on the proportion of dual-eligible stays among Medicare Fee-For-Service and managed care (that is, Medicare Advantage) stays between July 1, 2021, and June 30, 2023. Hospitals' excess readmission ratios (ERRs)—based on the data used to calculate preliminary Medicare Advantage and Medicare Fee-for-Service readmission measure results from January 1, 2022, through December 31, 2023—are assessed relative to their peer group median. A neutrality modifier is applied in the payment adjustment factor calculation to maintain budget neutrality.

The results in Table I.G.6.–01 include 2,832 non-Maryland hospitals estimated as eligible to receive a penalty during the performance period based on the most recently available data at the time of publication of this final rule. Hospitals are eligible to receive a penalty if they have 25 or more eligible discharges for at least one measure between January 1, 2022, and December 31, 2023. The third column in Table I.G.6.–01 indicates the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is, penalized hospitals). The total estimated Medicare savings for all hospitals is about $361 million.

The fourth column in Table I.G.6.–01 indicates the estimated percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 78.64 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 87.93 percent of eligible hospitals with fewer than 100 residents and 93.90 percent of eligible hospitals with 100 or more residents are expected to be penalized. The fifth column in Table I.G.6.–01 estimates the financial impact on hospitals by hospital characteristic. Table I.G.6.–01 also shows the share of penalties as a percentage of all base operating DRG payments for hospitals with each characteristic. This is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals between October 1, 2022, through September 30, 2023 (FY 2023). For example, the penalty as a share of payments for non-teaching hospitals is 0.51 percent. This means that total penalties for all non-teaching hospitals are 0.51 percent of total payments for non-teaching hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals with the characteristic when comparing the financial impact of the program on different groups of hospitals.

TABLE I.G.6.-01: ESTIMATED PERCENTAGE OF HOSPITALS PENALIZED AND PENALTY AS SHARE OF PAYMENTS FOR FY 2027 HOSPITAL READMISSIONS REDUCTION PROGRAM BY HOSPITAL CHARACTERISTIC

Hospital Characteristic	Number of Hospitals Eligible for a Penalty[a]	Number of Penalized Hospitals[b]	Percentage of Hospitals Penalized[c] (%)	Penalty as a Share of Payments[d] (%)
All Hospitals	2,832	2,358	83.26	0.48
By Geographic Location (n= 2,826)				
Urban hospitals	2,180	1,876	86.06	0.48
1-99 beds	511	358	70.06	0.48
100-199 beds	635	562	88.50	0.56
200-299 beds	393	365	92.88	0.57
300-399 beds	270	251	92.96	0.49
400-499 beds	118	111	94.07	0.45
500 or more beds	253	229	90.51	0.39
Rural hospitals	646	480	74.30	0.47
1-49 beds	295	183	62.03	0.37
50-99 beds	184	148	80.43	0.49
100-149 beds	94	82	87.23	0.52
150-199 beds	42	38	90.48	0.50
200 or more beds	31	29	93.55	0.46
By Teaching Status[e] (n= 2,826)				
Non-teaching	1,578	1,241	78.64	0.51
Fewer than 100 Residents	953	838	87.93	0.50
100 or more Residents	295	277	93.90	0.42
By Ownership Type (n= 2,826)				
Government	397	324	81.61	0.32
Proprietary	611	492	80.52	0.66
Voluntary	1,818	1,540	84.71	0.47
By Safety-Net Status[f] (n= 2,826)				
Safety-net hospitals	566	470	83.04	0.44
Non-safety-net hospitals	2,260	1,886	83.45	0.49
By Disproportionate Share Hospital (DSH) Patient Percentage[g] (n= 2,826)				
0-24	1,069	868	81.20	0.54
25-49	1,470	1,255	85.37	0.44
50-64	166	132	79.52	0.51
65 and over	121	101	83.47	0.58
By Medicare Cost Report (MCR) Percentage[h] (n= 2,826)				
0-24	1,404	1,192	84.90	0.39
25-49	1,355	1,124	82.95	0.56
50-64	60	38	63.33	0.71
65 and over	7	2	28.57	2.73
By Region (n= 2,831)				
New England	120	115	95.83	0.63
Middle Atlantic	313	293	93.61	0.62
East North Central	443	379	85.55	0.49
West North Central	223	176	78.92	0.38
South Atlantic	485	424	87.42	0.49
East South Central	252	208	82.54	0.43
West South Central	422	322	76.30	0.37
Mountain	206	140	67.96	0.32
Pacific	367	301	82.02	0.43

Source: The table results are based on the data used to calculate preliminary readmission measure results for Medicare Advantage and Medicare Fee-for-Service patients that were available using data from January 1, 2022, through December 31, 2023; Fee-for-Service DRG ratios and dual proportions from July 1, 2021, through June 30, 2023. Although data from all subsection (d), Maryland hospitals, and hospitals that are not eligible to participate in the Hospital Readmissions Reduction Program (such as CAHs) were used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals, hospitals that are not eligible to participate in the Hospital Readmissions Reduction Program, and hospitals that are not open as of the October 2025 public reporting open hospital list because these hospitals are not eligible for a penalty under the program. Hospitals are sorted into five peer groups based on the proportion of Fee-for-Service and Medicare Advantage dual-eligible stays from July 1, 2021, through June 30, 2023. Hospital characteristics are from the FY 2026 IPPS/LTCH PPS Proposed Rule Impact File.

Note: The total number of hospitals with hospital characteristics data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. Not all hospitals had data for geographic location, teaching status, ownership type, safety-net status, DSH patient percentage, and MCR percentage (n=2,826; missing=6) and region (n=2,831; missing=1). The methodology differs from the impact analyses included in the FY 2026 IPPS/LTCH PPS final rule in that this table includes the removal of the COVID-19 exclusion, use of a two-year performance period for DRG ratio calculations, and updated input datasets.

[a] This column is the number of applicable hospitals within the characteristic that could receive a penalty (that is, they have 25 or more eligible discharges for at least one measure).

[b] This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an estimated payment adjustment factor less than 1) within the characteristic.
[c] This column is the percentage of applicable hospitals that are penalized among hospitals that are eligible to receive a penalty by characteristic.
[d] This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments in this way allows for comparisons across hospital characteristics that accounts for differences in the amount of base operating DRG payments for different groups of hospitals. MedPAR data from October 1, 2022, through September 30, 2023 (FY 2023), are used to estimate the total base operating DRG payments.
[e] A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operating PPS greater than zero.
[f] A hospital is considered a safety-net hospital if it is in the top DSH quintile.
[g] DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.
[h] MCR (Medicare Cost Report) percentage is the percentage of total inpatient stays from Medicare patients

7. Effects of Finalized Changes Under the FY 2027 Hospital Value-Based Purchasing Program

The Secretary makes value-based incentive payments to hospitals under the Hospital Value-Based Purchasing Program based on their performance on measures during the performance period with respect to a fiscal year. These incentive payments will be funded for FY 2027 through a reduction to the FY 2027 base operating DRG payment amount for hospital discharges for such fiscal year, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2027 and subsequent years is 2 percent. The total amount available for value-based incentive payments must be equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary. In section V.J.1.b. of the preamble of this final rule, we estimate the available pool of funds for value-based incentive payments in the FY 2027 program year, which, in accordance with section 1886(o)(7)(C)(v) of the Act, will be 2.00 percent of base operating DRG payments, or a total of approximately $1.9 billion. This estimated available pool for FY 2027 is based on the historical pool of hospitals that were eligible to participate in the FY 2026 program year and the payment information from the March 2026 update to the FY 2025 MedPAR file.

The estimated impacts of the FY 2027 program year by hospital characteristic, found in Table I.G.8.-01, are based on historical TPSs. We used the FY 2026 program year's TPSs to calculate the proxy adjustment factors used for this impact analysis. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the March 2026 update to the FY 2025 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this final rule (available via the internet on the CMS website).

The estimated impact analysis shows that, for the FY 2027 program year, the number of hospitals with a positive percent change in base operating DRG (51.7 percent) is higher than the number of hospitals with a negative percent change (48.3 percent). Approximately half of all hospitals experience a percent change in base operating DRG between -2.1 percent and 0.0 percent. On average, both urban hospitals in the West North Central region and rural hospitals in the Pacific region have the highest positive percent change in base operating DRG. Urban hospitals in the Middle Atlantic, South Atlantic, and East South Central regions experience an average negative percent change in base operating DRG. All other regions (both urban and rural) experience an average positive percent change in base operating DRG. Hospitals in higher MCR percent categories have higher average net percentage payment increases compared to hospitals with lower MCR percent. Hospitals in higher DSH percent categories (50–64 and 65 and over) have negative average net percentage payment, compared to hospitals in the lower DSH categories. On average, non-teaching hospitals have a higher percent change in base operating DRG compared to teaching hospitals.

BILLING CODE 7169–69–P

TABLE I.G.8.-01: IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNTS RESULTING FROM THE FY 2027 HOSPITAL VBP PROGRAM			
		Number of Hospitals	**Average Net Percentage Payment Adjustment**
BY GEOGRAPHIC LOCATION:			
	All Hospitals	**2,448**	0.132%
	Urban Area	1,918	0.061%
	Rural Area	530	0.387%
	Urban Hospitals	**1,918**	0.061%
	0-99 beds	356	0.620%
	100-199 beds	582	0.094%
	200-299 beds	376	-0.165%
	300-499 beds	364	-0.178%
	500 or more beds	240	-0.125%
	Rural Hospitals	**530**	0.387%
	0-49 beds	202	0.641%
	50-99 beds	169	0.397%
	100-149 beds	92	0.174%
	150-199 beds	38	-0.056%
	200 or more beds	29	-0.186%
BY REGION:			
	Urban By Region	1,918	0.061%
	New England	91	0.116%
	Middle Atlantic	246	-0.080%
	South Atlantic	362	-0.002%
	East North Central	278	0.098%
	East South Central	110	-0.122%
	West North Central	126	0.194%
	West South Central	233	0.075%
	Mountain	155	0.110%
	Pacific	317	0.174%
	Rural By Region	530	0.387%
	New England	16	0.547%
	Middle Atlantic	41	0.301%
	South Atlantic	89	0.289%
	East North Central	97	0.497%
	East South Central	94	0.130%
	West North Central	67	0.642%
	West South Central	69	0.122%
	Mountain	32	0.804%
	Pacific	25	0.837%
BY MCR PERCENT:			

	0-24	1,254	0.060%
	25-49	1,156	0.196%
	50-64	36	0.526%
	65 and Over	0	-
	Missing	2	1.016%
BY DSH PERCENT:			
	0-24	895	0.310%
	25-49	1,313	0.050%
	50-64	140	-0.070%
	65 and Over	100	-0.060%
BY TEACHING STATUS:			
	Non-Teaching	1,284	0.303%
	Teaching	1,164	-0.056%

BILLING CODE 7169–69–C

The actual FY 2027 program year's TPSs will not be reviewed and corrected by hospitals until after the FY 2027 IPPS/LTCH PPS final rule has published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2026 program year have been used for the updated impact analysis in this final rule.

8. Effects of Requirements Under the Hospital-Acquired Condition Reduction Program for FY 2027

We present the estimated impact of the FY 2027 Hospital-Acquired Condition (HAC) Reduction Program on hospitals by hospital characteristic based on previously adopted policies for the program. We are not adding or removing any measures from the HAC Reduction Program in this final rule, nor are we changing reporting or submission requirements. Table I.G.8.–01 in this section presents the estimated proportion of hospitals in the worst-performing quartile of Total HAC Scores by hospital characteristic. Hospitals' CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure results are based on Medicare fee-for-service (FFS) discharges from July 1, 2022, through June 30, 2024, and version 15.0 of the PSI software. Hospitals' measure results for Centers for Disease Control and Prevention (CDC) Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Colon and Abdominal Hysterectomy Surgical Site Infection (SSI), Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, and *Clostridium difficile* Infection (CDI) are derived from standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the CDC's National Healthcare Safety Network (NHSN) for infections occurring between January 1, 2023, and December 31, 2024. Hospital characteristics are based on the FY 2026 IPPS Proposed Rule Impact File.

Table I.G.8.–01 includes 2,891 non-Maryland hospitals with an estimated FY 2027 Total HAC Score based on the most recently available data at the time of publication of this final rule. Maryland hospitals and hospitals without a Total HAC Score are excluded from the table. Actual results for FY 2027 will be determined in the fall of 2026 after a 30-day review and corrections period for hospitals to review their program results. The first column presents a breakdown of each characteristic and the second column indicates the number of hospitals for the respective characteristic.

The third column in Table I.G.8.–01 indicates the estimated number of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores. For example, with regard to teaching status, 401 hospitals out of 1,620 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 210 out of 959 hospitals with fewer than 100 residents and 100 out of 295 hospitals with 100 or more residents would be subject to a payment reduction.

The fourth column in Table I.G.8.–01 indicates the estimated proportion of hospitals for each characteristic that would be in the worst performing quartile of Total HAC Scores and thus receive a payment reduction under the FY 2027 HAC Reduction Program. For example, 24.8 percent of the 1,620 hospitals characterized as non-teaching hospitals, 21.9 percent of the 959 teaching hospitals with fewer than 100 residents, and 33.9 percent of the 295 teaching hospitals with 100 or more residents would be subject to a payment reduction.

We received no comments on these effects.

TABLE I.G.8.-01: ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORES FOR THE FY 2027 HAC REDUCTION PROGRAM BY HOSPITAL CHARACTERISTIC

Hospital Characteristic	Number of Hospitals	Number of Hospitals in the Worst-performing Quartile[a]	Percent of Hospitals in the Worst-Performing Quartile[b]
All Hospitals[c]	2,891	721	25
By Geographic Location (n = 2,874)			
Urban hospitals	**2,245**	**510**	**22.7**
1-99 beds	562	129	23.0
100-199 beds	645	144	22.3
200-299 beds	396	85	21.5
300-399 beds	271	55	20.3
400-499 beds	118	26	22.0
500 or more beds	253	71	28.1
Rural hospitals	**629**	**201**	**32.0**
1-49 beds	276	93	33.7
50-99 beds	186	59	31.7
100-149 beds	94	23	24.5
150-199 beds	42	12	28.6
200 or more beds	31	14	45.2
By Teaching Status[d] **(n = 2,874)**			
Non-teaching	1,620	401	24.8
Fewer than 100 residents	959	210	21.9
100 or more residents	295	100	33.9
By Ownership (n = 2,874)			
Government	390	146	37.4
Proprietary	655	94	14.4

Voluntary	1,829	471	25.8
By Safety-Net Status[e] (n = 2,874)			
Safety-net	583	162	27.8
Non-safety net	2,291	549	24.0
By Disproportionate Share Hospital (DSH) Patient Percentage[f] (n = 2,874)			
0-24	1,103	232	21.0
25-49	1,465	387	26.4
50-64	164	45	27.4
65 and over	142	47	33.1
By Medicare Cost Report (MCR) Percentage (n = 2,872)			
0-24	1,455	352	24.2
25-49	1,350	339	25.1
50-64	56	14	25.0
65 and over	11	4	36.4
By Region (n = 2,891)			
New England	120	38	31.7
Middle Atlantic	318	86	27.0
East North Central	456	118	25.9
West North Central	227	56	24.7
South Atlantic	491	97	19.8
East South Central	248	83	33.5
West South Central	438	86	19.6
Mountain	219	45	20.5
Pacific	374	112	29.9

Source: FY 2027 HAC Reduction Program estimated final rule results are based on CMS PSI 90 data from July 1, 2022, through June 30, 2024, and CDC's NHSN HAI results from January 1, 2023, through December 31, 2024. Hospital Characteristics are based on the FY 2026 IPPS Proposed Rule Impact File.

Note: The total number of hospitals with hospital characteristic data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. Not all hospitals had data for geographic location, teaching status, ownership, Safety-net status, and DSH percent (n = 2,874; missing = 17), and MCR percentage (n = 2,872; missing = 19).

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[c] The number of non-Maryland hospitals with a Total HAC Score (N = 2,891).

[d] A hospital is considered a teaching hospital if it has an Indirect Medical Education (IME) adjustment factor for Operating PPS (based on the TCHOP variable in the IPPS Impact File) greater than zero.

[e] A hospital is considered a safety-net hospital if it is in the top quintile for DSH percent.

[f] The DSH patient percentage is equal to the sum of: (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income; and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

9. Implementation of the Rural Community Hospital Demonstration (RCHD) Program in FY 2027

In section V.L.2 of the preamble of this final rule for FY 2027, we discussed our general budget neutrality methodology for section 410A of Public Law 108173, as amended by sections 3123 and 10313 of Public Law 111–148, by section 15003 of Public Law 114–255, and most recently, by section 128 of Public Law 116–260, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural hospitals.

Section 128 of Public Law 116–260 requires the Secretary to conduct the Rural Community Hospital Demonstration for a 15-year extension period (that is, for an additional 5 years beyond the previous extension period). In addition, the statute provides for continued participation for all hospitals participating in the demonstration program as of December 30, 2019.

Section 410A(c)(2) of Public Law 108–173, as amended, requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented (budget neutrality). To ensure budget neutrality, we proposed to continue with the general methodology used in previous years, whereby we estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration and then adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. This proposed methodology applies budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented but does not identify the range across which aggregate payments must be held equal.

For this final rule, we are not yet able to finalize the estimated FY 2027 costs of the demonstration at this time, based on available ''as submitted'' cost reports to apply the budget neutrality offset to the national IPPS rates as we have done in previous years.

In previous years, we have also incorporated a second component into the budget neutrality offset amounts identified in the IPPS/LTCH PPS final rules. As finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier given year differed from the estimated costs for the demonstration set forth in the IPPS/LTCH PPS final rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We have calculated this difference for FYs 2018 through 2020 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS/LTCH PPS final rules for these years.

With the extension of the demonstration for another 5-year period, as authorized by section 128 of Public Law 116–260, we proposed to continue with this general procedure. As stated, for the FY2027 final rule, we are not yet able to finalize the estimated FY 2027 costs of the

demonstration. Therefore, we are not proposing to apply a budget neutrality offset for the FY 2027 IPPS/LTCH PPS final rule. Instead, we proposed to apply both the FY 2027 and FY 2028 estimated costs of the demonstration into the budget neutrality offset to national IPPS rates in the FY 2028 IPPS/LTCH PPS final rule. Consistent with our methods in previous years, these estimates will also include the difference between estimated costs and actual costs for the demonstration for FY 2021 and FY 2022 in the budget offset amount. We invited public comments.

We received a few public comments, most of which were out of scope. However, all of the comments we received were supportive of continuing the Rural Community Hospital Demonstration.

Comment: A commenter recommended that CMS allow RCHD hospitals whose 5-year participation agreements have expired or will be expiring under the CAA extension reenter the program until the demonstration's statutory end date of June 30, 2028.

Response: We thank the commenter for their interest and recommendation. In the absence of new authorizing legislation, it is CMS' position that we cannot extend expired participation agreements beyond the statutorily defined 5-year periods under the same reauthorization.

Comment: The parent company for two of the participating hospitals expressed support for the continuation of the Rural Community Hospital Demonstration program, but noted that it does not offer long-term financial stability needed to maintain health care access in rural areas. The commenter requests that the demonstration be made a permanent program. Furthermore, the commenter requests several technical adjustments to the administration of the demonstration that may enhance stability in the payment to the participating hospitals.

Response: We appreciate the comments. We have conducted the demonstration program in accordance with section 410A of the MMA, and there is no authority to make the demonstration a permanent program. With regard to any technical adjustments to the demonstration, we intend to work with the commenter and other rural stakeholders to examine the issues involved.

After consideration of the public comments we received, primarily requesting to extend the demonstration, we are finalizing our policy without modification.

10. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VII.C.2 of the preamble of this final rule we discuss the implementation of the FCHIP Demonstration, which was authorized under section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act of 2010 (Pub. L. 114–158), and most recently re-authorized and extended by the Consolidated Appropriations Act of 2021 (Pub. L. 116–260). The legislation authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries in certain rural areas. The FCHIP demonstration initial period was conducted in 10 critical access hospitals (CAHs) from August 1, 2016, to July 31, 2019, and the demonstration ''extension period'' began on January 1, 2022, to run through June 30, 2027. Section 123(g)(1)(B) of Public Law 110–275 required that the demonstration be budget neutral. Specifically, this provision stated that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Budget neutrality estimates for the demonstration described in the preamble of this final rule are based on the demonstration extension period.

As described in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), CMS waived certain Medicare rules for CAHs participating in the demonstration extension period to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: telehealth services, ambulance services, and skilled nursing facility/nursing facility services. These waivers were implemented with the goal of increasing access to care with no net increase in costs. As we explained in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), section 129 of Public Law 116–260, stipulates that only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. Among the eligible CAHs, five elected to participate in the extension period. The selected CAHs are located in two states—Montana and North Dakota—and are implementing the three intervention services.

As explained in the FY 2026 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we finalized for the demonstration extension period of performance in the FY 2026 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met.

In the FY 2026 IPPS/LTCH PPS final rule, we adopted the same budget neutrality policy contingency plan used during the demonstration initial period to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met during the demonstration extension period. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 5-year extension period is not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide.

As explained in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality for the demonstration extension period by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration extension period is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration extension period were not implemented, CMS policy is to comply with the budget neutrality requirement finalized in the FY 2026 IPPS/LTCH PPS final rule, by reducing payments to all CAHs, not just those participating in the demonstration extension period.

In the FY 2026 IPPS/LTCH PPS final rule, we stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. As we explained in the FY 2026 IPPS/LTCH PPS final rule, we believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented and does not identify the range across which aggregate payments must be held equal.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS concluded that the initial period of the FCHIP Demonstration had satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, CMS did not apply a budget neutrality payment offset policy for the initial period of the demonstration. As explained in the FY 2022 IPPS/LTCH PPS final rule, we finalized a policy to address the demonstration budget neutrality methodology and analytical approach for the initial period of the demonstration. In the FY 2026 IPPS/LTCH PPS final rule, we finalized a policy to adopt the same budget neutrality methodology and analytical approach used during the demonstration initial period to be used for the demonstration extension period. As stated in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36971 through 36975), our policy for implementing the 5-year extension period for section 129 of Public Law 116–260 follows same budget neutrality methodology and analytical approach as the demonstration initial period methodology. While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during the initial period of the demonstration to assess the financial impact of the demonstration during this

extension period, upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured. Therefore, we did not propose to apply a budget neutrality payment offset to payments to CAHs in FY 2027. This policy will have no impact for any national payment system for FY 2027. We received no comments on this proposal and therefore are finalizing this provision without modification.

11. Effects of the Transforming Episode Accountability Model (TEAM)

In section X.A. of the preamble of this final rule, we discuss testing the mandatory episode-based payment model titled the Transforming Episode Accountability Model (TEAM) under the authority of the CMS Center for Medicare and Medicaid Innovation (CMS Innovation Center). Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. The intent of TEAM is to improve beneficiary care through financial accountability for episode categories that begin with one of the following procedures: coronary artery bypass graft, lower extremity joint replacement, major bowel procedure, surgical hip/femur fracture treatment, and spinal fusion. TEAM tests whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate that TEAM will benefit Medicare beneficiaries through improving the coordination of items and services paid for through Medicare fee-for-service (FFS) payments, encouraging provider investment in health care infrastructure and redesigned care processes, and incentivizing higher value care across the inpatient and post-acute care settings for the episode.

As finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), with subsequent updates made in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36536), TEAM is mandatory for acute care hospitals located within mandatory CBSAs and includes acute care hospitals that were eligible for voluntary opt-in.[6] TEAM began on January 1, 2026, and will end on December 31, 2030. Payment approaches that hold providers accountable for episode cost and performance can potentially create incentives for the implementation and coordination of care redesign between participants and other providers and suppliers such as physicians and post-acute care providers. We anticipate TEAM will enable hospitals to consider the most appropriate strategies for care redesign, including (1) increasing post-hospitalization follow-up and medical management for patients; (2) coordinating care across the inpatient and post-acute care spectrum; (3) conducting appropriate discharge planning; (4) improving adherence to treatment or drug regimens; (5) reducing readmissions and complications during the post-discharge period; (6) managing chronic diseases and conditions that may be related to the episodes; (7) choosing the most appropriate post-acute care setting; and (8) coordinating between providers and suppliers such as hospitals, physicians, and post-acute care providers.

Under TEAM, TEAM participants continue to bill Medicare under the traditional FFS system for items and services furnished to Medicare FFS beneficiaries. The TEAM participant may receive a reconciliation payment from CMS if Medicare FFS expenditures for a performance year are less than the reconciliation target price, subject to a quality adjustment. TEAM does not have downside risk for Track 1, meaning TEAM participants will only be accountable for performance year spending below their reconciliation target price, subject to a quality adjustment, that would result in a reconciliation payment amount. For Track 2 and Track 3, TEAM will be a two-sided risk model that requires TEAM participants to be accountable for performance year spending above or below their reconciliation target price, subject to a quality adjustment, that would result in a reconciliation payment amount or a repayment amount.

a. Effects on the Medicare Program

TEAM is a mandatory episode-based payment model which will have a direct effect on the Medicare program because TEAM participants are incentivized to reduce Medicare spending. Additionally, TEAM participants could receive a reconciliation payment amount from CMS or have to pay CMS a repayment amount based on their spending and quality performance. In the FY 2026 IPPS/LTCH PPS final rule (90 FR 37271), we estimated and projected financial impacts of TEAM over the course of the five-year model test. We estimated that on net, that CMS will pay TEAM participants $381 million and TEAM participants will pay CMS $469 million, and that TEAM will save the Medicare program approximately $368 million over the 5 performance years (2026 through 2030).

In this final rule, we are finalizing several policies. We believe several final policies, including policies related to MS–DRGs in the spinal fusion episode category, episode attribution, quality measurement performance and baseline periods, and updates to the preliminary target price methodology will not have a material impact on the Medicare savings estimate. For example, we anticipate the policy to include the updated spinal fusion MS–DRGs would help maintain episode volume and spending, and we do not anticipate that updating the quality measure time periods will have a significant effect on Medicare spending or savings. Additionally, the policies that affect the pricing methodology, such as changes to the construction of the normalization factor and adding update factors to capture current payment system changes, aim to improve the accuracy of target prices and we do not anticipate they will result in dramatic shifts to the Medicare savings estimate.

We note that certain policy considerations in the Requests for Information (RFIs) included in the proposed rule, such as allowing additional voluntary participation for hospitals with physician ownership (POHs) or adding ASC episodes to TEAM would impact the Medicare savings estimate. However, we are not finalizing any policy related to the RFIs in this final rule. We anticipate in future notice and comment rulemaking to propose voluntary participation of POHs and would at that time update the Medicare savings estimate, as applicable. Therefore, TEAM's financial impact to the Medicare program remains unchanged from the FY 2026 IPPS/LTCH PPS final rule.

We received no comments and therefore are finalizing this provision without modification.

b. Effects on Medicare Beneficiaries

We believe the refinements to TEAM in this final rule will not materially alter the potential effects of the model on beneficiaries that we had initially indicated in the FY 2025 IPPS/LTCH PPS final rule (89 FR 70028). We believe the majority of the changes will not alter the effects of the model on beneficiaries because the changes predominantly alter how hospitals interact with the model, rather than how beneficiaries receive care. However, we believe any changes finalized that may have a direct effect on TEAM beneficiaries are positive. In section X.A.2.a.(2) of the preamble of this final rule, we finalized the policy to include new spinal fusion episode categories MS–DRGs with the belief that doing so would continue to capture Medicare beneficiaries in TEAM so they could benefit from improved care transitions and quality of care.

We invited public comments on the impact of TEAM on Medicare beneficiaries. We received no comments and therefore are finalizing this provision without modification.

c. Effects on TEAM Participants

We believe TEAM will not have significant impact on TEAM participant burden. TEAM will not alter the way participating hospitals bill Medicare. Therefore, we believe there will be no additional burden for TEAM participants related to billing practices.

We also believe that TEAM does not impose additional burden related to quality reporting because the quality measures used in the model are measures that TEAM participants already report to CMS under existing CMS quality reporting programs. Accordingly, TEAM participants will not be required to establish new quality reporting systems or submit additional quality measure data solely for purposes of TEAM.

In addition, TEAM does not require TEAM participants to hire additional staff, such as care coordinators, establish a governing board, or otherwise implement new organizational structures as a condition of participation. Therefore, we do not believe TEAM imposes additional regulatory burden on TEAM participants for such activities.

[6] Acute care hospitals that participate in the BPCI Advanced or the CJR model, that are not located in a mandatory CBSA selected for TEAM participation, and continue to participate in BPCI Advanced or CJR until the last day of the last performance period or last performance year of the respective model, were eligible to voluntarily opt into TEAM.

We recognize there may be administrative burden associated with the TEAM requirement that participants submit a financial arrangements list or clinician engagement list, as applicable. TEAM participants that do not have any financial arrangements or clinician engagement relationships that meet the definitions established for the model, as defined at § 512.505, must attest that there are no such relationships, as defined at § 512.522 (d), which we believe would be associated with nominal administrative burden.

For purposes of estimating burden for TEAM participants that submit a list, we assume that approximately 17 percent of participating hospitals may submit a financial arrangements list or clinician engagement list on a quarterly basis, as applicable. We estimate that preparing, reviewing, and submitting the applicable list will require approximately 1 hour per quarterly submission, or 4 hours annually, for each participating hospital that submits one of these lists. We assume this work will be completed by a Medical and Health Services Manager. To estimate costs, we used the May 2025 wage rate data from the U.S. Bureau of Labor Statistics and doubled the mean hourly wage to account for overhead and fringe benefits. Accounting for overhead and benefits, we used an hourly labor cost of $135.54 for a Medical and Health Services Manager.

Based on these assumptions, we estimate that the annual burden for a participating hospital that submits a financial arrangements list or clinician engagement list will be approximately 4 hours at a cost of approximately $542.16 per hospital (4 hours × $135.54 per hour). As noted, we estimate that approximately 17% or 122 of the 719 TEAM participants will submit one of these lists on a quarterly basis. Therefore, we estimate a total annual burden of approximately 488 hours at a cost of approximately $66,143.52 (488 hours × $135.54 per hour) across all TEAM participants. We note this is likely an upper estimate, as a TEAM participant's financial arrangements list or clinician engagement list may remain unchanged between quarters, reducing preparation and review time. We believe this represents the only meaningful administrative reporting requirement under TEAM because TEAM participants are not required to report new quality measures, modify Medicare billing practices, establish new governance structures, or hire additional personnel solely for participation in the model.

Finally, we acknowledge potential burden with respect to TEAM participants at § 512.582(b)(1)(iii), where a TEAM participant must be able to generate a list of all beneficiaries who have received the beneficiary notification. We expect that TEAM participants are able to easily produce lists of beneficiaries who have received the beneficiary notification. We provide flexible guidelines for this requirement as specific record keeping methods can be chosen by individual TEAM participants so long as the necessary information is maintained readily available to report upon request. We don't anticipate such requests to TEAM participants would occur often, unless warranted by monitoring, program integrity, or other concerns. Given we expect this reporting requirement to be nominal, we are unable to provide a direct cost estimate for this requirement.

Overall, we anticipate marginal additional reporting burden resulting from the model.

12. Effects of the Comprehensive Care for Joint Replacement Expansion (CJR–X) Model

In section X.C. of this final rule, we are expanding the CJR Model, with the expanded model referred to as CJR–X. CJR–X will be a mandatory episode-based payment model under the authority of the Center for Medicare and Medicaid Innovation (Innovation Center). Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. We believe the CJR–X model will further the mission of the Innovation Center to pay for value rather than for volume because it holds CJR–X participants accountable for the cost and quality of care for Medicare beneficiaries during a lower extremity joint replacement (LEJR) episode and promotes alignment across all health care providers and suppliers during the episode of care. In the CJR–X model, the acute care hospital where the anchor hospitalization or anchor procedure occurs will be held accountable for spending during the episode. CJR–X participants will be afforded the opportunity to earn performance-based payments by appropriately reducing expenditures and meeting certain quality metrics. CJR–X participants will also gain access to claims data, pursuant to a request and data sharing agreement, to better understand CJR–X beneficiaries' post-acute care needs and associated spending. Payment approaches that reward providers that assume financial and performance accountability for a particular episode of care create incentives for the implementation and coordination of care redesign between hospitals and other providers and suppliers. Given evidence from the CJR Model, we anticipate CJR–X will continue to reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries.

It is important to note that CJR–X may have effects beyond the effects to the Medicare program or to Medicare beneficiaries. Since CJR–X will be expanded nationally, except to hospitals excluded in section X.C.2.b.(2)(i). of this final rule, we anticipate there may be spillover effects in the non-Medicare market, or even in the Medicare market in other areas as a result of this model. Changes in Medicare payment policy often have substantial implications for non-Medicare payers. As an example, non-Medicare patients may benefit if CJR–X participants introduce system wide changes that improve the coordination and quality of health care. Other payers may also be developing episode payment models and may align their payment structures with CMS. While there is uncertainty on how much spillover effect will occur with respect to CJR–X, we generally anticipate the effect to be positive given a growing body of evidence.[736] [737]

a. Effects on the Medicare Program

CJR–X will be a mandatory episode-based payment model that will have a direct effect on the Medicare program because CJR–X participants will be incentivized to reduce Medicare spending by aiming to have episode expenditures come under the reconciliation target price. CJR–X participants will be subject to two-sided financial risk, therefore CJR–X participants could receive a reconciliation payment amount from CMS or have to pay CMS a repayment amount based on their spending and quality performance. Financial safeguards are included to ensure outlier high-cost episode spending is capped, stop-gain and stop-loss limits would be applied to prevent extreme reconciliation amounts or repayment amounts, and hospitals meeting the low volume threshold are not held accountable for episodes where there is insufficient volume to spread risk or have opportunities for savings.

Table K–CL–01 has been updated to account for the 3-month delay in starting CJR–X, as discussed in section X.C.2.a of this final rule, and shows the projected financial impacts of CJR–X over a 5-year period, with estimated savings to Medicare in each performance year. For the first performance year (January 1, 2028–December 31, 2028), we project CJR–X will generate $129 million in Medicare savings. Estimated savings increase to $133 million in performance year 2 and $137 million in performance year 3. In performance years 4 and 5, projected savings rise to $166 million and $171 million, respectively.

Across the five-year period, we project CMS will pay $1.463 billion to CJR–X participants, while we project CJR–X participants will repay $1.855 billion to CMS. Combined with expected savings from the assumed 1 percent behavior change from CJR–X participants, which affects both episode spending and reconciliation payments, CJR–X will result in estimated net Medicare savings of approximately $736 million. We note these projections represent a portion of the potential savings to Medicare that CJR–X may produce since the model does not have an end date.

[736] Navathe, A. S., Liao, J. M., Linn, K. A., Zhang, Y., Mishra, A., Wang, R., Dinh, C. T., Zhu, J., Cousins, D. S., Lindner, J., & Emanuel, E. J. (2020). Spillover effects of Medicare's voluntary bundled payments for joint replacement surgery to patients insured by commercial health plans. Annals of Internal Medicine, 174(2), 200–208. *https://doi.org/10.7326/m19-3792*

[737] Kim, N., & Jacobson, M. (2025). The spillover effects of Medicare's comprehensive care for joint replacement (CJR) model in California. PLoS ONE, 20(4), e0319582. *https://doi.org/10.1371/journal.pone.0319582*

TABLE K-CL.-01: PROJECTED FINANCIAL IMPACTS OF CJR-X (IN MILLIONS)

	Performance Year 1	Performance Year 2	Performance Year 3	Performance Year 4	Performance Year 5
CJR-X Episode Spending	$7,964	$8,202	$8,419	$12,320	$12,654
(-) Baseline Episode Spending	$8,026	$8,266	$8,486	$12,394	$12,731
(+) Reconciliation Amounts*					
Reconciliation Payment Amounts	$241	$248	$254	$355	$365
Repayment Amounts	-$307	-$317	-$325	-$447	-$459
Total Impact	-$129	-$133	-$137	-$166	-$171
Impact as % of Baseline	-1.6%	-1.6%	-1.6%	-1.3%	-1.3%

* Reconciliation payments and repayments are attributed to the performance year, not the year the payments occur.

(1) Assumptions

Baseline episode spending is projected using 2024 actual spending trended forward for changes in price and Medicare enrollment. We assume price updates will be consistent with projections for payment increases to hospital payments included in the 2025 Trustees Report.[738] We also assume enrollment projections will be consistent with the report. There were no changes to 2024 volume and intensity applied in our projections, as these trends have historically been negative but have begun to level off. These assumptions have no bearing on savings percentage impacts, only the baseline spending levels.

We also note that baseline spending includes a small impact assumption to account for previous CJR participants increasing spending as a result of not participating in a bundled payment model anymore. We assume about half of the savings from the most recent CJR Model evaluation report (3.4 percent) comes back as a cost to Medicare because they didn't sustain their episode spending reductions given the lapse of participation in an episode-based payment model from the end of CJR to the start of CJR–X.[739] We note mandatory CJR model participants comprise about 12 percent of episode spending.

CJR–X excludes TEAM participants and since TEAM ends in 2030, TEAM participants are assumed to enter CJR–X in 2031, performance year 4. We expect TEAM participants will not reduce episode spending when they enter CJR–X in 2031 because their savings are part of CJR–X's baseline. The baseline already assumes that spending was reduced by 1 percent in 2026, consistent with what was estimated for the Medicare savings estimate for TEAM. We also expect TEAM participants to have more spending capped when the stop loss limits are applied. As demonstrated in Table K–CL.–01, overall estimated CJR–X model savings impacts as a percentage of baseline spending are reduced when TEAM participants enter the CJR–X model.

We also assume that CJR–X participants will reduce episode spending by 1 percent in the first year of the model and maintain that reduction going forward. Comparing this assumption to CJR experience, our savings assumption is lower due to the unbiased selection of CJR hospitals (average episode spending for CJR hospitals was much greater than average) and perhaps less potential for similar spending reductions from less costly providers. Further, post-acute care has steadily decreased over time for LEJR procedures, and there may be less opportunity for future decreases in episode spending. This assumption was sensitivity tested in and displayed in Table K–CL.–02.

We also note the assumed quality adjustment distribution is based on simulations provided by internal analysis and the average quality adjusted discount is 1.3 percent. Lastly, the financial impacts assume that the retrospective trend adjustment isn't capped, meaning the difference between prospective trend and retrospective trend are less than 3 percent in magnitude.

(2) Sensitivity Analysis

We also performed a sensitivity analysis to assess various intervention effects on CJR–X. Overall financial impacts are sensitive to the intervention effect CJR–X will have on participating hospitals' episode spending. Table K–CL.–02 includes financial impacts at various intervention effect assumptions (note that negative values indicate savings).

TABLE K-CL.-02: CJR-X SENSITIVITY ANALYSIS AT DIFFERENT INTERVENTION EFFECTS

Intervention effect	CY 2028	CY 2029	CY 2030	CY 2031	CY 2032
-3.0%	-2.9%	-2.9%	-2.9%	-2.6%	-2.6%
-1.0%	-1.6%	-1.6%	-1.6%	-1.3%	-1.3%
0.0%	-1.0%	-1.0%	-1.0%	-0.7%	-0.7%

Reductions in episode spending lead to lower target prices, however costs from stop loss limits increase as targets prices become more aggressive, since more episode spending is capped. For this reason, overall CJR–X savings does not increase at the same rate as episode spending reductions.

The following is a summary of comments we received on the effects to Medicare and our responses to these comments:

Comment: A couple of commenters stated that the CJR–X Model and its improvements have the potential to realize significant savings for the Medicare program LEJR episodes of care.

Response: We agree with the commenter that the CJR–X Model has the potential to achieve savings for the Medicare program for LEJR episodes. We believe the savings expected under CJR–X are commensurate with the savings opportunities that remain available for LEJR procedures, including opportunities to improve care coordination, reduce avoidable complications, and encourage efficient use of post-acute care and other episode services.

At the same time, we recognize that savings opportunities are not unlimited. As CJR–X participants improve performance and move closer to peak efficiency in furnishing and coordinating LEJR episode care, the amount of additional savings that can be achieved may reduce over time. In that circumstance, we may shift the model focus to maintain efficient spending levels while continuing to protect beneficiary access, choice, and quality of care. Any modifications to CJR–X would be proposed in future notice and comment rulemaking and would also be subject to continued certification of the model.

Comment: A few commenters requested that CMS conduct a more detailed impact analysis given concerns on the model's effect on certain types of hospitals. Commenters requested stratifying the impacts at the hospital level and display impacts of the

[738] *https://www.cms.gov/oact/tr/2025*

[739] Comprehensive Care for Joint Replacement Model—Seventh Annual Report: *https://www.cms.gov/priorities/innovation/data-and-reports/2025/cjr-py7-annual-report.*

various classes of hospitals, such as safety net hospitals and hospitals with no prior experience in episode-based accountability. A commenter urged publishing the results of an expanded analysis in the final rule.

Response: We recognize the commenters' concern that model-level financial projections may not fully describe how the model could affect particular categories of hospitals, including safety net hospitals and hospitals with no prior experience in episode-based accountability. The projected financial impacts presented in Table K–CL.–01 are model-level estimates of the expected Medicare program impacts of CJR–X. These model-level estimates help inform whether the model is expected to achieve Medicare savings and ensure CJR–X supports the purpose of the CMS Innovation Center in testing payment and service delivery models that reduce program expenditures while preserving or enhancing the quality of care furnished to individuals, as described in section 1115A(a) of the Act. Those estimates are not intended to project the financial impact for any individual hospital or category of hospital. CJR–X participants will be subject to two-sided financial risk, and the model includes financial safeguards such as high-cost episode caps, stop-gain and stop-loss limits, and a low-volume threshold, as discussed in section X.C.2.f. of this final rule, to mitigate extreme reconciliation payment amounts or repayment amounts and to avoid holding hospitals accountable where there is insufficient episode volume to spread risk or support opportunities for savings.

Similar to the CJR Model and other episode-based payment models, we intend to rely on monitoring and evaluation to help us determine effects of CJR–X on certain categories of hospitals, like safety net and rural hospitals. Findings from monitoring and evaluation will help inform future policy modifications. We also note that CMS took lessons learned from the CJR Model evaluations into account in designing CJR–X. For example, the CJR Model evaluation demonstrated that safety net hospitals had lower financial performance.[740] Therefore, CJR–X includes modifications intended to improve the model methodology and support hospital performance, including improved target price risk adjustment, as discussed in section X.C.2.f.(4) of this final rule, and lower stop-loss limits for safety net hospitals, as discussed in section X.C.2.f.(5)(g) of this final rule. These policies are intended to improve payment accuracy and reduce the potential for disproportionate financial risk, including for hospitals serving higher-risk or more resource-intensive beneficiary populations.

With respect to commenters' concerns about hospitals with no prior experience in episode-based accountability, we acknowledge that CJR–X would include hospitals that did not previously participate in the CJR Model or other Innovation Center episode-based payment models. However, the CJR Model experience also indicates that care redesign practices for lower extremity joint replacement episodes may extend beyond participating hospitals. In CJR Model evaluations, non-participating comparison hospitals also demonstrated reductions in spending.[741] This may suggest that broader changes in LEJR care patterns and episode management may have occurred outside of formal CJR participation. In addition, we anticipate that some hospitals may have experience relevant to CJR–X participation through other CMS models, Medicare Advantage or commercial episode-based arrangements, or existing hospital efforts to manage LEJR care transitions, post-acute care use, quality, and spending. We believe these experiences, together with the model's lead time, data sharing policies, financial safeguards, and target price methodology, will help support hospitals as they prepare for CJR–X participation.

Comment: Some commenters raised concerns about the operational and financial effects of broader mandatory bundled payment models. They stated that hospitals were already balancing quality reporting obligations, interoperability investments, and adoption of new technologies across service lines. A commenter also requested that CMS address structural design features that they believed could create automatic and compounding payment reductions unrelated to care improvement, asserting that CMS's own analysis projected Medicare savings even if hospitals made no changes to care delivery.

Response: We disagree that CJR–X savings would necessarily result from an automatic compounding payment reduction rather than from the model's episode-based accountability structure. Under CJR–X, target prices will be constructed using regional episode spending and will be updated through prospective and capped retrospective trend adjustments intended to better reflect changes in spending patterns between the baseline period and the performance year. Preliminary target prices will also be updated at reconciliation to account for payment-system changes that may not be fully captured by the capped retrospective trend factor. These features are intended to improve pricing accuracy and reduce the risk that target prices become disconnected from actual performance-year spending.

Further, while the target price methodology includes a discount factor, the discount factor is not applied without regard to quality. A CJR–X participant's composite quality score would affect both reconciliation payment eligibility and the effective discount factor used at reconciliation, as discussed in section X.C.2.f.(5)(e) of this final rule. CJR–X Participants with ''Good'' quality performance would be eligible for a reduced 1.0 percent discount factor, and participants with ''Excellent'' quality performance would be eligible for a 0.0 percent discount factor. CJR–X Participants with ''Below acceptable'' quality performance would not be eligible for a reconciliation payment, even if actual episode spending were below the reconciliation target price.

This structure is intended to align financial incentives with quality performance and encourage hospitals to achieve high-quality episode care while managing episode spending efficiently. Because stronger quality performance can reduce or eliminate the effective discount factor, CJR–X does not create the same financial result for all hospitals regardless of care quality. We believe this approach will encourage appropriate reductions or changes in utilization that achieve high-quality care in a more efficient manner.

We recognize that CJR–X participants may be managing multiple operational priorities, including quality reporting, health information technology, interoperability, and adoption of new clinical or operational technologies. We will consider these operational factors as we evaluate model performance and implementation experience. We may consider modifications, as appropriate, through future notice-and-comment rulemaking if model experience indicates that changes are warranted.

b. Effects on Medicare Beneficiaries

CJR–X may benefit beneficiaries receiving lower extremity joint replacements because the model is intended to improve the coordination and transition of care, invest in infrastructure and redesigned care processes for high quality and efficient service delivery, and incentivize higher value care across the inpatient and post-acute care spectrum spanning the episode of care. We believe the model has a patient-centered focus such that healthcare delivery and communication with the patient and or patient caregivers is based on the needs of the beneficiary, thus benefitting the beneficiary community.

We are finalizing several quality of care and patient experience measures to assess hospital quality performance in CJR–X with the intent that it will encourage the provider community to focus on and deliver improved quality care for the Medicare beneficiary. We are finalizing the adoption and public reporting of five quality measures, as discussed in section X.C.2.e of this final rule, for CJR–X. Those measures include two complications measures, two patient experience survey measures, and one patient reported outcome measure. These measures will be used to ensure CJR–X participants are continually measured on the quality of their care and to also monitor for beneficiary safety. Additionally, CJR–X participants must meet the quality performance standards to qualify to receive a reconciliation payment, as discussed in section X.C.2.f.(5).(f). of this final rule. The accountability of CJR–X participants for both quality and cost of care provided for Medicare beneficiaries with an LEJR episode provides the hospitals with incentives to improve the health and well-being of the Medicare beneficiaries they treat.

Additionally, the model does not affect the beneficiary's freedom of choice to obtain health services from any individual or organization qualified to participate in the Medicare program guaranteed under section 1802 of the Act. Eligible beneficiaries who choose to receive services from a CJR–X participant will not have the option to opt

[740] Comprehensive Care for Joint Replacement Model—Safety Net Hospital Experience in Bundled Payment Model Report: *https://www.cms.gov/priorities/innovation/data-and-reports/2025/cjr-safety-net-hospital-exp-rpt.*

[741] Comprehensive Care for Joint Replacement Model—Fifth Annual Report: *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cjr-py5-annual-report.*

out of inclusion in the model. Although the model allows CJR–X participants to enter into financial arrangements with certain other providers and these hospitals may recommend those providers to the beneficiary, hospitals may not prevent or restrict beneficiaries to any list of preferred or recommended providers.

Many controls exist under Medicare to ensure beneficiary access and quality and in addition we will monitor hospitals and, if necessary, audit CJR–X participants if claims analysis indicates an inappropriate change in delivered services. As described in section X.C.2.f.(5)(i). of this final rule, given that CJR–X participants will receive a reconciliation payment when they are able to spend below the reconciliation target price and meet quality thresholds, they could have an incentive to avoid complex, high-cost cases by referring them to nearby facilities or specialty referral centers. We intend to monitor the claims data from CJR–X participants—for example, to compare a hospital's case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded.

We will implement several safeguards to ensure that Medicare beneficiaries do not experience a delay in services. We believe that the longer the episode duration, the lower the risk of delaying care beyond the episode duration, and we believe that a 90-day episode is sufficiently long to minimize the risk that any lower extremity joint replacement related care will be delayed beyond the end of the episode. Moreover, as part of the pricing methodology, as described in section X.C.2.f.(5).(h). of this final rule that certain outlier costs post-episode payments occurring in the 30-day window subsequent to the end of the 90-day episode will be counted as an adjustment against the reconciliation payment or repayment amount. Importantly, approaches to saving costs will include taking steps that facilitate patient recovery, that shorten recovery duration, and that minimize post-operative problems that might lead to readmissions. Thus, the model itself rewards better patient care.

We invited public comments on the impact of CJR–X on Medicare beneficiaries.

Comment: A commenter stated that beneficiaries undergoing lower-extremity joint replacement procedures vary substantially in medical complexity, functional status, caregiver support, and rehabilitation needs. The commenter expressed concern that CJR–X financial incentives could create pressure to reduce post-acute care utilization without sufficient regard to individual patient needs. The commenter encouraged CMS to continue prioritizing patient protections, quality measurement, and monitoring for unintended consequences, including inappropriate discharge patterns, reduced access for medically complex beneficiaries, avoidance of high-risk patients, delays in medically necessary post-acute care, and disparities in outcomes among vulnerable populations. The commenter also raised concern about the ability to sustain ambulatory surgical centers (ASCs) in underserved urban communities that could support outpatient surgeries.

Response: We agree that lower-extremity joint replacement beneficiaries may have differing clinical, functional, social support, and rehabilitation needs, and we believe that care redesign under CJR–X must be consistent with those individualized needs. As discussed in section X.C.2.c of this final rule, CJR–X would not limit Medicare coverage of medically necessary items and services or restrict a beneficiary's freedom to choose providers or suppliers, including post-acute care providers. The beneficiary protections are intended to help preserve freedom of choice, and provide mechanisms to raise concerns through clinicians, 1–800–MEDICARE, and Quality Improvement Organizations.

We also recognize the commenter's concern that episode-based payment incentives could lead to inappropriate reductions in post-acute care. CJR–X includes multiple quality and monitoring mechanisms intended to balance cost accountability with patient safety, care experience, and outcomes. CJR–X includes quality measures addressing complications, patient experience, and patient reported outcomes, as discussed in section X.C.2.e of this final rule, and CJR–X participants are incentivized to improve quality of care provided to CJR–X beneficiaries because improved quality performance results in a lower discount factor, as discussed in section X.C.2.f.(5)(e) of this final rule. We believe that the quality measure set will provide sufficient information to monitor quality performance and support model evaluation.

In addition to the standard monitoring activities, as discussed in section X.C.2.m of this final rule, we will also monitor activities related to post-acute care use, discharge patterns, and use of model waivers, including the SNF 3-day rule waiver and post-discharge home visit waiver, as discussed in section X.C.2.j of this final rule, to help identify potential inappropriate reductions in care, premature discharges, steering, or other unintended consequences.

We have also included in the payment methodology safeguards intended to reduce incentives that could adversely affect beneficiaries with greater medical complexity. Specifically, target prices are risk-adjusted, as discussed in section X.C.2.f.(4) of this final rule, which includes more precise adjustments for beneficiary clinical and socioeconomic factors to improve the accuracy of target prices. By better accounting for differences in patient complexity and expected episode spending, this methodology helps reduce incentives for CJR–X participants to avoid medically complex or higher-risk beneficiaries.

Further, CJR–X includes a policy that monitors increased episode spending after the episode has ended, as discussed in section X.C.2.f.(5)(h) of this final rule. This policy will hold CJR–X participants accountable for excess spending and is intended to identify and address inappropriate shifting of care, including withholding or delaying medically necessary services until after the episode period ends.

Regarding ASCs, we recognize the value they provide to communities by creating greater access to medically necessary outpatient procedures. While ambulatory surgical centers are not CJR–X participants, nor can an episode be initiated in an ASC setting, we will continue to consider how ASCs can be incorporated into value-based care.

After consideration of the public comments we received, we are finalizing this provision without modification.

c. Effects on CJR–X Participants

We believe CJR–X will not have significant impact on CJR–X participant burden. CJR–X will not alter the way participating hospitals bill Medicare. Therefore, we believe there will be no additional burden for CJR–X participants related to billing practices.

We also believe that CJR–X does not impose additional burden related to quality reporting because the quality measures used in the model are measures that CJR–X participants already report to CMS under existing CMS quality reporting programs. Accordingly, CJR–X participants will not be required to establish new quality reporting systems or submit additional quality measure data solely for purposes of CJR–X.

In addition, CJR–X does not require CJR–X participants to hire additional staff, such as care coordinators, establish a governing board, or otherwise implement new organizational structures as a condition of participation. Therefore, we do not believe CJR–X imposes additional regulatory burden on CJR–X participants for such activities.

We recognize there may be administrative burden associated with CJR–X for the requirement that CJR–X participants submit a financial arrangements list or clinician engagement list, as applicable. CJR–X participants that do not have any financial arrangements or clinician engagement relationships that meet the definitions established for the model, as defined at § 512.605, must attest that there are no such relationships, as defined at § 512.615(d), which we believe would be associated with nominal administrative burden.

For purposes of estimating burden for CJR–X participant that submit a list, we assume that approximately 17 percent of CJR–X participants may submit a financial arrangements list or clinician engagement list on a quarterly basis, as applicable. We estimate that preparing, reviewing, and submitting the applicable list will require approximately 1 hour per quarterly submission, or 4 hours annually, for each CJR–X participants that submits one of these lists. We assume this work will be completed by a Medical and Health Services Manager. To estimate costs, we used the May 2025 wage rate data from the U.S. Bureau of Labor Statistics and doubled the mean hourly wage to account for overhead and fringe benefits. Accounting for overhead and benefits, we used an hourly labor cost of $135.54 for a Medical and Health Services Manager.

Based on these assumptions, we estimate that the annual burden for a CJR–X participants that submits a financial arrangements list or clinician engagement list will be approximately 4 hours at a cost of approximately $542.16 per hospital (4 hours × $135.54 per hour). As noted, we estimate that approximately 17% or 425 of the approximate 2,500 CJR–X participants will

submit one of these lists on a quarterly basis. Therefore, we estimate a total annual burden of approximately 1,700 hours at a cost of approximately $230,418.00 (1,700 hours × $135.54 per hour) across all CJR–X participants. We note this is likely an upper estimate, as a CJR–X participant's financial arrangements list or clinician engagement list may remain unchanged between quarters, reducing preparation and review time. We believe this represents the only meaningful administrative reporting requirement under CJR–X because CJR–X participants are not required to report new quality measures, modify Medicare billing practices, establish new governance structures, or hire additional personnel solely for participation in the model.

Finally, we acknowledge potential burden with respect to CJR–X participants at § 512.622(a)(3), where a CJR–X participant must be able to generate a list of all beneficiaries who have received the beneficiary notification. We expect that CJR-x participants are able to easily produce lists of beneficiaries who have received the beneficiary notification. We provide flexible guidelines for this requirement as specific record keeping methods can be chosen by individual CJR–X participants so long as the necessary information is maintained readily available to report upon request. We don't anticipate such requests to CJR–X participants would occur often, unless warranted by monitoring, program integrity, or other concerns. Given we expect this reporting requirement to be nominal, we are unable to provide a direct cost estimate for this requirement.

Overall, we anticipate marginal additional reporting burden resulting from the model.

13. Effects of the Finalized Policies Regarding Acquisition Costs, Reasonable Costs, and Other Cost-Related Policies

a. Effects of the Finalized Policy To Reconcile Non-Renal Organ Acquisition Costs for Independent Organ Procurement Organizations and Histocompatibility Laboratories

In section X.D.1. of the preamble of this final rule, we are finalizing, with modifications, our proposal to reconcile non-renal organ acquisition costs for independent organ procurement organizations (IOPOs) and histocompatibility laboratories (HCLs), and to require the Medicare contractor to establish, adjust if necessary, and publish non-renal standard acquisition charges (SACs) and non-renal testing rates. We proposed a 1-year delay in implementation, to allow IOPOs and HCLs time to prepare for increased reporting that would be necessary. Our final policies will be effective after a 2-year delay, for cost reporting periods beginning on or after October 1, 2028. Our final policies require reconciliation of non-renal organ acquisition costs for IOPOs and HCLs as proposed but require IOPO and HCL involvement in estimating and in adjusting IOPO SACs and HCL testing rates, as detailed in section X.D.1. of this final rule. We are also finalizing as proposed our listing of allowable costs that can be included in the IOPO SACs, and the requirement for the Medicare contractor to publish IOPO SACs and HCL testing rates.

Impacts. In the proposed rule, we estimated that reconciling non-renal organ acquisition costs would result in an annual cost savings to the Medicare trust fund of $0 in FY 2027 due to the proposed 1-year delay in implementation, $100 million in FY 2028, $500 million over 5 years from FYs 2027 to 2031, and $1.28 billion over 10 years from FY 2027 to FY 2036. In response to public comments, we are finalizing, with modification, a 2-year implementation delay, rather than the proposed 1-year delay, effective for cost reporting periods beginning on or after October 1, 2028. As a result, our updated total estimated cost savings to the Medicare Trust Fund will be $0 in FY 2027 and FY 2028, $110 million in FY 2029, $380 million over 5 years (FYs 2027 to 2031), and $1.16 billion over 10 years (FYs 2027 to 2036). The CMS Office of the Actuary (OACT) estimated these savings on a cash basis using 2024 Medicare cost report data for IOPOs, comparing total revenue to total organ acquisition costs, by organ type. We do not have the required data to estimate the impact on HCLs. In accordance with 42 CFR 413.20(a), CMS follows standardized definitions, accounting, statistics, and reporting practices that are widely accepted in the healthcare industry. Changes in these practices and systems are not required to determine costs payable under the principles of reimbursement.

Comment: Multiple commenters questioned CMS's conclusion that a systemic overpayment exists due to the absence of a reconciliation process for non-renal organs, pointing to the Agency's finding that IOPO non-renal organ revenue would exceed costs by $100 million in FY 2028. Commenters contended that a single year's aggregate surplus is insufficient evidence of systemic overpayment and urged CMS to conduct additional analysis before drawing such a conclusion. Specifically, commenters contended that CMS failed to account for timing differences between cost occurrence and reimbursement, year-to-year variability in donor volume and case complexity, costs associated with organs recovered but not transplanted, and wide variation in financial performance across individual OPOs. Commenters also noted that some IOPOs reported non-renal costs exceeding revenue, meaning Medicare would be required to make those organizations whole, and requested that CMS model the impacts to reflect both payments due from over-reimbursed IOPOs and Medicare's payments made to under-reimbursed IOPOs. Commenters further observed that aggregate national averages may obscure significant variation among OPOs, since factors that differ substantially across donation service areas can materially affect operational costs and financial performance.

Commenters also raised concerns regarding the transparency and completeness of CMS's underlying analysis. One commenter noted that CMS stated additional Medicare contractor costs would offset against the $100 million in estimated savings, without explaining the extent of that offset. Another observed that the $100 million estimated impact was based on OIG audit findings and cost report data, and a few noted that IOPO cost reports are already subject to annual review and audit by the MACs. One commenter requested that CMS publish the complete underlying data and methodology used by the Office of the Actuary to derive the $100 million, $500 million, and $1.28 billion savings estimates, including the distribution of revenue-to-cost ratios across individual IOPOs, the organ types driving the aggregate gap, and any assumptions regarding future volume growth, cost inflation, and behavioral responses to reconciliation of non-renal organ acquisition costs.

Commenters also argued that CMS omitted any monetized health costs, which they stated is a requirement under OMB Circular A–4, and that CMS must quantify the transplant volume implications of the proposals. A commenter encouraged CMS to assess the proposal's impact on pediatric transplant programs and to ensure that reasonable and necessary activities supporting successful transplantation continue to be appropriately recognized within the payment framework.

Commenters further requested additional methodological clarification, including the methods used to allocate expenses between renal and non-renal acquisition activities, the role of timing differences in producing cost reports, distributional analysis across individual OPOs rather than aggregate averages, and the results of sensitivity testing reflecting operational variability. A few commenters requested CMS quantify the change in transplant volumes as a result of our proposed policies and a few encouraged CMS to recognize the impact of process improvement and clinical innovation costs on improving OPO performance and contributing to cost efficiency.

Finally, several commenters encouraged CMS to engage with IOPOs and other stakeholders to better understand the practical and operational implications of the proposals before finalizing major structural reforms.

Response: We included a discussion of our impact analysis of our proposals in the FY 2027 IPPS/LTCH proposed rule (see 91 FR 19838, 19868 and 19869, 19882). Our impact analysis estimated $100 million in savings in FY 2028. This estimate was not based on OIG reports, but on Medicare cost report data for cost reporting years ending in 2024, the most recent complete data available. The analysis followed the same process we use to reconcile kidney acquisition costs and was completed for liver, pancreas, heart, and lung for each IOPO and then summed for a total impact among all IOPOs. Our proposed impact assumed all usable non-renal organs were Medicare usable organs because we currently do not collect data on non-renal organs furnished to military or VA hospitals or to foreign countries; and all non-renal organ acquisition costs were Medicare acquisition costs.

The data we used were from each IOPO's certified Medicare Cost Report (Form CMS–216–94) for the cost reporting period ending in 2024. Worksheet S–1, Part 1, lines 8.01 (liver), 8.02 (pancreas), 8.04 (heart), and 8.09 (lung) showed counts for total non-renal organs and non-viable non-renal organs and their associated revenue. We subtracted the

non-viable non-renal organs from the total non-renal organs to determine the total usable non-renal organs. Worksheet B, column 11, lines 5 (liver), 6 (heart), 7 (pancreas), and 8 (lung) showed total non-renal organ acquisition costs after allocation of general and administrative costs and other overhead costs. In reviewing the data, we discovered that two providers in their 2024 data separately reported double lung organ counts and revenue on Worksheet S–1 on lines other than line 8.09 for lungs, and double lung organ acquisition costs on worksheet B, line 9 rather than on line 8. We included these data to ensure our lung counts, revenue, and costs were complete. We excluded data on islet cells from the analysis because the revenue per pancreas appeared very low and there appeared to be only three viable pancreata. We also excluded data on intestinal transplants because there is not currently a specific line on Worksheet S–1 for intestinal procurements, and IOPOs reported those statistics and revenue on different lines of that worksheet. We excluded combination procurements (for example, heart/lung), which were relatively infrequent. Finally, we excluded five IOPOs in the 2024 data that failed to include non-renal organ revenue on Worksheet S–1. Therefore, our impact analysis was based on non-renal organ data for hearts, livers, lungs, and pancreata for 44 of 49 IOPOs in 2024. We subtracted the total non-renal organ acquisition costs from the total revenue for each organ type, for each IOPO, and in the aggregate. We summed that result for each of the four types of non-renal organs we included and were able to determine whether an IOPO had total non-renal organ revenue greater than its total non-renal organ acquisition costs, or whether an IOPO had total non-renal organ revenue less than its total non-renal organ acquisition costs. Each IOPO is able to run this analysis using its own MCR data, as well as data from all other IOPOs from the publicly available HCRIS cost report data available at *https://www.cms.gov/data-research/statistics-trends-reports/cost-reports/organ-procurement-organization.*

As we noted in the FY 2027 IPPS/LTCH proposed rule, 20 percent of the 49 IOPOs that filed costs reports in 2024 had costs that were greater than their non-renal revenue and would have been made whole if reconciliation of non-renal organ acquisition costs had been in place. After excluding the five IOPOs that did not report non-renal revenue in the 2024 data and using the 44 IOPOs in the impact analysis, that percentage rose to almost 23 percent. In response to commenters asking that we separate the impacts for the IOPOs that were underpaid from those that were overpaid, the 2024 data showed that 10 IOPOs had costs exceeding their revenue and were short by $19,132,720, in the aggregate, while 34 IOPOs had revenue exceeding their costs and were over by $118,819,590, in the aggregate; the difference is $99,686,870. The CMS OACT did not model the data to separate out utilization and price assumptions from the spending trend, nor did it account for any behavioral responses to reconciliation.

Some commenters expressed concern that we chose a single year, 2024, for our analysis. Table Appendix A I.G.14–01 shows the same calculations described above, performed for each IOPO and then summed, without any OACT adjustments, but calculated for cost reporting years ending in 2022, 2023, and 2024, to demonstrate that our findings were not a single-year anomaly but an ongoing pattern. We made the same manual adjustment in 2022 and 2023 that we did in 2024 to include double lung organ counts, costs, and revenue, but in 2022 a third IOPO also separately reported double lung organ acquisition cost data. The excess of revenue over costs incurred is driven in all three years by livers, hearts, and lungs; for all three years, pancreata consistently showed costs exceeding revenue. Consistent with the reasonable cost principle underlying Medicare reimbursement, under which payment is intended to approximate the actual, reasonable costs incurred in furnishing covered services, no more and no less, we have separated the providers that had costs incurred exceeding revenue from those with revenue exceeding incurred costs, as a few commenters requested. Because IOPOs are required to account for their costs and revenue on an accrual basis in accordance with § 413.24(a), we do not believe timing differences between incurring costs and receiving reimbursement account for these overages. Rather, the persistence of this revenue-over-cost pattern across three consecutive years for the same organ types indicates a structural misalignment between payment and actual costs incurred, rather than a transient or timing-related artifact.

TABLE APPENDIX A I.G.14-01.: SUMMARY OF NON-RENAL RECONCILIATION IMPACTS FOR COST REPORTING YEARS ENDING IN 2022, 2023, AND 2024

	2022	2023	2024
Total Usable Non-renal Organs	**19,151**	**18,341**	**18,077**
Avg Rev / Organ	$50,502	$55,314	$56,204
Avg Cost / Organ	$46,042	$50,112	$50,689
Total Non-renal Revenue	$967,170,836	$1,014,514,230	$1,015,999,036
Total Non-renal OACs*	$881,753,312	$919,103,062	$916,312,166
Net Overage	**$85,417,524**	**$95,411,168**	**$99,686,870**
Total IOPO Cost > Revenue	-$14,192,603	-$17,316,202	-$19,132,720
Total IOPO Revenue > Cost	$99,610,127	$112,727,370	$118,819,590
Highest Provider Amt Over Cost	$9,816,794	$11,946,639	$12,762,595
Highest Provider Amt Under Cost	-$4,552,270	-$4,729,631	-$7,808,357
Number IOPOs Over Cost	37	36	34
Numbers IOPOs Under Cost	11	8	10
Total IOPOs	50	49	49
Total Excluded**	2	5	5
IOPOs in Analysis	48	44	44
% of IOPOs Under Cost	22.9%	18.2%	22.7%
% of IOPOs Over Cost	77.1%	81.8%	77.3%

*OACs = organ acquisition costs

**We excluded 2 providers in 2022, 5 providers in 2023, and 5 providers in 2024 because they reported no revenue for their non-renal organs. Non-renal organs included are heart, liver, lung, and pancreas.

Table Appendix A I.G.14–01 includes the usable non-renal organs, which appear to decline from 2022 to 2024. Because we excluded IOPOs that were missing revenue data from the analyses, their non-renal organ counts were not included in these totals. Having three fewer providers in the 2023 and 2024 data compared to the 2022 data is why the organ counts appear to have declined sharply since 2022. If the organ counts of the excluded IOPOs were included in the totals from Table Appendix A I.G.14–01, the table would have shown a 0.8 percent increase in total non-renal organs from 2022 to 2023, and a 0.9 percent decrease in total non-renal organs from 2023 to 2024. The organ counts shown in Table Appendix A I.G.14–01 are associated with the costs and revenue shown in the table.

This ongoing pattern of revenue exceeding costs for non-renal organs has occurred despite annual review and audits by the Medicare contractor, which have not addressed the issues driving that overage. We recognize that some of the excess revenue may be due to procuring more organs than expected, thus lowering fixed costs per organ; however, that cannot fully explain the excess.

Table Appendix A I.G.14–02 shows the distribution of the 37 (2022), 36 (2023), and 34 (2024) IOPOs that had excess revenue over organ acquisition costs for non-renal organs. We are unable to present individual IOPO data, so we instead grouped IOPOs with excess revenue by dollar ranges and by percentages over incurred cost. Some IOPOs' excess revenue was over $10 million, with the highest annual amount from an IOPO that generated almost $13 million in excess revenue over incurred costs in 2024. This excess in non-renal revenue resulted from non-renal SACs that were too high and not commensurate with incurred costs. At the same time, the 10 IOPOs whose 2024 costs exceeded revenue, who are not represented in Table Appendix A I.G.14–02, had losses on non-renal organs that ranged from $225,000 to slightly over $7.8 million.

As a few commenters requested, we calculated revenue-over-cost percentages using the formula ((Total Non-renal Revenue—Total Non-renal Organ Acquisition Costs)/(Total Non-renal Organ Acquisition Costs)) for each of the 3 years to determine the percentage over incurred cost and show them in Table Appendix A I.G.14–02. The revenue-over-cost percentages calculated using the 2024 data ranged from a low of 0.7 percent to a high of 145.4 percent.

While we recognize that SAC estimation may be challenging, we do not believe that timing differences from when SACs are established and when costs are incurred account for these cost overages. Additionally, as average charges, SACs account for cost differences between complex cases and less costly procurements within a given year. Year-to-year variability in case complexity and volume would be reflected in the costs and revenues used in the impact analyses. IOPOs have the ability to adjust their SACs during the year to reflect lower or higher costs reasonably expected to be incurred but it does not appear that most IOPOs have chosen to do so. We believe that THs would likely have welcomed SAC adjustments from IOPOs to more accurately reflect costs incurred, or reasonably expected to be incurred, to account for IOPOs' cost variances during the year, as downward SAC adjustments would have also lowered THs' costs. The IOPOs that had excess revenue also caused inflated costs throughout the transplant ecosystem.

TABLE APPENDIX A I.G.14-02.: DISTRIBUTION OF IOPOS WITH NON-RENAL ORGAN REVENUE GREATER THAN NON-RENAL ORGAN COSTS USING 2022 THROUGH 2024 MEDICARE COST REPORT DATA FOR HEART, LIVER, LUNG, AND PANCREAS, IN DOLLARS AND IN PERCENTAGE EXCESS OVER COSTS

Number of IOPOs with Revenue Greater Than Costs			
Range of Excess	**2022**	**2023**	**2024**
$0-$1 million	9	10	8
>$1 to 5 million	23	17	18
>$5 to 10 million	5	8	6
>10 million	0	1	2
Distribution of IOPOs by Cost > Revenue Percentage (Revenue - Organ Acquisition Costs) / Organ Acquisition Costs			
< 5%	5	2	8
5% to < 10%	5	9	2
10% to <15%	7	7	5
15% to <20%	2	4	3
20% to <25%	5	6	4
25% to <30%	5	1	3
30% to <35%	2	2	1
>35%	6	5	8

Based on cost report revenue and organ acquisition costs for heart, liver, lung, and pancreas for IOPOs with revenue > cost.

Commenters requested that we conduct a sensitivity analysis across a range of IOPO operational scenarios to assess the financial impact of our final policies. We considered such an analysis, adjusting for scenarios such as unanticipated increases in perfusion or transportation costs, or increases in the number of marginal or complex organs that were recovered but not transplanted, and for which no revenue was received. However, because IOPOs are reimbursed on a reasonable cost basis, year-end reconciliation would make IOPOs whole for losses and would return excess amounts to Medicare if revenue exceeded costs. The issue, therefore, is less about the financial outcome and more about the *timing* of SAC adjustments and of being made whole for losses or returning excess revenue to Medicare, which can affect the size of the loss. IOPOs and HCLs can use the protections included in this final rule to substantially mitigate the effects of higher-than-estimated costs or lower-than-estimated revenue earlier in their fiscal year potentially avoiding losses, or large liabilities owed back to Medicare at reconciliation. These protections include:

- Requiring IOPO and HCL involvement in setting and adjusting their SACs or testing rates, respectively;
- Permitting four rate adjustments during the year;
- Providing the opportunity to receive or make lump sum adjustments when a rate is revised following a review; and
- Requiring year-end non-renal organ acquisition cost reconciliation.

We considered the data from the 10 IOPOs with losses in 2024, which are not included in Table Appendix A I.G.14–02. The 2024 data from these 10 IOPOs showed that two IOPOs had losses less than $500,000, six had losses between $500,000 and $1.5 million, one had a loss of $3.1 million, and one had a loss of $7.8 million. If each of these IOPOs had addressed these losses by the end of their first quarter, these IOPOs may have been able to adjust their SACs upward, potentially mitigating losses for the rest of the year, and would have had opportunity to receive a lump sum adjustment to address the shortfall. Each IOPO's monitoring, and if indicated, adjusting of its non-renal SACs will be necessary to avoid large over- or under-payments at cost report settlement. As with any business, each IOPO must maintain operating reserves to manage operational changes that increase cost or decrease revenue; we believe the ability to receive SAC adjustments and the opportunity to receive lump sum adjustments during the year will reduce the need for large reserves. We also believe the 2-year implementation delay provided under this final rule will provide time for IOPOs to build adequate reserves, to the extent that they have not already done so.

As we noted previously, procurement costs are allowable for organs intended for transplant but that are subsequently not transplanted (see § 413.412 (a)(2) and (d)(2)); we assume IOPOs have reported those costs and that they were included in the cost data used in this analysis. Because those organs were not transplanted, there would be no revenue associated with them, and yet most IOPOs still had revenues that greatly exceeded costs. We appreciate IOPOs' investing in improving performance and cost efficiency; reasonable costs associated with process improvements or innovation that are administrative and general operating costs are allowable, in accordance with § 413.402(a). Regarding offsetting additional costs to our Medicare contractor against the estimated impacts, our use of the term ''offset'' may have led some to believe that there is a formal offset calculation when there is not. To clarify, we acknowledge there will be an increase in the Medicare contractor's workload and associated increased costs, but those costs are very small relative to the estimated savings.

The impact analysis in the FY 2027 IPPS/LTCH proposed rule included a full discussion of our proposals in the Regulatory Impact Analysis section, found in Appendix A of the final rule, and included a table showing the monetized health costs required under Circular A–4 (see 91 FR 19882). Regarding commenters who requested that CMS quantify the transplant volume implications of the proposals, we have given multiple reasons in section X.D.1. of this final rule why we do not believe that the policy changes we are finalizing will negatively impact organ procurement. We have addressed provider misunderstanding of existing payment policy by emphasizing that Medicare covers the costs of procuring organs or attempting to procure organs intended for transplant that are subsequently not used for transplant, thus protecting them from losses; we believe this policy removes a financial disincentive to procuring marginal organs or organs from complex donors. We have also addressed some IOPO's misunderstanding of existing payment policy related to high-cost services and explained that Medicare covers the reasonable costs of organ perfusion and preservation technologies, and transportation.

As discussed in section X.D.1., based on comments received, we addressed provider concerns about operational flexibility by finalizing our proposal with modifications to allow IOPOs to be an integral part of the process of establishing and adjusting all organ SACs. We also reminded IOPOs that the Medicare contractor will review SACs at least once during the year, and that existing policy gives IOPOs the ability to request SAC

reviews to address cost change concerns if their SACs need adjusting during the fiscal year. Furthermore, we noted that if a SAC is adjusted during the year, the provider may request a lump sum payment to address cash flow concerns due to costs exceeding revenue. We acknowledged IOPO concerns about cash flow or financial reserves related to the timeliness of the Medicare contractor in adjusting SACs, in providing lump sum adjustments, and in reconciling costs, and said we would address this during the implementation process with the contractor. We also believe that our discussion and finalization of certain reasonable cost policy proposals in sections X.D.2. and X.D.3. of this final rule will provide more understanding to IOPOs, to ensure that they can carry out mission-related activities with greater confidence regarding what costs are allowable under Medicare. We also pointed out that multiple OPO commenters on the July 2022 RFI wrote that reconciling non-renal organs would not affect their procurements, as procurements are incentivized by their organ metrics and their desire to procure every organ every time. Additionally, we have discussed how reconciling non-renal organs will protect those IOPOs whose costs have exceeded revenue by making them whole. We also reiterated that IOPOs are charged with procuring both organs and tissue, and that they are currently allowed a margin on tissue, as tissue procurement is not required to be paid on a reasonable cost basis. For all of these reasons, we believe that organ procurement will not be hindered. We do not believe that our proposals will affect pediatric or adult transplant programs except to lower the procurement cost of non-renal organs that IOPOs are providing to them.

In providing additional details with respect to the methodology and data used in calculating the impacts in this final rule, we noted that we used cost and revenue data that IOPOs reported on their cost report for cost reporting periods ending in 2024, and therefore, we did not allocate costs but relied on what IOPOs reported. In this final rule, we are finalizing a modified implementation date of cost reporting periods beginning on or after October 1, 2028, rather than our proposed implementation date of cost reporting periods beginning on or after October 1, 2027, and we have revised our impact estimates to reflect this 2-year delay. Our revised estimates now project savings of $110 million in FY 2029, a 5-year savings of $380 million, and a 10-year savings of $1.16 billion. Changes to the IOPO/HCL Medicare Cost Report forms and instructions (currently Form CMS–216–94) will be detailed in a forthcoming Paperwork Reduction Act package, to be published in the **Federal Register**.

Burden Estimate. The methods of determining costs payable under Medicare involve making use of data available from the institution's basis accounts, as usually maintained, to arrive at equitable and proper payment for services. Burden hours for each IOPO/HCL are the estimated time required (number of hours) to complete ongoing data gathering and recordkeeping tasks, search existing data resources, review instructions, and complete the IOPO/HCL Medicare cost report, which is OMB number 0938–0102, Form CMS–216–94. Therefore, this burden estimate is solely focused on the additional time that will be required to complete the updated IOPO/HCL cost report. Currently there are 94 Medicare certified IOPOs/HCLs that file Form CMS–216–94 annually. The current estimated average burden per IOPO/HCL is 45 hours (30 hours for recordkeeping and 15 hours for reporting). We updated our burden estimate for this final rule to use the most recent 2025 Bureau of Labor Statistics median hourly wage data. In this final rule, we do not estimate additional recordkeeping burden as IOPOs and HCLs already maintain the data needed but estimate an average additional reporting burden of 10 hours per IOPO/HCL and an estimated additional cost of $804.60 per IOPO/HCL. The most recent median hourly wage data is available from the Bureau of Labor Statistics using their 2025 national table (available at *https://www.bls.gov/oes/tables.htm*). The median hourly wage for Category 13–2011 (accounting and audit professionals) is $40.23. We added 100% of the median hourly wage to account for fringe benefits and overhead costs, which calculates to $80.46 ($40.23 + $40.23) and multiplied it by 10 hours, to determine the additional annual reporting costs per IOPO/HCL to be $804.60 ($80.46 × 10 hours). We recognize this average reporting burden varies depending on the IOPO/HCL's size and complexity. Because there are 94 IOPOs and HCLs, the total reporting burden cost would be $75,632 (94 × $804.60). In section XII.B.10. of this final rule (the Collection of Information section), we invited public comment on the hours estimate as well as the staffing requirements utilized to compile and complete the Medicare cost report. Because we are finalizing this policy with a 2-year delay rather than the 1-year delay which we proposed, these estimated reporting burden costs would not occur until the cost reporting year beginning on or after October 1, 2028. Comments received on the burden estimate to complete the IOPO/HCL cost report are discussed in the Collection of Information section of this final rule, found at section XII.B.10.

b. Effects of the Finalized Reasonable Cost Policies

In section X.D.2. of the preamble of this final rule, we are finalizing our proposals, with certain modifications, pertaining to longstanding Medicare reasonable cost reimbursement policies applicable to all providers. Some commenters requested CMS consider the broad initiatives impacting the transplant ecosystem in parallel with this rule, and some IOPOs indicated they would have increased administrative burden to update their public education programs to comply with our finalized policies, as discussed in section X.D.2. of this final rule. To address these concerns, we are also finalizing our provision pertaining to OPO public education to be effective with the effective date of this final rule; however, we are allowing a 1-year delay in enforcement.

We believe these final policies will not result in additional costs to the Medicare program. The reasonable cost policies finalized in section X.D.2. of this final rule impose no new information collection requirements for all providers, including OPOs; accordingly, no burden estimate has been provided. We believe our final policies will alleviate administrative burden on most providers by providing more clarity as to certain reasonable cost policies. We believe these finalized policies may result in cost savings to the Medicare program due to increased payment accuracy, but we do not have sufficient data to estimate an amount.

c. Effects of the Finalized Cost Allocation Policy

In section X.D.3. of the preamble of this final rule, we are finalizing without modification the proposal to codify cost allocation principles. This finalized policy is applicable to all providers. We believe there will be no additional costs to the Medicare program resulting from these policies. However, we believe these finalized policies may result in a cost savings to the Medicare program due to increased payment accuracy, although we do not have sufficient data to estimate an amount. We believe these finalized policies will not increase burden to providers because these finalized policies are clarifications and codifications of cost allocation policies that providers are already required to follow to properly allocate overhead costs. Comments on these proposals are discussed in section X.D.3. of this final rule.

d. Effects of the Finalized Policy for Discretionary Administrator Review of CMS Reviewing Official Determinations With Respect to Appeals Under § 413.420(g) for Independent Organ Procurement Organizations and Histocompatibility Laboratories

In section X.D.4. of the preamble of this final rule, we are finalizing without modification the proposal to codify the discretionary Administrator review of CMS reviewing official determinations with respect to appeals under § 413.420(g) for IOPOs and HCLs. We believe there will be no additional costs to the Medicare program and no increased burden placed upon providers as a result of our final policy. Comments on these proposals are discussed in section X.D.4. of this final rule.

e. Effects of the Finalized Technical Corrections and Clarifications of §§ 412.116(c) and 413.404(b)(3)(ii)(A) and (C).

In section X.D.5. of the preamble of this final rule, we are finalizing technical corrections or clarifications to regulation text at §§ 412.116(c) and 413.404(b)(3)(ii)(A) and (C). These clarifications and corrections will not create any additional costs to the Medicare program or increased burden upon providers. We received no comments on the proposals in section X.D.5. and are finalizing these corrections and clarifications as proposed.

14. Effects of ONC's Adoption of Health IT Standards and Incorporation by Reference (45 CFR 170.215 and 45 CFR 170.299)

ONC proposed to adopt new updated standard versions of a series of IGs in the 2026 CMS Interoperability Standards and

Prior Authorization for Drugs Proposed Rule (91 FR 20028 through 20029). These IGs were originally adopted by the Secretary in the HTI–4 final rule (90 FR 37130), which appeared in the **Federal Register** on August 4, 2025 as part of the FY 2026 IPPS/LTCH final rule (90 FR 36536). Since the FY 2026 IPPS/LTCH final rule appeared in the **Federal Register**, newer versions of the standards adopted by the Secretary in the HTI–4 final rule have been released. In addition, ONC proposed to adopt an additional standard, the HL7 FHIR® Da Vinci Clinical Data Exchange (CDex) IG [Implementation Guide] in 45 CFR 170.215(k)(3). Therefore, ONC proposed to adopt the following standards on behalf of the Secretary (91 FR 20001 through 20005):

- HL7 FHIR® Da Vinci—Coverage Requirements Discovery IG [Implementation Guide], Version 2.2.1—STU 2.2 (proposed in 45 CFR–170.215(j)) [742]
- HL7 FHIR® Da Vinci—Documentation Templates and Rules Implementation Guide, Version 2.2.0—STU 2.2 (proposed in 45 CFR–170.215(j)) [743]
- HL7 FHIR® Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.2.1—STU 2.2 (proposed in 45 CFR–170.215(j)) [744]
- HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) [Implementation Guide], Version 2.2.0—STU 2.2 (proposed in 45 CFR–170.215(k)) [745]
- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.1.0—STU 2.1 (proposed in 45 CFR–170.215(m)) [746]
- HL7 FHIR® Da Vinci PDex [Payer Data Exchange] Plan Net Implementation Guide, Version 1.2.0—STU 1.2 (proposed in 45 CFR–170.215(n)) [747]
- HL7 FHIR® Da Vinci Clinical Data Exchange (CDex) IG [Implementation Guide], Version 2.1.0—STU 2.1 (proposed in 45 CFR–170.215(k)) [748]

As part of the HTI–4 final rule, ONC finalized certification criteria for electronic prior authorization in the ONC Health IT Certification Program that incorporated the CRD, DTR, and PAS IGs. As part of the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (91 FR 19905 through 19906), CMS proposed to incorporate cross-references to 45 CFR 170.215 where these standards would be adopted as part of proposed technical requirements for payer APIs CMS previously established in the 2020 CMS Interoperability and Patient Access and the 2024 CMS Interoperability and Prior Authorization final rules.

ONC analysis of these new standard versions finds that the changes between currently adopted standard versions and these new standard versions are small in scope and would not require significant effort to adopt. Furthermore, ONC adopted the current standard versions in regulation as part of the HTI–4 final rule, with no required date to adopt the new certification criteria and the associated standards, lowering any duplication of effort to first adopt the current standard version and the proposed new standard version (90 FR 36536 through 37308). Because standard versions 2.0.1 and 2.2 (for the purposes of this discussion we refer to the 2.2.1 versions of the CRD and PAS IGs, and the 2.2.0 version of the DTR IG, as the 2.2 versions) are directionally aligned (*i.e.* version 2.2 builds on top of 2.0), time spent by developers of certified health IT to build toward version 2.0 is effort needed to build toward version 2.2, which includes new clarifications that improve specificity over the prior implementation guides. ONC also finds that the finalized updates would not require new adoption of technology by health IT users or adoption of new certification criteria by developers of certified health IT, as those requirements are associated with prior finalized CMS and ONC rulemaking. ONC estimates that developers of certified health IT would face little burden to adopt the updated standard version given these factors. ONC estimates that the effort on developers of certified health IT to adopt these standard versions would be de minimis.

This analysis parallels the ONC HTI–2 proposed rule impact analysis for the proposed update to adopt SMART App Launch IG version 2.2 (89 FR 63498).[749] Similarly here, the proposed update from SMART App Launch IG version 2.0 to 2.2 involved enhancements that would require low effort on developers of certified health IT to adopt to maintain certification to the applicable criteria. Public comments from the HTI–2 proposed rule did not raise any concerns with our impact analysis of the SMART App Launch IG version update, but we recognize that differing standard maturity levels and implementation challenges for the previously proposed IG updates may create more burden on developers to update their certified technology. We requested comment to that effect on the expected level of burden to update certified technology to the latest IG versions proposed previously.

We received public comment on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they agreed with our assessment that development costs would be *de minimis* for most certified health IT developers but suggested that development costs may be greater for less-resourced entities, such as smaller health IT developers, entities delivering technology systems for payers, and entities that function as intermediaries.

Response: The final impact analysis is consistent with the proposed rule and finds that these provisions would impose de minimis costs.

Regarding the comment about disparate costs associated with updating these standards, we note with respect to health IT developers that, as of the publication of this final rule, no products certified to the certification criteria at 45 CFR 170.315(g)(31) through (33) are listed on the Certified Health IT Product List. This indicates that developers are still likely investing resources to build products to meet the existing requirements. Accordingly, finalizing requirements at 45 CFR 170.315(g)(31) through (33) that leverage the 2.2.1 and 2.2.0 versions of the Da Vinci IGs is expected to impose only de minimis incremental costs.

We are also mindful of the disparate costs and level of effort across different developers of certified health IT. In our impact analysis of the criteria and standards adopted in HTI–4, we discussed how costs may vary by the size of developer and whether the developer had already adopted prior versions of the standards in their technology or development plans. Because standard versions 2.0.1 and 2.2 are directionally aligned (*i.e.* version 2.2 builds on top of 2.0.1), time spent by developers of certified health IT to build toward version 2.0 is effort needed to build toward version 2.2. If a small developer, for instance, faced higher average costs to adopt the standard and associated criteria, as finalized in HTI–4, we do not believe the same would hold for this standard update. A small developer may face higher initial build costs than a larger developer, but once it builds toward 2.0.1, we find that the effort to then adopt version 2.2 should be very similar across developers who have adopted version 2.0.1. Furthermore, finalizing these requirements will create more alignment across ONC and CMS programs and give developers of all sizes and scopes more certainty about how to configure their certified health IT.

Developers that have not yet completed certification can align their development efforts with the updated CRD, DTR, and PAS 2.2 versions now, rather than first completing development and certification to the 2.0.1 versions of the Da Vinci IGs and then, shortly thereafter, undertaking additional development and certification efforts to support the 2.2 versions. This approach should reduce duplicative effort and avoid the greater costs that would result from sequential development and certification to two versions of the same IGs.

[742] Health Level Seven International. (2026, March 27). Da Vinci—Coverage Requirements Discovery IG. Retrieved from *https://hl7.org/fhir/us/davinci-crd/2.2.1/en/*.

[743] Health Level Seven International. (2026, March 27). Da Vinci—Documentation Templates and Rules IG. Retrieved from *https://hl7.org/fhir/us/davinci-dtr/2.2.0/en/*.

[744] Health Level Seven International. (2026, March 27). Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide. Retrieved from *https://hl7.org/fhir/us/davinci-pas/2.2.1/en/*.

[745] Health Level Seven International. (2026, March 27). CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®). Retrieved from *https://hl7.org/fhir/us/carin-bb/STU2.2/*.

[746] Health Level Seven International. (2025, February 26). Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide. Retrieved from *https://hl7.org/fhir/us/davinci-drug-formulary/STU2.1/*.

[747] Health Level Seven International. Da Vinci PDex [Payer Data Exchange] Plan Net Implementation Guide. Retrieved from *https://hl7.org/fhir/us/davinci-pdex-plan-net/STU1.2/*.

[748] Health Level Seven International. (2025, February 11). Da Vinci Clinical Data Exchange (CDex) IG. Retrieved from *https://hl7.org/fhir/us/davinci-cdex/STU2.1/*.

[749] See section III.B.2. on the SMART App Launch 2.2 in the HTI–2 proposed rule at *https://www.federalregister.gov/d/2024-14975/p-2093*.

H. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of July 2026, there were 94 children's hospitals, 11 cancer hospitals, 6 short term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, 1 extended neoplastic disease care hospital, and 8 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, the rehabilitation hospitals and units, and the LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and the psychiatric hospitals and units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the rate updates discussed in this final rule. The impacts of the changes on LTCHs are discussed in section I.J. of the appendix of this final rule.

For the children's hospitals, cancer hospitals, short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs, the update of the rate-of-increase limit (or target amount) is the estimated FY 2027 percentage increase in the 2023-based IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. Consistent with current law, based on IGI's fourth quarter 2025 forecast of the 2023-based IPPS market basket increase, we are estimating the FY 2027 update to be 3.2 percent (that is, the estimate of the market basket rate-of-increase), as discussed in section VI.B. of the preamble of this final rule. Section 1886(b)(3)(B)(xi)(I) of the Act requires a productivity adjustment (0.9 percentage point reduction for FY 2027), resulting in a 2.3 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section VI.B. of the preamble of this final rule. Children's hospitals, cancer hospitals, short term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under section 1886(b)(3)(B)(xi)(I) of the Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the update is the percentage increase in the 2023-based IPPS operating market basket for FY 2027, currently estimated at 3.2 percent.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

I. Effects of Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented in this section of this final rule, we used data from the March 2026 update of the FY 2025 MedPAR file and the March 2026 update of the Provider-Specific File (PSF) that was used for payment purposes. Although the analyses of the changes to the capital prospective payment system do not incorporate cost data, we used the March 2026 update of the most recently available hospital cost report data to categorize hospitals. Our analysis has several qualifications and uses the best data available, as described later in this section of this final rule.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the March 2026 update of the FY 2025 MedPAR file, we simulated payments under the capital IPPS for FY 2026 and the payments for FY 2027 for a comparison of total payments per case. Short-term, acute care hospitals that are not paid under the general IPPS (for example, hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the capital IPPS payments in FY 2027 is as follows:

(Standard Federal rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH adjustment factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the geographic adjustment factor (GAF) and the hospital's case-mix. Then we added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- The capital Federal rate was updated, beginning in FY 1996, by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1. of the Addendum to this final rule, the update to the capital Federal rate is 3.4 percent for FY 2027.
- In addition to the FY 2027 update factor, the FY 2027 capital Federal rate was calculated based on a GAF/DRG budget neutrality adjustment factor of 0.9901, a budget neutrality factor for the 5-percent cap on wage index decreases policy and the continuation of the transition for the discontinuation of the low wage index hospital policy of 0.9990, and a outlier adjustment factor of 0.9677.

2. Results

We used the payment simulation model previously described in section I.I. of the Appendix of this final rule to estimate the potential impact of the changes for FY 2027 on total capital payments per case, using a universe of 3,005 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the March 2026 update of the FY 2025 MedPAR file, the March 2026 update to the PSF, and the most recent available cost report data from the March 2026 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2026 and estimated total payments per case for FY 2027 based on the FY 2027 payment policies. Column 2 shows estimates of payments per case under our model for FY 2026. Column 3 shows estimates of payments per case under our model for FY 2027. Column 4 shows the total percentage change in payments from FY 2026 to FY 2027. The change represented in Column 4 includes the 3.4 percent update to the capital Federal rate and other changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2027 are expected to increase 3.0 percent compared to capital payments per case in FY 2026. This expected increase is primarily due to the 3.4 percent update to the capital Federal rate being partially offset by a projected decrease in capital outlier payments. In general, regional variations in estimated capital payments per case in FY 2027 as compared to capital payments per case in FY 2026 are primarily due to the changes in GAFs, and are generally consistent with the projected changes in payments due to the changes in the wage index (and policies affecting the wage index), as shown in Table I in section I.F. of this final rule.

The net impact of these changes is an estimated 3.0 percent increase in capital payments per case from FY 2026 to FY 2027 for all hospitals (as shown in Table III). The geographic comparison shows that, on average, hospitals in both urban and rural classifications will experience an increase in

capital IPPS payments per case in FY 2027 as compared to FY 2026. Capital IPPS payments per case will increase by an estimated 3.0 percent for hospitals in urban areas and 3.1 percent for rural areas from FY 2026 to FY 2027.

The comparisons by region show that the change in capital payments per case from FY 2026 to FY 2027 for urban areas range from a 1.7 percent increase for the Pacific urban region to a 4.2 percent increase for the East North Central urban region. Meanwhile, the change in capital payments per case from FY 2026 to FY 2027 for rural areas range from a 1.2 percent increase for the Mountain rural region to a 4.8 percent increase for the New England rural region. Capital IPPS payments per case for hospitals located in Puerto Rico are projected to decrease by 1.3 percent. These regional differences are primarily due to the changes in the GAFs.

The comparison by hospital type of ownership (Voluntary, Proprietary, and Government) shows that voluntary hospitals are expected to experience an increase in capital payments per case from FY 2026 to FY 2027 of 3.2 percent. Proprietary hospitals are expected to experience an increase in capital payments per case from FY 2026 to FY 2027 of 2.2 percent. Government hospitals are expected to experience an increase in capital payments per case from FY 2026 to FY 2027 of 2.7 percent.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2027. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this final rule for FY 2027, we show the average capital payments per case for reclassified hospitals for FY 2027. Urban reclassified hospitals are expected to experience an increase in capital payments per case of 3.2 percent; urban non-reclassified hospitals are expected to experience an increase in capital payments of 2.4 percent. Rural reclassified hospitals are expected to experience an increase in capital payments per case of 3.0 percent; rural non-reclassified hospitals are expected to experience an increase in capital payments per case of 3.0 percent.

TABLE III.-- COMPARISON OF TOTAL PAYMENTS PER CASE

FY 2026 PAYMENTS COMPARED TO FY 2027 PAYMENTS	Number of Hospitals	Average FY 2026 Payments/Case	Average FY 2027 Payments/Case	Change
All Hospitals	3,005	1,241	1,278	3.0
By Geographic Location:				
Urban hospitals	2,357	1,275	1,313	3.0
Rural hospitals	648	848	874	3.1
Bed Size (Urban):				
0-99 beds	640	965	976	1.1
100-199 beds	673	1,062	1,094	3.0
200-299 beds	400	1,155	1,189	2.9
300-499 beds	393	1,266	1,303	2.9
500 or more beds	249	1,529	1,575	3.0
Bed Size (Rural):				
0-49 beds	309	705	722	2.4
50-99 beds	174	812	835	2.8
100-149 beds	95	824	849	3.0
150-199 beds	41	909	936	3.0
200 or more beds	29	1,033	1,069	3.5
Urban by Region:				
New England	102	1,364	1,411	3.4
Middle Atlantic	272	1,445	1,496	3.5
East North Central	364	1,179	1,228	4.2
West North Central	155	1,210	1,237	2.2
South Atlantic	393	1,133	1,175	3.7
East South Central	139	1,037	1,058	2.0
West South Central	356	1,175	1,199	2.0
Mountain	177	1,267	1,294	2.1
Pacific	347	1,591	1,618	1.7
Rural by Region:				
New England	19	1,097	1,150	4.8
Middle Atlantic	46	991	1,022	3.1
East North Central	104	837	870	3.9
West North Central	71	863	876	1.5
South Atlantic	110	763	797	4.5
East South Central	119	757	769	1.6
West South Central	114	754	774	2.7
Mountain	41	922	933	1.2
Pacific	24	1,067	1,097	2.8
Puerto Rico:				
Puerto Rico Hospitals	52	611	603	-1.3
By Payment Classification:				
Urban hospitals	1,524	1,158	1,187	2.5
Rural areas	1,481	1,295	1,336	3.2
Teaching Status:				
Nonteaching	1,696	1,004	1,029	2.5
Fewer than 100 residents	1,003	1,151	1,186	3.0
100 or more residents	306	1,665	1,715	3.0
Urban DSH:				
Non-DSH	370	1,058	1,081	2.2
100 or more beds	827	1,203	1,235	2.7
Less than 100 beds	327	870	890	2.3
Rural DSH:				
Non-DSH	130	1,135	1,172	3.3
SCH	212	874	900	3.0
RRC	923	1,340	1,382	3.1
100 or more beds	31	1,195	1,244	4.1
Less than 100 beds	185	697	718	3.0
Urban teaching and DSH:				
Both teaching and DSH	480	1,260	1,295	2.8
Teaching and no DSH	68	1,106	1,143	3.3
No teaching and DSH	674	1,063	1,088	2.4
No teaching and no DSH	302	1,023	1,037	1.4

FY 2026 PAYMENTS COMPARED TO FY 2027 PAYMENTS	Number of Hospitals	Average FY 2026 Payments/Case	Average FY 2027 Payments/Case	Change
Special Hospital Types:				
SCH	419	993	1,025	3.2
MDH	166	786	812	3.3
Type of Ownership:				
Voluntary	1,905	1,238	1,277	3.2
Proprietary	693	1,159	1,185	2.2
Government	405	1,358	1,395	2.7
Medicare Utilization as a Percent of Inpatient Days:				
0-25	1,664	1,290	1,327	2.9
25-50	1,265	1,187	1,221	2.9
50-65	41	1,146	1,191	3.9
Over 65	9	844	880	4.3
Medicaid Utilization as a Percent of Inpatient Days:				
0-25	2,037	1,146	1,181	3.1
25-50	860	1,419	1,459	2.8
50-65	84	1,567	1,587	1.3
Over 65	24	1,345	1,360	1.1
FY 2027 Reclassifications:				
All Reclassified Hospitals	1,103	1,287	1,329	3.3
Non-Reclassified Hospitals	1,902	1,182	1,212	2.5
Urban Hospitals Reclassified	977	1,345	1,388	3.2
Urban Non-Reclassified Hospitals	1,398	1,157	1,185	2.4
Rural Hospitals Reclassified Full Year	272	863	889	3.0
Rural Non-Reclassified Hospitals Full Year	358	822	847	3.0
All Section 401 Rural Reclassified Hospitals	885	1,357	1,399	3.1
Other Reclassified Hospitals (Section 1886(d)(8)(B))	52	869	896	3.1

J. Effects of Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section X. of the preamble of this final rule and section V. of the Addendum to this final rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2027. In the preamble of this final rule, we specify the statutory authority for the provisions that are presented, identify the policies for FY 2027, and present rationales for our provisions as well as alternatives that were considered. In this section, we discuss the impact of the changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this final rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a), reduced by 4.6 percent for FYs 2018 through 2026; or 100 percent of the estimated cost of the case as determined under § 412.529(d)(2).

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.533 and 412.535. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and short stay outliers (SSOs). LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate).

In addition, when certain thresholds are met, LTCHs also receive high-cost outlier (HCO) payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

2. Updates to Payments for LTCH PPS Standard Federal Payment Rate Cases

This section details the updates to the LTCH PPS payment rates and related factors that will affect payments for LTCH PPS standard Federal payment rate cases and serve as the basis for the impact analysis presented in this final rule.

- As discussed in section V.A.2. of the Addendum to this final rule, for FY 2027, we are establishing an LTCH PPS standard Federal payment rate of $52,132.76 which reflects the 2.3 percent annual update to the LTCH PPS standard Federal payment rate and the budget neutrality factor for updates to the area wage level adjustment of 1.002679. For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $51,113.55. This LTCH PPS standard Federal payment rate reflects the updates and factors previously described, as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP.
- As discussed in section V.B.3. of the Addendum to this final rule, for FY 2027, we are establishing a labor-related share of 73.0 percent for FY 2027, based on the most recent available data (IGI's second quarter 2026 forecast) of the relative importance of the labor-related share of operating and capital costs of the 2022-based LTCH market basket.
- As discussed in section V.B.4. of the Addendum to this final rule, for FY 2027, we are updating the wage index values based on the most recent available data (data from cost reporting periods beginning during FY 2023 which is the same data used for the FY 2027 IPPS wage index).
- As discussed in section V.C. of the Addendum to this final rule, for FY 2027, we are updating the COLA factors used to adjust non-labor related costs for LTCHs located in Alaska and Hawaii using the Overseas Cost-of-Living Allowance (OCOLA) data published by the Department of Defense (DOD).
- As discussed in section X.B of the preamble of this final rule, for FY 2027, we are updating the MS–LTC–DRG classifications and MS–LTC–DRG relative weights.

• As discussed in section V.C. of the Addendum to this final rule, for FY 2027, we are maintaining the fixed-loss amount for LTCH PPS standard Federal payment rate cases at its FY 2026 level of $78,936. We estimate this will result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2027 payments for such cases.

3. Impact Analysis

a. Basis and Methodology of Estimates

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this final rule on different categories of LTCHs for FY 2027, it is necessary to estimate payments per discharge for FY 2026 using the rates, factors, and the policies established in the FY 2026 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2027 using the rates, factors, and the policies in this final rule (as discussed in section X. of the preamble of this final rule and section V. of the Addendum to this final rule). The resulting analyses can then be used to compare how our policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

Specifically, to estimate the per discharge payment effects of our policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2026 and FY 2027 payments on a case-by-case basis using historical LTCH claims from the FY 2025 MedPAR files that met or would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for all cases in the FY 2025 MedPAR files. We note that in modeling payments for HCO cases, we scaled outlier payments to equal 7.975 percent of total estimated LTCH PPS payments for standard Federal payment rate cases in both FY 2026 and FY 2027.

There are 319 LTCHs included in this impact analysis. We note that, although there are 325 LTCHs in the claims data used for this final rule, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the FY 2027 MS–LTC–DRG relative weights (discussed in section X.B.3. of the preamble of this final rule). Moreover, in the claims data used for this final rule, one of the 325 LTCHs only had claims for site neutral payment rate cases and, therefore, does not affect our impact analysis for LTCH PPS standard Federal payment rate cases presented in Table IV.

Based on the FY 2025 LTCH cases that were used for the analysis in this final rule, approximately 7 percent of those cases were classified as site neutral payment rate cases (that is, 7 percent of LTCH cases would not meet the statutory patient-level criteria for exclusion from the site neutral payment rate). Accordingly, based on the FY 2025 LTCH cases that were used for the analysis in this final rule, approximately 93 percent of LTCH cases would meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2027 and would be paid based on the LTCH PPS standard Federal payment rate.

Comment: Some commenters expressed concern that the projected increase in payments stated in the proposed rule for LTCH PPS standard payment rate cases for FY 2027 is insufficient to address the financial pressures facing LTCHs. One commenter argued that the projected increase would fail to keep pace with actual cost growth that is being driven by workforce shortages, increased reliance on contract labor, elevated pharmaceutical and supply costs, and rising patient acuity. Another commenter contended that the projected increase is inadequate given that LTCHs serve Medicare's most medically complex and seriously ill beneficiaries. The commenter stated that persistent reimbursement shortfalls under the current payment system have already contributed to reduced care volumes and facility closures.

Response: We appreciate commenters' concerns about the proposed 2.3 percent increase in payments to LTCH PPS standard Federal payment rate cases. Based on the finalized payment rates and factors in this final rule, we project a 2.2 percent increase in payments to LTCH PPS standard Federal payment rate cases for FY 2027. As discussed later in this section of the rule, that estimated increase is primarily due to the 2.3 percent annual update to the LTCH PPS standard Federal payment rate. We received several comments on the proposed annual update to the LTCH PPS standard Federal payment rate that we fully summarized and responded to in section X.C. of the preamble to this final rule. As stated in that section, we believe the LTCH market basket increase appropriately reflects the input price growth that LTCHs will incur providing medical services in FY 2027.

Comment: A few commenters noted that in the proposed rule CMS did not include a payment projection for site neutral payment rate cases. One commenter stated that this omission made it harder to assess the rule's full financial impact.

Response: We appreciate the commenters' sharing their feedback. The site-neutral payment rate is the lower of the IPPS comparable per diem amount (including any applicable outlier payments) reduced by 4.6 percent for FYs 2018 through 2026; or 100 percent of the estimated cost of the case. Projecting site-neutral payments therefore requires an accurate projection of the costs of site-neutral payment rate cases. For the same reasons that preclude us from determining a FY 2027 fixed-loss amount using our standard methodology (as discussed in section V.C. of the Addendum to this final rule)—namely, the uncertainty surrounding the reliability of the historical data available for projecting LTCH costs—we do not believe a reliable projection of site-neutral payment rate payments is feasible for purposes of this rulemaking. We note that payments to site neutral payment rate cases in FY 2025 represented approximately 3 percent of aggregate FY 2025 LTCH PPS payments.

In the following section, we present in Table IV our provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs, reflecting the estimated ''losses'' or ''gains'' from FY 2026 to FY 2027 based on the payment rates and policy changes presented in this final rule. We note that our analysis does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of the policies in this final rule. Consistent with prior years, Table IV only reflects changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

In Table IV, LTCHs are grouped based on characteristics provided in hospital cost report data and PSF data. LTCH groups included the following:

- Location: large urban/other urban/rural.
- Ownership control.
- Census region.
- Bed size.

We include the following columns in Table IV:

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2026 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fifth column shows the estimated FY 2027 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2026 to FY 2027 due to the annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this final rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027 due to the changes to the area wage level adjustment (that is, the updated hospital wage data and the labor-related share) and the application of the corresponding budget neutrality factor (as discussed in section V.B.6. of the Addendum to this final rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 (Column 4) to FY 2027 (Column 5) due to all changes.

TABLE IV: IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2027
(ESTIMATED FY 2026 PAYMENTS COMPARED TO ESTIMATED FY 2027 PAYMENTS)

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2026 LTCH PPS Payment Per Standard Payment Rate (4)	Average FY 2027 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Percent Change Due to the Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Changes to Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Standard Payment Rate Changes[4] (8)
ALL PROVIDERS	319	41,580	58,586	59,881	2.2	0.0	2.2
BY LOCATION:							
RURAL	16	1,032	47,271	48,060	2.2	-0.3	1.7
URBAN	303	40,548	58,874	60,182	2.2	0.0	2.2
BY OWNERSHIP TYPE:							
VOLUNTARY	53	4,933	59,132	60,203	2.2	-0.3	1.8
PROPRIETARY	257	36,119	58,266	59,569	2.2	0.0	2.2
GOVERNMENT	9	528	75,399	78,224	2.2	1.1	3.7
BY REGION:							
NEW ENGLAND	9	1,299	49,082	50,211	2.2	0.7	2.3
MIDDLE ATLANTIC	20	3,003	69,794	72,151	2.2	1.1	3.4
SOUTH ATLANTIC	60	9,293	57,085	58,207	2.2	-0.3	2.0
EAST NORTH CENTRAL	46	5,059	61,409	62,480	2.2	-0.5	1.7
EAST SOUTH CENTRAL	32	3,107	51,875	52,570	2.2	-0.8	1.3
WEST NORTH CENTRAL	22	2,124	53,603	54,801	2.2	0.2	2.2
WEST SOUTH CENTRAL	82	9,524	51,091	51,976	2.2	-0.2	1.7
MOUNTAIN	25	2,227	57,878	59,441	2.2	0.0	2.7
PACIFIC	23	5,944	72,508	74,667	2.2	0.6	3.0
BY BED SIZE:							
BEDS: 0-24	34	2,019	60,063	61,556	2.2	0.2	2.5
BEDS: 25-49	151	15,578	52,674	53,655	2.2	-0.2	1.9
BEDS: 50-74	75	10,580	60,072	61,439	2.2	0.0	2.3
BEDS: 75-124	41	8,349	66,152	67,803	2.2	0.1	2.5
BEDS: 125+	18	5,054	60,611	62,054	2.2	0.3	2.4

[1] Estimated FY 2027 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this final rule.
[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027 due to the annual update to the LTCH PPS standard Federal payment rate.
[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027 due to the changes to the area wage level adjustment under § 412.525(c) (that is, the updated hospital wage data and the labor-related share) with budget neutrality.
[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 (shown in Column 4) to FY 2027 (shown in Column 5), due to all of the changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this final rule.

b. Results

Based on the FY 2025 LTCH cases (from 319 LTCHs) that were used for the analyses in this final rule, we have prepared the following summary of the impact (as shown in Table IV) of the LTCH PPS payment rate and policy changes for LTCH PPS standard Federal payment rate cases presented in this final rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are projected to increase 2.2 percent, on average, for all LTCHs from FY 2026 to FY 2027, as a result of the payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this finale rule. This estimated 2.2 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2027 LTCH PPS payments for LTCH PPS standard Federal payment rate cases (using the payment rates and factors discussed in this final rule) to estimated FY 2026 LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

As stated previously, we established an annual update to the LTCH PPS standard Federal payment rate for FY 2027 of 2.3 percent. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. The estimated change attributable solely to the annual update of 2.3 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 2.2 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027, on average, for all LTCHs (Column 6). The estimated increase of 2.2 percent shown in Column 6 also includes estimated payments for SSO cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP data. For all hospital categories, the projected increase in payments based on the LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases also rounds to approximately 2.2 percent.

(1) Location

The vast majority of LTCHs are located in urban areas. The impact analysis presented in Table IV shows that the average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027 for all LTCHs is 2.2 percent. Urban LTCHs are also projected to experience an increase of 2.2 percent.

Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 2 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. As shown in Table IV, we are projecting a 1.7 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases for LTCHs located in a rural area. This increase is primarily due to the 2.3 percent annual update to the LTCH PPS standard Federal payment rate for FY 2027 being partially offset by a projected decrease in payments due to the changes to the area wage level adjustment and the changes to the MS–LTC–DRG classifications and relative weights.

(2) Ownership Control

LTCHs are grouped into three categories based on ownership control type: voluntary, proprietary, and government. Based on the best available data, approximately 17 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 81 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, proprietary LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases of 2.2 percent. Voluntary LTCHs are expected to experience an

increase in payments to LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027 of 1.8 percent. Government owned and operated LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027 of 3.7 percent.

(3) Census Region

The comparisons by region show that the changes in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2026 to FY 2027 are projected to increase from 1.3 percent in the East South Central region to 3.4 percent in the Middle Atlantic region. These regional variations are primarily due to the changes to the area wage adjustment.

(4) Bed Size

LTCHs are grouped into five categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; and greater than 125 beds. We project that LTCHs with 0–24 beds and LTCHs with 75–124 beds will experience the largest increase in payments with 2.5 percent. The remaining bed size categories are projected to experience an increase in payments in the range of 1.9 percent to 2.4 percent.

4. Effect on the Medicare Program

We project that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2027 relative to FY 2026 of approximately 2.2 percent for the 319 LTCHs in our database. We estimate that aggregate FY 2027 LTCH PPS payments to LTCH PPS standard Federal payment rate cases will be approximately $2.490 billion, as compared to estimated aggregate FY 2026 LTCH PPS payments of approximately $2.436 billion, resulting in an estimated overall increase in payments of approximately $54 million.

As we discuss in detail throughout this final rule, based on the best available data, we believe that the provisions of this final rule relating to the LTCH PPS and the resulting LTCH PPS payment amounts will result in appropriate Medicare payments that are consistent with the statute.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this final rule, and we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program. As discussed previously, we do not expect the implementation of the site neutral payment system to have a negative impact on access to or quality of care. As demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs.

K. Effects of Requirements for the Hospital Inpatient Quality Reporting Program

In sections IX.B. and IX.C. of the preamble of this final rule, we discuss the requirements for hospitals reporting quality data under the Hospital Inpatient Quality Reporting Program to receive the full annual percentage increase for the FY 2029 payment determination and subsequent years.

In this final rule, we are adopting three new measures: (1) the Advance Care Planning electronic clinical quality measure (eCQM) beginning with the CY 2028 reporting period/FY 2030 payment determination; (2) the Hospital Harm-Postoperative Venous Thromboembolism (VTE) eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination; (3) the Excess Days in Acute Care After Hospitalization for Diabetes measure beginning with the July 1, 2025 through June 30, 2027 performance period, associated with the FY 2029 payment determination. We are also adopting five mortality measures for the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination, through the July 1, 2027 through June 30, 2029 performance period, associated with the FY 2031 payment determination: (1) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction Hospitalization measure; (2) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization measure; (3) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization measure; (4) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease Hospitalization measure; and (5) the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery measure. We are also modifying three measures beginning with the July 1, 2024 through June 30, 2026 performance period, associated with the FY 2028 payment determination: (1) the Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction measure; (2) the Excess Days in Acute Care after Hospitalization for Heart Failure measure; and (3) the Excess Days in Acute Care after Hospitalization for Pneumonia measure. We are removing three eCQMs beginning with the CY 2028 reporting period/FY 2030 payment determination: (1) the VTE Prophylaxis eCQM; (2) the Intensive Care Unit VTE Prophylaxis eCQM; and (3) Discharged on Antithrombotic Therapy eCQM. We are also updating the reporting and submission requirements for the Maternal Morbidity Structural measure beginning with the CY 2026 reporting period/FY 2028 payment determination. Lastly, we are modifying the reporting and submission requirements for eCQMs to require mandatory reporting of the Malnutrition Care Score eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination, and to require mandatory reporting of Hospital Harm eCQMs after 2 years of self-selected reporting beginning with the CY 2028 reporting period/FY 2030 payment determination.

As shown in the summary tables in section XII.B.4.h. of the preamble of this final rule, we estimate an increase of 8,133 hours at a cost of $447,803 in information collection burden associated with the finalized policies compared to the currently approved information collection burden estimates under OMB control number 0938–1022 (expiration date December 31, 2028).

In section IX.B.1. of the preamble of this final rule, we are adopting the Advance Care Planning eCQM beginning with the CY 2028 reporting period/FY 2030 payment determination. Additionally, in sections IX.C.3.b. and IX.C.4. of the preamble of this final rule, we are adopting the Hospital Harm-Postoperative VTE eCQM and subsequently removing the VTE–1 and VTE–2 eCQMs beginning with the CY 2028 reporting period/FY 2030 payment determination. While there is no change in information collection burden associated with these policies because the VTE–1 and VTE–2 eCQMs are available for hospitals to self-select to meet eCQM reporting requirements and the finalized Hospital Harm-Postoperative VTE eCQM will also be available for hospitals to self-select, we note that there will be a reduction in administrative burden as the policies will result in replacing two process eCQMs with a single comprehensive outcome eCQM. We note that the Hospital Harm-Postoperative VTE eCQM will become mandatory due to the finalized policy to require Hospital Harm eCQMs after two years of self-selected reporting, and we have provided estimates for the Collection of Information burden in section XII.B.4.g. in the preamble of this final rule. We note the administrative costs associated with adoption of eCQMs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program requirements, such as maintaining measure specifications in hospitals' EHR systems for the eCQMs used in the Hospital Inpatient Quality Reporting Program.

We do not anticipate any additional economic impact beyond those discussed in section XII.B.4. of the preamble of this final rule (Collection of Information) for the remaining policies.

Historically, 100 hospitals, on average, that participate in the Hospital Inpatient Quality Reporting Program do not receive the full annual percentage increase in any fiscal year due to the failure to meet all requirements. We anticipate that the number of hospitals not receiving the full annual percentage increase will be approximately the same as in past years based on review of previous performance.

L. Effects of Requirements for the PPS-Exempt Cancer Hospital (PCH) Quality Reporting Program

In sections IX.B. and IX.D. of this final rule, we discuss requirements for PPS-Exempt Cancer Hospitals (PCHs) reporting quality data under the PCH Quality Reporting Program. The PCH Quality Reporting Program is authorized under section 1866(k) of the Act. There is no financial impact to Medicare reimbursement if a PCH does not submit data.

We are adopting two measures with voluntary reporting for the CY 2028 reporting

period/FY 2030 program year, followed by mandatory reporting beginning with the CY 2029 reporting period/FY 2031 program year: (1) the Advance Care Planning electronic clinical quality measure (eCQM); and (2) the Malnutrition Care Score eCQM. This is a modification from the FY 2027 IPPS/LTCH PPS proposed rule, in which we proposed to adopt both measures with mandatory reporting beginning with the CY 2028 reporting period/FY 2030 program year (91 FR 19564 through 19568 and 91 FR 19605 through 19608). We are also removing the COVID–19 Vaccination Coverage among Healthcare Personnel measure beginning with the CY 2026 reporting period/FY 2028 program year.

As shown in the summary tables in section XII.B.5. of this final rule, across all PCHs we estimate an increase of 15 hours at a cost of $826 in information collection burden associated with the finalized policies compared to the currently approved information collection burden estimates under OMB control number 0938–1175 (expiration date January 31, 2029). We also estimate a decrease of between 88 hours at a savings of $4,972 and 99 hours at a savings of $5,801 in information collection burden associated with the finalized policies compared to the currently approved information collection burden estimates under OMB control number 0920–1317 (expiration date January 31, 2028).

With regard to administrative costs associated with adoption of eCQMs, we believe they are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program requirements, such as maintaining measure specifications in PCHs' electronic health record systems for the eCQMs used in the PCH Quality Reporting Program. As discussed in section IX.D.5.b.(1). of this final rule, we intend to transition to a fully digital quality measure landscape by transitioning eCQMs to Health Level 7® Fast Healthcare Interoperability Resources® (FHIR®)-based eCQMs to promote interoperability and increase the value of quality measure data.[749] [750]

We do not believe removal of the COVID–19 Vaccination Coverage among Healthcare Personnel measure will result in any additional economic impact beyond that discussed in section XII.B.5.c. of this final rule (Collection of Information).

M. Effects of Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In section IX.E.3. of this final rule, we finalized our proposal to remove the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) (HCP COVID–19 Vaccine) measure. We also finalized, in section IX.E.4. of this final rule, our proposal to remove the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID–19 Vaccine) measure. Both measure removals will be effective beginning with the FY 2028 LTCH QRP. In section IX.E.6.b. of this final rule, we finalized our proposal to revise the data submission deadline for LCDS assessment and CDC NHSN data for the LTCH QRP. Finally, in sections IX.E.5. of this final rule, we summarize public comments received in response to our request for information on future measure concepts for the LTCH QRP.

The effect of these finalized provisions for the LTCH QRP will be an overall decrease in burden for LTCHs participating in the LTCH QRP. As shown in summary table I.M.-01, we estimate a decrease in total annual burden of 4,473 hours and $203,059.30 for 318 eligible LTCHs associated with our finalized policies. We refer readers to section XII.B.8. of this final rule, where CMS has provided an estimate of the burden and cost to LTCHs.

TABLE I.M.-01: ESTIMATED BURDEN ASSOCIATED WITH THE FY 2028 LTCH QRP

Requirement	Per LTCH		All LTCHs	
	Change in Annual Burden Hours	Change in Annual Cost	Change in Annual Burden Hours	Change in Annual Cost
Proposed Removal of the Patient/Resident COVID-19 Measure	-1.61	-$123.51	-513	-$39,276.58
Proposed Removal of the HCP COVID-19 Vaccine Measure.	-12.00	-$515.04	-3,960	-$163,782.72
Total estimated change in burden associated with the FY 2028 LTCH QRP	-13.61	-$638.55	-4,473	-$203,059.30

We sought comments specific to the estimates.

We received no comments on the estimates of burden related to the removal of the HCP COVID–19 Vaccine and Patient/Resident COVID–19 Vaccine measures and therefore are finalizing this provision without modification.

N. Effects of Requirements Regarding the Medicare Promoting Interoperability Program

In sections IX.B. and IX.F. of the preamble of this final rule, we discuss requirements for eligible hospitals and critical access hospitals (CAHs) to report on objectives, measures, and electronic clinical quality measures (eCQMs) under the Medicare Promoting Interoperability Program.

In this final rule, we are adopting three new measures: (1) the Advance Care Planning eCQM beginning with the CY 2028 reporting period; (2) the Hospital Harm-Postoperative Venous Thromboembolism (VTE) eCQM beginning with the CY 2028 reporting period; and (3) the Unique Device Identifiers for Implantable Medical Devices measure beginning with the EHR reporting period in CY 2027. Additionally, we are removing two attestations and five measures: (1) the Office of the National Coordinator for Health Information Technology (ONC) Direct Review Attestation beginning with the EHR reporting period in CY 2026; (2) the optional ONC-Authorized Certification Body (ONC–ACB) Surveillance Attestation beginning with the EHR reporting period in CY 2026; (3) the Support Electronic Referral Loops by Sending Health Information measure beginning with the EHR reporting period in CY 2029; (4) the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure beginning with the EHR reporting period in CY 2029; (5) the Venous Thromboembolism Prophylaxis (VTE) Prophylaxis eCQM beginning with the CY 2028 reporting period; (6) the Intensive Care Unit VTE Prophylaxis eCQM beginning with the CY 2028 reporting period; and (7) the Discharged on Antithrombotic Therapy eCQM beginning with the CY 2028 reporting period. We are also updating the Electronic Prior Authorization measure by modifying the ONC certification criteria eligible hospitals and CAHs must use to attest ''Yes,'' modifying the measure text, and making the measure an optional bonus measure for the EHR reporting period in CY 2027 and a required measure beginning with the EHR reporting period in CY 2028. Lastly, we are modifying the reporting and submission requirements for the Malnutrition Care Score eCQM beginning with the CY 2028 reporting period and modifying the reporting and submission requirements for Hospital Harm eCQMs to require mandatory reporting after 2 years of self-selected reporting beginning with the CY 2028 reporting period.

As discussed in section XII.B.7.i. of the preamble of this final rule, we estimate a decrease of 3,886 hours at a cost of $213,982 in information collection burden associated with our finalized policies and updated burden estimates for the EHR reporting period in CY 2026 and future years compared to our currently approved information collection burden estimates. We refer readers to section XIII.B.7. of the preamble of this final rule (Collection of Information) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Medicare Promoting Interoperability Program.

[749] For more information on dQMs, visit: *https://ecqi.healthit.gov/dqm/about-dqms.*

[750] FHIR® is the registered trademark of Health Level Seven International (HL7), and its use does not constitute endorsement by HL7.

In section IX.F.9.b. of the preamble of this final rule, we are adopting the Hospital Harm Postoperative VTE eCQM and removing the VTE Prophylaxis eCQM and Intensive Care Unit VTE Prophylaxis eCQM beginning with the CY 2028 reporting period. There is no change in information collection burden associated with these policies because the two current VTE eCQMs are available for CAHs to self-select to meet reporting requirements. The Hospital Harm VTE eCQM adopted in this final rule will be available for CAHs to self-select before becoming mandatory after two years in light of our finalized policy to require Hospital Harm eCQMs after two years of self-selected reporting. We note that there will be a reduction in administrative costs, as the policies result in replacement of two process measures with a single comprehensive outcome measure. In section IX.B.1. of the preamble of this final rule, we are adopting the Advance Care Planning eCQM beginning with the CY 2028 reporting period, for which there is also no change in information collection burden. Regarding administrative costs associated with adoption of eCQMs, we believe they are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program requirements, such as maintaining measure specifications in EHR systems for the objectives, measures, and eCQMs used in the program.

In section IX.F.4. of the preamble of this final rule, we are removing the Support Electronic Referral Loops by Sending Health Information measure and Support Electronic Referral Loops by Receiving and Reconciling Health Information measure, with a modification such that the removal will begin with the EHR reporting period in CY 2029. Eligible hospitals and CAHs currently reporting on these measures will be required to report on either the Health Information Exchange (HIE) Bi-Directional Exchange measure or the Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) measure. Based on Medicare Promoting Interoperability Program data from the EHR reporting period in CY 2024, the 26.6 percent of eligible hospitals and CAHs that reported on the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures may incur some onboarding labor and vendor costs associated with the process to plan, procure, configure, and technically validate the functionality of the information being exchanged. Eligible hospitals and CAHs may also incur some recurring costs associated with joining a health information exchange or TEFCA QHIN, such as annual subscription fees, transaction fees, and vendor maintenance and support, depending on the nature of their agreement with health IT vendors or other entities through which they participate. However, because each eligible hospital, CAH, and health IT vendor or other entity is unique and we lack sufficient insight into individual organizational decisions, the extent of these costs is difficult to quantify generally. Published literature largely does not evaluate the costs and benefits associated with HIE or TEFCA participation in any detail, although some published papers indicate a mixture of both cost benefits and savings associated with HIE participation.[752] We sought public comment describing the direct costs and benefits associated with HIE or TEFCA adoption because it may improve our ability to quantify the financial impacts for eligible hospitals and CAHs affected by the policy. We did not receive any comments.

We do not believe the remaining provision results in any additional economic impact beyond those discussed in section XII.B.7. of the preamble of this final rule.

O. Alternatives Considered

This final rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

1. Alternatives Considered to the LTCH QRP Reporting Requirements

With regard to the proposals to remove both the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) and COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure, we considered keeping both measures. However, when these measures were adopted, there were well-defined parameters for receiving the COVID–19 vaccination. We determined that these measures no longer align with current clinical guidelines and therefore the publicly reported measures may not reliably give consumers information on the number of HCP that are vaccinated, or the percent of stays in which patients in an LTCH are up to date on their COVID–19 vaccinations.

With regard to the proposal to revise the LTCH QRP assessment data submission deadline from 4.5 months to 45 days, we considered keeping the deadline unchanged. We determined that 45 days is a reasonable amount of time for LTCHs to submit data and make any necessary corrections, and that the benefits of this shortened timeframe include making the data timelier and more actionable which increases the value of publicly reported data, both for consumers and their families and for LTCHs to use in their quality improvement activities.

We summarize and respond to comments related to our proposals to remove both the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) and COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure and provide responses in sections IX.E.3 and IX.E.4 of the preamble of this final rule. We summarize and respond to comments related to our proposal to revise the LTCH QRP Data Submission Deadlines in section IX.E.6.b of the preamble of this final rule.

2. Alternatives Considered for the Transforming Episode Accountability Model

In section X.A. of the preamble of this final rule, we discuss the mandatory episode-based payment model called the Transforming Episode Accountability Model (TEAM). TEAM is designed to improve beneficiary care through financial accountability for episodes categories that begin with one of the following procedures: coronary artery bypass graft, lower extremity joint replacement, major bowel procedure, surgical hip/femur fracture treatment, and spinal fusion. TEAM tests whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate that TEAM will benefit Medicare beneficiaries through improving the coordination of items and services paid for through Medicare FFS payments, encouraging provider investment in health care infrastructure and redesigned care processes, and incentivizing higher value care across the inpatient and post-acute care settings for the episode.

Throughout this final rule, we have identified our policies and alternatives that we have considered and provided information as to the effects of these alternatives and the rationale for each of the proposed policies. For example, in section X.A.2.c.(2).(c). of the preamble of this final rule we considered removing the 3 percent cap on the retrospective trend factor to account for MS–DRG and HCPCS–APC changes that may occur after preliminary target prices are released. However, we remain concerned that removing the cap on the retrospective trend factor would introduce target price instability and would present challenges for TEAM participants to predict performance in the model.

We solicited and welcomed comments on our proposals, on the alternatives we have identified, including starting the proposed changes for MS–DRG and APC update factors in performance year 2, as discussed in section X.A.2.c.(2). of the preamble of this final rule, and on other alternatives that we should consider. We addressed the alternatives considered comments in each applicable section of this final rule.

3. Alternatives Considered for the Comprehensive Care for Joint Replacement Expanded (CJR–X) Model

In section X.C. of this final rule, we are finalizing the Comprehensive Care for Joint Replacement Expanded (CJR–X) Model, which builds upon the Comprehensive Care for Joint Replacement (CJR) Model that was tested from April 1, 2016 to December 31, 2024. Based on the strength of evidence from the CJR Model test, the Innovation Center is expanding the model to all acute care hospitals in the 50 United States, District of Columbia, and U.S. Territories, except for hospitals participating in the Transforming Episode Accountability Model (TEAM) and hospitals located in Maryland. CJR–X will include several updates to the CJR Model. CJR–X will begin January 1, 2028.

The model will focus on improving care and reducing spending for Medicare beneficiaries undergoing lower extremity joint replacement (LEJR) procedures. Participant hospitals will be held accountable for spending and quality of care during an initial LEJR admission and for the 90 days following hospital discharge.

[752] Menachemi N, Rahurkar S, Harle CA, Vest JR. The benefits of health information exchange: an updated systematic review. Journal of the American Medical Informatics Association. 2018 Sep;25(9):1259–65.[574]

Throughout the proposed rule, we identified proposed policies and alternatives considered. In the proposed rule, we also provided background and rationale for each of the proposed policies and discussion of alternative policies including their potential effects. For example, we considered several original CJR quality reporting and payment methodology policies but ultimately proposed updates in response to the CJR Model evaluation results, stakeholder feedback, and changes to national care delivery patterns among both CJR and non-CJR hospitals. Throughout the preamble, we solicited comments on our proposals, alternatives policies, and other options we should consider. We addressed the alternatives considered comments in each applicable section of this final rule.

P. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately $2.9 billion in FY 2027, including operating, capital, and the effects of: (1) new technology add-on payment changes; (2) the changes to estimated uncompensated care payments; and (3) the statutory expiration of the MDH program and the temporary changes to the low-volume hospital payment adjustment on January 1, 2027. The estimated change in operating payments including outlier payments, and uncompensated care payments is approximately $2.1 billion (discussed in sections I.F of this Appendix). The estimated change in capital payments is approximately $0.24 billion (discussed in section I.I. of this Appendix). The estimated change in the combined effects of other changes including new technology add-on payment changes and the statutory expiration of the temporary changes to the low-volume hospital payment adjustment on January 1, 2027, is approximately $0.52 billion as discussed in sections I.F and I.G. of the Appendix of this final rule. Totals may differ from the sum of the components due to rounding.

Table I. of section I.F. of the Appendix and Table III of section I.I. of this Appendix of this final rule also demonstrates the estimated redistributional impacts of FY 2027 changes on IPPS operating and capital payments, respectively, relative to FY 2026.

The discussions presented in the previous pages, in combination with the remainder of this final rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments in FY 2027. In the impact analysis, we are using the rates, factors, and policies presented in this final rule based on the best available data to estimate the change in payments under the LTCH PPS for FY 2027. Accordingly, based on the best available data for the 319 LTCHs included in our analysis, we estimate that aggregate FY 2027 LTCH PPS payments to LTCH PPS standard Federal payment rate cases would increase approximately $54 million relative to FY 2026, primarily due to the annual update to the LTCH PPS standard Federal rate.

Q. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcomed comments on the approach in estimating the number of entities which will review this final rule.

We recognize that different types of entities are in many cases affected by mutually exclusive sections of the rule. Thus, for the purposes of our estimate we assume that each reviewer read approximately 50 percent of the proposed rule. Finally, in our estimates, we have used the 979 number of timely pieces of correspondence on the FY 2027 IPPS/LTCH PPS proposed rule as our estimate for the number of reviewers of this rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the final rule is $113.42 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 29.33 hours for the staff to review half of this final rule. For each IPPS hospital or LTCH that reviews this final rule, the estimated cost is $3,326.61 (29.33 hours × $113.42). Therefore, we estimate that the total cost of reviewing this final rule is $3,256,751 ($3,326.61 × 979 reviewers).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf*) in Table V. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the changes to the IPPS presented in this final rule. All expenditures are classified as transfers to Medicare providers.

As shown in Table V. of the Appendix of this final rule, the net costs to the Federal Government associated with the policies in this final rule are estimated at $2.9 billion.

TABLE V.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2026 TO FY 2027

Category	Transfers
Annualized Monetized Transfers	$2.9 billion
From Whom to Whom	Federal Government to IPPS Medicare Providers

B. LTCHs

As discussed in section I.J. of the Appendix of this final rule, the impact analysis of the payment rates and factors presented in this final rule under the LTCH PPS is projected to result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2027 relative to FY 2026 of approximately $54 million based on the data for 319 LTCHs in our analysis. Therefore, as required by OMB Circular A–4 (available at *https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf*), in Table VI. of the Appendix of this final rule, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate LTCHs. Table VI. of this Appendix provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the payment rates and factors and other provisions presented in this final rule based on the data for the 319 LTCHs in our analysis. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. of the Appendix of this final rule, the net cost to the Federal Government associated with the policies for LTCHs in this final rule are estimated at $54 million.

TABLE VI.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2026 LTCH PPS TO THE FY 2027 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	$54 million
From Whom to Whom	Federal Government to LTCH Medicare Providers

C. Quality Reporting Programs

As required by OMB Circular A–4 (available at *https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf*) in Table VII. of this Appendix, we have prepared an accounting statement showing the classification of the costs associated with the provisions of this final rule as they relate to the following quality reporting programs: Hospital Inpatient Quality Reporting Program, PPS-Exempt Cancer Hospital Quality Reporting Program, Medicare Promoting Interoperability Program and the Long-Term Care Hospital Quality Reporting Program.

TABLE VII.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS RELATED TO THE VARIOUS QUALITY REPORTING PROGRAMS

Hospital Quality Burden Costs, CYs 2026-2030		
Category	**Primary Estimate**	
Costs	3% Discount Rate	7% Discount Rate
Annualized Monetized Net Costs	$0.1 million	$0.09 million

D. Non-Renal Organ Acquisition Costs for Independent Organ Procurement Organizations and Histocompatibility Laboratories

As required by OMB Circular A–4 (available at *https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf)* in Table VIII. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures and costs associated with the provisions of this final rule as they relate to non-renal organ acquisition costs for independent organ procurement organizations, and histocompatibility laboratories.

TABLE VIII.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES AND COSTS

Non-Renal Organ Acquisition Costs for Independent Organ Procurement Organizations FYs, 2027-2036		
Category	**Transfers**	
Costs	3% Discount Rate	7% Discount Rate
Annualized Monetized Transfers	-$111.6 million	-$105.7 million
From Whom to Whom	Federal Government to Medicare OPOs	
Burden Reporting Costs to IOPOs and HCLs, FY 2029		
Category	**Primary Estimate**	
Annualized Monetized Costs	$75,632	

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. The North American Industry Classification System (NAICS) was adopted in 1997 and is the current standard used by the Federal statistical agencies related to the U.S. business economy. Hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having revenues of less than $9.0 million to $47.0 million in any 1 year). (For details, see the SBA's website at *http://www.sba.gov/content/small-business-size-standards* (refer to the 620000 series or Sector 62, Health Care and Social Assistance).)

We utilized the NAICS U.S. industry title ''Hospitals'' and corresponding NAICS code 622 in determining impacts for small entities for this rule. The NAICS code 622 has a size standard of $47 million.[753] Table IX shows the number of firms, revenue, and estimated impact per hospital category.

[753] *https://www.sba.gov/sites/sbagov/files/2023-03/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%281%29%20%281%29_0.pdf.*

TABLE IX: NUMBER OF FIRMS, REVENUE, AND AVERAGE REVENUE PER FIRM OF HOSPITALS FOR NAICS CODE 622

NAICS	NAICS Description	Enterprise Size ($1,000)	Number of Firms	Receipts ($1,000)	Average Receipts Per Firm ($1,000)
622	Hospitals	<100	68	3,235	48
622	Hospitals	100-499	176	47,198	268
622	Hospitals	500-999	61	43,484	713
622	Hospitals	1,000-2,499	36	55,875	1,552
622	Hospitals	2,500-4,999	43	160,867	3,741
622	Hospitals	5,000-7,499	45	285,858	6,352
622	Hospitals	7,500-9,999	77	653,169	8,483
622	Hospitals	10,000-14,999	158	1,852,000	11,722
622	Hospitals	15,000-19,999	173	2,919,720	16,877
622	Hospitals	20,000-24,999	154	3,391,347	22,022
622	Hospitals	25,000-29,999	128	3,342,680	26,115
622	Hospitals	30,000-34,999	126	3,876,502	30,766
622	Hospitals	35,000-39,999	87	3,061,225	35,186
622	Hospitals	40,000-49,999	162	6,839,652	42,220
622	Hospitals	50,000+	1,642	1,328,006,166	808,774
622	Hospitals	Total	3,136	1,354,538,978	431,932

Source: Data obtained from United States Census Bureau table "us_6digitnaics_rcptsize_2022" (SOURCE: 2022 SUSB Annual Data Tables by Establishment Industry) Release Date: 4/10/2025: https://www2.census.gov/programs-surveys/susb/tables/2022/us_6digitnaics_rcptsize_2022.xlsx.

Notes: The 'Average Receipts Per Firm' is calculated as the Receipts ($1,000)/Number of Firms. The 'Total' row represents all the hospital firms under NAICS 622. Overall receipts (revenue) for the 3,136 firms (NAICS 622) are approximately $1,355 billion.

TABLE X: ESTIMATED IMPACT ON SMALL BUSINESSES*

	Total Facilities	Estimated Small Businesses	Total Impact ($1 million)	Estimated Impact to Small Businesses	Estimated Average Impact per Small Business
IPPS Hospitals	3,005	1,385	$2,900	$52,200,000	$37,690
LTCHs	319	147	$54	$1,000,000	$6,803

* Based on the assumptions that small firms represent 46.1 percent of affected entities and account for approximately 1.8 percent of total industry revenues using the SBA size standards.

For purposes of the RFA, approximately half of all hospitals are considered to be small entities. As shown in Table IX, hospitals with enterprise size of $49 million or less (1,494) are approximately 48 percent of total firms (3,136). Because roughly half of hospitals qualify as small entities under the RFA, the impacts described in this final rule generally affect small entities. Individuals and States are not included in the definition of a small entity. MACs are also not considered to be small entities because they do not meet the SBA definition of a small business.

HHS interprets the RFA to consider economic effects ''significant'' when more than 5 percent of providers incur impacts of at least 3 to 5 percent or more of total revenue or total costs. Approximately 44 percent of Medicare-participating hospitals report Medicare utilization of at least 25 percent of their total inpatient days (see the ''Medicare Utilization as a Percent of Inpatient Days'' category in Table I in section I.F. of the Appendix to this final rule), indicating that Medicare payments constitute a substantial portion of hospital revenue. In addition, approximately 5 percent of hospitals qualify as MDHs and report Medicare utilization at least 60 percent of the hospital's inpatient days or discharges. Based on this analysis, we estimate that the policies finalized in this rule would affect more than 5 percent of hospitals with changes in Medicare revenue of at least 3 to 5 percent.

For example, we estimate that a majority of the 3,005 IPPS hospitals included in the impact analysis presented in ''Table I.—Impact Analysis of Changes to the IPPS for Operating Costs for FY 2027'' will experience average payment increases of approximately 1.7 percent. We attribute these increases primarily to outlier payments, the hospital rate update, and uncompensated care payments, as described in section I.F. of the Appendix to this final rule. Across hospital categories, we estimate that impacts will range from an increase of 2.7 percent for urban Middle Atlantic hospitals to a decrease of 6.8 percent for MDHs, as described in section I.F. of the Appendix to this final rule.

We project that LTCHs would experience overall an increase in payments for LTCH PPS standard Federal payment rate cases in FY 2027. In this impact analysis, we use the rates, factors, and policies in this rule, based on the best available data, to estimate payment changes for FY 2027. Accordingly, using the best available data for the 319 LTCHs included in our analysis, we estimate that LTCH PPS payments for LTCH PPS standard Federal payment rate cases would increase approximately $54 million relative to FY 2026, primarily due to the annual update to the LTCH PPS standard Federal rate.

We further estimate that the 319 LTCH PPS hospitals included in the impact analysis presented in ''Table IV: Impact of Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2027 (Estimated FY 2026 Payments Compared to Estimated FY 2027 Payments)'' will experience an average increase of approximately 2.2 percent. We attribute this increase primarily to the annual standard Federal rate update of 2.3 percent for FY 2027, as discussed in section I.J. of the Appendix to this final rule. Across LTCH categories, we estimate that impacts will range from an increase of 1.3

percent for LTCHs located in the East South Central region to an increase of 3.7 percent for government-owned LTCHs to, as described in section I.J. of the Appendix to this final rule.

As shown in Tables V. and VI. of the Appendix, we estimate that this final rule will result in aggregate transfers of approximately $2.9 billion to IPPS hospitals and $54 million to LTCHs. In Table X, we estimate the impact of this rule on small entities by applying the SBA size standards and approximating the share of affected firms and revenues attributable to small entities. Specifically, we assume that small firms represent 46.1 percent of affected entities and account for approximately 1.8 percent of total industry revenues. Using these assumptions, we estimate that of the 3,005 IPPS hospitals, approximately 1,385 are small entities, and of the 319 LTCHs, approximately 147 are small entities. Applying the 1.8 percent revenue share, we estimate that approximately $52.2 million of the IPPS impacts and approximately $1.0 million of the LTCH impacts will accrue to small entities, which corresponds to an average impact of approximately $37,690 per small IPPS hospital and approximately $6,803 per small LTCH.

This final rule includes a range of policies. It provides descriptions of the statutory provisions that are addressed, identifies the finalized policies, and presents rationales for our decisions and, where relevant, alternatives that were considered. Rationales for various policies are outlined in the Statement of Need in section I.A. of the Appendix to this final rule. For example, under the statutory requirement at section 1886(b)(3)(B) of the Act, we are updating the national standardized amount for inpatient hospital operating costs by the applicable percentage increase of 2.3 percent, as described in section I.A of the Appendix to this final rule, and we did not consider an alternative for small businesses. Alternatives considered for various proposals are described in section I.O. of the Appendix to this final rule.

The analyses presented in this Appendix and throughout the preamble of this final rule constitute our initial regulatory flexibility analysis. We invited public comment on our estimates and our assessment of the impact of the proposed policies on small entities in the FY 2027 IPPS/LTCH PPS proposed rule (19883 through 19884). We received no comments on those analyses.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals.

As shown in Table I. in section I.F. of the Appendix of this final rule, rural IPPS hospitals with 0–49 beds (309 hospitals) are expected to experience an increase in payments from FY 2026 to FY 2027 of 0.3 percent and rural IPPS hospitals with 50–99 beds (174 hospitals) are expected to experience an increase in payments from FY 2026 to FY 2027 of 0.5 percent. These changes are primarily driven by the hospital rate update and the increase in estimated uncompensated care payment offset by the statutory expiration of the MDH program and the budget neutral changes to the MS–DRGs and relative weights. We refer readers to Table I. in section I.F. of the Appendix of this final rule for additional information on the quantitative effects of the policy changes under the IPPS for operating costs.

All rural LTCHs (16 hospitals) shown in Table IV. in section I.J. of the Appendix of this final rule have less than 100 beds. These hospitals are expected to experience an increase in payments from FY 2026 to FY 2027 of 1.7 percent. This increase is primarily due to the 2.3 percent annual update to the LTCH PPS standard Federal payment rate for FY 2027 being partially offset by a projected decrease in payments due to the changes to the area wage level adjustment and the changes to the MS–LTC–DRG classifications and relative weights.

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately $193 million. This final rule would not mandate any requirements that meet the threshold for State, local, or Tribal governments, nor would it affect private sector costs.

VI. Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This final rule would not have a substantial direct effect on State or local governments, preempt States, or otherwise have a federalism implication.

VII. Executive Order 13175

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having Tribal implications. Section 1880(a) of the Act states that a hospital of the Indian Health Service, whether operated by such Service or by an Indian Tribe or Tribal organization, is eligible for Medicare payments so long as it meets all of the conditions and requirements for such payments which are applicable generally to hospitals. Consistent with section 1880(a) of the Act, this final rule contains general provisions also applicable to hospitals and facilities operated by the Indian Health Service or Tribes or Tribal organizations under the Indian Self-Determination and Education Assistance Act. We continue to engage in consultations with Tribal officials on IPPS issues of interest. We use input received from these consultations, as well as the comments on the proposed rule, to inform our rulemaking.

VIII. Executive Order 14192

Executive Order 14192, titled ''Unleashing Prosperity Through Deregulation,'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations. We estimate that this final rule would generate $41.6 million in annualized costs at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommends update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2027, consistent with our approach for FY 2026, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2027

A. FY 2027 Inpatient Hospital Update

As discussed in section VI.B. of the preamble to this final rule, for FY 2027, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in

all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket percentage increase or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket percentage increase or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then an adjustment based on changes in economy-wide productivity (the productivity adjustment). Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36859 through 36879), we replaced the 2018-based IPPS operating and capital market baskets with the rebased and revised 2023-based IPPS operating and capital market baskets beginning in FY 2026.

In the FY 2027 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we proposed to base the proposed FY 2027 market basket update used to determine the applicable percentage increase for the IPPS on IGI's fourth quarter 2025 forecast of the 2023-based IPPS market basket rate-of-increase with historical data through third quarter 2025, which was estimated to be 3.2 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section VI.B. of the preamble of the FY 2027 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2025 forecast, we proposed a productivity adjustment of 0.8 percentage point for FY 2027. We also proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2027 market basket update and productivity adjustment for the FY 2027 IPPS/LTCH PPS final rule.

In the FY 2027 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2025 forecast of the 2023-based IPPS market basket percentage increase and the productivity adjustment, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we presented four possible applicable percentage increases that could be applied to the standardized amount.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are establishing the applicable percentage increase for the FY 2027 updates based on IGI's second quarter 2026 forecast of the 2023-based IPPS market basket percentage increase of 3.2 percent and the productivity adjustment of 0.9 percentage point, as discussed in section VI.B of the preamble of this final rule, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, as shown in the table that follows.

FY 2027	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
IPPS Market Basket Rate-of-Increase	3.2	3.2	3.2	3.2
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	-0.8	-0.8
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.4	0.0	-2.4
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.9	-0.9	-0.9	-0.9
Applicable Percentage Increase Applied to Standardized Amount	**2.3**	**-0.1**	**1.5**	**-0.9**

B. FY 2027 SCH and MDH Update

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs is also subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act.

As discussed in section VI.F. of the preamble of this final rule, section 6202 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75) extended the MDH program for FY 2027 discharges occurring before January 1, 2027. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2027. We refer readers to section V.E. of the preamble of this final rule for further discussion of the MDH program.

As previously stated, the update to the hospital specific rate for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are establishing the same four possible applicable percentage increases in the previous table for the hospital-specific rate applicable to SCHs and MDHs.

C. FY 2027 Puerto Rico Hospital Update

Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section VI.B.1. of the preamble of this final rule.

In addition, as discussed in section VI.B.2. of the preamble of this final rule, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022.

Section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that for FY 2024 and subsequent fiscal years, any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments).

Based on IGI's fourth quarter 2025 forecast of the 2023-based IPPS market basket update with historical data through third quarter 2025, in the FY 2027 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as previously discussed, for Puerto Rico hospitals, we proposed an IPPS market basket increase of 3.2 percent and a productivity adjustment of 0.8 percentage point. Therefore, for FY 2027, depending on whether a Puerto Rico hospital

is a meaningful EHR user, we stated that there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we proposed the following applicable percentage increases to the standardized amount for FY 2027 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we proposed an applicable percentage increase to the operating standardized amount of 2.4 percent (that is, the FY 2027 estimate of the proposed IPPS market basket rate-of-increase of 3.2 percent less an adjustment of 0.8 percentage point for the proposed productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we proposed an applicable percentage increase to the operating standardized amount of 0.0 percent (that is, the FY 2027 estimate of the proposed market basket rate-of-increase of 3.2 percent, less an adjustment of 2.4 percentage point (the proposed IPPS market basket rate-of-increase of 3.2 percent × 0.75 for failure to be a meaningful EHR user), and less an adjustment of 0.8 percentage point for the proposed productivity adjustment).

As noted previously, we proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2027 market basket percentage increase and the productivity adjustment for the FY 2027 IPPS/LTCH PPS final rule.

As discussed in section V.A.1. of the preamble of this final rule, based on more recent data available for this FY 2027 IPPS/LTCH PPS final rule, we estimate that the FY 2027 market basket update used to determine the applicable percentage increase for the IPPS is 3.2 percent less a productivity adjustment of 0.9 percentage point. Therefore, in accordance with section 1886(b)(3)(B) of the Act, for this final rule, for Puerto Rico hospitals the more recent update of the market basket update is 3.2 percent less a productivity adjustment of 0.9 percentage point. For FY 2027, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we determined the following applicable percentage increases to the standardized amount for FY 2027 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, an applicable percentage increase to the FY 2027 operating standardized amount of 2.3 percent (that is, the FY 2027 estimate of the market basket rate-of-increase of 3.2 percent less 0.9 percentage point for the productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, an applicable percentage increase to the operating standardized amount of −0.1 percent (that is, the FY 2027 estimate of the market basket rate-of-increase of 3.2 percent, less an adjustment of 2.4 percentage point (the market basket rate-of-increase of 3.2 percent × 0.75 for failure to be a meaningful EHR user), and less 0.9 percentage point for the productivity adjustment).

D. Update for Hospitals Excluded From the IPPS for FY 2027

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. In addition, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (described in § 412.22(i) of the regulations) also are subject to the rate-of-increase limits. As discussed in section VI. of the preamble of this final rule, we are finalizing our policy to use the percentage increase in the 2023-based IPPS operating market basket to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals for FY 2027 and subsequent fiscal years. Accordingly, for FY 2027, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, extended neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2027 percentage increase in the 2023-based IPPS operating market basket. For this final rule, the current estimate of the IPPS operating market basket percentage increase for FY 2027 is 3.2 percent.

E. Update for LTCHs for FY 2027

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this final rule, we are updating the LTCH PPS standard Federal payment rate for FY 2027 by 2.3 percent, consistent with section 1886(m)(3) of the Act which provides that any annual update be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, the productivity adjustment). Furthermore, in accordance with the LTCH QRP under section 1886(m)(5) of the Act, we are reducing the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are establishing an update factor of 1.023 in determining the LTCH PPS standard Federal rate for FY 2027. For LTCHs that fail to submit quality data for FY 2027, we are establishing an annual update to the LTCH PPS standard Federal rate of 0.3 percent (that is, the annual update for FY 2027 of 2.3 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying an update factor of 1.003 in determining the LTCH PPS standard Federal rate for FY 2027. (We note that, as discussed in section IX.C. of the preamble of this final rule, the update to the LTCH PPS standard Federal payment rate of 2.3 percent for FY 2027 does not reflect any budget neutrality factors.)

III. Secretary's Recommendations

MedPAC is recommending inpatient hospital rates be updated by the amount specified in current law. MedPAC's rationale for this update recommendation is described in more detail in this section. As previously stated, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix. We are recommending that the same applicable percentage increases apply to SCHs and MDHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa and extended neoplastic disease care hospitals of 3.2 percent.

For FY 2027, consistent with policy set forth in section IX.C. of the preamble of this final rule, for LTCHs that submit quality data, we are establishing an update of 2.3 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2027, we are establishing an annual update to the LTCH PPS standard Federal rate of 0.3 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2026 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost

base. MedPAC recommended an update to the hospital inpatient rates by the amount specified in current law. MedPAC anticipates that their recommendation to update the IPPS payment rate by the amount specified under current law in FY 2027 would generally be adequate to maintain beneficiaries' access to hospital inpatient and outpatient care and keep IPPS payment rates close to, if somewhat below, the cost of delivering high-quality care efficiently.

MedPAC recommended redistributing the current Medicare safety-net payments (disproportionate share hospital and uncompensated care payments) using the MedPAC-developed Medicare Safety-Net Index (MSNI) for hospitals. In addition, MedPAC recommended adding $1 billion to this MSNI pool of funds to help maintain the financial viability of Medicare safety-net hospitals and recommended to Congress transitional approaches for a MSNI policy.

We refer readers to the March 2026 MedPAC report, which is available for download at *https://www.medpac.gov/document-type/report/*. We look forward to working with Congress on these matters.

We are establishing an applicable percentage increase for FY 2027 of 2.3 percent as described in section 1886(b)(3)(B) of the Act, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements. We note that, because the operating and capital payments in the IPPS remain separate, we are continuing to use separate updates for operating and capital payments in the IPPS. The update to the capital rate is discussed in section III. of the Addendum to this final rule.

We note that section 1886(d)(5)(F) of the Act provides for additional Medicare payment adjustments, called Medicare disproportionate share hospital (DSH) payments, for subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. Section 1886(r) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay each such subsection (d) hospital that is eligible for Medicare DSH payments an empirically justified DSH payment equal to 25 percent of the Medicare DSH adjustment they would have received under section 1886(d)(5)(F) of the Act if subsection (r) did not apply. The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments if subsection (r) of the Act did not apply, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and has uncompensated care. These additional payments are called uncompensated care payments. We refer readers to section V. of the preamble of this final rule for further discussion of Medicare DSH and uncompensated care payments.

[FR Doc. 2026–15833 Filed 7–31–26; 4:15 pm]

BILLING CODE 4169–69–P

FEDERAL REGISTER

Vol. 91 Tuesday,

No. 148 August 4, 2026

Part V

The President

Presidential Determination No. 2026–19 of July 30, 2026—Presidential Determination Pursuant to Section 101 of the Defense Production Act of 1950, as Amended, on Recoverable Critical Minerals and Materials

Presidential Permit of July 30, 2026—Authorizing Cameron County, Texas, To Own, Operate, and Maintain the Brownsville and Matamoros Bridge in Brownsville, Texas

Federal Register
Vol. 91, No. 148
Tuesday, August 4, 2026

Presidential Documents

Title 3—

The President

Presidential Determination No. 2026–19 of July 30, 2026

Presidential Determination Pursuant to Section 101 of the Defense Production Act of 1950, as Amended, on Recoverable Critical Minerals and Materials

Memorandum for the Secretary of Commerce

Section 1. *Policy and General Findings.* (a) Recoverable critical minerals and materials (CMMs) are industrial resources necessary to promote the national defense.

(b) America's inadequate supply of CMMs poses an increasing risk to our national defense and security. The United States relies heavily on imports of certain CMMs from foreign sources, and this reliance threatens serious, sustained supply chain disruptions.

(c) It is imperative that the United States takes immediate action to secure the supply of recoverable CMMs.

Sec. 2. *Definitions.* For the purposes of this determination:

(a) The term ''recoverable critical minerals and materials'' includes black mass, end-of-life, rare-earth permanent magnets or other goods that have fully completed the manufacturing process; swarf; and other waste and scrap containing critical minerals and materials. The term ''recoverable critical minerals and materials'' does not include copper scrap, which is already covered under Proclamation 10962 of July 30, 2025 (Adjusting Imports of Copper Into the United States).

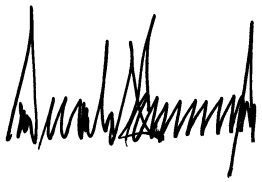
(b) The term ''critical minerals and materials'' includes minerals as defined in Executive Order 14241 of March 20, 2025 (Immediate Measures to Increase American Mineral Production); strategic and critical materials, as defined by 50 U.S.C. 98h-3; critical materials, as defined by section 7002(a)(2) of the Energy Act of 2020, Public Law 116–260, 134 Stat. 1182, 2562; and, notwithstanding Executive Order 13603 of March 16, 2012 (National Defense Resources Preparedness), any other mineral or material designated by the Secretary of Commerce.

Sec. 3. *Ensuring an Adequate Supply of Recoverable CMMs.* (a) By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 101 of the Defense Production Act of 1950, as amended (the ''Act'') (50 U.S.C. 4511), I hereby find, pursuant to section 101 of the Act, that:

(i) recoverable CMMs are scarce and critical materials essential to the national defense; and

(ii) the requirements of the national defense for recoverable CMMs cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship.

(b) You are authorized and directed to implement this determination by taking all appropriate action under section 101 of the Act pursuant to the authority delegated to the Secretary of Commerce in Executive Order 13603, including by issuing regulations, rules, guidance, and procedures, and to publish this determination in the *Federal Register*.



THE WHITE HOUSE,
Washington, July 30, 2026

[FR Doc. 2026–15859
Filed 8–3–26; 11:15 am]
Billing code 3510–DT–P

Presidential Documents

Presidential Permit of July 30, 2026

Authorizing Cameron County, Texas, To Own, Operate, and Maintain the Brownsville and Matamoros Bridge in Brownsville, Texas

By virtue of the authority vested in me as President of the United States of America (the ''President''), I hereby grant permission, subject to the conditions set forth herein, to Cameron County, Texas (the ''permittee''), to own, operate, and maintain a vehicular, pedestrian, and bicycle crossing, known as the Brownsville and Matamoros Bridge (B&M Bridge), at the Brownsville and Matamoros Port of Entry located on the United States border with Mexico in Brownsville, Texas, as described in the ''Brownsville & Matamoros Bridge Presidential Permit Application'' dated March 30, 2026 (the ''Application''), submitted by the permittee to the Secretary of State, in accordance with 33 U.S.C. 535d and associated procedures.

The term ''Border facilities'' as used in this permit refers to bridges over the Rio Grande River connecting downtown Brownsville, Texas, and Matamoros, Mexico, including a concrete bridge that consists of four spans, four vehicle lanes, and a pedestrian crossing on the bridge's downstream side, as well as any approaches, land, structures, installations, or equipment appurtenant thereto located on the United States side of the international boundary between the United States and Mexico.

This permit is subject to the following conditions:

Article 1. The Border facilities herein described and all aspects of their operation shall be subject to all the conditions, provisions, and requirements of this permit and any subsequent Presidential amendment to it. The maintenance and operation of the Border facilities shall be in all material respects as described in the Application.

Article 2. The standards for and the manner of maintenance and operation of the Border facilities shall be subject to inspection by the representatives of appropriate Federal, State, and local agencies. The permittee shall grant officers and employees of such agencies that are duly authorized and performing their official duties free and unrestricted access to said Border facilities.

Article 3. The permittee shall comply with all applicable Federal laws and regulations regarding the maintenance and operation of the Border facilities.

Article 4. The permittee shall be responsible for obtaining and maintaining any required Federal, State, and local permits, approvals, and authorizations connected to its ownership, operation, and maintenance of the Border facilities. The permittee shall take all necessary and appropriate measures to satisfy conditions placed on the issuance of such permits.

Article 5. The permittee shall immediately notify the President or his designee of any decision to transfer custody and control of the Border facilities or any part thereof to any executive department or agency (agency) of the United States Government. Said notice shall identify the transferee agency and seek the approval of the President for the transfer of the permit. In the event of approval by the President of such transfer, this permit shall remain in force and effect, and the Border facilities shall be subject to all the conditions, permissions, and requirements of this permit and any amendments thereof. The permittee may transfer ownership or control of the Border facilities to a non-Federal entity or individual only upon the

prior express approval of such transfer by the President, which approval may include such conditions, permissions, and requirements that the President, in the President's discretion, determines are appropriate and necessary for inclusion in the permit, to be effective on the date of transfer.

Article 6. The permittee shall be responsible for acquiring and maintaining any right-of-way grants or easements, permits, and other authorizations as may become necessary or appropriate. To ensure the safe operation of the Border facilities, the permittee shall maintain them and every part of them in a condition of good repair and in compliance with applicable law, employing use of best management practices.

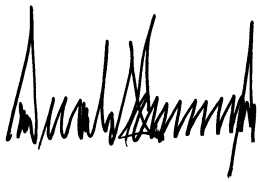
Article 7. Upon request, the permittee shall provide appropriate information to the President or his designee with regard to the Border facilities. Such requests could include requests for information concerning current conditions, legal compliance, or anticipated changes in ownership or control, operation, or maintenance of the Border facilities.

Article 8. The permittee shall file any applicable statements and reports required by applicable Federal law in connection with the Border facilities.

Article 9. The permittee shall make no substantial change inconsistent with the Application to the Border facilities, in the location of the Border facilities, or in the operation authorized by this permit, unless such changes have been approved by the President. The President may terminate, revoke, or amend this permit at any time at his sole discretion. The permittee's obligation to implement any amendment to this permit is subject to the availability of funds. If the permittee permanently closes the B&M Bridge and it is no longer used as an international crossing, then this permit shall terminate, and the permittee may manage, utilize, or dispose of the Border facilities in accordance with applicable laws and regulations. This permit shall continue in full force and effect for only so long as the permittee continues the operations hereby authorized.

Article 10. This permit is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of July, in the year of our Lord two thousand twenty-six, and of the Independence of the United States of America the two hundred and fifty-first.



[FR Doc. 2026–15860

Filed 8–3–26; 11:15 am]

Billing code 4710–10–P

Reader Aids

Federal Register

Vol. 91, No. 148

Tuesday, August 4, 2026

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6050**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.govinfo.gov.**

Federal Register information and research tools, including Public Inspection List and electronic text are located at: **www.federalregister.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html and select** *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, AUGUST

48755–49268	3
49269–50468	4

CFR PARTS AFFECTED DURING AUGUST

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Administrative Orders:

Presidential Determinations:

No. 2026–19 of July 30, 2026 50465

Permits:

Presidential Permit of July 30, 2026 50467

5 CFR

11 49072
230 49072
315 49072
316 49178
330 49178
351 (2 documents) 49178, 49230
353 49178
359 49178
362 49178
430 49178
432 49072
731 49034
751 49072
752 49072

12 CFR

Proposed Rules:

215 49526
217 49490
225 49526
239 49490

14 CFR

39 49269
71 ..... 48755, 48756
95 49271
382 49272

Proposed Rules:

71 ..... 48785, 49372

16 CFR

Proposed Rules:

1 49376

21 CFR

Proposed Rules:

10 48785
56 48785
106 48785
201 48785
251 48785
310 48785
312 48785
314 48785
329 48785
600 48785
803 48785
862 48785
866 48785
870 48785
882 48785
1114 48785
1310 48786

22 CFR

41 48757

26 CFR

Proposed Rules:

1 48794

29 CFR

1404 49273

30 CFR

Proposed Rules:

75 ..... 48807, 48808

31 CFR

22 48766

33 CFR

165 49278

36 CFR

Proposed Rules:

1120 49377

40 CFR

180 ..... 48772, 49279

42 CFR

405 49570
412 ..... 48982, 49570
413 49570
414 48982
415 49570
418 49118
419 49570
495 49570
512 49570

45 CFR

170 49570
611 49283
1370 48775

47 CFR

Proposed Rules:

1 48809
27 48809
54 48823

49 CFR

107 ..... 49291, 49295, 49298
171 ..... 49301, 49305, 49310, 49315, 49320
172 ..... 49305, 49325, 49329, 49332, 49335
173 ..... 49305, 49310, 49315, 49332, 49335, 49340, 49345
174 49320

177.....49349
180.....49354

Proposed Rules:
210.....48823

571.....49385
585.....49385

50 CFR
648.....49358

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List July 16, 2026

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.